FINAL REPORT OF A MISSION
CARRIED OUT IN
BRAZIL
FROM 15 TO 24 MARCH 2010
IN ORDER TO ASSESS THE CONTROL SYSTEM IN PLACE TO CONTROL AFLATOXIN CONTAMINATION IN BRAZIL NUTS 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 Brazil from 15 to 24 March 2010.

The objective was to assess the control systems in place to control aflatoxin contamination in Brazil nuts intended for export to the European Union (EU) and to follow up on recommendations made in report SANCO 7074/2004.

Several competent authorities (CAs) are involved in this area, but their competence and responsibilities are not always clearly defined.

Since the last mission, improvements have been made regarding good practices for Brazil nut harvesting and first drying. However, a recommendation on quick delivery of collected nuts for industrial drying resulting from research projects in Brazil since the last mission is not being implemented, so further improvements are necessary in this regard.

Not all Brazil nut establishments exporting Brazil nuts to the EU have procedures based on HACCP in place as required by Article 10 and Article 5 of Regulation (EC) No 852/2004.

In the establishments visited by the mission team, the facilities used for the storage of incoming nuts and for the final product did not always comply with the requirements of section 2.8 of the Codex Alimentarius Code of Practice for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59-2005, REV.1-2006), and full traceability is not always possible as required by Article 33 of the Code of Practice.

There are procedures for the control of Brazil nut exports to the EU by the Ministry of Agriculture and Livestock (MAPA) at the point of export. However, as there is no link between MAPA and customs controls at the point of export, there is a possibility that products may be exported to the EU without a health certificate as required by Article 4(1)(a) of Regulation (EC) No 1152/2009.

There are administrative structures and procedures in place for RASFF follow-up within MAPA. However the procedure is very slow and does not ensure that all RASFF notifications concerning Brazil nuts are investigated.

Overall, the current control system in place cannot guarantee that all Brazil nuts exported to the EU meet the conditions of Commission Regulation (EC) No 1152/2009 and comply with the aflatoxins limits specified in the Commission Regulation (EC) No 1881/2006. Further efforts are needed, in particular to implement good manufacturing practices throughout the Brazil nut production chain.
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<th>Explanation</th>
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<tbody>
<tr>
<td>ANVISA</td>
<td>National Health Surveillance Agency</td>
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<tr>
<td>AOAC</td>
<td>Association of Analytical Communities</td>
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<tr>
<td>ASBRAER</td>
<td>Brazilian Association of State Technical Assistance and Rural Extension Entities</td>
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<td>CA</td>
<td>Competent Authority</td>
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<td>CCA</td>
<td>Central Competent Authority</td>
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<tr>
<td>CCRC</td>
<td>Coordination for Control of Residues and Contaminants</td>
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<tr>
<td>CGAL</td>
<td>General Coordination for Laboratory Support</td>
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<tr>
<td>CN</td>
<td>Combined Nomenclature</td>
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<tr>
<td>DIPOV</td>
<td>Department of Plant Product Inspection</td>
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<td>DNSF</td>
<td>Department of Sanitary and International Relations</td>
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<tr>
<td>EMBRAPA</td>
<td>Brazilian Agricultural Research Corporation</td>
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<td>EU</td>
<td>European Union</td>
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<td>FBO</td>
<td>Food Business Operator</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<td>GAP</td>
<td>Good Agricultural Practice</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>GSP</td>
<td>Good Storage Practice</td>
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<td>HACCP</td>
<td>Hazard Analysis and Critical Control Point</td>
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<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
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<tr>
<td>IBGE</td>
<td>Brazilian Institute of Geography and Statistics</td>
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<tr>
<td>INMETRO</td>
<td>Brazilian National Accreditation Body</td>
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<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<tr>
<td>LACQSA/LANAGRO-MG</td>
<td>Quality Control and Food Safety Laboratory of the National Agricultural and Livestock Laboratory</td>
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<td>LOQ</td>
<td>Limit of Quantification</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>MAPA</td>
<td>Ministry of Agriculture, Livestock and Food Supply</td>
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<td>MS</td>
<td>Member States</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>SDA</td>
<td>Secretariat for Animal and Plant Health</td>
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<td>SFA</td>
<td>Regional Office of MAPA</td>
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<td>SIPAG</td>
<td>Plant and Animal Products Inspection Service</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>STDF</td>
<td>Standards and Trade Development Facility</td>
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<td>TLC</td>
<td>Thin-Layer Chromatography</td>
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<tr>
<td>VIGIAGRO</td>
<td>Coordination for International Agricultural and Livestock Surveillance</td>
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1 INTRODUCTION

The mission took place in Brazil from 15 to 24 March 2010. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one Member State expert.

The mission team was accompanied during 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 15 March 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 Product Inspection — DIPOV, General Coordination for Laboratory Support — CGAL, Coordination for International Agricultural and Livestock Surveillance — VIGIAGRO) were present. At this meeting, the objectives of the mission were confirmed and itinerary for the mission finalised 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 Brazil nuts intended for export to the European Union (EU) within specified European Union contaminant limits, complying with or being at least equivalent to Commission Regulation (EC) No 1881/2006.
- assess compliance with conditions in Commission Regulation (EC) No 1152/2009 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins.

