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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

VIET NAM

FROM 18 TO 27 FEBRUARY 2014

IN ORDER TO EVALUATE CONTROLS OF PESTICIDES IN FOOD OF PLANT ORIGIN INTENDED FOR EXPORT TO THE EU

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Viet Nam, carried out between 18 and 27 February 2014. The objective of the audit was to assess controls on pesticide residues in fresh vegetables and herbs, in particular chilli peppers and basil, intended for export to the European Union (EU).

A pilot project was initiated in mid-2013 to strengthen pre-export controls to the EU for sweet and chilli peppers, basil, mint and celery, which were previously the subject of RASFF alerts. This includes the registration of growers involved in their production and is considered to be a positive step towards ensuring that exported produce will meet the EU standards. However, many plant protection products (PPPs) authorised in Viet Nam are not authorised in the EU and the limited analytical scope under the pilot project inhibits the effectiveness of this initiative. There are no specific pre-export controls in place for the other commodities. There are no systematic controls at pack-houses and follow-up of RASFF notifications is either lacking or insufficient. Official laboratories for pesticide residues have modern equipment, good facilities and experienced staff. However, the limited scope covered and weaknesses identified with regard to internal quality procedures cannot ensure the reliability and correctness of results.

The report makes a number of recommendations to the competent authorities of Viet Nam, 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)
CAC/GL	Codex Alimentarius Commission/Guideline
CODEX	Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization
CPD	Crop Production Department
DG(SANCO)	Health and Consumers Directorate-General
EFSA	European Food Safety Authority
EU	European Union
EUROSTAT	Statistical Office of the European Union
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GC	Gas Chromatograph
GC-MS	Gas chromatograph coupled to mass spectrometer
GC-ECD	Gas chromatograph coupled to electron capture detector
GC-MS/MS	Gas chromatograph coupled to tandem mass spectrometer
HCM City	Ho Chi Minh City
HPLC-UV	High Performance liquid chromatograph coupled to ultraviolet detector
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatograph coupled to tandem mass spectrometers

LOD(s)	Limit(s) of Detection
MARD	Ministry of Agriculture and Rural Development
MoH	Ministry of Health
MRL(s)	Maximum Residue Level(s)
MRM(s)	Multi-Residue Method(s)
MS(s)	Member State(s)
NAFIQAD	National Agri-Forestry-Fishery Quality Assurance Department
NCP	National Contact Point
NFSMP(s)	National Food Safety Monitoring Programme(s)
NPCTC	Northern Pesticide Control and Testing Centre
PEQ	Post-Entry Quarantine
PPD	Plant Protection Department
PPP(s)	Plant Protection Product(s)
PPSD(s)	Plant Protection Sub-Department(s)
RASFF	Rapid Alert System for Food and Feed
SOP(s)	Standard Operation Procedure(s)
SRM(s)	Single Residue Method(s)
TC(s)	Third Country(ies)

1 Introduction

The audit took place in Viet Nam from 18 to 27 February 2014 in order to assess controls on pesticide residues in fresh vegetables and herbs, in particular chilli peppers and basil, 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 in the context of a wider series of audits in third countries (TCs) to evaluate control systems and operational standards in this sector.

The FVO team was accompanied during the audit by representatives of the central Competent Authority (CA), the Plant Protection Department (PPD) at the Ministry of Agriculture and Rural Development (MARD).

An opening meeting was held on 18 February 2014 with the central CA and the National Agri-Forestry-Fishery Quality Assurance Department (NAFIQAD) at MARD. At this meeting, the objectives of and itinerary for the audit were confirmed, and additional information required for the satisfactory completion of the audit was requested.

2 Objectives and Scope

The **objective** of the audit was to verify whether there are systems in place for the control of pesticide residues in fresh vegetables and herbs, in particular chilli peppers and basil, intended for export to the EU, and assess whether these systems offer adequate assurance that the produce concerned is within the specified residue limits laid down in EU legislation.

In terms of **scope**, the audit reviewed the controls in place on production and export, including a review of national legislation, CA organisation, their controls and enforcement capability, laboratory capability and measures in place for the determination of pesticide residues. As the residue controls are directly related to the national rules governing the authorisation, placing on the market and use of Plant Protection Products (PPPs), the control systems in this area were also part of the audit.

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

Competent Authority/ies			**Comments**
Competent Authority	Central	1	PPD, MARD
	Regional/local	1	Plant Protection Sub-Department (PPSD) in the province of Ho Chi Minh (HCM) City
Laboratory/ies			
Public Laboratories		2	Official laboratory for pesticide residues Quatest 3 in HCM City Official laboratory for pesticide residues at the Regional Plant Protection Centre 2 in Hanoi

Producers		
	5	One cooperative, two chilli pepper growers and two basil growers in the HCM Region
Exporters/Pack-Houses		
	2	Two pack-houses for fresh vegetables and herbs in the region of HCM
Points of Export		
HCM City International Airport Customs Sub-Directorate		

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.

