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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

INDONESIA

FROM 13 TO 22 MARCH 2012

IN ORDER TO ASSESS THE CONTROLS OF AFLATOXIN CONTAMINATION IN NUTMEGS INTENDED FOR EXPORT TO THE EUROPEAN UNION

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Indonesia from 13 to 22 March 2012.

The objective was to assess the control systems in place for the control of aflatoxin contamination in nutmegs intended for export to the European Union (EU). This mission was included in the FVO 2012 audit programme due to the high volume of exports of this commodity to the EU, and the increase in Rapid Alert System for Food and Feed (RASFF) notifications. From 2008 to the time of the audit 19 notifications relating to aflatoxins in nutmegs from Indonesia have been notified through the RASFF.

The implementation of Good Agricultural Practices (GAP) and Good Manufacturing Practice (GMP) by the growers, processors and exporters is not supervised by the Competent Authorities (CAs) as they are not required to be registered with them. GAP and GMP were not always followed in the facilities visited.

The FVO team observed that the control system relied on aflatoxin sampling and laboratory analysis prior to the export of nutmegs to the EU. However, as these controls are not carried out in line with EU requirements on sampling and only 10 percent of consignments are covered by official sampling and sample taken is not representative and identified enough, the aflatoxin sampling cannot fully guarantee that all nutmegs exported to the EU comply with the aflatoxin limits specified in the Commission Regulation (EC) No 1881/2006.

The report makes a number of recommendations to the CAs, aimed at rectifying the shortcomings identified and enhancing the implementation of the control measures.

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Abbreviations and special terms used in this report

Abbreviation	Explanation
AQA	Agriculture Quarantine Agency
CA(s)	Competent Authority(ies)
CAC/RCP	Codex Alimentarius Commission/Recommended Code of Practice
CAC/GL	Codex Alimentarius Commission/Guideline
CCA(s)	Central Competent Authority(ies)
CCP	Competent Contact Point
CODEX	Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization
DGEC	Directorate General of Estate Crops
DG(SANCO)	Health and Consumers Directorate-General
EU	European Union
FAPAS	Food Analysis Performance Assessment Scheme, UK
FBO(s)	Food Business Operator(s)
FVO	Food and Veterinary Office
GAP	Good Agricultural Practices
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardization

LC-MS/MS	Liquid Chromatography - Mass Spectrometry/Mass Spectrometry
MOA	Ministry of Agriculture
MS(s)	Member State(s)
NADFC	National Agency for Drug and Food Control
OKKP	Competent Authority for Food Safety
PT(s)	Proficiency Test(s)
RASFF	Rapid Alert System for Food and Feed
RQO	Regional Quarantine Office
SNI	Indonesian National Standard
SOP	Standard Operation Procedure(s)
TC(s)	Third Country(ies)

1 Introduction

The audit took place in Indonesia from 13 to 22 March 2012 in order to assess the control of aflatoxin contamination in nutmegs, intended for export to the European Union (EU). The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one National Expert from a Member State (MS).

The audit was undertaken as part of the FVO's annual audit programme in the context of a series of audits in Third Countries (TCs) to evaluate the control systems and the operational standards in this sector.

The team was accompanied during the audit by a representative of the Central Competent Authority (CCA) - the Ministry of Agriculture (MOA).

An opening meeting was held on 13 March with the CCA - the MOA. At this meeting, the objectives of and itinerary for the audit were confirmed.

2 Objectives and Scope

The **objectives** of the audit were to verify whether there are control systems in place to control aflatoxin contamination in nutmegs intended for export to the EU and to assess whether they are adequate to ensure that the produce concerned is within the specified contaminant limits laid down in EU legislation, in particular complying with or being at least equivalent to Commission Regulation (EC) No 1881/2006.

In terms of **scope**, the audit reviewed the controls on the production, processing and export, including the national legislation in place, Competent Authorities (CAs) organisation, their controls and enforcement capability.

