EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2014-7200 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THAILAND

FROM 29 JANUARY TO 07 FEBRUARY 2014

IN ORDER TO EVALUATE THE CONTROLS OF GENETICALLY MODIFIED ORGANISMS IN FOOD OF PLANT ORIGIN

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 Food and Veterinary Office (FVO) audit in Thailand, carried out between 29 January to 07 February 2014. Genetically modified (GM) papaya is not authorised in the European Union (EU). The objective of the audit was to assess the system of controls to ensure that GM papaya and GM papaya products are not exported to the EU.

The audit was carried out due to RASFF notifications of genetically modified organism (GMO) in papaya and papaya products from Thailand issued in 2012 and 2013.

Although GM papaya has never been authorised for cultivation in Thailand, the CA detected a significant presence of GM papaya. The origin of the GM papaya is not known. There is an incentive for farmers to use GM papaya as non-GM plants are susceptible to the serious disease PRSV. The farmers met had been using farm saved papaya seed for a number of years and the original seed was sourced before official GMO controls started.

In response to the RASFF notifications issued by the EU from 2012, the CA has put in place a system to ensure that GM papaya is not exported to the EU. The system is based on obligatory export certification, and papaya intended for export to the EU must be sampled and analysed for GMO presence. However, DOA does not verify whether sampling for export certification is representative. The CA requires GMP certification of packing facilities and performs official annual surveillance schemes. Certification of papaya growers to the GAP scheme is encouraged and includes systematic testing for GMOs. However, GAP certification is currently not compulsory and a number of growers of papaya for export to the EU are not certified. Some shortcomings were identified in the GMO laboratories such as sensitivity and quality control procedures. Official controls are supported by additional private controls.

While the control measures are capable of ensuring that papaya exported to the EU is not GM, the system put in place requires more time to be completed. At the time of the audit it was too early to conclude on its effectiveness.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CRM	Certified Reference Material
DG(SANCO)	Health and Consumers Directorate-General
DOA	Department of Agriculture
EU	European Union
EUROSTAT	Statistical Office of the European Union
FAO	Food and Agriculture Organisation
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GM	Genetically Modified
GMO(s)	Genetically Modified Organism(s)
GMP	Good Manufacturing Practice
HACCP	hazard analysis and critical control points
IBC	Institutional Biosafety Committee
IRMM	Institute for Reference Materials and Measurements
ISO	International Organisation for Standardisation
LOD	Limit of Detection
MOAC	Ministry of Agriculture and Cooperatives
MS(s)	Member State(s)
OAR	Office of Agricultural Regulation
OARD	Office of Agriculture Research and Development
PCR	Polymerase Chain Reaction
PRSV	papaya ringspot virus
PSCO	Plant Standard and Certification Office

PT	Proficiency test
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operation Procedure
TC(s)	Third Country(ies)

1 Introduction

The audit took place in Thailand from 29 January to 7 February 2014 in order to assess GMO controls of papaya intended for export to the European Union (EU). The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one Member State (MS) expert.

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

The FVO team was accompanied during the audit by a representative of the central competent authority (CCA), the Department of Agriculture (DOA) of the Ministry of Agriculture and Cooperatives (MOAC).

An opening meeting was held on 29 January 2014 with the DOA. At this meeting, the objectives of and itinerary for the audit were confirmed.

2 Objectives

The objective of this audit was to evaluate the system of controls to ensure that GM papaya and GM papaya products are not exported to the European Union (EU).

In terms of **scope**, the audit reviewed the controls in place on the production and packing facilities, including a review of national legislation, competent authority (CA) organisation, their controls and enforcement capability, facilities (laboratory capability) and measures in place to ensure absence of GMO in exports to the EU.

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

Competent Authority/ies			**Comments**
Competent Authority	Central	1	DOA
	Regional/local		Central region OARD5*
Laboratory/ies			
Public Laboratories		1	GMO laboratory of DOA
Private Approved Laboratories		1	
Producers			
		4	Papaya growers in Lopburi (2) and Saraburi (2)
Exporters/Pack-houses			
		4	Four exporters involved in GMO RASFF notifications (all have their own packing facility) in Nakonpathom, Bangkok and Pathumthani provinces

*Not visited, but during the audit representatives, including inspectors were met from this regional authority.

3 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 third countries may verify compliance or equivalence of Third Country (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.