EU legal acts quoted in this report refer, where applicable, to the last amended version (see Annex 1).

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 Organisation (CODEX) were taken into account.

A full list of applicable standards referred to in this report is provided in Annex 2.

4 Background

The FVO has carried out audits in a number of exporting countries to assess official controls for pesticide residues in food of plant origin originating from these countries. The reports on these audits are available on the internet site of Health and Consumers Directorate-General (DG(SANCO)) at http://ec.europa.eu/food/fvo/index_en.cfm. An overview report summarising findings and conclusions of these audits has also been published at this site: http://ec.europa.eu/food/fvo/specialreports/rep_details_en.cfm?rep_id=17.

This specific audit was decided mainly on the basis of the non-compliances notified by the EU MSs with regard to products originating from Viet Nam. In the period between 01 January 2011 and 15 February 2014, a total of eleven cases were reported *via* the EU Rapid Alert System for Food and

Feed (RASFF), where either a direct or indirect risk for consumers has been identified. Eight of these were related to fresh vegetables and herbs, mainly chilli peppers. In most cases, the pesticide found to exceed the EU Maximum Residue Levels (MRLs) was *carbendazim*. Further pesticides found were *carbofuran, dichlorvos, dimethoate, fenpropathrin, hexaconazole, omethoate, profenofos* and *tricyclazole.* In six cases, two or more pesticides were found in the same sample.

In 2010, MRL exceedances were reported by MSs to the European Food Safety Authority (EFSA) for samples taken under the EU multi-annual control programme and MSs' own national control programmes for pesticide residues from plant products originating from Viet Nam. The MRL exceedance rates were, as follows: for guava, 29.4 %; tea leaves, 33.3 %; rice, 40 % and lychee, 20 %. In 2011, the number of MRL exceedances reported to EFSA increased significantly as well as the range of plant products concerned. A total of 351 samples were taken and 169 MRL exceedances were found. The main products involved and MRL exceedance rates found were the following: celery (leaves and bulbs), 80 %; peppers, 59 %; basil, 52 %; beans with pods, 40%; rice, 37 %; lychee, 33 %; guava, 29 % and aubergines, 18 %. The most frequently found pesticides included the following: *carbendazim,* a wide range of triazole fungicides (i.e. *cyproconazole, difenoconazole, diniconazole, fenbuconazole, flusilazole, hexaconazole, propiconazole, tebuconazole, tricyclazole),* as well as insecticides, including *carbofuran, fenpyroximate, methamidofos, methidathion, phentoate* and *profenofos.*

Based on data from the Statistical Office of the EU (EUROSTAT), in the period 2009 – 2011, the volume of vegetable imports from Viet Nam into the EU increased from 6 400 to 7 400 tonnes. In 2012, the volume of vegetable imports doubled to 15 100 tonnes. In 2013, the total volume of imported vegetables reduced to 7 150 tonnes.

Based on previous non-compliances, since 01 January 2013 Viet Nam has been listed in Annex I to Regulation (EC) No 669/2009 for coriander leaves, basil, mint, parsley, peppers (other than sweet) and okra (20 % checks).

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.

Findings

The Law on Plant Protection and Quarantine No 41/2013/QH13 provides the legal framework for the authorisation of PPPs and official controls on their marketing and use and regulates issues in the area of plant protection, including pest control and related preventive measures.

The Law on Food Safety No 55/2010/QH12 sets out the main requirements with regard to general food hygiene, covering also official controls for pesticide residues and allocation of responsibilities within the Ministry of Health (MoH) in this regard.

The Law on Inspection No 56/2010/QH12 provides the legal framework for performance of official

controls in general, including controls within the scope of the audit. According to the requirements of this Law, CAs have the legal power to carry out control activities within their responsibilities and they are allowed to access establishments, ask for documentary evidence and take the necessary measures in the case of violations and non-compliances identified.

Within the scope of the audit, the following secondary legislation is in place:

- Decree 58/2002/ND-CP on plant protection and pesticide management;
- Decree 38/2012/ND-CP on the implementation of the Food Safety Law;
- Decree 86/2011/ND-CP on the implementation of the Law on Inspection;
- Decree 114/2013/ND-CP on administrative sanctions with regard to plant protection and plant quarantine;
- Decree 178/2013/ND-CP on administrative sanctions with regard to food safety.