In pursuit of these objectives, the following sites were visited :

Table 1

Sites visited			**Comments**
Competent Authorities			
	Central	4	The MOA, The National Agency for Drug and Food Control (NADFC), The Ministry of Trade, The Ministry of Finance - Directorate General of Customs,
	Regional/Local	4	3 Regional offices: Maluku, East Java, and Northern Sulawesi 1 District office Siau in Northern Sulawesi region

Laboratories		
Public laboratory	1	NADFC's laboratory Northern Sulawesi region
Private approved laboratory	1	East Java region
Producers		
Growers	3	1 small scale grower in the Maluku region 2 small scale growers in the Northern Sulawesi region
Processors/Exporters/Collectors		
Collectors	3	1 co-operative of growers in the Maluku region 2 collection points in the Northern Sulawesi region
Processors, exporters	4	2 small processors/exporters to the EU in Maluku and East Java regions 2 large processors/exporters to the EU in Northern Sulawesi region

3 Legal Basis and Standards

3.1 Legal Basis

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

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

3.2 Standards

Additionally Guidelines and Codes of Practice of the CODEX Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization (CODEX)

were taken into account in the frame of the audit.

A full list of the applicable standards referred to in this report is provided in Annex 2. Reference to the specific provisions of these texts is provided at the beginning of each section.

4 Background

The FVO has carried out audits to the main exporting countries to evaluate official control systems for preventing aflatoxin contamination in foodstuffs. The reports on these missions are available on the Health and Consumers Directorate-General (DG(SANCO)) internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm.

According to Article 15(1) of Regulation (EC) No 882/2004 foodstuffs imported into the EU are checked by the CAs of the MSs.

Information on foodstuffs found to have public health implications are disseminated as alert notifications through the Rapid Alert System for Food and Feed (RASFF) to all MSs and to the exporting country. In the case of nutmegs the notifications relate to the mycotoxin content of goods exceeding EU limits of 5 µg/kg for aflatoxin B1 and 10 µg/kg for total aflatoxins. From 2008 to the time of the audit 19 notifications relating to aflatoxin contamination in nutmegs from Indonesia have been notified through the RASFF. The break down of these notifications as well as the volume of imports into the EU is presented in table 2.

Table 2

Indonesia	Imports to EU (metric tonnes)			Number of RASFF notifications		
	2009	2010	2011	2009	2010	2011
Nutmegs (Combined Nomenclature code 0908 10 00)	3 552	4 754	4 756	3	9	7

Source: Eurostat, Statistic Agency of Indonesia, RASFF window

In view of the number of notifications and the volume of export to the EU the FVO decided to undertake this audit.

5 Findings And Conclusions

5.1 Relevant national legislation

Legal requirements

Article 46(1)(a) of Regulation (EC) No 882/2004 stipulates that EU controls shall have, *inter alia* particular regard to the legislation of the TC.

Regulation (EC) No 1881/2006 lays down the specific standards for the admissible levels of

aflatoxins and sets maximum levels for certain contaminants (including mycotoxins) in foodstuffs.

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

Findings

The main legislation in the context of this audit is as follows:

- The framework legislation is the law No. 7/1996 on Food. This law establishes the general requirements on food safety and food safety certification of foodstuffs, however, certification is voluntary.
- Government Regulation No. 28/2004 on Safety, Quality and Nutrional Food defines food safety requirements and requires that foodstuffs should meet them.
- The Regulation of the Minister of Agriculture No. 20/2010 on Food Safety and Quality Assurance Systems designates the Competent Authority for Food Safety (OKKP) within the MOA as the CA for the official controls of fresh agricultural produce including nutmegs, with the exception of border controls. It defines also central and regional levels of this CA. The regulation designates the Agriculture Quarantine Agency (AQA) as the CA responsible for the border controls of fresh produce. The FVO team noted, that AQA is designated also by the Regulation of the Minister of Agriculture No. 88/2011 on Fresh Produce of Plant Origin Control at exit and entry points.
- Regulation No. 20/2010 lays down that the requirements for general hygiene and their implementation is obligatory for all Food Business Operators (FBOs) including the growers, processors and exporters of nutmegs.
- Regulation No. 20/2010 sets down the requirements for the implementation of good hygiene practice, good manufacturing practice (GMP), good agricultural practices (GAP) and for procedures based on the hazard analysis critical control points (HACCP) principles and the traceability of foodstuffs. However, the implementation of these requirements is voluntary.
- The Guidelines for the OKKP, which were issued by the central level of the OKKP, describe how to establish the regional officess of the OKKP including provisions concerning the developement of the quality manual and the standard operating procedures (SOPs) for the official controls and sampling.
- The Regulation of the Minister of Agriculture No. 55/2008 on Fresh Produce Registration establishes a voluntary system for the registration of the producers of fresh produce. To date no producer of nutmegs has been registered by the OKKP.
- Article 23 of Regulation of the Minister of Agriculture No. 88/2011 on Fresh Produce of Plant Origin Control at exit and entry points requires that exported fresh produce must be in line with the legal requirements of the country of destination.
- The Indonesian National Standard (SNI) No. 7385:2009 “Maximum Limit of Mycotoxin in Foods” establishes the aflatoxin limits in foodstuffs. This Standard was developed by the technical team and consists of representatives of the stakeholders, consumers, researchers and CAs. The use of the SNI is voluntary. There is no limit for aflatoxins in nutmegs, however, there is a limit in spices. The limit for aflatoxin B1 in spices is 15 µg/kg and for total aflatoxins is 30 µg/kg.

