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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
THE DOMINICAN REPUBLIC
FROM 27 JANUARY 2015 TO 05 FEBRUARY 2015
IN ORDER TO
EVALUATE CONTROLS OF PESTICIDES IN FOOD OF PLANT ORIGIN INTENDED FOR EXPORT TO THE EUROPEAN UNION

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Dominican Republic, carried out from 27 January to 05 February 2015. The objective of the audit was to assess controls on pesticide residues in plant produce, in particular in aubergines, peppers and yard long beans intended for export to the European Union (EU).

Since the last FVO audit in 2010, there has been an improvement in post-authorisation controls, with increased inspections at pesticide importers and at retailers. The effectiveness of the system of pesticide authorisation continues to be limited by the absence of a single, accurate, reliable, regularly updated and publically available database of approved pesticides, with all relevant data on their correct use. Indeed, the authorisation process is practically unchanged since the first FVO audit to the Dominican Republic on this subject in 2008 and remains a significant weak link in the reliability of the overall control system. This is compounded by the absence of pesticide quality controls and formulation analysis. The regular checks by the competent authority (CA) on exporting farms provides a certain guarantee that pesticides are correctly applied. However, this guarantee is restricted by the sometimes incorrect information coming from the central competent authority, including nationally banned plant protection products being recommended for use, and the lack of farmers implementing good agricultural practice. There has been insufficient improvement in laboratories, as there has been no significant increase in the scope of pesticide residue analysis or the quality of results. The lack of pre-export official and private sampling and analysis to determine compliance with maximum residue levels (MRL) reduces the confidence that exported products are within the allowable EU MRLs. There is a strong, immediate and coordinated follow-up by the CAs to rapid alert notifications issued on rejection of products to be imported to the EU due to excessive residue levels. Only two of the seven recommendations made in the 2010 audit have been fully addressed.

Overall, while certain progress has been achieved in improving the pesticide control system for exported plant produce since the 2010 audit, the Dominican Republic authorities still have some distance to go before they can offer adequate assurance that the exported products are within the specified residue limits of EU legislation.

The report makes a number of recommendations to the CAs, 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
CCA(s)	Central Competent Authority(ies)
CODEX	Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization
DG (SANCO)	Health and Consumers Directorate-General
DIA	Department of Food Safety (*Departamento de Inocuidad Agroalimentaria*)
DINVOFEX	National Directorate for Export of Fruits and Oriental Vegetables (*Direccion Nacional de Exportación de Vegetales Orientales y Frutas Frescas*)
DSV	Department of Vegetable Health (*Departamento de Sanidad Vegetal*)
EU	European Union
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GMP	Good Manufacturing Practice
ISO	International Organisation for Standardisation
LAVECEN	Central Veterinary Laboratory (*Laboratorio Veterinario Central*)
LIAAI	Food Safety and Industrial Analysis Laboratory at ISA University, Santiago
MA	Ministry of Agriculture
MRL(s)	Maximum Residue Level(s)
MS(s)	Member State(s)
PHI	Pre-Harvest Interval
PPP(s)	Plant Protection Product(s)
PROVEFEX	Programme for Export of Fruits and Vegetables (*Programa de Vegetales y Frutas Frescas de Exportación*)
RASFF	Rapid Alert System for Food and Feed
TC(s)	Third Country(ies)

1 INTRODUCTION

The audit took place in Dominican Republic from 27 January to 05 February 2015 in order to assess controls on pesticide residues in plant produce, in particular in yard long beans, peppers and aubergines, 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 competent authority (CA) representatives.

An opening meeting was held on 27 January 2015 with the Minister for Agriculture and representatives of the main CAs, the Department of Food Safety (DIA), Department of Vegetable Health (DSV), National Directorate for Oriental Vegetables and Fresh Fruit for Export (DINVOFEX) and the Central Veterinary Laboratory (LAVECEN). At this meeting, the objectives of and itinerary for the audit were confirmed.

2 OBJECTIVES AND SCOPE

The objectives of the audit were to:

• Verify whether there are control systems in place for the control of pesticide residues in plant produce, in particular in yard long beans, peppers and aubergines 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;

• follow-up recommendations of report Health and Consumers Directorate-General DG(SANCO)/2010-8588.

