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FINAL REPORT OF A MISSION  
CARRIED OUT IN BRAZIL  
FROM 25 APRIL TO 4 MAY 2007  
IN ORDER TO  
ASSESS THE OFFICIAL CONTROL SYSTEMS IN PLACE TO CONTROL  
AFLATOXIN CONTAMINATION IN PEANUTS INTENDED FOR EXPORT INTO  
THE EUROPEAN UNION

*Please note that in response to comments from the Brazilian competent authorities  
factual errors in the draft report have been corrected*



## TABLE OF CONTENTS

1.	INTRODUCTION .....	5
2.	OBJECTIVES OF THE MISSION .....	5
3.	LEGAL BASIS AND OTHER RELEVANT LEGISLATION FOR THE MISSION.....	6
3.1.	Legal basis .....	6
3.2.	Other relevant legislation .....	6
4.	BACKGROUND.....	6
4.1.	Overview of previous missions regarding aflatoxin contamination in foodstuffs.....	6
4.2.	Background to present mission .....	6
4.3.	Food product information related to public health issues .....	7
5.	MAIN OBSERVATIONS .....	7
5.1.	Relevant national legislation .....	7
5.2.	Competent authorities.....	8
5.3.	Process controls in the peanut production chain .....	10
5.4.	Method of sampling for peanut consignments .....	12
5.5.	Procedure for exporting nuts to the EU .....	12
5.6.	Laboratory services .....	13
5.7.	Response to RASFF notifications .....	16
6.	CONCLUSIONS .....	17
6.1.	Relevant national legislation .....	17
6.2.	Competent authorities.....	17
6.3.	Process controls in the peanut production chain .....	17
6.4.	Method of sampling for peanut consignments .....	18
6.5.	Procedure for exporting nuts to the EU .....	18
6.6.	Laboratory services .....	18
6.7.	Response to RASFF notifications .....	18
6.8.	Overall conclusion.....	18
7.	CLOSING MEETING.....	19
8.	RECOMMENDATIONS .....	19
9.	COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS.....	19

## EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office in Brazil, from 25 April to 4 May 2007.

The objective was to assess the control systems in place to control aflatoxin contamination in peanuts intended for export into the European Union (EU).

There is national legislation in place establishing requirements for the control of peanuts exported to the EU. However this legislation is not systematically implemented and there are still gaps in the established legislation that allow consignments of that do not comply with EU requirements to customs clear for EU export.

Responsibilities for policy making, supervision and controls have been assigned to the Ministry of Agriculture, Livestock and Food Supply (MAPA). Training of staff with regard to aflatoxin control has recently taken place, but not specifically for the control of peanuts for export to the EU.

There are no GAP standards or guidelines established by the CA for peanut growers. Peanut growers apply those principles of GAP that are provided by the peanut processors; however, there is no supervision by the CA of GAP implementation at the peanut growers. A well advanced research project Safe Food Monitoring Program to reduce the contamination of peanuts with aflatoxins is ongoing at the Brazilian market. This is a self controlling initiative of some peanut processing companies. As a consequence of this program, there is the establishment of a number of special drying facilities.

Conditions at the peanut processors visited by the mission team were found to be in line with international standards, such as *Codex Alimentarius*. In general a traceability system has been established.

The samplings demonstrated were in line with the requirements of Commission Regulation (EC) No 401/2006. Laboratories assessed by the mission team were also found to be in compliance with the criteria's of the above-mentioned Regulation.

No routine procedure and responsibilities have been established for RASFF follow-up and to date only very limited RASFF follow-up measures have been taken.

Overall a system for control of peanuts exported to the European Union is in place. It includes legislative and procedural provisions regarding export control of peanuts and including also export to the EU. However, this system is incomplete because it does not link the custom clearance of the consignments to the relevant checks done by MAPA. RASFF follow-up is also not part of the system. In addition, the system in place is not fully implemented. Therefore the current system does not fully ensure that peanuts exported to the EU comply with or are at least equivalent to the relevant requirements as regards to aflatoxin. To a certain extent this risk is mitigated by the good lab services provided, the private sector initiative of developing GMP practices at producer level and a comprehensive in-house control systems including HACCP and traceability at processor level.

The report puts forward a number of recommendations to the authorities of Brazil to address the deficiencies noted.

## **ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT**

ABICAB	The Brazilian Chocolate, Cocoa, Peanut and Candies Manufacturers Association
AOAC	Association of Analytical Communities
CA	Competent Authority
CCA	Central Competent Authority
CCRC	Coordination for Control of Residues and Contaminants
CGAL	General Coordination for Laboratory Support
DIPOV	Department of Plant Products Inspection
EU	European Union
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardization
LACQSA/LAN AGRO-MG	Quality Control and Food Safety Laboratory of the Agricultural and Livestock National Laboratory
LOD	Limit of Detection
LOQ	Limit of Quantification
MAPA	Ministry of Agriculture, Livestock and Food Supply
MS	Member States
RASFF	Rapid Alert System for Food and Feed
SDA	Secretariat for Animal and Plant Health
SFA	State Office of MAPA in the regions
SVA	VIGIAGRO Regional Office within SFA
UTRA	Regional Office of MAPA within SFA
VIGIAGRO	Coordination for International Agricultural and Livestock Surveillance

## 1. INTRODUCTION

The mission took place in Brazil from 25 April to 4 May 2007. The mission team comprised 2 inspectors from the Food and Veterinary Office (FVO) and one national expert.