A further series of official Circulars and Decisions, covering technical aspects and providing procedures and written instructions for staff members is in place. However, there are no specific requirements with regard to pre-export controls in the national legislation. In the context of this specific audit, official letter No 5 by the Minister of MARD was issued on 14/02/2012 to all relevant CAs with regard to strengthening controls at farm level in order to meet the EU importing requirements, but it does not list any specific measures to be undertaken in order to ensure that EU standards applicable will be met.

Conclusions

National legislation within the scope of the audit is in place. However, there are no specific provisions with regard to pre-export controls so as to ensure compliance with or equivalence to EU standards applicable.

5.2 Competent Authorities

Legal Requirements

Article 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 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 main CA within the scope of the audit is the PPD at MARD. This is the CA responsible for drafting legislation and developing policies in the area of plant protection, as well as the supervision of regional and provincial CAs and reporting on results from official controls at national level.

At central level, the following divisions of PPD are involved in activities related to plant protection and, in particular, pesticide related issues:

- The Plant Protection Division, under which four Regional Plant Protection Centres and 63 PPSDs at provincial level operate. The PPSDs are in charge of the implementation of official controls at pesticide retailers, registration of pesticide retailers, providing training for farmers and processors, including pack-houses for fresh vegetables and herbs, as well as official controls under two National Food Safety Monitoring Programmes (NFSMPs);

- The Pesticide Management Division, whose main responsibilities are related to the authorisation of PPPs;

- The Food Safety Division, which, in co-operation with the Plant Protection Division, drafts, communicates and supervises the implementation of the NFSMP for food of non-animal origin, covering all stages (production, transport, processing) before placing on the market;

- The Plant Quarantine Division, under which are two Post Entry Quarantine (PEQ) Centres and nine Regional Plant Quarantine Sub-Departments. The latter are responsible for pre-export controls of plant products and issue phytosanitary certificates which accompany the shipped commodities; both PEQ Centres are in charge of pre-export exports under the pilot project described later on under chapter *5.4.2 Export Control Programmes*.

The NAFIQAD is the CA for development, co-ordination and monitoring of the implementation of the NFSMP for both food of animal and non-animal origin on the domestic market. Within the scope of the audit, NAFIQAD is the CA nominated as the National Contact Point (NCP) for the EU RASFF; NAFIQAD has two Regional Centres and six branches at provincial level.

The Crop Production Department (CPD) at MARD is one of the CAs, in parallel with private Control Bodies, designated for accreditation of growers under private schemes for good agricultural practices (GAPs).

During the audit, the PPSD in the province of HCM City was visited by the audit team. There are five district offices in this province.

Most PPD staff have a university degree in agriculture or other relevant areas and the rest have vocational education in the same fields. For some technical areas, a university degree in other relevant areas is required, such as chemistry. Newly appointed staff attend an introductory training, which is organised once a year. On-going training for PPD and PPSD staff is provided. Training covers topics related to plant protection, pesticides and control activities within the responsibilities of the CAs.

Within the scope of the audit, the MoH is the CA in charge of setting national MRLs for pesticides and drafting, publishing and up-dating national legislation with regard to chemical contaminants, including pesticide residues.

Conclusions

CAs within the scope of the audit have been designated and their responsibilities are defined.

The staff members met by the audit team had the knowledge and skills to perform their tasks. Regular training is provided to staff members so as to keep them up-to-date in their areas of competence.

5.3 Official Controls of the Marketing and Use of Plant Protection Products

Legal requirements

Article 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;

Article 28 of Regulation (EC) No 1107/2009 requires PPPs not be placed on the market or used unless they have been authorised in the MSs in accordance with this Regulation.

Article 55 of Regulation (EC) No 1107/2009 provides for the proper use of PPPs, including compliance with the conditions established and specified on the labelling.

Article 68 of Regulation (EC) No 1107/2009 requires MSs to carry out controls in order to enforce compliance with this Regulation.

Article 10 of Regulation (EC) No 852/2004, in conjunction with Article 4.1 and Annex I, Part A.III of the same Regulation, requires that FBOs producing or harvesting plant products are, in particular, to keep records on any use of PPPs.

Findings

5.3.1 Authorisation of Plant Protection Products

In accordance with the requirements laid down in Circular 03/2013/TT-BNNPTNT, PPPs have to be authorised prior to their placing on the market and their use.

Under Article 7 of the Circular, the Pesticide Management Division at PPD is responsible for the assessment of detailed technical application and arranging the efficacy field trials, which usually take two years. Trial data are evaluated by the Efficacy Evaluation Committee, comprising nine independent members who are representatives of Universities and research Institutes. The next step is drafting a justified proposal for authorisation of PPPs by the same Committee, which is transmitted to the Advisory Committee. The Advisory Committee comprises nine members, including representatives from MARD, PPD, Universities and other scientists and their opinion, in the form of a recommendation, is provided to MARD. MARD takes the final decision on authorisations and these are valid for five years and are subject to renewal. Before the authorisation certificate is granted, PPPs cannot be placed on the market nor used.