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

<table>
<thead>
<tr>
<th>COMPETENT AUTHORITY VISITS</th>
<th>COMMENTS</th>
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<tbody>
<tr>
<td>Competent authority</td>
<td>Central 1 MAPA</td>
</tr>
<tr>
<td></td>
<td>Regional 1 Regional Office of MAPA (SFA) in Pará State</td>
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</table>

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<tr>
<th>LABORATORY VISITS</th>
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<tr>
<td>Official laboratories 2</td>
</tr>
<tr>
<td>Private laboratory authorised for official analysis (in Santos)</td>
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<tr>
<td>Private laboratory authorised for official analysis (in São Paulo)</td>
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<thead>
<tr>
<th>FOOD PROCESSING ESTABLISHMENTS</th>
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<tbody>
<tr>
<td>Harvesting areas 1 1 community around Óbidos</td>
</tr>
<tr>
<td>Brazil nut processors/exporters 2 1 processor/exporter in Belém 1 processor/exporter in Óbidos</td>
</tr>
</tbody>
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<tr>
<th>PORTS OF EXPORT</th>
<th></th>
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<tbody>
<tr>
<td>1 Port of Belém, Pará State</td>
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</table>
3 Legal Basis for the Mission

3.1 Legal Basis

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


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

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, Brazil, India, Argentina, USA, Ghana, Peru and Azerbaijan to evaluate official control systems for preventing aflatoxin contamination in foodstuffs originating from these countries. In addition, there have been missions to 18 Member States (MS) to assess controls on imported products of plant origin. The reports on these missions are available on DG Health and Consumers’ internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm.

4.2 Background to Present Mission

The competent authorities (CA) of the EU MS are obliged to carry out routine sampling and analysis of various agricultural products originating from third countries. These include nuts and nut products.

As outlined in reports SANCO 9027/2003 and SANCO/7074/2004, an increased number of Brazil nut consignments rejected due to aflatoxin contamination were notified to the Commission’s Rapid Alert System for Food and Feed (RASFF) in 2001 and 2002. The FVO, in consultation with relevant Commission services, decided to conduct a mission with the agreement of the Brazilian authorities to address this rise in non-compliance in 2003. Follow-up mission was conducted in 2004. Both missions resulted in several recommendations made to the Brazilian authorities.

In order to address the shortcomings found, specific conditions for the import of Brazil nuts have been laid down by EU legislation, most recently Commission Regulation (EC) No 1152/2009. Under this Regulation, Brazil nuts exported to the EU have to be accompanied by a health certificate issued by MAPA to show that the consignment was sampled and analysed in accordance with Commission Regulation (EC) No 401/2006. MS are obliged to perform documentary checks and further sampling and analysis for aflatoxin B1 and total aflatoxin on each consignment at the point of entry. Any non-compliance found results in the consignment being refused entry into the EU and its subsequent return to the place of origin or destruction.

The main MS of entry (based on figures for 2008-2009 provided by EUROSTAT) are the Netherlands, Germany, Italy and the UK. The majority of nuts are imported between June and September. According to EUROSTAT data, there has been a significant decline in Brazil nut imports from Brazil to the EU since the last mission.

Table 1: Imports into the European Union in tonnes/year:

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>3314</td>
<td>1859</td>
<td>135</td>
<td>-</td>
<td>126</td>
<td>133</td>
<td>159</td>
<td>161</td>
</tr>
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</table>
### 4.3 Food Product Information Concerning 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) in food and the aflatoxin B1 content. Maximum limits for aflatoxins in food have been fixed in legislation taking into account the known possible effects of sorting, mixing or other physical treatment methods to reduce aflatoxin content. In accordance with Annex I to Regulation (EC) No 1881/2006, the maximum admissible aflatoxin levels in groundnuts, nuts and dried fruit are as follows:

- **Hazelnuts and Brazil nuts intended for direct human consumption or use as an ingredient in foodstuffs:**
  - 5.0 μg/kg aflatoxin B1 content, and
  - 10.0 μg/kg total aflatoxin content (sum of B1, B2, G1 and G2).
- **Hazelnuts and Brazil nuts subject 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 (sum of B1, B2, G1 and G2).

Sampling also plays a crucial part in determining mycotoxin levels, which may be very heterogeneously distributed in a consignment. Commission Regulation (EC) No 401/2006 therefore establishes sampling procedures and general criteria to ensure that laboratories carrying out analyses use methods of analysis with comparable levels of performance.

### 5 Findings And Conclusions

#### 5.1 Legal Requirements

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

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.

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 nuts (Brazil nuts), the method of sampling is laid down in Annex I.D.

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.

Article 3 of Regulation (EC) No 1152/2009 requires that consignments of foodstuffs as referred to in Article 1 of the Regulation may only be imported into the EU in accordance with the procedures laid down in this Regulation. Article 1(a) of the Regulation states that it applies to imports of the following Brazil nuts originating or consigned from Brazil: Brazil nuts in shell coming under category CN code 0801 21 00 and mixtures of nuts and dried fruits coming under CN code 0813 50 and containing Brazil nuts in shell.

Article 4 of Regulation (EC) No 1152/2009 requires that Brazil nuts presented for import into the EU must be accompanied by the results of sampling and analysis and a health certificate in accordance with the model set out in Annex I for foodstuffs from Brazil, completed, signed and verified by an authorised representative of the MAPA.

5.2 RELEVANT NATIONAL LEGISLATION

Findings
Main legislation relevant to this mission:

- Decree No 6268/2007, implementing Law 9972/2000, establishes among other things that establishments involved in the classification of plant products (such as Brazil nuts) have to be registered in the General Classification Registry. This also includes establishments producing nuts for the domestic market.

- MAPA Normative Instruction No 66/2003, in connection with paragraph 2 of Article 2 of Normative Instruction No 13/2004, establishes mandatory requirements for the registration of exporters of Brazil nuts to the EU. It also establishes a general requirement for exporting establishments to implement Good Manufacturing Practices (GMP), but does not specify what requirements these establishments have to meet. According to the CAs, MAPA Administrative Order No 377/2009, which is currently in the public consultation stage, will replace Normative Instruction No 66/2003.