The mission team was accompanied throughout the mission by representatives from the central competent authority (CCA), the Ministry of Agriculture, Livestock and Food Supply (MAPA).

An opening meeting was held on 25 April at the premises of MAPA in Brasilia. Representatives from the different units of MAPA (Secretariat for Animal and Plant Health - SDA, Coordination for Control of Residues and Contaminants - CCRC, Department of Plant Products Inspection - DIPOV, General Coordination for Laboratory Support - CGAL, Coordination for International Agricultural and Livestock Surveillance - VIGIAGRO) were present. During this meeting, the objectives of and itinerary for the mission were finalised and confirmed by the mission team.

## 2. OBJECTIVES OF THE MISSION

The objectives of the mission were:

- to verify whether the control systems are in place to control aflatoxin contamination in peanuts intended for export to the European Union within specified European Union (EU) contaminant limits, complying with or being at least equivalent to Commission Regulation (EC) No 1881/2006<sup>1</sup>.

In pursuit of these objectives, the visits were carried out in accordance with the itinerary agreed between MAPA and the FVO and were as follows:

COMPETENT AUTHORITY VISITS			Comments
Competent authority	Central	1	MAPA
	Provincial Level	1	Sao Paulo State Office (SFA) of MAPA
		1	Marilia Regional Office of MAPA (UTRA) within SFA of Sao Paulo State
		1	VIGIAGRO Regional Office (SVA) within SFA at the port of Santos
	1	Santos customs authorities	
<b>LABORATORY VISITS</b>			
Private laboratories in Tupa and Santos		2	Cities of Tupa and Santos
<b>FARMERS</b>			
Peanut cultivations		3	Sao Paulo State
<b>PROCESSING ESTABLISHMENTS</b>			
		4	Processors/exporters of peanuts in Sao Paulo State
<b>PORTS OF EXPORT</b>			
Santos		1	Port of Santos, Sao Paulo State

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<sup>1</sup> Legal acts quoted in this report refer, where applicable, to the last amended version. Full references to the acts quoted in this report are given in the Annex.

### **3. LEGAL BASIS AND OTHER RELEVANT LEGISLATION FOR THE MISSION**

#### **3.1. Legal basis**

The mission was carried out in agreement with MAPA and under the general provisions of Community legislation, in particular:

- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

#### **3.2. Other relevant legislation**

All other relevant legislation referred to in this report is listed in Annex 1 to the report.

### **4. BACKGROUND**

#### **4.1. Overview of previous missions regarding aflatoxin contamination in foodstuffs**

The European Commission has carried out missions to Iran, Egypt, Turkey, China, India, Argentina and the United States with the objective of evaluating official control systems for the prevention of aflatoxins contamination in foodstuffs originating from these countries. In addition, missions to 16 Member States (MS) with the objective of assessing controls on imported products of plant origin have been carried out. The reports on these missions are available on the DG Health and Consumer Protection Internet site at

[http://europa.eu.int/comm/food/fvo/index\\_en.htm](http://europa.eu.int/comm/food/fvo/index_en.htm).

#### **4.2. Background to present mission**

The average yields of peanuts achieved annually in Brazil total some 315 000 tons. Peanuts are cultivated in at least 11 states in Brazil. The main peanut cultivation area in Brazil is Sao Paulo State. It produces 225 000 tons per year (2005 data), representing 71% of Brazil's total peanut production. In 2006 approximately 36 000 tonnes were exported to the EU, mainly originating from Sao Paulo State.

Information regarding foodstuffs found by Member State (MS) competent authorities (CA) to have public health implications is disseminated through the Rapid Alert System for Food and Feed (RASFF) to all MS and to the exporting country. From 2005 to the time of the mission 56 notifications relating to aflatoxins in peanuts from Brazil were made through the RASFF. The breakdown of RASFF notifications as well as the volume of imports into the EU is shown in Table 1. The main importing MS are indicated in brackets.

**Table 1: Imports of peanuts originating from Brazil into the EU**

	Imports to EU (metric tonnes)		Number of alerts		
	2005	2006	2005	2006	2007 (Jan-March)
12021090 Groundnuts in shell	2 491 (UK, ES, IT, BE, DK)	2 091 (UK, ES, DK, IT )	31	24	1
12022000 Shelled groundnuts	45 093 (NL, UK, IT, DE)	36 185 (NL, UK, DE, IT)			

Source: Eurostat, Comext database and EC, RASFF database

In view of the high number of RASFF notifications, and the fact that in case of some notified consignments the aflatoxin levels were up to 150 ppb for aflatoxin B1, the European Commission decided to undertake a mission to Brazil with the above-mentioned objectives.