There is no legal requirement in place for collectors and exporters of fresh produce of plant origin to be registered by the CAs.

Conclusions

There is a legal framework established for the control of the export of nutmegs to the EU which among other things, requires FBOs to meet the relevant food hygiene requirements laid down in the legislation of the importing country.

There are no mandatory requirements for the processors exporting to the EU to implement procedures based on HACCP principles which is not equivalent with the requirements of Article 5 of Regulation (EC) No 852/2004 in conjunction with Article 10 of the same Regulation.

There are no mandatory requirements for the FBOs to be registered which is not equivalent with the requirements of Article 6 of Regulation (EC) No 852/2004 in conjunction with Article 10 of the same Regulation.

The implementation of traceability is voluntary.

5.2 Competent Authorities

Legal requirements

Articles 46(1)(b) and (c) of Regulation (EC) No 882/2004 stipulate that EU controls shall have, *inter alia*, particular regard to the organisation of the TC's CAs, their powers and independence, the authority they have to enforce the applicable legislation effectively, and the training of staff in the performance of official controls.

Findings

The CCA in the scope of this audit is the MOA. There are two Directorates General and the OKKP responsible for the activities in the context of this audit :

- The Directorate General of Estate Crops (DGEC) develops the policy and legislation for production and drafts of the quality standards for fresh produce of plant origin.
- The Directorate General of Processing and Marketing of Agricultural Products develops the policy for the food safety control system and the legislation on food safety.
- The control and monitoring function is carried out by the OKKP which was established in 2007.

The main task of the central OKKP is to verify the establishment of and the work carried out by the regional level. If the regional level were not able to perform tasks correctly the central level would take over its responsibility. However the FVO team did not note such undertaking.

There is an OKKP office in each region. Before the regional office starts the official controls its establishment must be verified by the central level. The OKKP is responsible for official controls of the food chain including the production of fresh produce of plant origin and nutmegs intended for export to the EU. Currently the regional offices are fully operational in 15 out of 33 regions. In the main nutmeg producing regions they are in the process of being established and are not yet operational. The central level plans to have all regional offices established and fully operational by the end of 2014.

Each regional office must report the results of the official controls on a quarterly basis to the central level. Reports are based on the requirements of the guidelines of the OKKP.

The NADFC is an independent agency responsible for the development of the legislation on methods of the laboratory testing and sampling including mycotoxins. The NADFC is the national

contact point for the RASFF notifications and in each region are established competent contact points (CCP).

The AQA of the MOA develops the policy and legislation on food export and import.

The Regional Quarantine Office (RQO) controls food safety at the border and issues the phytosanitary certificate for nutmegs intended for export to the EU on the basis of the food safety export certificate called "Recommendation" issued by the OKKP. See also chapter 5.4.

For the purpose of the official controls in the context of this audit only one private accredited laboratory in the East Java region is used. The laboratory was chosen by the OKKP on the basis of its accreditation.

There is a total of 40 staff working in the central OKKP, all with third level education in agriculture or natural sciences. Training is organised annually for staff members however, it does not include any training on mycotoxins.

In the East Java region visited by the audit team, six OKKP inspectors are involved in the controls within the context of this audit. A training course is provided annually on different topics including general sampling requirements. However, there was no specific training organised on sampling for aflatoxin contamination of foodstuffs. See also chapter 5.5.