EU legal acts quoted in this report refer, where applicable, to the last amended version. Full

references to the EU acts quoted in this report are given in Annex 1.

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

4 Background

4.1 Background to present audit

This was the first audit regarding GM papaya in Thailand.

Genetically modified papaya was developed to provide papaya ringspot virus (PRSV) resistance and is not authorised for cultivation in Thailand. The PRSV is a significant disease of the papaya. The virus is transmitted between plants by mechanical activities such as pruning and by numerous aphid species. No, or very limited seed transmission has been identified. The symptoms are typical of viral diseases: yellowing, leaf distortion, and severe mosaic. First, oily or water-soaked spots and streaks appear on the trunk and petioles. Eventually, the fruits show bumps and the classic "ringspot".

Information of foodstuffs found to have public health implications are disseminated as alert notifications through the EU Rapid Alert System for Food and Feed (RASFF) to all MS and to the exporting country. The first RASFF notification of GM papaya was issued in April 2012. From 2012 to the time of the audit, 37 notifications relating to GM papaya from Thailand have been notified through the RASFF. The products involved in RASFF notifications included fresh fruits such as green and Hawaii papaya, and dehydrated papaya. Fresh green papaya was subject to the largest number of RASFF notifications.

4.2 Production and trade information

Based on the information gathered during the audit, primarily green papaya is exported to the EU for use in ethnic restaurants.

Table 1 provides a summary of the papaya import from Thailand to the EU:

	Fresh papaya (t)	Provisionally preserved papaya (e.g. By sulphur dioxide gas, in brine, in sulphur water or in other preservative) (Common Nomenclature code 08129030)	Dried papaya
2012	1 752	1 337	1 408
2013	563	865	935

Source: EUROSTAT

5 Findings And Conclusions

5.1 Relevant National Legislation

Legal requirements

Art. 46 (1) (a) of Reg. (EC) No 882/2004 stipulates that EU controls shall have, inter alia, particular regard to the legislation of the TC with respect to exports to the EU.

Findings

The International Economic Policy Committee at the Ministry of Commerce issued a policy guideline for the production, export, import, and information disclosure on genetically modified products in 1999.

A Government (Cabinet) Resolution issued in 2001 concluded that the Biosafety Act should be drafted and all GMO field trials must be terminated until the Act enters into force.

The draft Biosafety Act is to provide a general framework for GMO controls. It was approved by the Government (Cabinet) in 2008 and is still in the process of adoption. At the time of the audit, it was not expected to be adopted in a short term.

Under a Government (Cabinet) Resolution published in January 2008, open field trials and eventually commercial cultivation of GM crops must be authorised by the government.

A "Biosafety guidelines for work related to modern biotechnology and genetic engineering (B.E.2556) (2013)" was developed to manage GMO trials in 1992 and was last amended in 2013. The guideline is revised every two years.

The Notification on "determination of the type and quantity of article to be used, mixed, or added into regulated seed, and designate article or pest prohibited for use, mix, or addition into regulated seed" B.E. 2556 (2013) of MOAC requires that papaya seed shall not contain GMO. Imported papaya seed shall be sampled and tested for GMO before the entry is permitted.

Under the Plant Quarantine Act B.E.2507 (1964) as amended by B.E. 2542 (1999) and B.E. 2551 (2008), any material of GM plants is categorised as a prohibited article and can only be imported into Thailand after having obtained an authorisation for import. The authorisation process is regulated by Notification of DOA "Guideline for import/transit authorisation of prohibited articles under the Plant Quarantine Act B.E.2507 (1964) as amended by volume 3 B.E. 2544 (2001) and dated 7 March B.E. 2544 (2001)".

DOA Notification on "Export of Papaya to the European Union, Norway, Switzerland, and Iceland B.E. 2555 (2012) requires a GM free laboratory certificate for papaya exported to the EU, Norway, Iceland, and Switzerland. It entered into force in May 2012. The test certificate shall be presented at the plant quarantine border station to issue Phytosanitary Certificate. Only non-GM papaya is permitted for export.

A Notification designating fresh papaya as a specifically regulated article for EU export was drafted by DOA. Under this Notification, papaya shall be from Good Agricultural Practice (GAP) certified production. In addition, the Department of Foreign Trade of the Ministry of Commerce drafted a Notification for the control of processed papaya intended for EU export.