#### **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 food were set in EU legislation taking into account the known possible effects of sorting, mixing or of other physical treatment methods to reduce the aflatoxin content of the nuts. In accordance with Annex I to Commission Regulation (EC) No 1881/2006, the maximum admissible aflatoxin levels in groundnuts are as follows:

- a) Groundnuts, nuts and dried fruit and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs:
  - 2.0 µg/kg aflatoxin B1 content, and
  - 4.0 µg/kg total aflatoxin content;
- b) Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs:
  - 8.0 µg/kg aflatoxin B1 content, and
  - 15.0 µg/kg total aflatoxin content.

## **5. MAIN OBSERVATIONS**

### **5.1. Relevant national legislation**

The following national legislation regarding control of aflatoxins in peanuts is in place:

- Law 9972 of 25 May 2000 establishes the requirements for the classification of plant products (including peanuts) intended for the domestic market. Detailed criteria and requirements for the classification of peanuts are established by Regulation 147 of 14 July 1987.

- Normative Instruction 66 of 11 September 2003 establishes the general rules for the voluntary registration of plant products processors but does not specifically apply to exports. However, draft Normative Instruction 65, which is currently at the public consultation stage, is expected to make registration of both processors and exporters compulsory.
- A limit for total aflatoxin content in peanuts of 20 ppb is set by Resolution No 274 of 15 October 2002 and is applicable in the Brazilian domestic market.
- Normative Instruction No 9 of 16 January 2002 and internal rule No 1 of 24 February 2003 stipulate that all exported peanuts, including export to the EU, must comply with the requirements of the importing country and all consignments must be accompanied by the analytical certificate issued by a laboratory authorised by MAPA. The mission team noted that there is no legal requirement in the customs legislation to take into account the requirements of Normative Instruction No 9.
- Normative Instruction No 2 of 5 March 2001 is used as a legal basis for the authorisation of private bodies for sampling for classification purposes.
- Normative Instruction No 1 of 16 January 2007 lays down requirements for the authorisation of laboratories by the CGAL. These requirements include compliance with the criteria of ISO 17025 or GLP as appropriate. However, there is no legal requirement for the accreditation of these laboratories by the Brazilian National Accreditation Body (INMETRO).

The mission team noted that there is no legal requirement for traceability and the application of HACCP in peanut processing establishments. Neither is there any legal basis for the inspection of exporters without prior approval by the company in cases of RASFF follow-up.

It was stated by the CA that a future law on the inspection of products of plant origin, which should provide a legal basis for the classification and export control of peanuts (including export to the EU), has been drafted. Approval of the law is expected to take at least five years.

## **5.2. Competent authorities**

### *5.2.1. MAPA*

The CCA within the scope of the mission is the SDA within MAPA. There are several units of the SDA, in particular the CCRC, DIPOV, the CGAL and VIGIAGRO, that fall within the scope of this mission.

The CCRC is responsible for policy setting in the area of aflatoxins control in peanuts in general and coordination of the follow-up of RASFF notifications. Currently the CCRC has 1 person (Plant Products Manager) responsible for the above-mentioned tasks.

DIPOV is responsible for drafting legislation regarding export controls on peanuts, for coordinating the work of the State offices of MAPA (the SFAs - *Superintendência Federal de Agricultura*) in the regions, for the approval of exporters, for the authorisation of private bodies for sampling for classification purposes and for the follow-up of RASFF notifications. Within DIPOV there are 110 inspectors for food of plant origin located in 27 SFAs at state level. The SFAs are responsible for :

- inspecting the private bodies during the process of authorisation for sampling for classification purposes,
- inspecting exporters during the process of approval for export,
- inspecting exporters for RASFF follow-up,
- inspecting peanuts intended for the domestic market for classification purposes at retailers and distributors level.

The CGAL is responsible for authorising and auditing laboratories as required by Normative Instruction No 1 of 16 January 2007. Within the CGAL the Auditing and Authorisation Service is responsible for authorising and auditing laboratories, including the mycotoxin ones.

VIGIAGRO is responsible for import controls on food, feed and other products of animal and plant origin, and also agricultural and livestock inputs. For export controls, when demanded by customs authorities, VIGIAGRO inspectors check consignments, including peanuts, enforce presentation of required sanitary certificates and issue phytosanitary and zoosanitary certificates, prior to export. There are 110 control points (border points, inland customs posts, ports and international airports) where VIGIAGRO is represented with total staff of 530 inspectors. Out of the 530 inspectors, 323 are responsible for food of plant origin including peanuts.

In 2006 training was organised by MAPA for 130 inspectors, focusing on plant products quality control. However, this training did not specifically cover aspects related to the control of peanuts for EU export.

#### *5.2.2. The Ministry of Health*

The Ministry of Health has responsibility for the food hygiene control of peanut processors producing peanut products intended for direct human consumption in the internal market only.

#### *5.2.3. Customs*

The customs administration of Brazil is responsible for customs clearance of peanut consignments to be exported.

#### *5.2.4. Other organisations*

The Brazilian Chocolate, Cocoa, Peanut and Candies Manufacturers Association (ABICAB) ran the *Pro-Amendoim* research project a Safe Food Monitoring Program to establish Good Manufacturing Practice (GMP) regarding aflatoxin controls among peanut processors in various Brazilian States, mainly in São Paulo State. The Program is financed by the 12 participating peanut processors. Since the beginning of the Program in 2001 a significant number of peanut drying facilities were established in São Paulo State. At the Program all participants were systematically and periodically audited against GMP requirements by a private body. At the end, successful companies were certified and granted the right to use an ABICAB quality seal.