In terms of scope, the audit reviewed the controls in place on the production and export of these products, including a review of national legislation, CA organisation, their controls and enforcement capability, facilities (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/meetings held:

Competent Authority/ies		Number	Comments
Competent Authority	Central	3	DIA, DSV, DINVOFEX
	Regional/local	1	La Vega Region
Laboratory/ies			
Public Laboratories		1	LAVECEN
Private Approved Laboratories		1	Food Safety and Industrial Analysis Laboratory (LIAAI) at ISA University, Santiago
Producers			
Farms		3	La Vega region
Exporters/Packhouses			
Packhouses		3	La Vega region

3 LEGAL BASIS AND STANDARDS

3.1 LEGAL BASIS

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

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.

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 in the context of the audit.

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

4 BACKGROUND

Since 2004, the FVO has carried out audits on pesticide controls in all main countries exporting fruit, vegetables, herbs and spices to the EU. Reports of these audits have been published, together with an overview report summarising their findings and conclusions. All reports are available on Health and Food Safety Directorate-General's (DG SANTE) internet site at http://ec.europa.eu/food/fvo/index_en.cfm.

This was a follow-up to the FVO audit DG(SANCO)/2010-8588 on the same subject. The report of that audit contained recommendations to the CAs of Dominican Republic, which covered the control systems for pesticides in fruit and vegetables intended for export to the EU, the setting up of a proper authorisation system and a post-registration control for pesticides, the allocation of adequate staff for technical support for farmers and the improvement of laboratory performance, capacity and capability with regard to analysis of pesticide residues. Action plans received at the time were considered not entirely satisfactory to address these recommendations.

According to Annex I of Regulation (EC) No 669/2009, yard long beans, peppers and aubergines imported to the EU from Dominican Republic are subject to an increased level of import control by EU Member States, ranging from 10% for aubergines to 20% for yard long beans and peppers. From January 2013 to December 2014, 39 out of a total of 47 alert notifications through the EU Rapid Alert System for Food and Feed (RASFF) for exports of food of plant origin from the Dominican Republic related to these three products. The trend on non-compliances identified by importing EU MSs over this period varied, depending on the product. For aubergines, the rate increased slightly from 2.3% in the first quarter of 2013 to 3.6% in the second quarter of 2014, dropping to zero in the third quarter. The rate for peppers increased from 8.5% to 11.5% over the corresponding period, while for yard long beans it dropped from 13% to 5%. The checks identified many pesticides exceeding EU Maximum Residue Levels (MRL), among them *carbofuran, chlorpyrifos, cypermethrin, dimethoate, endosulfan, fipronil, hexaconazole, methomyl, omethoate, permethrin* and *profenofos.*

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

1. The main legislation remains unchanged and is as described in the 2010 pesticides audit report. Some new Resolutions (Ministerial Decisions) have since been introduced and include the following:

- Resolution 05/2011 on the ban of *Paraquat*, followed by Resolution 08/2012 on the regulation of *Paraquat*;
- Resolution 61/2011 on the ban/ restricted use of certain pesticides;
- Resolution 06/2014 on the ban of *Endosulfan*.
- Other Resolutions have been enacted to set up new administrative bodies within the CAs.

Conclusions on National Legislation

2. Adequate national legislation within the scope of this audit is in place, as far as can be reasonably ascertained.

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 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

One recommendation from the 2010 audit report covered this subject:

2010-8588-4 The CA of Dominican Republic should consider allocating enough technicians to reach all farmers involved in EU exports for technical support and to follow up the recommendations as well as following up recommendations made during inspections of PPP retailers.

3. The CAs are as described in report DG(SANCO)/2010-8588 and come under the Ministry of Agriculture (MA). In brief, the Department of Vegetable Health (DSV) is responsible for authorisation of PPPs, controls on their import and marketing and for providing advice to growers on integrated pest management. The Department for Food Safety (DIA) is responsible for registration of packhouses, food safety controls at packhouses and at farms, advice on and inspecting good agricultural practice (GAP) and good manufacturing practice (GMP), and pesticide residue controls under the annual monitoring plan. The DIA does not differentiate between packhouses/growers for domestic or export markets. A new Risk Analysis Division has been set up in the DIA under Resolution 08/2014, but has not yet begun to function. Another new Resolution, 49/2014, upgraded the Programme for the Export of Oriental Vegetables, Fresh Fruit and Related Products (PROVOFEX) to the status of National Directorate for Oriental Vegetables and Fresh Fruit for Export (DINVOFEX), responsible for all export-related activities for fruit and vegetables, including advising growers on correct pesticide use. The Extension Department is responsible for training staff and farmers and for providing advice to growers. The MA is responsible for the Rapid Alert System for Food and Feed (RASFF), implemented by DSV, DIA and DINVOFEX. Laboratories are covered under Chapter 5.4.4 of this report.
4. There are around 30 staff working in DSV, including one technician in each of the eight regions. There is also a DSV technician permanently present in most packhouses for export, primarily for plant health checks. DIA has 32 staff in total, including 10