The audit team was informed that a workshop was organised in June 2011 in the North Sulawesi region by the CCP, the regional CA and the EU delegation for growers, collectors, processors and exporters, in order to raise awareness of the problem of aflatoxin in nutmegs and to propose ways to reduce the risk of contamination.

In the context of this audit the Customs authorities under the Ministry of Finance are responsible for Customs clearance of the consignments for export to the EU. The Directorate General of Customs develops the legislation and procedures for Customs controls. The FVO team was informed by them that currently there is no specific procedure in place for nutmegs intended for export to the EU.

Conclusions

There are several CAs clearly designated in the context of this audit, however, not all of them are fully operational in the main producing regions.

No specific training was provided to the staff involved in the official controls in the context of this audit.

5.3 Official Controls on Production and Processing

Legal Requirements

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

EU aflatoxin levels are specified in the Annex of Commission Regulation (EC) No 1881/2006.

The CODEX Code of Hygienic Practice for Spices and Dried Aromatic Plants (CODEX Alimentarius Commission/Recommended Code of Practice (CAC/RCP 42-1995)) contains recommended practices based on GAP, GMP and HACCP.

Findings

In both of the regions visited the FVO team was informed that currently no official controls are

carried out on growers and processing or exporting facilities.

Cultivation

According to the information from the State Crops Statistic, nutmegs intended for export to the EU are cultivated in three regions – North Maluku, Maluku and North Sulawesi covering an area of approximately 28,431 hectares with approximately 74,211 growers.

GAP guidelines for nutmegs were developed by the DGEC; however, no information on the prevention of aflatoxin contamination is provided. Dissemination to the growers was provided through the regional offices of DGEC.

The audit team visited three nutmeg growers in the Maluku and the North Sulawesi regions.

In the Maluku region the grower visited was small scale with nutmegs cultivated on approximately one hectare. The nutmegs are collected directly from the tree with a special collection stick. They are then dried naturally on the farm and after drying, they are delivered to the collection point owned by the local growers' co-operative.

In the Northern Sulawesi region both growers visited are small scale with approximately 100 trees. The nutmegs are knocked down by a hook on a long stick and then collected from the ground. Drying takes place naturally (outdoors) for 5 days and the nutmegs are then stored in the open air for approximately one month.

The collection point visited in the Maluku region receives shelled nutmegs from the members of the co-operative. After arrival, visual sorting based on practical experience takes place. If the nutmegs are not dry enough, they are placed in the sun on plastic sheets to continue drying. The nutmegs are stored at the collection point for approximately one week in the open air and then delivered to the processing plant.

The FVO team visited two collectors in the North Sulawesi region, who receive unshelled nutmegs from the local growers. After arrival the nutmegs are sorted according to the quality parameters established by the collector. If the nutmegs are not dry enough (based on the practical experience), they are placed in the sun on plastic sheets or on the jute bags to continue drying. In the storage area the nutmegs are stored in piles or bags for approximately one month in the open.

The buildings used by the collectors visited are not designed to prevent the entrance of pests and it is impossible to control temperature and moisture therein.

Processing and storage

The level of implementation of the procedures, based on HACCP principles, by the FBOs is not known to the CAs as FBOs are not obliged to be registered with any of the CAs.

The FVO team visited one processor in the Maluku region and two in the North Sulawesi region. These processors did not have any internal quality assurance system in place. All the plants visited partly implemented the CODEX Alimentarius Code of Hygienic Practice CAC/RCP 42-1995 for Spices and Dried Aromatic Plants. However, the storage conditions for spices did not comply with this Code, as there was no possibility for controlling the relative humidity and temperature in the storage area in order to reduce the risk of mould growth. The buildings at the two plants visited were not designed to prevent the entrance of pests as required by the CAC/RCP 42-1995 Code.

One of the processors visited had written requirements in place on the quality of raw materials, and these were provided to each grower or the cooperation of growers. This processor received shelled nutmegs. The processor provided training to the growers on the prevention of contamination with aflatoxins. Currently, approximately 50 percent of growers supplying the company were trained.