Conclusions

National legislation covering GMOs is in place. The draft framework Act for GMOs and a DOA Notification requiring GAP certification for growers producing papaya for EU export have not been adopted yet.

5.2 Competent Authorities

Legal Requirements

Art. 46 (1) (b) and (c) of Reg. (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 Department of Agriculture (DOA) of MOAC is the CA as designated by the Plant Quarantine Act.

The Office of Agricultural Research and Development (OARD) of DOA carries out GMO sampling at Good Agricultural Practice (GAP) certified papaya farms according to the GMO surveillance system implemented by the DOA. The Plant Standard and Certification Office (PSCO) takes samples for GMO analysis and follows up on notifications of Rapid Alert System for Food and Feed (RASFF) at packing facilities.

Staff involved in GMO controls have the power to perform official GMO controls. Inspectors met by the audit team were trained for sampling for GMO in papaya.

Conclusions

CAs are clearly designated and have the authority to implement the applicable legislation effectively. Staff are adequately trained to perform GMO controls of papaya.

5.3 GMO RELATED AUTHORISATION PROCEDURES

Legal Requirements

The following EU legislation provided a basis for the evaluation of the national system included in Article 46 of Regulation 882/2004:

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.
- Regulation (EC) 2004/641 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

Findings

Under the Government Resolution issued in 2008, applications for open field trials and commercial cultivation of GM crops must be submitted to the DOA. They evaluate the application, prepare and submit the request to the Prime Minister's Office for Government approval.

No GMO open field trials have been authorised and no authorisation has been granted for commercial cultivation of GM crops in Thailand. (See 5.4.1 for GM papaya trials carried out in the past).

Trials using GM material internally developed by research institutes can be carried out in laboratories and greenhouses.

Where a person intends to import GM plant material, the conditions specified in the Notification of DOA on Guideline for import/transit authorisation of prohibited articles under the Plant Quarantine Act must be followed. A risk analysis of the planned GMO trial and an evaluation of the trial plan are carried out by various committees representing agricultural public administration and research institutions.

An Institutional Biosafety Committee (IBC) has been established within each institution involved in GMO trials. The main role of IBC is to approve and monitor research in laboratories and greenhouses involving internally developed GMO.

According to the draft Biosafety Act, authorisation of GMO trial of agricultural crops and for cultivation will be the responsibility of DOA.

Conclusions

There is an authorisation system in place for GMOs. No GM crops are authorised for cultivation and no open field trials were taking place at the time of the audit.

5.4 GMO Controls of papaya

Legal Requirements

Article 46 (1)(b), (c), (d), (e) and (h) 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, the CA's capability to enforce applicable legislation, the resources including diagnostic facilities available to competent authorities, the training of staff in the performance of official controls and the assurances which the third country can give regarding compliance with, or equivalence to, EU requirements.

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

Articles 4 (2) and 16 (2) of Regulation (EC) No 1829/2003 provide that no genetically modified food and feed is to be placed on the EU market unless it is covered by an authorisation granted in accordance with the Regulation.
Commission Recommendation 2004/787/EC[1] establishes technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms. Article 11 of Regulation (EC) No 882/2004 establishes requirements for sampling and analysis.

5.4.1 Trials of GM papaya

Findings

In the past, GM papaya trials were carried out by DOA and by a public research institution. Both trials were for resistance to PRSV and were granted authorisation in 1997.

The DOA trial was a confined small scale experiment and was terminated in 2007. The other trial had a confined small scale experiment phase between 1998 and 2001 and a greenhouse experiment between 2005 and 2010. The CA stated that the GMO trials in the past were not carried out in open fields. The trials may be continued once the Biosafety Act enters into force. GMO trials were regulated by the Plant Quarantine Act (for import of GMOs) and guidelines (for internally developed research studies) in the past. Their activity was solely monitored by the relevant internally established IBC (see also 5.3 above).

Conclusions

No GM papaya trials are taking place at the moment. Trials in the past were not officially inspected.

5.4.2 Official GMO controls of papaya

Findings

At the time of the audit, papaya export for EU, both from GAP and non-GAP production, was allowed. Under DOA Notification on “Export of Papaya to the European Union, Norway, Switzerland, and Iceland B.E. 2555 (2012)”, papaya intended for EU export must be sampled and analysed for GMO presence. The analysis must be carried out in laboratories approved by the DOA. The GMO-free test report must be submitted to the Plant Quarantine Station of DOA who then issue

1Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003Text with EEA relevance. Official Journal L 348, 24/11/2004 pg18 - 26

the phytosanitary certificate and the lot can be exported.

The draft DOA Notification on GAP, if adopted, will allow only GAP certified papaya for EU export. The DOA stated that there were 361 GAP certified papaya orchards at the time of the audit.

All pack-houses producing fresh fruits and vegetables for EU export are required to have Good Manufacturing Practice (GMP) certification and to have hazard analysis and critical control points (HACCP) principles implemented. At the time of the audit, there were 42 GMP certified packing facilities producing papaya for EU export.

The DOA introduced an annual surveillance scheme in 2012. Under this scheme, samples are to be taken at farms and at packing facilities who are GAP and GMP certified, respectively. The GMO controls (sampling) are carried out by inspectors of OARDs at farms and inspectors of PSCO at packing facilities. For details of sampling see 5.4.4 and for sample numbers see 5.5 below.

The audit team noted that, based on the data provided by the DOA, GMO was detected in some 10% of the papaya samples taken under the annual surveillance scheme in the fiscal year 2012 and over 6% in the fiscal year 2013. The origin of the GMO is not known, as controls only started in 2012. The DOA stated that the GAP certificates of the growers involved in positive cases are withdrawn.

Controls at papaya growers

The audit team requested visits to both GAP certified and non-GAP farmers. The CA stated that papaya is grown all over the country and pack-houses often source papaya from an intermediary. Non-GAP growers are difficult for DOA to identify and verify for the purpose of export to the EU as they are not registered with them. Therefore, the audit team visited farmers producing papaya under the GAP scheme and a grower who was in the process of GAP certification.

The audit team visited two farmers growing papaya for EU export in each of the Lopburi and Saraburi provinces. They supply papaya directly to exporters who have their own packing facilities.

Most papaya growers met operate on a contract basis with exporters.

In Lopburi, one farmer visited produced papaya under the GAP certification scheme. He purchased the seed from OARD in 2008 and he has been using his own farm saved seed since then. He has been the subject of a RASFF notification. The farmer explained that the exporter had informed him that a papaya lot exported to the EU had been notified in the RASFF system. In response to the RASFF notification, the exporter started to sample papaya fruit at the farm twice a month. No GMO has been detected. The other farmer visited in Lopburi was in the process of GAP certification.

Both farmers stated that the PRSV is a serious problem for their papaya production. They explained that the first symptoms are visible on the leaves some six months after plantation. They remove the infected plant(s), generally when the symptoms appear on the fruit. One of the farmers stated that if the infection is serious, he abandons the infected field and looks for another plot for papaya cultivation.

The inspection carried out in Saraburi followed the same principle as in Lopburi.

Under the GAP scheme, it is required to use seed from reliable sources. The audit team noted that farmers used farm saved seed at all orchards visited and certified seed was not required for EU export. DOA stated that certified seed is available for papaya.

Positive GMO samples were detected from non-GAP orchards tested to obtain GAP certification and from GAP certified papaya. The CA stated that GAP certification is not granted or is revoked where GMO is detected. The farmer is offered non-GM papaya seedlings and is requested to destroy their GM papaya plants voluntarily.

Controls at packing facilities and exporters

For export certification, papaya intended for EU export is sampled by the exporter or by the extension service on behalf of the exporter. For this purpose, the exporters visited had sampling procedures for random sampling in place, but DOA has not verified whether samples are representative for the exported consignment.

Under the GMP scheme, official papaya samples are taken by inspectors of PSCO for GMO analysis at least once a year. In addition, samples are taken in response to RASFF notifications where fruit is available.

The audit team visited four packing facilities who export papaya to the EU.

The inspector stated at one of the exporting establishments visited that they recommend the companies to export papaya from GAP certified production. A meeting was held with the participation of DOA and papaya exporters on the 26 July 2013. It was agreed that GAP certification is recommended. Currently, it is not obligatory pending the adoption of the relevant DOA Notification. It was also agreed that the exporter would take samples or have samples taken by their field staff (extension service) from seeds before planting, from young leaves in the field and from papaya fruits. The audit team noted that in response to RASFF notifications, packing facilities started to work with GAP certified farms or requested their contracted grower(s) to initiate GAP certification.