- MAPA Normative Instruction No 12/2004 states that the export of in-shell Brazil nuts is subject to specific health certification by MAPA when required by importing countries.

- MAPA Normative Instruction No 13/2004 establishes detailed procedures for the certification of Brazil nuts exported to the EU, sampling and procedures for the control of consignments rejected at the point of import.

- MAPA Normative Instruction No 42/2008 establishes general requirements for the implementation of the National Residues and Contaminants Control Plan for Plant Products. MAPA Normative Instruction No 21/2009 approves this National Residues and Contaminants Control Plan for the 2009/2010 harvesting season.

- A limit of 30 ppb for total aflatoxin content in Brazil nuts is set for the Brazilian domestic
market by Resolution CNNPA/MS No 34/76.

- Ministerial Normative Instruction No 1 of 16 January 2007 establishes the guidelines, requirements and rules for the authorisation of official laboratories. These requirements include compliance with the criteria of ISO 17025, participation in proficiency tests provided or designated by MAPA, mandatory use of the MAPA Official Certificate of Analysis template, and use of MAPA-approved methods or validation guidelines. There is also a legal requirement for accreditation of these laboratories by the Brazilian National Accreditation Body (INMETRO).

- Currently, there is no legal requirement for Brazil nut exporters exporting to the EU to have traceability and HACCP systems in place. The mission team was informed that MAPA Normative Instruction No 11/2010 had been adopted and published during the mission (23 March 2010). This new legislation, which will enter into force 60 days after its publication, establishes among other things GMP and traceability requirements for Brazil nut processing.

- There is a legal basis for RASFF follow-up activities in Administrative Order No 53/2009. Additionally, Normative Instruction No 3/2009 establishes criteria for inspection and follow-up activities for peanut exporters notified to the RASFF, but not yet for exporters of Brazil nuts. The mission team was informed that Normative Instruction No 11/2010, once in force, would require sampling of five consecutive unshelled Brazil nut consignments for aflatoxin controls at companies notified to the RASFF.

The mission team was informed that new legislation was currently under preparation, such as:

- MAPA Administrative Order No 54/2009, which would establish additional hygiene requirements for Brazil nut processors. Once in place, these would provide the basis for food hygiene controls at Brazil nut exporters.

### Conclusions

Since the last mission, SANCO/7074/2004, a set of national legislation has been established by MAPA in order to comply with the requirements of Regulation (EC) No 1152/2009. National provisions equivalent to the EU legislation regarding HACCP and traceability are not in place.¹

### 5.3 Competent Authorities

**Findings**

#### 5.3.1 The Ministry of Agriculture, Livestock and Food Supply

The CCA for the mission is the SDA of MAPA. Several units of the SDA are involved in the official control of Brazil nuts, in particular:

- The CCRC is responsible for coordination of the National Residues Control Plan.
- DIPOV is responsible for coordination of the activities of the regional offices of MAPA (the SFAs — Superintendência Federal de Agricultura), the formal approval of Brazil nut exporters, the practical follow-up of RASFF notifications, and drafting legislation for the official control of Brazil nuts.

¹ In their response to the draft report the Brazilian Authorities noted that Normative Instruction No 11, of 22 March 2010 establishes the HACCP procedures for the processors and requires the same implement measures to guarantee the traceability.
• DIPOV has 15 federal inspectors for food of plant origin involved in the supervision of the Brazil nut production chain. These inspectors are located in 6 SFAs — in the main Brazil nut production states — 3 in Acre, Amazonas, Pará and Mato Grosso, 1 in Rondônia, Amapá and Roraima.

• The CGAL is responsible for authorising and auditing laboratories as required by Ministerial Normative Instruction No 1 of 16 January 2007.

• According to MAPA, VIGIAGRO is responsible for import and export controls on animals and foodstuffs, including the control of Brazil nut consignments at the point of export prior to export. There are 106 control points (border points, inland customs posts, ports and international airports) where VIGIAGRO is represented in Brazil. There are 4 points of export in Pará State — the Belém, Santarém and Vila do Conde ports and Val de Cans International Airport, with a total VIGIAGRO staff of 32 persons. The mission team was informed by the VIGIAGRO office in Belém that VIGIAGRO controls on Brazil nuts at the point of export include checks to ensure that the Health Certificate is present and that the exporter is authorised to export Brazil nuts. However, the mission team noted that neither MAPA Normative Instruction No 12/2004 nor MAPA Normative Instruction No 13/2004 mention VIGIAGRO or contain clear procedures for VIGIAGRO controls. In addition, the mission team was informed by MAPA that VIGIAGRO would only control products subject to phytosanitary certification; however, there is no such phytosanitary certification requirement for the export of Brazil nuts to the EU. The mission team was informed by the CA at the closing meeting that the recently adopted MAPA Normative Instruction No 11/2010 clarified VIGIAGRO’s role in the whole control procedure. In addition, VIGIAGRO representatives told the team that all 106 points of export had already been notified of the requirements of MAPA Normative Instruction No 11/2010.

The MAPA has state offices, the SFAs, where the Plant and Animal Products Inspection Service (SIPAG) units are located, which are responsible for:

• the inspection of Brazil nut exporters for registration purposes (MAPA Normative Instruction No 66/2003);
• the sampling of nuts to be exported for aflatoxin controls;
• the inspection of exporters for RASFF follow-up purposes;
• the control of GMP and hygiene requirements in Brazil nut exporters once MAPA Normative Instruction No 11/2010 is in force.