Following the arrival of the nutmegs they are checked for moisture content and if this is higher than 11 percent they undergo drying. After drying the nutmegs are sorted, packed and labelled, and the batch number is included. The traceability of the product back to each co-operative of growers is possible before sorting. After the sorting process has taken place all nutmegs are mixed together and traceability is impossible. After packing, the FBO takes a one-kg sample from each 10-tonnes consignment for internal aflatoxin testing. The processor informed the FVO team that all samples taken for the purpose of the internal control are in line with EU legal requirements laid down in Regulation EC No 1881/2006. However sampling is not carried out in line with requirements of Regulation (EC) No 401/2006. Following this, consignments for the EU are shipped to the East Java region, where all procedures for clearance are carried out by brokers on behalf of the company.

The other two processors visited did not have food safety criteria in place for the reception of raw material. See also chapters 5.4 and 5.5.

The nutmegs are received unshelled and shelling is the first step in the production process, followed by sorting and packing in jute bags.

In all the processing facilities visited the risk of aflatoxin contamination is reduced by strict visual sorting, whereby sorting is repeated at least two to three times.

Non- conforming products

The FVO team was informed by the CA that no consignment intended for export to the EU and rejected at the border was re-exported back to Indonesia. However, the exporter in the Maluku region visited informed the FVO team that rejected consignments were returned to Indonesia and sold on the local market.

There are no procedures in place to deal with consignments rejected at the EU border and re-exported back to Indonesia.

Conclusions

The growers, processors and exporters in the main nutmeg producing regions are not covered by any official food hygiene controls. There is no CA responsible to ensure that the establishments comply with the requirements of Article 4 of Regulation (EC) No 852/2004 in conjunction with Article 10 of the same Regulation and the exact level of the implementation of the procedures based on the HACCP principles, GAP and GMP in the above mentioned establishments is not known to the CA.

Official information on GAP does not contain any information on aflatoxin contamination of nutmegs.

The traceability of the product was not possible in the facilities visited.

In the growers visited not all of the principles established in the CODEX Alimentarius Code of Practice CAC/RCP-42-1995 for Spices and Dried Aromatic Plants are applied.

In the nutmeg processors visited, the principles of GMP, established in the CODEX Alimentarius Code of Practice CAC/RCP-42-1995 for Spices and Dried Aromatic Plants, are followed with some shortcomings concerning storage and the prevention of the entrance of pests, which is not in compliance with the requirements set out in points 7.1.4 and 7.6 of the Code of Practice.

5.4 Procedure for exporting to the EU

Legal requirements

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

The CODEX General Guidelines on sampling (CAC/GL 50-2004) contains recommended procedures for the acceptance or refusal of the lot after inspection.

Findings

The export procedure for nutmegs that fall within the mandatory aflatoxin inspection requirements laid down by Regulation No 88/2011 of the MOA, requires exporters to apply to the relevant regional OKKP for sampling and aflatoxin analysis of every consignment intended for export to the EU. However, the FVO team was provided with sampling evidence for less than 500 tonnes of nutmegs out of 4,756 tonnes exported to the EU.

In the East Java region sampling is carried out by the regional OKKP sampling inspector. These results together with a food safety certificate, issued by the OKKP, are delivered by the exporter to the RQO. The RQO issues the phytosanitary certificate on the basis of a favourable food safety certificate. The FVO team checked five consignments which were for export to the EU. All of them complied with the procedure. However, neither phytosanitary certificate nor food safety certificate contained a batch identification number. The product could be identified only by the name of the exporter and the total volume of the consignment.

In the East Java region, the FVO team was informed by the exporter visited, that in the case of non-compliant results, nutmegs are sorted and are repeatedly sampled. The FVO team noted, that the weight of the consignment after the sorting was the same like before. The batch is exported to the EU only when the result is compliant with the legal requirements. See also chapter 5.5.

In the Maluku region only phytosanitary controls are carried out by the RQO on each consignment of nutmegs, before shipment to the East Java region, as the regional office of OKKP is not yet established in this region. There are no exports going directly from this region to the EU. Each consigment goes through the East Java region.

In the Maluku region the FVO team visited one exporter and checked five files of exported consignments. They were in compliance with the procedure for export to the EU described above. However, neither phytosanitary certificate nor food safety certificate contained a batch identification number. The product could be identified only by the name of the exporter and the total volume of the consignment.

In the Northen Sulawesi region, clearance for the export of nutmegs to the EU is done directly. The RQO, on the basis of the results of private samplings carried out by the exporter, issue a phytosanitary certificate. No food safety certificate was issued by the OKKP because the regional OKKP is not yet established in this region.