Conclusions

An official GMO control system has been put in place for papaya intended for export to the EU. It is based on obligatory GMO-free export certification, GMP certification of packing facilities with HACCP implementation and official annual surveillance schemes. Although GM papaya has never been authorised for cultivation in Thailand, the CA detected a significant presence of GM papaya. There is an incentive for farmers to use GM papaya as non-GM plants are susceptible to the serious disease PRSV. Papaya growers outside the GAP certification scheme, which can potentially involve GMO, are not controlled by the DOA as GAP certification of papaya for EU export is not obligatory. DOA does not verify whether sampling for export certification is representative.

5.4.3 Private controls of papaya intended for export to the EU

Findings

In addition to official controls, private controls are also carried out at growers and packing establishments of papaya for EU export. Generally, exporters take samples of papaya fruit before engaging in business with farmers. One pack-house visited regularly, samples the papaya production at farm level for monitoring purposes.

Two pack-houses stated that they require GAP certification from their contracted papaya grower(s). One packing facility visited has one GAP certified farmer among their three contracted farmers. One facility was working with a contracted farm which was in the process of GAP certification for papaya.

Two exporting establishments take samples themselves from each lot for EU export. In one case the samples are taken in duplicate. One sample is analysed by a private GMO laboratory in Thailand and the other one is sent to France to a private laboratory to confirm the laboratory result. One exporter contracts a GMO laboratory in Thailand to take samples and to perform the analyses. The Thai laboratories used by exporters met were approved by DOA for this purpose. The main purpose of this sampling is to fulfil the obligatory export certification requirement.

See 5.4.4 below for sampling details.

Conclusions

Private sampling and GMO analyses contributes to the control of papaya for export to the EU.

5.4.4 Sampling for GMO presence

Findings

DOA developed sampling instructions for sampling papaya seeds, leaves and fruit at farms. According to the instructions, samples must be taken randomly in a zig-zag pattern.

The audit team observed a sampling demonstration of papaya leaves carried out by an OARD inspector as part of the annual surveillance scheme. The inspector explained that one young leaf shall be taken from each tree and 10% of the trees shall be sampled. The sampling procedure observed followed the sampling instructions of DOA.

Official papaya fruit sampling is carried out by inspectors of PSCO at packing facilities. They use different centrally developed sampling instructions which are based on Commission Regulation (EC) 333/2007 (as amended).

All packing facilities visited sample papaya for GMO presence. One establishment explained that they sample papaya seeds, leaves and fruit at their contracted farm based on internally developed sampling guidelines twice a month. Additional sampling for monitoring purposes is carried out every four months at the packing facility. Two other packing facilities do not sample at farm level. They sample the papaya upon receipt. Generally, companies use sampling guidelines which are internally developed or based on the DOA sampling instructions.

All sampling instructions reviewed by the audit team require that samples are selected on a random basis.

Conclusions

Sampling instructions have been put in place by the CA and by the private establishment visited. During the demonstration observed by the audit team, samples were representative and randomly selected, which is in line with the relevant EU requirements.

5.4.5 Response to RASFF Notifications

Findings

EU RASFF notifications are submitted by emails to the DOA through the National Bureau of Agricultural Commodity and Food Standard. The DOA in turn circulates these notifications to the offices concerned such as PSCO. In addition, the RASFF information is also submitted to the Office of Agricultural Regulation (OAR) and OARDs.

At the exporting establishments visited, evidence was provided that GMO RASFF notifications are followed up soon after the notification is received by the CA in Thailand. DOA provided information on actions taken in relation to each notification issued in 2013. They stated that in these cases, the exporter is informed and follow up inspections, which include sampling, are carried out by the PSCO. As a consequence of the RASFF notifications, most of the exporters visited by the audit team had changed suppliers to source papaya directly from GAP certified growers and had started to sample papaya for GMO analysis. The follow-up inspections by the CA focussed on the corrective actions taken by the exporter as a result of the RASFF notification. The exporters' registrations, as well as GMP certifications, were suspended in the case of two exporters visited.

The suspension GMP certification was to remain in place until corrective actions had been put in place.

Conclusions

Substantial and timely follow up of GMO RASFF notifications is taking place. This includes on-site visits at the pack-houses, sampling and actions such as export suspension.

5.5 Laboratories for GMO analysis

Legal Requirements

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

Art. 12 of the same Regulation requires that laboratories charged with the analysis of GMO in products for export to the EU are accredited according to EN ISO/IEC 17025, or an equivalent international standard.

Point 41 of Guidelines of CODEX 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 EN ISO/IEC 17025 Guide.

Findings

There are five laboratories approved by DOA to carry out GMO analysis for EU export. Four of these have methods for GMO analysis in papaya, of which three are currently performing analysis.

During the audit, two laboratories performing GMO testing of papaya were visited (the GMO laboratory of the DOA and a private laboratory). They analyse papaya seed, leaf, fruit and processed products.

The testing for the presence of GM papaya is carried out using qualitative Polymerase Chain Reaction (PCR) methodology. Both, the DOA and the private laboratory apply 35S promoter and NOS terminator detection methods to screen for GM sequences. However, no specific methods are implemented to obtain genetic papaya constructs.

Staff involved in GM detection are adequately qualified and receive regular training.

Procedures for papaya testing, and Standard Operating Procedures (SOP) for the qualitative detection of GMOs in papaya and papaya products are in place.

Both laboratories are well organised and have adequate equipment.

The audit team noted that no Certified Reference Material (CRM) for GM papaya is available from any source, which could be used for full validation of detection methods. To overcome this situation, CRM for maize and soya purchased from Institute for Reference Materials and Measurements (IRMM) is used. However, in house-validation data for the papaya seed matrix and the matrix composite papaya samples are not available in the laboratories.

The Limit of Detection (LOD) for screening methods is 0.1% which has been achieved through in house experiments using soya CRMs. The sensitivity of the methods below 0.1% has not been assessed, which can be an issue when processed food and seed are analysed as they may contain low level of GMO.

Both laboratories have been successfully participating in comparative testing schemes with soya and maize. Only one of the laboratories participated in a ring trial of papaya in 2005.

GMO Laboratory of DoA

The laboratory carries out analysis of soya, maize and papaya seed, leaf and fruit samples. They are official and private samples.

Table 2 provides a summary on the samples analysed by the GMO Laboratory of DOA:

Type of papaya sample		FY 2012 (October 2011 to September 2012) Number of samples		FY 2013 (October 2012 to September) 2013) Number of samples	
		Total	GMO detected	Total	GMO detected
Annual surveillance of DOA	GAP certified	349	18	215	-
	Non-GAP certified	11	11	25	1
For export certificate by exporter		1 042	2	2 689	1
Voluntary control for export		520	160	1 904	270
Total		**1 922**	**191**	**4 833**	**272**

Source: DOA

The application for accreditation according to EN ISO/IEC 17025 is planned for the middle of 2014.

The technical equipment to carry out molecular reaction includes instruments for conventional PCR and real-time PCR. At present, reference system for papaya, targeting a taxon specific DNA sequence is analysed by conventional qualitative PCR only.

Regarding the testing for GM papaya, the following Real Time PCR methods are used:

- Screening for the CAMV 35S-promoter (Molecular Biology Methods, Swiss Food Manual, based on ISO 21569) and
- Screening for the NOS-terminator (Molecular Biology Methods, Swiss Food Manual, based on ISO 21569).

The laboratory has separate rooms for each test procedure and one way sample transmission to reduce the risk of cross contamination. Environmental controls to test for cross contamination are carried out.

PCR-controls are applied according to ISO Standard 24276. Positive control material extracted from papayas which was tested positive for the presence of GM elements is used.

Test reports reviewed by the FVO audit team did not include, among others, the address of the GMO laboratory and the identification of the methods used. Under Section 5.10.2 of ISO Standard 17025 this information is required. Furthermore, negative results state that ”GMO not present”. Section 6.3 of ISO Standard 24276 specifies that negative results shall never be expressed as zero or “GMO not present”.

Private GMO Laboratory

The laboratory is accredited according to EN ISO/IEC 17025 for GMO analysis by the national accreditation body. The scope of accreditation includes, among others, fruits and fruit products.

In the calendar year 2012, the laboratory analysed 579 samples out of which 81 was found to be positive. In 2013, 643 samples were analysed out of which 45 was found to be positive. Samples analysed were all private.

The technical equipment to carry out molecular reaction include instrument for real-time PCR. Regarding the testing for GM papaya, qualitative duplex PCR method for detection of CaMV 35S-promoter and NOS-terminator (QL-ELE-00-012, EU-JRC Compendium of Reference Methods for GMO Analysis)

The layout of the laboratory is not according to the "forward flow principle" and the laboratory has to share rooms with employees from other units. Environmental controls to test for cross contamination are applied.

PCR-controls are applied according to ISO standards. Positive control material extracted from papayas which was tested positive for the presence of GM sequences, are not used.

Results reported in the test report fulfil the requirements of EN ISO/IEC 17025. However, the test report does not indicate the matrix used to identify the limit of detection as requested by ISO 24276.

Conclusions

One laboratory visited was accredited and the other one was not accredited according to EN ISO/IEC 17025, or an equivalent international standard.

A substantial number of samples are analysed in Thailand.

The laboratories visited had adequate facilities and well trained staff.

The layout of the public laboratory was in line and that of the private laboratory was not according to ISO Standard 24276.

Screening methods applied by the laboratories visited are fit for purpose for single matrices.

The absence of quality control using identified test/secondary reference material and validated test methods for GM papaya events compromise the ability of the laboratories visited to carry out specific analysis following a positive screening.

Compared to EU laboratories, which are capable of detecting GM at a level of about 0.01%, the limit of detection for screening methods indicated by laboratories visited in Thailand is 0.1%. This level is not sufficient to ensure that GMO is detected also in processed papaya food and papaya seed.

The analytical investigation of the samples was not carried out according to the requirements of ISO 24276.

Comparative testing for papaya samples have not been conducted during the recent years.

6 Overall Conclusions

Although GM papaya has never been authorised for cultivation in Thailand, the CA detected a significant presence of GM papaya. The origin of the GM papaya is not known. There is an incentive for farmers to use GM papaya as non-GM plants are susceptible to the serious disease PRSV. The farmers met had been using farm saved papaya seed for a number of years and the original seed was sourced before official GMO controls started.

In response to the RASFF notifications issued by the EU from 2012, the CA has put in place a system to ensure that GM papaya is not exported to the EU. The system is based on obligatory export certification, and papaya intended for export to the EU must be sampled and analysed for

GMO presence. However, DOA does not verify whether sampling for export certification is representative. The CA requires GMP certification of packing facilities and performs official annual surveillance schemes. Certification of papaya growers to the GAP scheme is encouraged and includes systematic testing for GMOs. However, GAP certification is currently not compulsory and a number of growers of papaya for export to the EU are not certified. Some shortcomings were identified in the GMO laboratories such as sensitivity and quality control procedures. Official controls are supported by additional private controls.

While the control measures are capable of ensuring that papaya exported to the EU is not GM, the system put in place requires more time to be completed. At the time of the audit it was too early to conclude on its effectiveness.

7 Closing Meeting

A closing meeting was held on 07 February 2014 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The CAs provided initial comments and clarifications.

8 Recommendations

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

The CA should:

N°.	Recommendation
1.	adopt the planned national legislation requiring GAP certification for papaya for EU export to provide guarantees that exported produce meets the requirements laid down in Article 11 of Regulation (EC) No 178/2002 and Article 4.2 of Regulation (EC) No 1829/2003.
2.	verify that sampling for export certification is representative for the consignment exported to the EU to provide guarantees that exported produce meets the requirements laid down in Article 11 of Regulation (EC) No 178/2002.
3.	ensure that laboratories for GMO analysis of papaya are evaluated and/or accredited under officially recognised quality management and assurance programmes so as to guarantee reliability of analytical results provided as set out in Point 41 of CODEX CAC/GL 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.
4.	ensure that laboratories performing official controls use methods of analysis for GM papaya events which have been validated according to the principles laid down by the Codex Alimentarius Commission to ensure that adequate quality controls are in place to provide for the reliability of test results (point 41 of CAC/GL 26-1997 and point 3 of

N°.	Recommendation
	CAC/GL 27- 1997). The quality control should also include identified test/secondary reference material in all laboratories as set out in point 5.9 of EN ISO/IEC 17025.

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=2014-7200

Annex 1 - Legal References

Legal Reference	Official Journal	Title
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. 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
Dir. 2001/18/EC	OJ L 106, 17.4.2001, p. 1-39	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
Reg. 1829/2003	OJ L 268, 18.10.2003, p. 1-23	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs

Annex 2 - Standards quoted in the report

International Standard	Title
CODEX Guidelines 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
CODEX Guidelines 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