Training of the staff responsible for the official control of Brazil nuts has generally been organised in the course of research projects such as Conforcast project “Analytical Tools for Training in Brazil to Ensure Brazil Nut Conformity Regarding the Danger of Aflatoxin” and ASBRAER (Brazilian Association of State Technical Assistance and Rural Extension Entities) project “Good Practices in the management of Brazil Nut”. Within this project good practices were promoted by ASBRAER in partnership with the MAPA and Brazilian Agricultural Research Corporation (EMPRAPA).

The Conforcast project was implemented between 2006 and 2009 with a view to establishing analytical tools for Brazil nut control such as analytical methods, sampling criteria, and reference material for official laboratories, but also included training for official staff in the control of aflatoxin contamination in Brazil nuts. A total of 3 training sessions were provided for MAPA technical staff and representatives from the official laboratories. The training also covered aflatoxin sampling.

In 2008, some 50 local agricultural engineers and agronomists in different regions were trained as part of the ASBRAER project. The project was coordinated by the ASBRAER and training was
provided by the EMPRAPA and MAPA.

In March-April 2009, a one-week training session was organised by MAPA for 65 federal inspectors from all over Brazil. Among other things, it covered the sampling of Brazil nuts for aflatoxin control.

5.3.2 The National Health Surveillance Agency

The National Health Surveillance Agency (ANVISA) under the Ministry of Health has responsibility for food hygiene controls at Brazil nut processors and for aflatoxin controls of Brazil nuts intended for the Brazilian market. The mission team was informed that ANVISA’s role in the official control of the production and processing of Brazil nuts is complementary, as it can intervene in any situation whenever there is a health concern. In addition, under MAPA Normative Instruction No 13/2004, MAPA and ANVISA can take joint action in the case of rejected or returned Brazil nut consignments, in particular for the destruction or reuse of nuts in the domestic market.

5.3.3 Customs authorities

Customs authorities at the point of export are responsible for the customs clearance of Brazil nut consignments for export.

Conclusions

MAPA is designated as the main CA for export control of Brazil nuts, but its competence and responsibilities are not clearly defined with regard to the role of VIGIAGRO.²

Progress has been made since the last mission, SANCO/7074/2004, with regard to the training of official staff involved in the Brazil nut control chain.

5.4 Process controls in the Brazil nut production chain

5.4.1 Harvesting, transport and warehouse storage conditions

Annual Brazil nut production in Brazil is around 30 000 tonnes (2008). Of this amount, around 160 tonnes of in-shell nuts were exported to the EU in 2009. This represents a significant drop from 2003, when approximately 3000 tonnes of nuts in shell were exported.

The mission team noted that there have been no major changes in the overall procedures of Brazil nut collection and intermediate storage (prior to industrial processing) since the last mission SANCO/2004/7074. However, the mission team noted the following:

- Since the last mission, improvements have been made in the removal of nuts from pods and their first drying. The mission team noted that, as recommended in the Codex Alimentarius Code of Practice for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59-2005, REV.1-2006), nuts are now removed from the pods the same day when collected and left to dry in the sun.

- It may take almost 3 months to deliver collected nuts for industrial drying in processing facilities (storage of up to 40 days in the forest or community, a further 30 days in intermediate storage facilities, up to 30 days in the nut processor before actual drying). However, the Standards and Trade Development Facility (STDF) project — SAFENUT — which was implemented in Brazil between 2006 and 2008, recommends that collected nuts should be delivered quickly for industrial drying to a safe moisture content in order to

² In their response to the draft report the Brazilian Authorities noted that Normative Instruction No 11, of 22 March 2010 nowadays defines the competencies and responsibilities of VIGIAGRO (Article 20 of the Normative Instruction).
prevent fungal growth and aflatoxin contamination.

Conclusions

Since the last mission, improvements have been made in terms of good practices for Brazil nut harvesting and first drying. However, a recommendation made in a national project on quick delivery of collected nuts for industrial drying, has not been implemented.

5.4.2 Brazil nut processors visited

Findings

There are 5 Brazil nut processors authorised for EU export. Two of them were visited by the mission team in Belém and Óbidos. The mission team was informed by both companies that they had not exported in-shell Brazil nuts to the EU since at least 2002.

The mission team was informed that authorised companies were inspected by SIPAG inspectors when they applied for the licensing as EU exporters. There had not been any inspections since their authorisation because there was no such legal requirement at the moment. The mission team was informed that MAPA Normative Instruction No 11/2010, once in force, would provide a clear legal basis for such controls and establish GMP requirements for such establishments.3

As already described under point 5.2, there is no legal requirement for Brazil nut exporters exporting their nuts to the EU to have HACCP systems in place. The mission team was informed that only one of the three authorised EU exporters in the Pará region had an HACCP system in place.

In both factories visited, internal checks were performed to determine moisture content and also the percentage of rotten or mouldy nuts upon reception and in the final product. In addition, when required by the Brazil nut buyer, samples were taken for aflatoxin analysis prior to delivery of the consignment. The mission team was informed that the period between sampling and obtaining the results was at least 8 days.

The mission team noted in one of the factories visited that the device used for moisture control of incoming raw material could measure moisture content only up to 25 %, whereas the company stated that the average moisture content of incoming nuts would be between 28-32 %.

In the establishments visited, the mission team noted that the facilities used for storing the incoming nuts and the final product did not always follow the requirements of section 2.8 of the Codex Alimentarius Code of Practice for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59-2005, REV.1-2006). In particular, the facilities did not always provide protection against rain, were open to insects, rodents and birds, and also did not have any possibility to control temperature and humidity.

Both establishments had established traceability systems in the form of the registration of incoming and outgoing products. These data included the name of the supplier, the region, the quantity of nuts, and data on moisture control. However, full traceability was not always possible back to individual suppliers as nuts were generally stored in bulk.