### 5.3. Process controls in the peanut production chain

#### 5.3.1. Nut cultivation

Many of the farmers cultivating peanuts are contracted by nut processors or are members of cooperatives, which provide technical inputs such as certified seeds, fertilisers and plant protection products and give technical advice on cultivation and harvesting. The mission team visited 3 peanut producers/farmers. These applied those principles of Good Agricultural Practice (GAP) that are provided by the peanut processors, such as crop rotation, use of certified seeds and registered plant protection products, sowing and harvesting at the recommended time. The mission team noted that apart from the guidance given by the companies, there is no other written guidance available for farmers concerning GAP in connection with aflatoxin contamination of peanuts. The mission team also noted that farmers have never been visited by MAPA representatives to verify GAP implementation.

As a rule, relatively big farmers with an average field size of 50 to 150 hectares dominate production. Peanut cultivation normally takes place in rotation with sugarcane as follows: after every 5 years of sugarcane cultivation the field is used for 1 year for the cultivation of peanuts. The seeds can be certified, as is the case of cooperatives, or saved from previous crops in other cases. Harvesting begins 135-145 days after a period of cultivation, usually from February through to April, depending on the variety and climate conditions. Irrigation of the fields was not possible during periods of drought, however in general it was not considered necessary by the farmers thanks to regular rainfall during the production cycle.

Harvesting is usually carried out mechanically in 2 steps. First the plant is dug out and turned to let the pods containing the peanuts cure, to develop proper colour and flavour, and dry on the fields in windrows for a period of 3-7 days. One of the processors visited required the farmers to conduct a maturation test before harvesting could start (at least 70% of seeds in pods had to be matured). After drying of peanuts in windrows to moisture content of 18-20% the pods are separated from the plants and transported to the drying facilities of the processors or cooperative for a final drying down to 8-10% moisture content. As mentioned by the visited processors the usual waiting time for lorries on delivery of peanuts to the drying facilities ranges between 24 to 48 hours. However, MAPA stated that that in processors that do not organize the capacity of reception with the production intended to be bought, exceptionally in the peak moment of delivery the waiting time for lorries on delivery of peanuts to the drying facilities can be up to 120 hours, while it is recommended by the point 28 of the *Codex Alimentarius* "Code of Practice for the prevention and reduction of aflatoxin contamination in peanuts" that the nuts should be moved to a suitable storage, or to the processing area for immediate processing as soon as possible after harvesting or drying.

Finally, dried in-shell peanuts are usually cleaned, packed and stored either on-farm under ambient conditions or at the processors' facilities for a period of up to 1 year. The mission team noted that one of the farmers visited stored peanuts in pods in an open shed which was not sufficiently protected against rain and pests.

#### 5.3.2. Nut processing

The mission team visited 4 processors in Sao Paulo State; all of them received unshelled peanuts to produce shelled or blanched products. Three processors exported significant amounts – 20 to 30% of their produce – to the EU. The overall number of peanut

processors was not available at the Sao Paulo SFA, since Normative Instruction 66 does not require mandatory registration of peanut processors.

Once unshelled peanuts arrive at the processors' premises pods are dried in the specially designed drying facilities down to 8-10% of moisture content. Dried and cleaned peanuts are stored either in bulk or in 1 000 kg to 1 250 kg bags in specially designed warehouses equipped with thermometer and hygrometer. The visual, moisture and aflatoxin checks were performed by the peanut processors upon reception and aflatoxin checks when packaging final products as part of their quality procedure as recommended by the *Codex Alimentarius* "Code of Practice for the prevention and reduction of aflatoxin contamination in peanuts". All companies visited had an internal standard for the moisture content in peanuts before (18-20% of moisture content) and after (8-10% of moisture content) drying and a standard for the classification of peanuts according to the level of aflatoxins. For EU export purposes peanuts with total aflatoxin content below 1 ppb are considered satisfactory by the processors. All companies had their own laboratories for aflatoxin analysis with the same analytical method used, based on immuno-affinity cleanup and fluorescence detection. The limit of detection (LOD) of the method used was stated by the company representative to be 1 ppb.

For sorting of peanuts, in addition to manual sorting electronic infrared-based sorting machines are also used.

The mission team noted that 3 processors had implemented GMP and 2 companies were at an advanced stage of implementing HACCP principles, although none of them were assessed by CA for HACCP yet.

In 3 of the companies visited the traceability system was established and the final product could be traced back to the grower or group of growers or to the township or county of production.

The mission team noted that peanut processors are not routinely controlled by any of the CAs mentioned under point 5.2 for aflatoxin contamination. MAPA stated that the requirements for the classification of peanuts, which include also compliance with the national limit for aflatoxins of 20 ppb, apply to products ready for human consumption. Therefore the routine aflatoxin control conducted by the SFAs takes place at the retail or distributor level. The control conducted in 2006 included 24 samples taken for aflatoxin control at retail or distributor level (18 from Sao Paulo State). MAPA stated that the number of samples to be taken in 2007 is expected to increase.