technicians deployed in the regions. DINVOFEX, the CA most concerned with exports, is based in the main production region of La Vega. It is staffed by some 100 technicians who provide advice to farmers, make recommendations on pesticide use and follow these up. The recommendation from the previous audit has been addressed.

5. The staff are mainly university graduates of different levels, qualified in agriculture-related disciplines. Evidence of on-going relevant staff training was seen by the FVO team.
6. There appears to be close cooperation between the different CAs, as evidenced during visits to packhouses and farms. However, there is potential duplication or overlap of efforts, given the number of CAs carrying out either inspection or advisory visits to packhouses and farms for broadly similar objectives.

Conclusions on Competent Authorities

7. CAs within the scope of this audit have been clearly designated, but there is some apparent duplication of effort, which indicates an ineffective use of resources.
8. Staff are suitably qualified and experienced and are properly trained.
9. Recommendation 2010-8588-4 from the previous audit has been addressed.

5.3 Official Controls of the Marketing and Use of Plant Protection Products (PPPs)

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 states that PPPs may not be placed on the market and used unless they have been authorised.

Article 68 of Regulation (EC) No 1107/2009 requires MSs to carry out official controls in order to ensure 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

One recommendation from the 2010 audit report covered this subject:

2010-8588-2 The CA of the Dominican Republic should consider setting up an authorisation system for PPPs based on risk assessment and a register of authorised products and their uses, and to ensure this information is disseminated to regional offices, growers, pack houses and exporters.

10. There have been no changes in the procedure for authorisation of PPPs in the Dominican Republic since the first pesticide residues audit in 2008, described in report DG(SANCO)/2008-7848.

11. At the time of the 2015 audit, there were 67 authorisation holders listed in the register. They must submit supporting documents which are checked by the CA for completeness, but no further checks or expert evaluation work is carried out.

12. The authorisation certificates are issued following efficacy trials and only have minimal information related to the PPP and the active substance contained therein. Authorisations must be renewed every five years.

13. At the time of the audit, there were 2 906 PPPs authorised for placing on the market and use in the country, containing 388 active substances. Only 44 % of the active substances authorised in the Dominican Republic are currently approved in the EU.

14. Resolution 61/2011 completely bans the use for agricultural purposes of PPPs containing the active substances *acephate, aldicarb, methamidophos, monocrotophos* and *omethoate*, and bans the use of a further 22 substances in the three crops covered by the audit. Despite the ban, many of these pesticides, notably *endosulfan* and *carbofuran*, were repeatedly involved in border rejections notified *via* the EU RASFF and in cases of MRL exceedances reported by MSs to the European Food Safety Authority after the Resolution had entered into force. Moreover, some of these active substances were included in the approved CA lists of pesticides to be used on these three crops.

15. A pesticide database has been developed, but is only accessible at central level. Its benefit for inspectors, exporting pack-houses and growers would, in any event, be limited, given that only very general information appears in the database. It lacks such important data as details on authorised uses, application rates, timing of application, pre-harvest intervals (PHIs) and any risk mitigation measures to be applied. This data can only be acquired through a manual search of the central paper archives.

5.3.2 Controls of the marketing of plant protection products

One recommendation from the 2010 audit report covered this subject:

2010-8588-3 The CA of the Dominican Republic should consider setting up a post-registration control programme for the marketing, use and quality of PPPs.

16. The PPPs sold and used in the Dominican Republic are all imported. The main countries of origin are China, Mexico, South American countries and the USA, with small quantities imported from the EU.

17. CA approval is required for imports of individual PPP consignments. The CA checks the supporting documents, including invoices and analytical reports from formulation analysis in the country of origin, that the PPPs are authorised for use in Dominican Republic and that the importers are registered. On completion of a satisfactory CA documentary and physical check, Customs release the consignment for placing on the market.