Conclusions

There is no legal requirement for Brazil nut exporters exporting their nuts to the EU to have HACCP systems in place. Very few Brazil nut establishments exporting Brazil nuts to the EU had established system of control based on HACCP principles as required by Article 10 together with

3 In their response to the draft report the Brazilian Authorities noted that Normative Instruction No 11, of 22 March 2010 is already in force and provides clear requirements in relation to the control of Good Manufacturing Practice (GMP) and additional requirements.

The requirements of the section 2.8 on storage conditions for tree nuts of the Codex Alimentarius Code of Practice for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59-2005, REV.1-2006) were not always followed in the establishments visited by the mission team.

Traceability is not fully in line with section 33 of the Codex Alimentarius Code of Practice for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59-2005).

5.4.3 Non-compliant products rejected in the EU

Findings
Normative MAPA Instruction No 13/2004 lays down the procedure to follow for non-compliant Brazil nuts rejected and returned by importing countries. Under this procedure, rejected and returned consignments are subject to aflatoxin control by VIGIAGRO (as feed) and ANVISA (as food) at the point of import prior to further processing.

In accordance with the above Instruction, rejected and returned Brazil nuts can be imported into Brazil and used on the domestic market as food when aflatoxin analysis shows levels below 30 ppb, or as feed when aflatoxin analysis shows levels below 50 ppb. For levels above 50 ppb, the Brazil nuts have to be destroyed under the supervision of VIGIAGRO.

The mission team was informed that no consignments had so far been returned to Brazil, so the above procedure had never been used in practice.

Conclusions
There are national procedures in place for handling Brazil nuts rejected and returned by importing countries.

5.5 Method of sampling for Brazil nut consignments

Findings

The mission team was informed that under the National Residues and Contaminants Control Plan for Plant Products during 2009/2010 some 30 samples of Brazil nuts would be taken for aflatoxin control from April–June onwards. The mission team was informed that these samples would be taken only from establishments authorised as EU exporters. It was planned to extend these controls to other Brazil nut processors in future.

The mission team observed a sampling demonstration on a Brazil nut consignment of 26 000 kg (1 300 bags of 20 kg each) at one of the Brazil nut exporters. The SIPAG inspector took 100 incremental samples of 300 g each from 100 selected bags to produce an aggregate sample of 30 kg. The aggregate sample was put into a bag, which was then packed in a cardboard box, sealed and labelled by the inspector. Under the sampling procedure, the sampling and shipment reports are then completed and the sample is sent for analysis to the official laboratory — LACQSA/LANAGRO-MG — in Belo Horizonte. At the laboratory, the samples are then divided into three equal laboratory samples before homogenisation.

4 In their response to the draft report the Brazilian Authorities noted that the traceability criteria in the Normative Instruction No 11, of 22 March 2010 requires measures from the processors which guarantee the traceability with data from the Amazon region where the supplied Brazil nuts originates and to include data of this supplier.
Conclusions
The sampling procedure observed was in line with the requirements of Regulation (EC) No 401/2006.

5.6 Procedure for exporting Brazil nuts to the EU

Findings
According to MAPA, there has been no export of Brazil nuts in shell to the EU since 2003. According to EUROSTAT data, however, approximately 160 t were imported from Brazil in 2008 and 2009. Similar data collected by the Brazilian Institute of Geography and Statistics (IBGE) were provided to the mission team by the CAs and during the visit to the Brazil nut exporter in Belém. The CAs could not explain the differences in the statistical data from MAPA, IBGE and EUROSTAT.

The procedure for the export of Brazil nuts to the EU is set out in MAPA Normative Instruction No 13/2004. As, according to MAPA, there has been no export of in-shell Brazil nuts to the EU since 2003, this export procedure has never been applied in practice. Therefore the mission team could not verify its implementation.

Under the procedure for the export of Brazil nuts to the EU, exporters have to be registered with MAPA. However, 1 RASFF notification in 2007 and 4 RASFF notifications in 2009 concerned products exported by a non-authorised company. The CAs could not fully explain this to the mission team and investigations are currently ongoing.

For the export of each individual consignment, the exporting company has to apply to the local SFA for inspection of the consignment and sampling for aflatoxins. The results are reported to MAPA by the official laboratory and, if the EU requirements are met, a health certificate is issued for the consignment.

As already described under point 5.3.1, VIGIAGRO is responsible for import and export controls on animals and foodstuffs, including the control of Brazil nut consignments at the point of export. However, under national customs requirements, Brazil nut consignments can be customs-cleared for export at the point of export without requiring VIGIAGRO control results. At the same time, customs have no obligation to check for the presence of the documents required by EU legislation, or to check whether the company is registered by MAPA as an EU exporter. There is therefore a possibility that products may be exported by the company not registered for export and without a health certificate as required by Article 4(1)(a) of Regulation (EC) No 1152/2009.

Conclusions
There are procedures established for the control of Brazil nut exports to the EU, however these are not adequate. In particular, the lack of link between VIGIAGRO and customs controls at the point of export might lead to the possibility that products can be exported to the EU by the company not registered for export and without the health certificate required by Article 4(1)(a) of Regulation (EC) No 1152/2009.

5.7 Laboratory services

Findings
There are 3 laboratories currently authorised by the CGAL for aflatoxin analysis in Brazil nuts: 1 governmental and 2 private laboratories.

There is no official laboratory for Brazil nut analysis in Belém. The laboratory in Belém has been set up and has received equipment for conducting aflatoxin analysis. However, it does not yet
perform routine analyses. According to the CGAL, however, it is in the final stages of submitting a request for accreditation to standard ISO 17025 by the National Accreditation Body (INMETRO). The mission team noted in the establishments visited that in-house control samples are sent to the 2 authorised private laboratories in São Paulo State and a minimum of 8 days are required to receive results from these laboratories.