The list of PPPs authorised for use in Viet Nam is up-dated annually and is publicly available. Most relevant information is provided in the list, with the exception of the application rates and pre-harvest intervals. The last available version was published on 17 April 2013 based on Circular 21/2013/TT-BNNPTNT.

Establishing national MRLs is the responsibility of the MoH and these are listed in Decision 46/2007/QD-BYT on the maximum limits of chemical and biological contamination in food. At the time of the audit, work was on-going on the review of this Decision. The CAs of Viet Nam stated that for pesticides for which there are no national MRLs established, MRLs of the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization (CODEX) are applied.

At the time of the audit, some 4 800 PPPs were authorised for use in Viet Nam, containing approximately 1 200 active substances. Some of the pesticides, which have been involved in RASFF notifications and MRL exceedances reported to EFSA, are not authorised in the EU, for example *hexaconazole, flusilazole, diniconazole, profenofos, carbofuran*, *dichlorvos, phentoate, methidathion, acephate, diazinone, chlorfluazuron, isoprothiolane*. A few have never been notified in the EU, i.e. *fenobucarb, dinotefuran, crotoxyphos.* However, most of these are authorised in Viet Nam.

5.3.2 Controls of retailers of plant protection products

National legal provisions have been in place for the registration of manufacturers, distributors, retailers and importers of PPPs since 2003, most recently Circular 03/2013/TT-BNNPTNT.

Applicants for registration must prove the technical competence of their staff and provide health certificates for all staff members, which is verified by PPSDs. The provincial Department of Industry and Trade, Sub-Department for Investment and Planning performs an on-the-spot inspection and issues a full business license for manufacturing, importing and/or trading. These licenses are not subject to renewal. Licensees are subject to control by PPSD.

According to information provided by the CAs, there were about 40 000 registered traders (distributors, wholesalers, retailers, importers) and 97 manufacturers (formulators, packaging and re-packaging facilities). In 2012, 5 000 inspections were performed and 6 000 in 2013.

PPSD HCM City stated that there are about 300 traders on their territory. In 2013, 123 inspections were performed by PPSD staff from the five districts and a further 82 inspections by PPSD staff at provincial level.

5.3.3 Control of Growers

The PPD develops the inspection and sampling plan, based on risk, which is implemented by the 63 PPSDs, who select the targets for control in their areas. Non-compliances are reported to the PPD, which coordinates the follow-up by PPSD.

In 2013, 1 259 of the 5 600 farms in HCM City were visited and on-the-spot training on how to correctly use pesticide spray equipment was provided. A team of inspectors at provincial/local level carried out 144 joint inspections at farms to check compliance with food safety standards, including pesticide management, to take samples and address non-compliances.

A pilot project was initiated in mid-2013 for strengthening the pre-export controls of sweet and chilli peppers, basil, mint and celery. Under this project, farms which wish to export to the EU any of the five commodities, must register with and be certified by the PPD. At the time of the audit, two of the four farms visited, were exporting basil, chilli and coriander to the EU. Their vegetables for export to the EU were grown in their own greenhouses.

Decision 379/QD-BNN-KHCN promotes GAP for growing fresh fruit and vegetables in Vietnam. It is overseen by the local PPSDs and is recommended by the CAs for growers of fruit and vegetables. Three of the four farms visited by the audit team were registered under a GAP scheme and each grower could provide such a certificate. This was also the case for a co-operative visited, which held a certificate under a private scheme covering its members for 14 commodities they grow. No exports to the EU were taking place, as members were not registered with PPD. Although

there is no legal obligation for growers to keep records, those certified under a GAP scheme are required to do so. Records of the purchase and application of pesticides were examined in the farms visited. Examples were seen at all farms visited where either the same PPPs were repeatedly used throughout the growing season, or combinations of two to four PPPs were used in one single application.

At the growers visited, advice was provided on the PPPs to be used during the growing season either by exporting pack-houses or by the PPSD staff. Lists of PPPs to be applied were available at all growers visited, which were up-dated annualy. However, these lists did not take account of the PPPs authorisation status in the countries of destination, in particular the EU.