The FVO team was informed that Customs do not have any special procedure in place to clear nutmegs. Nutmegs are cleared on the basis of the phytosanitary certificate.

Conclusions

There is an export procedure for nutmegs exported to the EU in place with some shortcomings concerning the identification of the product. However, as only one region producing nutmegs intended for export to the EU has established CA only about 10 percent of consignments exported to

the EU underwent all the required controls and checks.

5.5 Method of Sampling Consignments

Legal requirements

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

The CODEX General Guidelines on Sampling (CAC/GL 50-2004) contains reguirements for the identification of the sample.

Findings

The audit team observed a sampling excercise conducted by the OKKP inspectors in East Java region.

The sampling was conducted on a typical consignment of 8 tonnes (160 x 50 kg bags). Consigment consisted of a pile of sacks without identification supplied by the different suppliers. From that pile of sacks a total of 13 incremental samples, each weighing approximately 500 grams, were taken from sacks from the top, the side and the bottom of the pile. The incremental samples were taken by hand only from the top of the sacks. An aggregate sample of about 8 kg was formed and mixed in empty plastic sacks. This aggregate sample was mixed and quartered. Two quarters were again mixed and quartered a second time. Again two quarters were taken mixed and quartered. Two of the four quarters were taken as a sample for analysis and as a counter sample. Both samples (half kg) were packed in transparent plastic bags together with a paper indicating the date and the name of company and closed with a knot but not sealed. They were taken to the laboratory together with a report about the sampling. Apart from those data the report did not contain any information regarding the specification of the sample for example an identification of the consignment or a unique lot number, because at the time of the sampling there was no lot number determined. The sacks are stamped with a lot number only before export. Therefore it is not possible to identify the sacks belonging to the consignment sampled. The sample is only linked to the exporter and in case of positive results there are not measures foreseen by the CA to prevent that the product is exported to the EU. The CA stated that they are unable to trace non compliant samples due to the non-existence of lot numbers in the time of sampling.

In the laboratory one of the samples was taken for analysis.

In the Northen Sulawesi region the FVO team was informed, that the sampling for the issuance of the phytosanitary certificate was done by the laboratory from a “pre-sample” taken by the exporter. In one case the laboratory took a half kg as a sample and in another the exporter took a sample weighing 3,3 kg.

Conclusions

The sampling procedure observed did not follow the requirements equivalent to Regulation (EC) No 401/2006 regarding the weight of the incremental sample, weight of the aggregate sample and representativeness of the laboratory sample.

The definition of the lot, sampling report and identification of the sample are not in line with CODEX General Guidelines on Sampling (CAC/GL 50-2004) in particular section 2.3.3 and 2.3.7.

5.6 Laboratory Services

Legal requirements

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

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

Points 41 and 42 of CODEX Guidelines CODEX Alimentarius Commission/Guideline (CAC/GL) 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems lays down that inspection services should utilise laboratories that are evaluated and/or accredited under officially recognized programmes to ensure that adequate quality controls are in place to provide for the reliability of test results. In accordance with Guidelines of CODEX CAC/GL 27-1997, point 3, the laboratories should comply with International Organisation for Standardization (ISO)/International Electrotechnical Commission Guide 17025.

Findings

In the East Java region the FVO team visited a private laboratory. The accredited laboratory was designated by the MOA to work with the AQA as a Food Safety Analytical Laboratory for fresh agricultural commodities. For this purpose it has an agreement with the East Java Province regional OKKP to conduct laboratory tests of pesticides, mycotoxins and heavy metals in samples of agricultural products. The laboratory is accredited to ISO 17025:2005 by *Komite Akreditasi Nasional* (Indonesian Accreditation body) since May 2011. The method of analysis for mycotoxins is included in the scope of the accreditation.

Since March 2010 the laboratory has been in the Food Analysis Performance Assessment Scheme (FAPAS) program for 12 Proficiency Tests (PTs) on mycotoxins. As nutmeg was not in the FAPAS program during this period, a comparable test, regarding the level of mycotoxin, was around. This PT sample contained 5.1 µg/kg aflatoxin B1 and 10 µg/kg total aflatoxins in peanut butter, for which z-scores of 0.3 and -0.2 were obtained, respectively.