The mission team visited the 2 private laboratories.

One laboratory is located in Santos. It focuses on inspections and quality certification. The laboratory performs chemical analyses for e.g. pesticide residues, GMO and mycotoxins. The laboratory is accredited to ISO 17025 by INMETRO. The accreditation certificate was issued on 23 September 2008 and is valid until 11 October 2010. The mission team was informed that the method used for the determination of aflatoxins B1, B2, G1, G2 and total aflatoxins was validated for peanuts, but not yet for Brazil nuts. However, the laboratory stated that a similar procedure was followed for the analysis of Brazil nuts. The procedure is in full conformity with European standard EN 12955, using HPLC, Kobra cell and fluorescence detection. LOQ values were around 0.4 μg/kg, well below the limits set in Regulation (EC) No 1881/2006. Calibration curves are constructed daily, recovery is checked daily and samples are run together with the calibration curve and a recovery check (spiked and blank samples). The laboratory participates in the AOCS Laboratory Proficiency Programme for peanut and corn samples, at a frequency of 8 times per year, as Brazil nut samples are not available. The expanded measurement uncertainty is 25 %, calculated according to the 2000 EURACHEM guide. Confirmation of results is based on the uniqueness of the immuno-assay, the retention time and the use of control samples. The recovery, the corrected analytical result and the expanded measurement uncertainty are reported.

The whole sample is homogenised. Depending on sample size, an appropriate milling device is used. Up to 3 kg, a meat mincing mill is employed. Above 3 kg, a slurry mixer is used. According to the Standard Operating Procedure (SOP), a minimum amount of 3 kg is requested, although an ideal size of 10 kg is prescribed. For Brazil nuts, this amount is meant to be without shell. All of the sample is slurried, with a sample/water ratio of 10:15. Four samples are taken from the slurry, for analysis, reference and defence purposes. The homogenisation process was tested once with a sample. A sample of nuts is analysed without shell. If it is delivered with shell, it is unshelled before analysis. The complete unshelled sample is analysed, so without any sorting.

The mission team visited a second private laboratory in Sao Paolo. This laboratory had already been visited during the first FVO mission to Brazil concerning Brazil nuts in 2003 (SANCO/9027/2003) and the second FVO mission in 2004 (SANCO/7074/2004). The laboratory was accredited by INMETRO to ISO 17025. The accreditation certificate was issued on 25 August 2008 and was valid until 25 August 2011. The mission team was informed that the method used for the determination of aflatoxins B1, B2, G1, G2 and total aflatoxins was validated for peanuts and validation for Brazil nuts was ongoing. It is a TLC method, in conformity with method 970.44 of the Official Methods of Analysis issued by AOAC International, 18th edition, 2005. The SOP reported LOQ values of 0.5 μg/kg for aflatoxins B1 and G1 and 0.25 for B2 and G2 in Brazil nuts, well below the limits set in regulation (EC) No 1881/2006.

Samples are all dry-milled. Up to 3 kg, a meat mincing mill is used, after which further homogenisation is performed using a Stephan mill. For samples up to 30 kg (until now only relevant for peanut samples), portions are first milled in a Stephan mill and then transferred to a cement mixer. When the entire pre-milled sample is in the cement mixer, it is homogenised further and samples are then taken for analysis, reference and defence purposes. The homogenisation process was tested once. A sample of nuts is analysed without shell. If it is delivered with shell, it is unshelled before analysis. The complete unshelled sample is analysed, without any prior sorting. Positive samples are re-run on a second TLC plate, together with calibration standards and a control
sample. The analytical result is reported together with the recovery. The expanded measurement uncertainty is not reported. Some preliminary calculations (based on an INMETRO method derived from the Eurachem 2000 document) are available, giving 12% at the LOQ level, but these have to be confirmed before they are used in the analysis certificates. According to the CCA, the laboratory was instructed by the CCA to express the measurement uncertainty on the reports of analysis in products destined to export to Europe. For other destinations, the report of uncertainty measurement is not mandatory.

The mission team was informed by both the laboratories visited that they have difficulties participating in international proficiency test schemes such as FAPAS. This is due to problems with customs clearance for the test material. Consequently, the laboratory in São Paulo was able to participate in only one FAPAS proficiency test in 2007. Every 3 months they send samples to another laboratory (using an HPLC method) to obtain confirmation. They performed well in the recent proficiency test by LACQSA/LANAGRO-MG (4 nut samples in 2009 at levels of 0.25-0.5 μg/kg).

Conclusions

There are three laboratories in Brazil authorised for official Brazil nut analysis, all accredited to ISO 17025 however none of them in the area where Brazil nuts are produced and processed.

The procedures in place for Brazil nut analysis as observed by the mission team are in accordance with the criteria established in Commission Regulation (EC) No 401/2006.

5.8 Response to RASFF notifications

Findings

The Department of Sanitary and International Relations (DNSF) within MAPA’s Secretariat of Agribusiness International Relations is the national contact point for the RASFF system. The DNSF’s coordination unit for Europe and Mercosur affairs is responsible for the daily management of RASFF notifications received via the RASFF window from the Commission’s RASFF services.

Under the RASFF procedure, DNSF forwards all RASFF notifications concerning Brazil nuts to DIPOV at MAPA, which is responsible for follow-up. The results of the follow-up or any request for further information, such as details of the consignment or results of the Member State laboratory analysis, are communicated to the Commission’s RASFF services directly via the RASFF window or, if necessary, via the Ministry of External Relations.

There are documented procedures in place for RASFF follow-up by DIPOV. The follow-up starts with a request by DIPOV to the company concerned to provide information on the notified consignments. This may also include evidence of internal company controls such as sampling for aflatoxins. The mission team noted that generally no deadline is given to companies to provide the required information, although Administrative Order No 53/2009 sets a deadline of 6 months for completion of the entire follow-up procedure. For RASFF notifications in September 2009 (2009.BSQ, 2009.BSP, 2009.BSO and 2009.BSM) concerning in-shell Brazil nuts, the mission team observed that no information had yet been received by DIPOV, so the investigation was still ongoing.

5 In their response to the draft report the Brazilian Authorities noted that a workshop with the involved customs bodies (MAPA, ANVISA and federal Revenue) was held in 2009 in order to train the responsible for imports and clarify doubts about the procedures for the import of laboratory inputs. An imports guideline considering the procedures of the 3 bodies mentioned is in its final steps of elaboration, in order to simplify the process and solve difficulties. These guidelines were put to the test on a Trial Run with real FAPAS samples in June 2010, and the customs clearance were successful with rapidity in at least 90% of them.

6 In their response to the draft report the Brazilian Authorities noted that the result of the investigation of the mentioned RASFFs were already forwarded to the EU for knowledge.
The mission team noted that at least one RASFF notification from 2007 (2007.BUB) concerning in-shell Brazil nuts had not been followed up. According to the representatives of DIPOV, it had received no such notification from DNSF, so no follow-up had been conducted.\textsuperscript{7}

Conclusions
There are administrative structures and procedures in place for RASFF follow-up within MAPA. However, the procedure does not always ensure that all RASFF notifications concerning Brazil nuts are investigated.

5.9 Research activities

Findings
Since the previous mission, SANCO/7074/2004, several research projects focusing on good agricultural practices (GAP), GMP and good storage practices (GSP) have been initiated and completed, with some concrete recommendations made on how to improve the quality of nuts. These projects include the Conforcast project (implemented since 2005) and the SAFENUT project (implemented between 2006 and 2008). According to the CCA the results of Conforcast show that influence of rotten nuts on the contamination level, being one of the conclusions that the removal of rotten nuts brings drastic reduction to the percentage of non-compliant samples (1.9% at the level of 20ppb, 3.8% at the level of 15ppb and 5.7% at the level of 10ppb).

The mission team noted during the on-site visits to the collector community and nut processors that some of the recommendations made in these projects have already been implemented, such as differentiation in the prices paid to collectors for Brazil nuts depending on product quality to encourage them to pay more attention to quality. The mission team was informed that additional studies are necessary in order to assess the possibility to implement GAP, GMP and GSP recommendations in practice. A further 3 projects are therefore currently being implemented, in particular to study the implementation of traceability during the transport of Brazil nuts from collector communities to processors, to examine technological innovations such as bringing drying facilities closer to collector communities, and to better understand mycotoxin growth throughout the Brazil nut production chain.

Conclusions
Since the last mission, progress have been made in the research activities on Brazil nuts. Several research projects focusing on good practices have been initiated and completed with some concrete recommendations on how to improve the quality of nuts. However, further efforts need to made in order to implement identified good practices.

5.10 Follow-up to mission 7074/2004

The current status of the recommendations made in 2004 are summarised in the following table:

<table>
<thead>
<tr>
<th>Recommendation made in report 7074/2004</th>
<th>Summary action described by MAPA</th>
<th>FVO comment</th>
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<tbody>
<tr>
<td>(1) Ensure that already drafted export and sampling procedures of Brazil nut consignments intended for export into the EU are enforced at the earliest</td>
<td>In order to guarantee customs controls on Brazil nuts, the consolidation of the measures required for the control procedure has been completed. These measures</td>
<td>Legislation for export control of Brazil nuts by MAPA has been established since last mission, but it is</td>
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\textsuperscript{7} In their response to the draft report the Brazilian Authorities noted that mentioned RASFF notification was not officially received by MAPA. However, the investigation is currently ongoing.
opportunity and that their application is in compliance with Commission Decision 2003/493/EC.

will be implemented by MAPA, the Ministry of Development, Industry and Commerce (MDIC) and the Ministry of Finance (MF). This will ensure that only consignments accompanied by health certificates and the appropriate report issued by a MAPA Federal Agriculture and Livestock Inspector can be released for export to the European Union.

(2) Consider proper co-ordination of scientific research and fieldwork in relation to GAP, GMP and GHP within the production chain of Brazil nuts in order to harmonise efforts and to accelerate dissemination of guidance to all parties and regions involved.

Tests to determine the influence of shell contamination on aflatoxin levels: LACQSA/DFA/MG (July 2004 to January 2006).

Research into the quality of Brazil nuts in Acre 'identification of critical contamination points in the production chain' - EMBRAPA/Acre (December 2006).

Introduction of alternative technologies to reduce aflatoxin-producing fungi in the Brazil nut production chain - Agência de Negócios e Desenvolvimento Sustentável (Sustainable Business and Development Agency)/AM - communities of Capana Grande and Projeto Democracia in Manicoré/AM (December 2006).

Several research projects have been initiated and coordinated by MAPA such as Conforcast and SAFENUT. MAPA has also taken part in other projects such as ASBRAER.

(3) Proceed with efforts to implement principles of GAP, GMP and GHP within the production chain of Brazil nuts in line with the conclusions of scientific research.

Formalisation of a technical cooperation agreement under the Safe Food Programme (PAS) with SENAI (National Industrial Training Service), in partnership with SEBRAE (Brazilian Support Service for Small Businesses), SENAR (National Rural Training Service), EMBRAPA (Brazilian Agricultural Research Company) and others, with a view to implementing basic hygiene and handling practices in the Brazil nut production chain.