18. According to the CA, there are 140 registered importers. Some 11 380 tonnes of PPPs were imported in the Dominican Republic in 2013 and 12 624 tonnes in 2014. The same upward trend was seen for PPPs containing some active substances frequently found in

Dominican Republic's plant products imported into the EU, i.e. *carbofuran* (645 tonnes in 2013 and 708 tonnes in 2014), *chlorpyrifos* (142 tonnes in 2013 and 191 tonnes in 2014).

19. In response to the above recommendation, the CA initiated a nation-wide survey in 2012 to identify pesticide retailers and check their facilities and conditions of storage. There were 776 PPP retailers identified, only 11 % of which were officially registered. Many non-compliances were discovered. The CA created the Post-Registration Division in October 2013 to tackle this situation and eight staff were appointed to perform controls at regional level. The number of registered retailers had increased to around 20% by the time of the audit. Based on results from the 2012 survey and inspections at retailers in 2013, a risk categorisation of operators was done, which was used for planning of controls in 2014 and 2015.

5.3.3 Control of Growers

20. The main pre-export checks are concentrated at farms and carried out by DINVOFEX, who stated that there are between 1 500 and 1 700 farms producing oriental vegetables, among them yard long beans, peppers and aubergines, for export.

21. There is no formal inspection programme for growers. A DINVOFEX technical inspector visits each farm once or twice weekly, recommends the pesticides to use and often supervises pesticide application. DIA carries out occasional visits to farms, primarily under the pesticide residue monitoring and sampling programme and in relation to good agricultural practice (GAP), but their visits to exporting farms are relatively few. DIA completes a very detailed and extensive checklist for each visit, which includes relevant sections on pesticide use, application equipment, safety, environment, etc. Since November 2014, DIA introduced test kits for instant analysis of pesticide residues as a reaction to the number of RASFF notifications. These kits have been proven by independent studies to be unreliable – see also under Laboratories, chapter 5.4.4.

22. According to DIA, some 250 farms, mainly those growing for export, were applying GAP principles. DIA is preparing to gain recognition as a GAP accreditation body. Under a programme funded by an international bank, the CA hopes to train 2 500 farmers in GAP principles over the next two years, with a view to certifying 800 of them.

23. The FVO team visited three farms in La Vega, the region accounting for some 90% of vegetable production. These were selected as they supply packhouses which were prominent in RASFF notifications in 2013/2014.

24. The team saw evidence of record keeping, which is a legal requirement. However, some important data was not always in evidence, such as actual pre-harvest interval (PHI) records for specific crops.

25. The inspector advises the farmer to extract this information from the pamphlet which accompanies each PPP. This information is not otherwise specified in writing by the inspector in his recommendations for pesticide use.

26. Cases were observed where pesticides were recommended by the inspector which were neither in the CA's own list of allowable products, nor in in the lists drawn up by the CA of EU allowable products.

27. The inspector's recommendations seen were all for use of a combination of three PPPs, leading to potential multiple residues and unclear PHI. The FVO team received conflicting information on which maximum residue level (MRL) was used, with some inspectors and farmers saying they used the lower EU limits as a default, regardless of the export destination, while the CA and others saying they differentiated between the EU MRLs for exports to the EU and the generally higher CODEX levels for other destinations.

5.3.4 Formulation Analysis

28. The situation is as described in the 2010 report. There is still no systematic sampling or control programme for quality checks of pesticides at any stage, despite the availability of formulation laboratory capacity. According to the CA, six samples were taken in 2014 for formulation analysis following suspicion.

Conclusions on Official Controls of the Marketing and Use of Plant Protection Products

29. The absence of any notable changes to the system of PPP authorisation since the 2008 FVO audit continues to undermine the effectiveness of the control system and indicates a lack of the CA's understanding or appreciation of the importance of this issue.

30. The use of PPPs, such as *endosulfan* and *carbofuran*, which are not authorised in the EU, can result in EU MRLs being exceeded in food of plant origin imported from the Dominican Republic. Indeed, the banning of these and other PPPs under national legislation does not appear to have had the effect of stopping their use being recommended by inspectors.

31. A well-functioning system is in place for controls at PPP imports. Since the last audit in 2010, progress has been made with regard to official controls at PPP retailers. Although this is a step forward, it is still at an early stage of development.

32. The lack of pesticide quality controls and formulation analysis is a limitation for ensuring that PPPs placed on the market meet the technical specifications.

33. Recommendation 2010-8588-2 from the previous audit has not been addressed, while recommendation 2010-8588-3 has only been partly addressed.

34. While there is no formal control programme of PPP use in place, the very regular presence of DINVOFEX inspectors on exporting farms means there is some control over pesticide use. However, the incomplete and sometimes incorrect information available to the inspectors and growers on allowable EU MRLs, combined with the absence of GAP-certified users, weakens guarantees that EU standards with regard to pesticide residues are met.

5.4 OFFICIAL CONTROLS OF PESTICIDE 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 in TCs 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 TC 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 food business operator 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 utilise laboratories that are evaluated and/or accredited under officially recognised 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

One recommendation from the 2010 audit report covered this subject:

2010-8588-1 The CA of the Dominican Republic should consider improving the control system for pesticides in fruit and vegetables intended for export to the European Union, in order to guarantee that the produce complies with, or is equivalent to, European Union standards in accordance with Article 11 of Regulation (EC) No 178/2002.

5.4.1 Sampling Programmes for Pesticide Residues

35. Sampling is carried out: under the DIA monitoring programme, which does not differentiate between the domestic and export markets; on request from clusters of

farmers; on suspicion of non-compliances; following notifications or rejections. In practice, there is only very limited sampling for pesticide residue analysis carried out at exporting packhouses or at their supply farms.

36. There are written procedures in place for sampling, both at packhouses and on farms, based on CODEX standards. A demonstration of a sampling procedure was observed by the FVO team at one packhouse visited and was seen to be correctly carried out by knowledgeable inspectors following the written procedures.

5.4.2 Export Control Programmes

37. Controls of fruit and vegetables intended for export to the EU are primarily concentrated at the grower level – see under Chapter 5.3.3. Quality checks on produce for export are carried out by DINVOFEX inspectors at packhouses, but these are for phytosanitary purposes.

38. There is no dedicated pre-export control programme for pesticide residues.

5.4.3 Control at Pack-Houses, Processors, Exporters

39. Registration of exporting packhouses is a legal requirement. There are currently 185 registered by the DIA and each has been inspected as a pre-condition of registration.

40. A risk-based control programme of these packhouses has been developed and inspections were to begin in early 2015. Around 160 control visits to all packhouses, for export and domestic markets, were carried out by the DIA in 2014 under the food safety monitoring programme. The inspector follows an extensive checklist, which includes pesticide-related questions and is aimed mainly at inspecting GMP at the packhouse.

41. The FVO team visited three exporting packhouses, selected as they featured in a high number of RASFF notifications. Traceability systems are legally obligatory and were seen to work effectively in the examples checked by the FVO team.

5.4.4 Laboratories for Pesticide Residue Analysis

Three recommendations from the 2010 audit report covered this subject:

2010-8588-5 The CA of the Dominican Republic should ensure that laboratories involved in official controls apply the principles of internationally recognised quality assurance techniques (such as ISO 17025) and are evaluated and/or accredited under officially recognised quality management and assurance programmes to ensure these laboratories provide reliable analytical results. (Point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997).

2010-8588-6 The CA of the Dominican Republic should consider expanding the range of analyses for pesticide residues for example by acquiring LC/MS equipment.

2010-8588-7 The CA of the Dominican Republic should consider a practical training programme for laboratory staff to reach the international standards within a reasonable

time.

Organisation

42. The FVO team visited the two laboratories involved in pesticide residue analysis, LAVECEN, which is part of MA, and LIAAI, which is contracted by MA.

43. LAVECEN was already visited during FVO audits in 2008 and 2010. Four people are directly involved in pesticide residue analysis. There were 241 official samples analysed in the laboratory in 2014 and 261 in 2013.

44. LIAAI was founded in 2011. Four people are directly involved in pesticide residue analysis. The FVO team was informed that the laboratory capacity is approximately 600 samples per year, while only 100 samples, of which 51 were official samples, were analysed in 2014.

45. The capability and capacity of both laboratories to analyse pesticide residues are under-used.

46. Neither laboratory is accredited, but both declared their intention to apply for accreditation and the basic steps in organisation and documentation related to the application are in place.