The laboratory receives half kg samples in transparent bags. These are renumbered in the laboratory system. The whole half kg is dry milled in 3 successive portions, which are collected in a plastic bag, mixed by a spatula and stored in the freezer upon analysis. A four gram portion is processed in the sample preparation upon analysis in a Liquid Chromatography - Mass Spectrometry/Mass Spectrometry (LC-MS/MS). Above 2.5 µg/kg aflatoxin B1, quantitative results are reported.

In the Northern Sulawesi region the FVO team visited the NADFC office. The office includes laboratory facilities for general food analysis. Among other tools, a High Performance Liquid Chromatography (HPLC) equipped with fluorescence detection is present for general purposes but not for aflatoxin analysis. The provision of milling equipment was not completed. One technician participated in a training course on the "Determination of Fusarium toxins by HPLC, LC-MS/MS and rapid techniques", organized in October 2011 in Turkey. This course consisted of deoxynivalenol and fumonisins analysis in wheat, maize and pasta by the HPLC. Currently this laboratory does not perform any tests of aflatoxins.

Conclusions

The authorised private laboratory visited was accredited according to the requirements of the ISO 17025 which is in line with point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997.

The laboratory performed well in terms of participation in PTs, in terms of the use of reference materials and having quality control measures in place.

5.7 Response to RASFF Notifications

Legal requirements

Point 6 of CODEX Guidelines CAC/GL 25-1997 requires exchange of information between countries on rejections of imported food. In particular the food control authorities in the exporting country should undertake the necessary investigation to determine the cause of any problem that has led to the rejection of the consignment. The food control authority in the exporting country, if requested, should provide the authorities in the importing country with information on the outcome of the necessary investigation, if available. Bilateral discussions should take place as necessary.

Findings

Since 2009 NADFC has access to the RASFF portal but no direct access to the database to download RASFF notifications related to aflatoxins in nutmegs from Indonesia. The NADFC checks the RASFF list on a daily basis. However, the complete notifications are in general received from the EU Delegation in Jakarta one week later. The NADFC explained to the audit team that they follow an SOP in which it is laid down that the notification should be forwarded within 24 hours to the CCP.

In the case of nutmegs, the previous CCP was the Agency for Food Security and since 2011 the Directorate General of Processing and Marketing of Agriculture Product in the MOA is responsible. Furthermore, the internal contact points under the MOA are the AQA, Agency of Food Security and the DGEC. The FVO team was informed that in the SOP for RASFF notifications it is also laid down that after 2 weeks the NADFC should ask the CCP for the results of the follow-up activity. The audit team was informed that this part of the SOPs is usually not followed.

When the regional CCP receive the notification they start investigations and after about 2 weeks they inform the central OKKP and the exporter involved in the notification. An inspection visit to the exporter is announced and usually conducted by the regional CCP. The audit team was informed by the NADFC that companies involved in the RASFF are not obliged to provide the NADFC with information related to their exports activities. Follow-up visits to the companies involved in the notifications were not always possible. The NADFC has no legal powers to enter the premises of exporters however, the RQO is the CA responsible for official controls of exporters, that has the legal power to enter premises.

In the East Java region the FVO team was informed by the central OKKP, that information about RASFF notifications is delivered to the regional OKKP only in some cases. In the same region the RQO informed the FVO team, that they are responsible for the follow-up of RASFF notifications. They receive information from the central Government.

In the East Java region the FVO team was informed by the exporter visited that he was informed about one in every two cases of nutmegs notified through RASFF by an importer to the EU. No information was received from the CAs.

In the Maluku region the FVO team was informed by the RQO that last year they received RASFF notifications, which they forwarded to all exporters and processors in the area. However, the exporter visited informed the FVO team, that he received information about the RASFF notification concerning his company only from his branch in the EU.

In the Northen Sulawesi region the exporter visited stated, that he was informed about notifications by his client.

The follow-up of the RASFF notifications is possible only back to the exporter, due to problems in the identification and lack of traceability of the product concerned. See also points 5.3., 5.4. and 5.5.

Conclusions

There are procedures for RASFF follow-up in place, however they are not implemented. Shortcomings were noted in the communication between CAs. Currently no follow-up investigation of notifications is carried out by the CAs involved in the RASFF network.