### 5.3.3. *Non-conforming products*

In relation to the export of peanuts to the EU, non-conforming products for EU export are considered as containing more than EU aflatoxin level as specified in Annex of Commission Regulation (EC) No 1881/2006. However, the mission team noted that some consignments exported to the EU were accompanied by an analytical certificate that confirmed compliance with the national aflatoxin limit of 20 ppb.

Products exceeding the EU aflatoxin level are normally diverted to domestic market. Products exceeding the national aflatoxin level of 20 ppb are normally diverted to peanut oil production.

#### **5.4. Method of sampling for peanut consignments**

Sampling of consignments exported to the EU has to be conducted by the private bodies authorised for sampling for classification purposes under Normative Instruction No 2. The mission team noted that the scope of the authorisation does not specifically refer to Regulation (EC) No 401/2006. When authorising companies for sampling, capability to sample according to the above-mentioned Regulation is not evaluated. It was also noted by the mission team that there are no instructions established by the CAs available for the private bodies authorised for official sampling that take the requirements of Regulation (EC) No 401/2006 into account. Persons responsible for sampling have received in-house training regarding sampling for EU export. No training has been provided by the CAs regarding sampling of peanuts for EU export.

To date 7 private bodies are authorised in the State of Sao Paulo to perform classification including sampling of peanuts. The mission team noted that non-authorised private body was used by one of the exporters for the official classification of the exported consignment.

Official sampling procedures cover automatic and manual sampling and various bag sizes. In general, the procedures for sampling of lots of 25 tons required an aggregate sample of 30 to 40 kg. Samples are taken either at the exporter's premises or at the point of export.

In the course of the mission the procedure for official sampling a lot of peanuts of 25 tons, packaged in 1 140 kg bags, was demonstrated to the mission team by one of the authorised private body. An autosampler was used and in total a 100 kg sample was taken for one lot of 25 tons. A 40 kg sample was taken from the 100 kg sample and divided into 4 subsamples using a special homogeniser. 3 subsamples of 10 kg were taken for the aflatoxin analysis and 1 subsample of 10 kg for grading purposes as required by Law 9972/2000 and Regulation 147. Samples were collected in opaque bags, clearly identified, closed and sealed and transferred to the laboratories. In general this sampling was in compliance with EU requirements.

The mission team also observed an auto-control sampling procedure for a lot of peanuts of 25 tons, packaged in 1 250 kg bags, performed by one of the companies whose laboratory is in the process of obtaining possible authorisation for aflatoxin analysis. During the observed procedure a sampling spear was used and in total 60 incremental samples of 600 g each was taken from the lot, giving an aggregate sample with a total weight of 36 kg. Samples were collected in opaque bags, clearly identified, closed and transferred to the laboratories. In general this sampling was in compliance with EU requirements.

#### **5.5. Procedure for exporting nuts to the EU**

In order to export peanuts to the EU, companies have to fulfil the provisions of Normative Instruction No 9. For every peanut lot to be exported an analytical report has to be issued by the CGAL-authorized laboratory to confirm compliance with EU legal limits for aflatoxin. The private bodies authorised for sampling by DIPOV carry out the sampling and send the samples to the CGAL-authorized laboratory for aflatoxin analysis.

The consignments are normally transported to the point of export by lorries, where they are loaded into the sea containers. The sea containers are sealed by the authorised private

body and by the container terminal operator. Container and seal numbers are recorded on the export documentation.

In general, peanuts are regarded as low-risk products by customs and are therefore customs cleared for export on the basis of electronic submission of the documents via the Integrated Foreign Trade System (SISCOMEX) without any identity or physical checks. However, before clearance for export, on a random basis, customs can require a written confirmation from VIGIAGRO that they have started to conduct all controls required by the national legislation and the consignments are usually customs cleared for export before completion of the VIGIAGRO controls. The abovementioned VIGIAGRO written confirmation issued for customs does not include any information about results of the conducted controls. The mission team also noted that this document does not always include information about the container number, lot number and seal number. In those cases it was not possible to demonstrate a clear link between the peanut lot to be exported, the VIGIAGRO control report and the analytical report for aflatoxin analysis.

At the VIGIAGRO office of the Port of Santos in Sao Paulo State, the main export point for peanuts dispatched to the EU, the mission team examined documents attached to some files concerning consignments of peanuts for export to EU such as the results of aflatoxin analysis and the phytosanitary certificate issued by the VIGIAGRO office. In some cases the results of the aflatoxin analysis were expressed just as "n.d." (not detectable), without any indication of the actual limit of detection (LOD), and an analytical certificate was issued by a laboratory not authorised by the CGAL. In addition, the mission team observed that no information about the sampling body was available in any of the documents included in the file.

The mission team were informed about the voluntary system for licensing processors of peanuts for EU export. The activities started in October 2006, when a meeting with the main exporters took place at MAPA. A deadline (December 2006) for submitting the relevant documents to MAPA was given to the exporters and 7 exporters submitted the requisite documents. The SFAs inspected the establishments in March 2007 following the requirements of Normative Instruction 66. The formal decision on licensing of processors was made by MAPA in April 2007. To date 4 exporters have been licensed.