5.3.4 Formulation Analysis

Samples are taken for quality control of pesticides during routine and/or *ad-hoc* inspections at pesticide traders and manufacturers. Additionally, in order to import PPPs into Viet Nam, samples must be taken for quality control from each individual consignment. At the time of the audit, there were three laboratories carrying out formulation analysis in Viet Nam, two of which were visited by the audit team, one each in HCM City and Hanoi. Both were involved in quality controls of pesticides. Samples were analysed for the content of active substance(s) and some physical-chemical properties. According to information provided by the Hanoi laboratory, they also analyse impurities. In 2013, a total of 3 000 samples, both private and official, were analysed in the HCM City laboratory. In the same period, the Hanoi laboratory analysed around 1 000 samples, of which 800 were stated to be taken from PPPs imported into the country.

Conclusions

Many of the PPPs authorised for placing on the market and use in Viet Nam are not authorised in the EU. Therefore, their use could lead to EU MRLs being exceeded, taking into account that, for most of the PPPs not authorized in the EU, the EU MRLs are very low.

Although there is no legal obligation to keep records on the application of PPPs, the growers visited were certified under private schemes and they recorded all PPP-related activities. This is in line with the requirements laid down in Article 10 of Regulation (EC) No 852/2004, in conjunction with Article 4.1 and Annex I, Part A.III of the same Regulation.

A system is in place for controls of users of PPPs and was seen to operate effectively. Under the pilot project, in order to be allowed to export sweet and chilli peppers, basil, mint and celery to the EU, growers must be registered and they are subject to greater control by the CAs.

Although there were initiatives to promote GAPs and training was provided to growers and PPD staff, examples were seen which could not be considered as good practice. The parallel use of two or more PPPs in one single application could be an explanation for the cases where multiple residues were found and reported by MSs. As advice provided to growers either by exporters or by CAs does not take account of the PPP authorisation status in the EU and EU MRLs, no guarantees could be provided that fresh fruit and vegetables exported from Viet Nam will meet the EU standards.

5.4 Official Controls of Pesticides Residues in Food of Plant Origin

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.

Article 18 of Regulation (EC) No 396/2005 requires that products covered by Annex I of the same Regulation shall not contain, from the time they are placed on the EU market as food or feed, any pesticide residue exceeding EU MRLs, or 0.01 mg/kg for those products for which no specific MRL is set.

The CODEX has also established MRLs for pesticides, which are considered for the establishment of EU MRLs (CAC/MRL 1-2009).

Commission Directive 2002/63/EC establishing EU methods of sampling for the official control of pesticides residues in and on products of plant and animal origin or equivalent international standards (e.g. CODEX Guidelines CAC/GL 33-1999).

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

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 utilize 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 ISO/IEC Guide 17025.

Point 6 of the CODEX Guidelines CAC/GL 25-1997 specifies that upon information about a rejection of a food consignment presented for import, 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.

Findings

5.4.1 Sampling Programmes for Pesticide Residues

The two annual NFSMPs are run by two different departments at MARD. The annual NFSMP run by PPD covers primary production. It covers different risks in the area of food safety, including

pesticide residues. According to the NFSMP 2013, a total of 1000 samples for pesticide residues were planned to be taken. Analytes to be sought were selected by the central CAs based on the assessment of results from 2012 and taking account of previous non-compliances notified *via* the EU RASFF, including some of the pesticides found by EU MSs. The second NFSMP is drafted and implemented by NAFIQAD and covers both food of animal and non-animal origin placed on the domestic market. Among the risks indicated were pesticide residues. In 2013, 82 pesticides were listed to be analysed.

Based on both NFSMPs, PPSDs develop their own control programmes, including sampling for pesticide residues.

According to information provided by the PPSD HCM City, a total of 1 180 samples were taken for pesticide residues at farm level in 2013, 1 030 for a non-laboratory "quick test" (see Chapter *5.4.4 Laboratories for Pesticide Residue Analysis*) and 150 for laboratory analysis. In the same period, 7 815 samples were taken at sale points for the "quick test" and 90 were sent for laboratory analysis. PPSD HCM City were not able to provide information on the number of samples taken from fresh fruit and vegetables intended for export to the EU, as they do not take account of the final destination of products.

Standard Operating Procedures (SOPs) were in place with regard to sampling for pesticide residues. Sampling for the purpose of pre-export control was demonstrated by a plant health inspector from the PEQ at a basil farm and the relevant SOP was followed.

5.4.2 Export Control Programmes

In accordance with national legislation, plant products intended for export shall meet the national requirements, the standards applicable in the country of destination and the requirements of any bilateral or international agreements. Pre-export controls can also be specifically requested by the exporters. In Viet Nam, a phytosanitary certificate suffices as the single document required by Customs for the shipment to be cleared for export.