Resources and training

47. Both laboratories have acceptable facilities with rooms for sample reception, sample preparation, analysis and quality control activities. The laboratory staff have appropriate qualifications. They have been trained by suppliers of equipment and by national and international consultants over the past years in different laboratory aspects, such as quality system, accreditation (ISO 17025), auditing, metrology, uncertainty of measurement, analytical methods and method validation. They have participated in training and conferences abroad and in a Better Training for Safer Food session in November 2014.

48. LIAAI has been supported by an international donor, which invested in staff training and laboratory equipment.

Analytical spectrum and methods

49. Both LAVECEN and LIAAI have implemented methods based on a modified QUECHERS extraction procedure in combination with Gas Chromatograph Mass Spectrometer detection for routine pesticide residue analysis. In LAVECEN, the method covers 46 pesticides. The analytical scope covers mostly organophosphorus and pyrethroid pesticides and only parent compounds are measured (no metabolites or degradation products are covered for any of pesticide - e.g. *endosulfane, amitraz, dimethoate*, etc). In LIAAI, the method has recently been extended with a Liquid Chromatograph Mass Spectrometer detection system and the number of analytes has been increased to sixty. The general reporting limit of 0.02 mg/kg in LAVECEN and 0.025 mg/kg in LIAAI, which is applied for the current analytical scope, is above the default EU MRLs (0.01 mg/kg) for a number of pesticides.

50. The absence of liquid chromatography equipment in LAVECEN does not allow broadening of the scope to cover some toxic pesticides which are frequently detected in the EU import controls, including *carbofuran* and *methomyl*.

51. LIAAI disposes of such equipment, and more effective use of it could be easily achieved for substantially broadening the scope.

52. The current scope in either laboratory does not cover all pesticides used in Dominican Republic, found in EU and in RASFF notifications.

53. Since November 2014, a test kit based on inhibition of cholinesterase for rapid screening detection of pesticides (organophosphates and carbamates) has been used by the CA in response to the number of notifications, mainly on farms. However, scientific studies show that such kits are unreliable, have too high detection limits and can give wrong or misleading information in terms of false positive or false negative results.

Quality assurance systems

54. Analytical methods in neither laboratory are internally validated or verified, although some basic performance criteria are in place. Both laboratories have implemented elements of quality control systems, though some important control checks are missing, e.g. no routine recovery checks for the whole scope (both laboratories), missing rolling programme for calibration (LIAAI), no routine check of lowest calibration level (LAVECEN), no matrix matched calibration (LAVECEN).

55. No single residue method is in place in either laboratory, nor is there any estimation of measurement uncertainty available.

56. Neither laboratory has participated in proficiency testing.

57. Quality assurance systems have not been fully developed, nor are any of the laboratories accredited. Although some new equipment has been acquired by LIAAI, the lack of liquid chromatography equipment in LAVECEN and the general under-use of existing equipment in both laboratories has limited the expansion of the analytical range. The previous recommendation on training has been addressed.

5.4.5 Response to RASFF Notifications

58. The procedure as described in the 2010 FVO audit report remains in place, with some small differences. DIA, DSV and DINVOFEX cooperate on follow-up to RASFF notifications. Although DIA is the formal contact point, it has experienced difficulties to date receiving the notifications in a timely manner. DINVOFEX is informed immediately by the exporter, who is legally obliged to so inform the CA, and passes this information on to the other two CAs. DSV independently receives notifications via the Common Entry Document, when the alert is triggered at import to the EU.

59. There is a formal RASFF follow-up written procedure in place, whereby all three CAs carry out an immediate inspection of the packhouse and supply farm involved in the alert, aided by the good traceability system. They check back pesticide use and details of recent sales to other clients and follow these up, as appropriate.

60. Sanctions of temporary bans on export of all products are imposed on packhouses and crops are destroyed at farms. In files examined by the FVO team, examples of sanctions

of 30 to 45-day bans on packhouses and destruction of whole plantations were seen. In the cases examined, the packhouse terminated the contract with the relevant supply farm.

61. A spike in notifications in mid-2014 at one packhouse visited was explained as being due to two farmers using pesticides incorrectly. These farmers were subsequently excluded by the packhouse from supplying their produce and the combined corrective action would appear to have resolved the problem.

Conclusions on Official Controls of Pesticide Residues in Food of Plant Origin

62. The absence of regular and systematic pre-export checks, sampling and subsequent analysis for pesticide residues means that respect of EU MRLs cannot be reasonably guaranteed. The previous recommendation 2010-8588-1 has not been addressed.

63. Recommendations on laboratories 2010-8588-5 and 6 have only been partly addressed, while recommendation 2010-8588-7 has been fully addressed. Current equipment is inadequate and, in any event, the equipment and analytical capability are under-used. The lack of accreditation and adequate methods and insufficient quality assurance systems compromise the reliability of results and, by extension, the control system.

64. The kits used cannot be considered reliable as they can lead to misleading results.

65. The tough measures taken to date by the CAs in reaction to RASFF notifications, assisted by a good traceability system, can act as a strong deterrent against incorrect pesticide use.

5.5 Private Controls on Vegetables Exported to the EU

Findings

66. There is practically no private control or own sampling carried out either in packhouses or on farms. Samples are sometimes taken and analysed by the importing client and results are sent to the packhouse.

Conclusions on Private Controls on Vegetables Exported to the EU

67. The absence of pre-export own control and sampling denies the control system a valuable tool to help guarantee compliance with EU MRLs.

6 Overall Conclusion

Since the last FVO audit in 2010, there has been an improvement in post-authorisation controls, with increased inspections at pesticide importers and at retailers. The effectiveness of the system of pesticide authorisation continues to be limited by the absence of a single, accurate, reliable, regularly updated and publically available database of approved pesticides, with all relevant data on their correct use. Indeed, the authorisation process is practically unchanged since the first FVO audit to the Dominican Republic on this subject in 2008 and remains a significant weak link in the reliability of the overall control system. This is compounded by the absence of pesticide quality controls and formulation analysis. The regular checks by the competent authority (CA) on exporting farms provides a certain

guarantee that pesticides are correctly applied. However, this guarantee is restricted by the sometimes incorrect information coming from the central competent authority, including nationally banned plant protection products being recommended for use, and the lack of farmers implementing good agricultural practice. There has been insufficient improvement in laboratories, as there has been no significant increase in the scope of pesticide residue analysis or the quality of results. The lack of pre-export official and private sampling and analysis to determine compliance with maximum residue levels (MRL) reduces the confidence that exported products are within the allowable EU MRLs. There is a strong, immediate and coordinated follow-up by the CAs to rapid alert notifications issued on rejection of products to be imported to the EU due to excessive residue levels. Only two of the seven recommendations made in the 2010 audit have been fully addressed.

Overall, while certain progress has been achieved in improving the pesticide control system for exported plant produce since the 2010 audit, the Dominican Republic authorities still have some distance to go before they can offer adequate assurance that the exported products are within the specified residue limits of EU legislation.

7 CLOSING MEETING

A closing meeting was held on 5 February 2015 with CA representatives. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit and received some clarifications and comments from the CAs. The Minister of Agriculture undertook to take the necessary measures to address any recommendations made.

8 RECOMMENDATIONS

The competent authorities are invited to provide details of the actions taken and planned, including 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:

No.	Recommendation
1.	Ensure the reliability of the authorisation system, for example, but not exclusively, by **a)**, strengthening and expanding the checks on the data accompanying the application, **b)**, further developing a single, accurate, reliable, regularly updated and publicly available source of all relevant data pertaining to pesticide use, to add, *inter alia*, details on authorised uses, application rates, timing of application, pre-harvest intervals (PHIs) and any risk mitigation measures to be applied, all to provide a guarantee that produce intended for export to the EU meets the requirements laid down in Article 11 of Regulation (EC) 178/2002 and Article 18 of Regulation (EC) No 396/2005. *Conclusions upon which this recommendation is based: 29, 30, 34* *Associated findings upon which this recommendation is based: 10, 11,12, 13, 14, 15, 26, 27*

No.	Recommendation
2.	Ensure that regular and systematic pre-export official and/or mandatory private sampling and pesticide residue analysis is carried out in laboratories accredited to ISO 17025, or equivalent, to provide a guarantee that the exported produce meets the requirements laid down in Article 11 of Regulation (EC) 178/2002 and Article 18 of Regulation (EC) No 396/2005. The analytical scope should include the pesticides commonly used and identified in EU RASFF notifications. *Conclusions upon which this recommendation is based: 62, 63, 67* *Associated findings upon which this recommendation is based: 35, 38, 45, 46, 49, 50, 52, 54, 55, 56, 57, 66.*

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
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
Reg. 669/2009	OJ L 194, 25.7.2009, p. 11-21	Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC

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 33-1999	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