## **5.6. Laboratory services**

There are 7 laboratories designated to perform official aflatoxin analysis for peanuts and peanut products including analysis for export to the EU: 2 government laboratories (1 fully working laboratory and 1 laboratory being equipped and its technical staff being trained to start work) and 5 CGAL-authorised private laboratories. To date, 4 additional private laboratories are in the process of being authorised.

To date 3 laboratories have been accredited according to ISO 17025 by the INMETRO, among other things for the determination of aflatoxins in food. All of them are private laboratories. The Quality Control and Food Safety Laboratory of the Agricultural and Livestock National Laboratory (LACQSA/LANAGRO-MG) is acting as Reference Laboratory for mycotoxins analysis and is currently in the final stage of the accreditation process.

The procedure for authorisation of laboratories by the CGAL is based on Normative Instruction No 1 and includes checks on the private laboratory's quality system, on-site audits, analysis of blind samples and participation in proficiency tests organised by the LACQSA/LANAGRO-MG. Evidences were presented to the mission team in relation to

the regular on-site inspections of the authorised labs. If shortcomings were found, these had to be rectified and reported upon by the laboratory concerned.

The mission team was informed that in 2006 a first proficiency test was organised by the LACQSA/LANAGRO-MG for all authorised laboratories and the report on the results was published in April 2007. The results were in general satisfactory.

#### *5.6.1. Laboratories visited*

The mission team visited 2 private laboratories. The laboratory in Santos was authorised by the CGAL for analysis of food of plant origin, including analysis for aflatoxins, in September 2003, while the laboratory in Tupa is in the process of possible authorisation.

The laboratory in Santos (Sao Paulo State, laboratory 1) has 9 sub-laboratories, among which a mycotoxins laboratory is responsible for aflatoxin analysis in peanuts. The mycotoxins laboratory employs 7 staff – 5 analysts and 2 technicians. Training records of these staff were shown to the mission team. The laboratory participated regularly in AOAC (Association of Analytical Communities) and NRL proficiency tests with satisfactory results.

For sample preparation, the aggregate sample of 30 kg is divided into three sub-samples of 10 kg each and ground. The analytical method used was based on HPLC determination with post column derivatisation and fluorescence detection.

The validation of the analytical procedure was found to cover the range from 1 to 10 µg/kg of aflatoxin B1. The LOD cited in the analytical reports was 0.2 ppb for aflatoxin B1. The limit of quantification (LOQ) was not cited in the analytical reports, but was stated by the representative of the laboratory to be 0.5 ppb. Method validation and performance was adequate to meet the requirements of Regulation (EC) No 401/2006. However, the analytical report did not always indicate whether the analytical results were corrected for recovery and did not state the measurement of uncertainty. It was stated by the representative of the laboratory that these are reported only at the client's request.

In 2006, 916 lots destined for export to the EU were tested for aflatoxins, of which 241 were found not to be in compliance with the EU limits.

The mission team was informed that the laboratory visited was also authorised as an official body for sampling for classification purposes under Normative Instruction No 2. The mission team noted that a sampling guideline based on Commission Directive 98/53/EC was available for the persons responsible for sampling. The mission team also saw evidence of the draft guideline based on Regulation (EC) No 401/2006. The laboratory was last audited by CGAL in April 2007, when a recommendation was made in the audit report that a new guideline based on Regulation (EC) No 401/2006 be established. It was also stated by the representative of the laboratory that no specific training on sampling for EU export had been provided by MAPA, although on-the-job training following the guideline did take place.

The laboratory in Tupa (laboratory 2) was established in 2005 and employs 5 staff. Currently the laboratory conducts only aflatoxin analysis in different matrixes of plant origin. The laboratory applied for CGAL authorisation in early 2006 and the CGAL audit was conducted in July 2006. However, no authorisation has been granted yet, mainly owing to the deficiencies found by the CGAL during the audit.

Training records of these staff were shown to the mission team. The laboratory also participated in AOAC proficiency tests with satisfactory results.

Sample preparation followed in principle the same method as described for laboratory 1. The analytical method used was based on HPLC determination with post column derivatisation and fluorescence detection. The validation report was assessed and the performance criteria were found to be in line with Regulation (EC) No 401/2006, regarding recovery and precision requirements. The validation of the analytical procedure was found to cover the range from 2 to 10 ppb of total aflatoxins. The reported LOD and LOQ cited in the analytical reports were 0.2 ppb and 0.5 ppb for aflatoxin B1. Analytical results were corrected for recovery, and measurement uncertainty was stated in the report. However, the level of recovery is not reported as required by point 4.4 of the Annex II of Regulation (EC) No 401/2006.

In 2006, approximately 350 lots destined for export to the EU were tested for aflatoxins, of which 200 were found to be in compliance with the EU limits. The mission team noted that, in several cases the analytical certificates issued by this laboratory were considered to be compliant with the requirements of Normative Instruction No 9 by VIGIAGRO at the point of export, despite the fact that this laboratory is not authorised by the CGAL for official aflatoxin analysis for peanuts and peanut products including analysis for export to the EU.

The laboratory performance as discussed is summarised in Table 2.

**Table 2: Summary of laboratory performance for the 2 laboratories visited**

	<b>LABORATORY 1</b>	<b>LABORATORY 2</b>
<b>Accreditation</b>	Accredited according to 17025 (INMETRO) and authorised by CGAL	Not accredited to ISO 17025
<b>Sample preparation</b>	Adequate (slurry)	Adequate (paste)
<b>Extraction method</b>	AOAC 991.31 with immuno-affinity clean-up	AOAC 991.31 without clean-up
<b>Detection by</b>	HPLC with post column derivatisation/Kobra cell and fluorescence detector	HPLC with post column derivatisation/Kobra cell and fluorescence detector
<b>Aflatoxin standard</b>	Commercial standards of each individual aflatoxin	Commercial mixture of aflatoxin B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub>
<b>Validation</b>	Validation in accordance with the performance criteria of Reg. 401/2006	Validation in accordance with the performance criteria of Reg. 401/2006
<b>Recovery</b>	Recovery rates (%) were in accordance with Reg. 401/2006	Recovery rates (%) were in accordance with Reg. 401/2006 and checked on a daily basis by using an in-house reference material

	<b>LABORATORY 1</b>	<b>LABORATORY 2</b>
<b>Measurements of uncertainty (U)</b>	Were calculated: +/- 18% for B <sub>1</sub> +/- 19% for B <sub>2</sub> +/- 23% for G <sub>1</sub> +/- 20% for G <sub>2</sub> +/- 16% for total aflatoxins	Were calculated: +/- 15% for B <sub>1</sub> +/- 13% for total aflatoxins
<b>Calibration curve</b>	4-point calibration	3-point calibration
<b>Proficiency test</b>	Successful annual participation in AOCS and LACQSA/LANAGRO testing schemes	Successful annual participation in AOCS
<b>Additional remark (not in accordance with Reg. 401/2006)</b>	Analytical reports indicate recovery and U only at client's request	Analytical results are corrected for recovery and U but the recovery % is not reported

### 5.7. Response to RASFF notifications

When peanut consignments, originating from Brazil, are rejected at EU borders because aflatoxin levels exceed the legal limits, they are mostly directed for further sorting or blanching in the country of destination to reduce the aflatoxin contamination level and then released for free circulation in the EU or diverted for use as animal feed. To date only one rejected consignment has arrived back in Brazil. On arrival in Brazil, the consignment is treated as a common imported good, subject to customs procedures and also requiring VIGIAGRO approval before the consignment is returned to the exporter.

RASFF notifications are received by MAPA's Secretariat for International Agribusiness Relations and forwarded to the CCRC, also in MAPA. The CCRC forwards these messages to DIPOV, which is responsible for follow-up. However, the mission team noted that this procedure is rather informal and no routine procedure and responsibilities have so far been established for RASFF follow-up.

The mission team was informed by MAPA that there is no legal basis for inspecting the peanut processors in the case of RASFF notifications. A formal letter therefore needs to be sent to the processor asking for their permission to conduct an inspection in their facilities for RASFF purposes. The mission team noted that no follow-up inspection was made in the premises of one of the processors since they did not reply to the MAPA letter.

MAPA started to conduct follow-up only in March 2006, when it informed the relevant peanut processors about the RASFF notifications received from the EU. The peanut processors were visited by MAPA in September 2006. The mission team noted that the

peanut processors involved in RASFF have been formally notified by MAPA once (in March 2006). The mission team also noted that Sao Paulo State SFA is not been informed about RASFF notifications relevant for the State on a regular basis.

It was stated by MAPA that infringement proceedings against the processor can be started only when the consignment is returned to Brazil, new sampling has been conducted by the private bodies authorised for sampling and the consignment has consequently been found non-compliant.

## **6. CONCLUSIONS**

### **6.1. Relevant national legislation**

- (1) There is legislation in place which includes requirements that all peanuts for export must comply with the requirements of the importing country and all lots must be accompanied by the analytical certificate issued by a laboratory authorised by MAPA. However, this legislation is not systematically implemented.
- (2) There are no legal requirements for the implementation of traceability and application of HACCP in the peanut processing establishments.
- (3) There is no any legal basis for the inspection of exporters without prior approval by the company in cases of RASFF follow-up.
- (4) There is no legal requirement in the customs legislation to take into account the requirements of Normative Instruction No 9.

### **6.2. Competent authorities**

- (5) The competent authorities are clearly defined.
- (6) Training of staff is not sufficient because it does not cover aspects of the control of peanuts for EU export.
- (7) A well advanced research project to reduce the contamination of peanuts with aflatoxins is ongoing with a number of specific results, such as establishment of special drying facilities.

### **6.3. Process controls in the peanut production chain**

- (8) Peanut growers apply those principles of GAP that are provided by the peanut processors. However, there are no GAP standards or guidelines established by the CA for peanut growers. There is no supervision by the CA of GAP implementation at the peanut growers.
- (9) Peanut processors are not routinely checked by CA for aflatoxin contamination control purposes.
- (10) At three peanut processors visited peanut processing conditions were assessed by the mission team and found to be in line with international standards, such as *Codex Alimentarius* "Code of Practice for the prevention and reduction of aflatoxin contamination in peanuts".