Under the pilot project, mentioned in chapter *5.3.3 Controls of Growers,* farms growing the five commodities concerned have to be registered with PPD, through PEQ, in order to be allowed to export their produce to the EU. Following an inspection and sampling at the farm, PEQ prepares a conclusion on compliance with EU MRLs. PPD takes the final decision on the authorisation of the export. An inspection takes place at the premises of the exporter by the relevant Regional Plant Quarantine Sub-Department, which issue the phytosanitary certificate if no plant health problems are identified.

For fresh fruit and vegetables, which fall outside the scope of the pilot project, the pre-export controls are focused on phytosanitary aspects and no further checks take place at exporters.

The Customs Sub-Department of HCM City International Airport was visited during the audit. Customs representatives were aware of the existing national legal provisions in the area of plant protection. Evidence was seen of adequate communication and co-operation between PPD and Customs.

5.4.3 Control at Pack-Houses, Processors, Exporters

Exporters have to be registered with the provincial Departments of Industry and Trade, Sub-

Departments for Investment and Planning in order to operate a business. According to MARD Circular 07/2013/TT-BNNPTNT of MARD on the compliance of fresh fruit, vegetables and tea with the food safety standards, operators throughout the food chain should be certified with the relevant PPSD and are subject to official controls, including sampling. However, as the legislation mentioned has only became applicable since mid-2013, the process is still on-going.

Two pack-houses were visited by the audit team. In the period January 2011– December 2013, one of the pack-houses was involved in six (out of eleven) cases for vegetables and herbs notified *via* the EU RASFF. As a result, this exporter stopped shipping fresh vegetables and herbs to the EU, but is still exporting fruit. The second pack-house visited was among two, which are currently allowed to export fresh vegetables and herbs to the EU. The main commodities exported to the EU included chilli peppers, basil, coriander and aubergines, of which chilli peppers and basils were covered by obligatory pre-export controls under the pilot project. All exported crops were grown in own greenhouses and a separate pack-house was used for exports.

Neither of the pack-houses visited has been certified yet by the relevant PPSD. For this reason, no official controls were taking place on food safety related issues. Neither HACCP systems nor good hygiene practices were in place. The traceability systems in place were quite simple. This could be problematic in one of both pack-houses visited, as produce might be only traced back to the co-operative, but not to individual farmers and/or individual plots.

5.4.4 Laboratories for Pesticide Residue Analysis

Organisation

In Viet Nam, there is a laboratory network comprising 16 official laboratories for pesticide residues. Official laboratories must be designated by MARD and all are accredited to ISO 17 025. The FVO team visited two of these official laboratories, as follows: the Quality Assurance and Testing Center 3 (QUATEST 3) laboratory in HCM City, which belongs to the Ministry of Science and Technology and the laboratory at the Northern Pesticide Control and Testing Center (NPCTC) at PPD in Hanoi. Both were involved in official controls for pesticide residues under the two NFSMPs, including pre-export controls for plant products intended for export to the EU. The CAs stated that there is no National Reference Laboratory for pesticide residues in Viet Nam.

Resources and training

QUATEST 3 has several laboratories dealing with different types of analysis in food and agricultural products, among which are the Chemical Testing Laboratory and the Environmental Testing Laboratory. A total of 92 staff are appointed, of which 60% have graduate or post-graduate education. Evidence was provided for continuous internal and external relevant training.

The Chemical Testing Laboratory deals with formulation analysis. The Environmental Testing Laboratory carries out pesticide residue analysis for both official and private samples with an average of 1 600 samples per year. It had seven staff, of whom five with university degree. The laboratory had adequate facilities and equipment, including two LC-MS/MS, one GC-MS/MS, three GC-MS and one GC-ECD. There was strong interaction between both laboratories through sharing analytical instruments.

The NPCTC has two laboratories, one for formulation analysis and another for pesticide residues. The latter had seven staff, most of whom with chemistry background. This laboratory carries out pesticide residue analysis of official and private samples. In 2013, 1 300 samples approximately were analysed. Internal training for analysts is provided, including a six-month introductory training

session and regular on-going training. The laboratory was well equipped with three GC-μECD, one HPLC-UV, one GC-MS, one GC-MS/MS and two LC-MS/MS.

Analytical spectrum and methods, status of accreditation

Quatest 3 laboratory was accredited to ISO 17025 by the Vietnamese Bureau of Accreditation and the Australian National Association of Testing Authorities in July 2013. The scope of accreditation for pesticide residue analysis in fruit and vegetables covers six methods and 61 analytes in total. For multi-residue method (MRM) amenable compounds, the "Quick Easy Cheap Effective Rugged Safe" (QuEChERs) method is applied. The only single residue method (SRM) within the accredited scope is for the determination of Dithiocarbamates (CS2). The current scope does not always cover the parent compound and/or metabolites and neither is in line with full residue definition according to EU MRL and/or CODEX residue definitions, e.g. for *carbendazim, dimethoate, methiocarb* and *methomyl*.