The follow-up procedure in place does not provide guarantees, that investigation will determine the cause of any problem that has led to the rejection of the consignment as required by the Point 6 of CODEX Guidelines CAC/GL 25-1997.

6 Overall Conclusion

The implementation of GAP and GMP by the growers, processors and exporters is not supervised by the CAs as they are not required to be registered with them. GAP and GMP were not always followed in the facilities visited.

The FVO team observed that the control system relied on aflatoxin sampling and laboratory analysis prior to the export of nutmegs to the EU. However, as these controls are not carried out in line with EU requirements on sampling and only 10 percent of consignments are covered by official sampling and sample taken is not representative and identified enough, the aflatoxin sampling cannot fully guarantee that all nutmegs exported to the EU comply with the aflatoxin limits specified in the Commission Regulation (EC) No 1881/2006.

7 Closing Meeting

A closing meeting was held on 22 March 2012 with representatives of the CCA. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The CAs did not express disagreement and offered some comments on the findings and preliminary conclusions.

8 Recommendations

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

The CA should:

N°.	Recommendation
1.	Ensure that the FBOs exporting nutmegs to the EU should implement standards at least

N°.	Recommendation
	equivalent to those required by Article 5 of Regulation (EC) No 852/2004 on food safety procedures based on the HACCP principles in conjunction with Article 10 of the same Regulation.
2.	Ensure that all establishments, where nutmegs for export to the EU are produced and processed, are registered in order to meet requirements equivalent to those in Article 6 of Regulation (EC) No 852/2004 in conjunction with Article 10 of the same Regulation.
3.	Ensure that all establishments where nutmegs for export to the EU are produced, processed and stored are under the official food safety controls, to ensure that produce exported to the EU meet the requirements of the CODEX Code of hygiene practice for spices and dried aromatic plants (CAC/RCP 42-1995).
4.	Ensure that the official information on GAP principles take into account information concerning aflatoxin contamination given in CODEX Code of hygiene practice for spices and dried aromatic plants (CAC/RCP 42-1995).
5.	Ensure that the storage conditions and the prevention of pests entering nutmeg processing and storage facilities comply with the requirements set out in the CODEX Code of hygiene practice for Spices and Dried Aromatic Plants (CAC/RCP 42-1995).
6.	Ensure that nutmegs exported to the EU meet the requirements of Regulation (EC) No 1881/2006 regarding aflatoxin contamination.
7.	Ensure that sampling procedures for aflatoxin analysis in nutmegs intended for export to the EU in particular the weight of the incremental sample, weight of the aggregate sample and representativeness of the laboratory sample, meet requirements at least equivalent to those laid down by Regulation No 401/2006.
8.	Ensure that the sample used for the decision for export to the EU is clearly identified in line with CODEX General Guidelines on sampling (CAC/GL 50-2004) Section 2.3.7 in connection with section 2.3.3.
9.	Ensure that internal investigation is undertaken in response to EU RASFF notifications taking into account the CODEX Guidelines CAC/GL 25-1997 for the exchange of information between countries on rejections of imported food, point 6 in order to determine the cause of any problem. For that purpose traceability of the product should be in place.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6322

Annex 1 – European Union Acts Quoted in the Report

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 1152/2009	OJ L 313, 28.11.2009, p. 40-49	Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

Annex 2 – Standards Quoted in the Report

Reference number	Full title	Publication details
CAC/RCP 42-1995	Code of hygiene practice for spices and dried aromatic plants (CAC/RCP 42-1995)	http://www.codexalimentarius.net/web/standard_list.jsp
CAC/GL 25-1997	Guidelines for the exchange of information between countries on rejections of imported food (CAC/GL 25-1997).	http://www.codexalimentarius.net/web/standard_list.jsp
CAC/GL 26-1997	Guidelines on the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1997).	http://www.codexalimentarius.net/web/standard_list.jsp
CAC/GL 27-1997	Guidelines for the Assessment of the competence of testing laboratories involved in the import and export control of food (CAC/GL 27-1997).	http://www.codexalimentarius.net/web/standard_list.jsp
CAC/GL 50-2004	General Guidelines on Sampling (CAC/GL 50 -2004)	http://www.codexalimentarius.net/web/standard_list.jsp