- (11) Traceability, linking final products to the grower/township/county of production, was adequate at three processors out of four.
- (12) Not all peanuts processors visited had established system of control based on HACCP principles as required by Article 10 together with Article 5 of Regulation (EC) No 852/2006.
- (13) There are legislative requirements and procedures in place for non-conforming products.

#### **6.4. Method of sampling for peanut consignments**

- (14) The samplings demonstrated by the private bodies authorised for sampling were in line with the requirements of Commission Regulation (EC) No 401/2006.

#### **6.5. Procedure for exporting nuts to the EU**

- (15) At the point of export the traceability of the exported lot was not always possible.
- (16) Consignments of that do not comply with EU requirements could be customs cleared for EU export.

#### **6.6. Laboratory services**

- (17) Accreditation to ISO 17025 is not a requirement for laboratories for analysis for aflatoxins for peanuts and to date only three out of seven laboratories undertaking analysis for aflatoxins in peanuts to be exported to the EU are accredited to ISO 17025.
- (18) Two laboratories were visited and assessed by the mission team and found to be in compliance with the criteria of Annex II to Regulation (EC) No 401/2006.
- (19) The analytical certificates issued by the laboratories were not fully in line with the requirements of Regulation (EC) No 401/2006, in particular those regarding the reporting of recovery and measurement of uncertainty.

#### **6.7. Response to RASFF notifications**

- (20) The establishment of RASFF follow-up system is not finalised yet.
- (21) To date only very limited RASFF follow-up has taken place with a significant time lag of up to 6 months.

#### **6.8. Overall conclusion**

- (22) Overall a system for control of peanuts exported to the European Union is in place. It includes legislative and procedural provisions regarding export control of peanuts and including also export to the EU. However, this system is incomplete because it does not link the custom clearance of the consignments to the relevant checks done by MAPA. RASFF follow-up is also not part of the system. In addition, the system in place is not fully implemented. Therefore the current system does not fully ensure that peanuts exported to the EU comply with or are at least equivalent to the relevant requirements as regards to aflatoxin. To a certain extent this risk is mitigated by the good lab services provided, the private

sector initiative of developing GMP practices at producer level and a comprehensive in-house control systems including HACCP and traceability at processor level.

## **7. CLOSING MEETING**

A closing meeting was held on 16 November 2006 at the premises of Sao Paulo SFA/MAPA in Sao Paulo. Representatives from the different units of MAPA (the CCRC, DIPOV and the CGAL) and the Sao Paulo State SFA were present. At this meeting, the main observations and initial conclusions were presented by the mission team. The representatives of the competent authorities offered some initial comments and provisionally accepted the preliminary findings.

## **8. RECOMMENDATIONS**

The Competent Authorities of Brazil should:

- (1) Ensure that fully operational control system for peanuts exported to the European Union is developed to guarantee that peanuts exported to the European Union are able to comply with EU standards regarding aflatoxins as specified in Regulation (EC) No 1881/2006.
- (2) Ensure that the traceability of the exported lot at the point of export is always possible as required by Article 18 of Regulation (EC) No 178/2002.
- (3) Ensure that food business operators exporting peanuts to the EU implement standards at least equivalent to Article 5 of Regulation (EC) No 852/2006 on food safety procedures based on HACCP principles.
- (4) Ensure that recovery and measurement of uncertainty in the analytical reports are reported in a way at least equivalent to Regulation (EC) No 401/2006.
- (5) Consider the accreditation to ISO 17025 of official control laboratories to ensure the equivalence with Article 18 of Regulation (EC) No 2076/2005. Equivalence to Art 12 (2) of Regulation (EC) No 882/2004 should be demonstrated by 1 January 2010.
- (6) Consider to systematically follow-up notifications, issued within the European Union Rapid Alert System for Food and Feed (Article 50 of Regulation (EC) No 178/2002) involving peanuts from Brazil.
- (7) Consider the possibility of developing and supervising the implementation of GAP standards in the area of peanut cultivation.

## **9. COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS.**

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

[http://ec.europa.eu/comm/food/fvo/ap/ap\\_brazil\\_7182\\_2007.pdf](http://ec.europa.eu/comm/food/fvo/ap/ap_brazil_7182_2007.pdf)

## ANNEX 1

European Legislation	Official Journal	Title
Regulation (EC) No 882/2004.	OJ L 165, 30.4.2004. 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.
Commission Regulation (EC) No 2076/2005	OJ L 338, 22.12.2005 p. 83.	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 the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.
Regulation (EC) No 178/2002.	OJ L 31, 1.2.2002, p. 1.	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.
Council Regulation (EEC) No 315/93.	OJ L 37, 13.2.1993, p. 1.	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food.
Commission Regulation (EC) No 1881/2006.	OJ L 364, 20.12.2006, p. 5.	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.
Commission Regulation (EC) No 401/2006.	OJ L 70, 9.3.2006, p. 12.	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the sampling methods and the methods of analysis for the official control of the levels for mycotoxins in foodstuffs.
Regulation (EC) No 852/2004	OJ L 139, 30.4.2004. 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.