The Pesticide Residue Laboratory at NPCTC has been accredited for eleven different methods, including MRMs and SRMs for pesticide residues, which cover approximately 70 individual analytes. The QuEChERs method is applied as a MRM and it is continuously expanded.

The number of analytes covered in both laboratories is very limited compared to the total of 1 200 active substances authorised in Viet Nam and it is considerably below the EU average.

In addition to state-of-the-art pesticide residue analysis, the non-laboratory "quick test" is implemented by provincial CAs in HCM City for official controls of pesticide residues. In 2010, this test has been approved by the MoH in Thailand. Trials were conducted by the two Pesticide Control and Testing Centers in Viet Nam before this methodology was introduced and used for the purposes of official controls for pesticide residues. However, the quick test can only detect some pesticide groups and is not sufficiently sensitive to detect low levels, which is necessary for the identification of pesticides with low EU MRLs. Moreover, the exact LODs for different pesticides are not known. For these reasons, on its own, the "quick-test" cannot be considered to provide sufficient reliability without follow-up analyses in an accredited laboratory.

Quality assurance systems

Quatest 3 laboratory has implemented quality assurance systems consisting of external and internal quality control elements. In each laboratory there is one staff member designated for quality management purposes. The quality system includes control checks on instruments on a daily basis using control charts following standard injections and quality control samples together with multiple-level calibration for recovery determination within each batch of samples. Certified analytical standards are bought and regularly replaced after being cross-checked. However, it was noticed that standard calibration solutions were stored inappropriately (+10°C, used for up to one month). Validation procedures are in place and Limits of Detection (LODs) are indicated in the accreditation certificate, as well as in the analytical reports. However, these levels are quite high.

The laboratory regularly participates in Proficiency Tests for pesticide residues with good results, but it could not provide the full analytical scope. In one case there was a non- reporting due to the high LOD established in the laboratory.

The NPCTC laboratory has one staff member designated as quality manager. Quality assurance is only partially covered as quality control samples are not included in routine analysis. Procedures for method validation are in place, but at levels beyond the stated LOD and/or limit of quantification (lowest level at 0, 4 mg/kg). Furthermore, Measurement Uncertainty is an aspect which is not

covered and not stated in the analytical report. The laboratory regularly participates in Proficiency Tests with good performance for most of the compounds.

Clients of both laboratories are provided with recommendation forms about the minimum weight of sample (Quatest 3: 0,5 kg without taking into account the number of units; NPCTC: 2 kg, taking account of the number of units) and transport conditions (e.g. delivery within 24 hours, temperature). Homogenization of samples in both laboratories visited is carried out at room temperature only. The audit team noted that, depending on the type of commodity, problems with regard to homogeneity of the sample, especially for fresh herbs, or degradation of the active substance cannot be ruled out. DG SANCO and/or Codex Guidelines on Method Validation and Quality Controls are generally known, but not fully implemented (e.g. sample homogenization, storage of standards).

5.4.5 Response to RASFF Notifications

NAFIQAD is designated as the NCP for EU RASFF. The procedure for the follow-up of RASFF notifications was explained to the audit team. However, no documentary evidence was provided to the audit team on the follow-up of non-compliant cases notified via the EU RASFF with regard to pesticide residues in fresh vegetables and herbs originating from Viet Nam. Moreover, representatives from NAFIQAD stated they have experienced problems with the identification of exporters involved in RASFF cases. Overall, there is no systematic approach for the follow-up of RASFF notifications.

Conclusions

There were no legal obligations for pack-houses to be registered with the relevant CAs in charge of food hygiene controls and to meet the general food hygiene requirements, as laid down in Article 10 of Regulation (EC) No 852/2004 in connection with Article 6 of the same Regulation. Moreover, this was seen to be a constraint for the follow-up of EU RASFF notifications, as the exporters were difficult to identify.

Strengthening of pre-export control for the five commodities covered under the pilot project is considered to be a positive measure undertaken in response to previous non-compliances. However, as the project is limited to five commodities only, no guarantees could be provided that the remaining plant products intended for export will meet the EU requirements, as set out in Article 11 of Regulation (EC) No 178/2002 and, in particular, regarding EU MRLs.

Although the pilot project could be considered as a positive step in strengthening pre-export controls by taking pre-harvest and pre-export samples, the limited analytical scope reduces confidence in the results.

In one of the laboratories visited, samples were accepted mainly on the basis of the sample weight and they did not take account of the type of commodity nor the minimum number of units, which is not in line with the requirements set out in CODEX Guidelines CAC/GL 33-1999.