Training of multipliers in the states of Amazonas, Acre, Amapá, Pará, Rondônia and Roraima, based on the safety and quality handbooks for the growing of Brazil nuts.

Progress have been made since last mission. A summary of the action taken was provided to the mission team, including information on GAP, GMP and GSP guidelines and training (points 5.4, 5.5 and 5.9). However, additional studies are necessary in order to assess the possibility to implement GAP, GMP and GSP recommendations in practice. A further 3 projects are therefore being implemented.
Training of nut collectors and transporters in the basic hygiene and handling measures at the various stages of the Brazil nut production chain.

Pilot project for the implementation of basic hygiene and handling practices for Brazil nuts throughout the production chain, in Oriximiná/PA (December 2005).

| (4) Proceed with development and application of systems to ensure traceability throughout the production chain of Brazil nuts. | Organisation and support of collectors and transporters in associative and cooperative organisations, with a view to registration with MAPA. Registration of these operators with MAPA, in accordance with Regulatory Order 66/2003. Implementation of safety and quality certification for Brazil nuts at these stages. | Action is in progress. New Normative Instruction No 11/2010, once in force, provides more detailed requirements on traceability throughout the Brazil nuts production and processing stages.  

| (5) Proceed with the development of analytical capabilities and ensure application of requirements with regard to homogenisation and analysis of samples according to Commission Directive 98/53/EC. | The procedures for sampling and sample preparation have been performed in accordance with Decision (EC) 493/2003, for the health certification of Brazil nuts for the European Union, since the publication of Regulatory Order No 13 of 27 May 2004. These procedures will be progressively extended to other operations for the inspection, checking, monitoring and control of shelled and unshelled Brazil nuts for the internal and external markets, in accordance with the National Plan for the Safety and Quality of Products of Plant Origin (PNSQV), established by MAPA Regulatory Order No 10/2003. MAPA's laboratory network will be expanded and equipped for the analysis of mycotoxins with homogenisers appropriate to the sample volume, in accordance with | Progress has been made since the last mission, but there is still no official laboratory in Belém. The laboratory in Belém has received equipment for conducting aflatoxin analysis, but does not yet perform routine analyses. However, according to the CCA, it is in final stages of submitting a request for accreditation to standard ISO 17025 by the INMETRO. |

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8 In their response to the draft report the Brazilian Authorities noted Normative Instruction No 11 of 22 March 2010 is already in force and contemplates the items mentioned above.
Regulatory Order 13/2004. Steps have already been taken to equip the LAV/PA laboratory in Belém, which is in the process of acquiring equipment. The EMBRAPA/ACRE laboratory is being refitted to meet the technical and quality requirements necessary for accreditation.

The adapting of procedures and methods for the determination of mycotoxins for all susceptible products is the subject of broad discussion within CLAV/MAPA, with the involvement of the relevant technical sectors and research, scientific and laboratory institutions with a view to defining and standardising criteria and, in particular, improving the reliability of analysis results to ensure effective control and monitoring of these products in line with and equivalent to similar control systems adopted internationally.

The monitoring of the accredited laboratory network is fully functional, with two accredited laboratories having already been suspended for producing unsatisfactory results in the interlaboratory trial (series III/2003).

6 Overall Conclusions

The current control system in place cannot guarantee that all Brazil nuts exported to the EU meet the conditions of Commission Regulation (EC) No 1152/2009 and comply with the aflatoxins limits specified in the Commission Regulation (EC) No 1881/2006. Further efforts are needed, in particular to implement good manufacturing practices throughout the Brazil nut production chain.

7 Closing Meeting

A closing meeting was held on 24 March 2010 with the CCA, MAPA. At this meeting, the main findings and conclusions of the mission were presented by the inspection team. The representatives of MAPA offered initial comments but did not express any major disagreement with these findings and conclusions.
To the Competent Authorities of Brazil.

An action plan in response to the recommendations should be forwarded to the Commission within 25 days of receipt of the report. This action plan should clearly set out the manner and deadline by which the CAs will address each of the following recommendations:

<table>
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<tr>
<th>№.</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>1.</td>
<td>Ensure that the responsibilities of VIGIAGRO for the export control of Brazil nuts are clearly defined.</td>
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<td>2.</td>
<td>Ensure that food business operators exporting Brazil nuts to the EU implement standards at least equivalent to Article 5 of Regulation (EC) No 852/2004 on food safety procedures based on HACCP principles.</td>
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<tr>
<td>3.</td>
<td>Ensure that establishments exporting Brazil nuts to the EU follow the requirements of section 2.8 of the Codex Alimentarius Code of Practice for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59-2005, REV.1-2006) on storage conditions for tree nuts.</td>
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<tr>
<td>4.</td>
<td>Proceed with the development and application of systems to ensure traceability throughout the Brazil nut production chain as required by Article 33 of the Codex Alimentarius Code of Practice for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59-2005) regarding traceability.</td>
</tr>
<tr>
<td>5.</td>
<td>Ensure that only Brazil nuts with a health certificate can be exported to the EU, as required by Article 4(1)(a) of Regulation (EC) No 1152/2009.</td>
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<tr>
<td>6.</td>
<td>Consider that all RASFF notifications, issued within the European Union Rapid Alert System for Food and Feed (Article 50 of Regulation (EC) No 178/2002) involving Brazil nuts exported from Brazil are investigated.</td>
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<tr>
<td>7.</td>
<td>Ensure the implementation of good practices identified by Brazil to avoid or reduce aflatoxin contamination in Brazil nuts.</td>
</tr>
</tbody>
</table>

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

## ANNEX 1 - LEGAL REFERENCES

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
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