Both laboratories visited were well equipped, had good facilities and experienced and trained staff. The equipment available in both laboratories visited could allow for MRMs to be set-up covering at least 400 - 500 pesticides in total for both GC-MS(/MS) and LC-MS/MS analysis. However, the number of analytes covered in both laboratories is far below the total of 1 200 active substances authorized for use in Viet Nam.

Although both laboratories are accredited to ISO 17025, the scope of accreditation is limited and covers only a short list of MRM-amenable compounds. The internal quality procedures in place require further revision in order to ensure that analytical results are reliable.

The vast majority of official samples in the province of HCM City were analysed *via* the "quick-test". This cannot be considered to provide sufficient reliability.

Although a NCP has been designated for the EU RASFF, current follow-up of RASFF notifications is either lacking or insufficient. This is not in line with the provisions laid down in Point 6 of the Guidelines CODEX CAC/GL 25-1997 for the exchange of information between countries on rejection of imported food.

5.5 Private Controls on Fresh Vegetables and Herbs Exported to the EU

Findings

At both pack-houses visited, evidence was seen that own controls for pesticide residues were taking place. At one of the exporters, samples were taken randomly from different suppliers throughout the year. However, in all cases samples were analysed only using the "quick test". The VietGAP certification was stated to provide enough guarantees that products supplied comply with the food safety standards, including MRLs for pesticides. At the second pack-house, samples were taken and sent for analysis to official laboratories for pesticide residues designated by MARD. In both cases, the scope of analysis was determined by the exporters themselves based on entries in the records on the application of PPPs. Decision on compliance with EU MRLs was taken by the exporters, as no conclusions were provided by the laboratories in the analytical reports. No information was available whether any other controls were performed by private bodies and/or associations.

Conclusions

Private controls are at a very early stage of development and these cannot ensure that produce exported will meet the EU standards.

6 Overall Conclusion

A pilot project was initiated in mid-2013 to strengthen pre-export controls to the EU for sweet and chilli peppers, basil, mint and celery, which were previously the subject of RASFF alerts. This includes the registration of growers involved in their production and is considered to be a positive step towards ensuring that exported produce will meet the EU standards. However, many PPPs authorised in Viet Nam are not authorised in the EU and the limited analytical scope under the pilot project inhibits the effectiveness of this initiative. There are no specific pre-export controls in place for the other commodities. There are no systematic controls at pack-houses and follow-up of RASFF notifications is either lacking or insufficient. Official laboratories for pesticide residues have modern equipment, good facilities and experienced staff. However, the limited scope covered and weaknesses identified with regard to internal quality procedures cannot ensure the reliability and correctness of results.

7 Closing Meeting

A closing meeting was held on 27 February 2014 with representatives of the CCA. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The CAs of

Viet Nam offered some initial comments on the preliminary conclusions presented, in particular with regard to the follow-up of RASFF notifications. In addition, some further clarifications were provided with regard to registration of exporting pack-houses, pre-export controls and analytical scope covered by official laboratories for pesticide residues depending on the type of samples.

8 Recommendations

The CAs of Viet Nam 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 CAs should:

N°.	Recommendation
1.	Ensure that PPP application schemes at vegetable and herb exporting growers follow the GAP main principles and take account of pesticides authorised in the EU in order to provide guarantee that exported produce meet the EU MRLs set out in Regulation (EC) No 396/2005.
2.	Ensure that exporting pack-houses are registered, as set out in Article 10 of Regulation (EC) No 852/2004 in connection with Article 6 of the same Regulation and general food hygiene requirements set out in Annex I, Parts A and B of the same Regulation are met.
3.	Ensure that the scope of analyses for pre-export samples is broadened in order to provide a guarantee that the exported produce meets the requirements laid down in Article 11 of Regulation (EC) No 178/2002 and Article 18 of Regulation (EC) No 396/2005; they should also ensure that all laboratories involved in export controls apply the principles of internationally recognised quality assurance techniques so as to provide reliable analytical results, 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 an internal investigation and corrective actions are undertaken in response to RASFF notifications taking into account the provisions specified in point 6 of the CODEX Guidelines CAC/GL 25-1997 for the exchange of information between countries on rejections of imported food.

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=2014-7177

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC

Annex 2 – Standards Quoted in the report

Reference number	Full title	Publication details
CODEX Guidelines 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
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
CODEX Guidelines CAC/GL 31-1999	Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs (CAC/GL 33-1999).	http://www.codexalimentarius.net/web/standard_list.jsp
CAC/MRL 1-2009	Maximum Residue Limits (MRLs) for Pesticides	http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp