FINAL REPORT OF A MISSION

CARRIED OUT IN

THE DOMINICAN REPUBLIC

FROM 08 TO 23 NOVEMBER 2010

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

The mission took place in the Dominican Republic from 8 to 23 November 2010. The mission team consisted of one inspector from the Food and Veterinary Office (FVO) and one Member State expert. The mission was undertaken as part of the FVO's planned mission programme in the context of a wider series of missions in third countries to evaluate control systems and operational standards in this sector.

The objective of the mission was to evaluate the systems in place to control pesticide residues in food of plant origin intended for export to the EU, in order to assess whether these systems offer adequate assurance that the produce concerned is within the residue limits laid down in European Union (EU) legislation and to follow up the previous mission No 2008-7848.

There were some improvements since the previous mission in particular regarding new legislation, advice for producers and exporters, follow-up of border rejections and laboratories.

This legislation, however, is not yet fully implemented and enforced, while the majority of small growers exporting to the EU are not covered by official supervision and do not have good agricultural practices (GAP) in place. The laboratories are not fully operational yet. The majority of plant protection products authorised in Dominican Republic may not be used in the EU and some of these have led to RASFF notifications.

Compliance with EU maximum residues levels (MRLs) for pesticides is partly ensured for mangoes by the comprehensive auto-control systems.

This report makes recommendations to the competent authorities with a view to addressing the shortcomings identified.
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<tr>
<td>CA</td>
<td>Competent Authority</td>
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<td>CCA</td>
<td>Central Competent Authority</td>
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<td>CED</td>
<td>Common Entry Document</td>
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<td>DIA</td>
<td>Department of Food Safety (<em>Departamento de Inocuidad Agroalimentaria</em>)</td>
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<td>DSV</td>
<td>Department of Vegetable Health (<em>Departamento de Sanidad Vegetal</em>)</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EU</td>
<td>European Union</td>
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<td>EUROSTAT</td>
<td>Statistical Office of the European Union</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<td>GAP</td>
<td>Good Agricultural Practice</td>
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<td>GC</td>
<td>Gas Chromatograph</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>IIBI</td>
<td>Institute for Innovation in Biotechnology and Industry</td>
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<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<td>JAD</td>
<td>Dominican Agribusiness Board (<em>Junta Agroempresarial Dominicana</em>)</td>
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<td>LA VECEN</td>
<td>Central Veterinary Laboratory (<em>Laboratorio Veterinario Central</em>)</td>
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<td>MA</td>
<td>Ministry of Agriculture</td>
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<td>MRL</td>
<td>Maximum Residue Level</td>
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<td>MRM</td>
<td>Multi Residue Method</td>
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<td>PPP</td>
<td>Plant Protection Product</td>
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<td>PROVOFEX</td>
<td>Programme for Export of Fruits and Vegetables (<em>Programa de Vegetales y Frutas Frescas de Exportación</em>)</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>SRM</td>
<td>Single Residue Method</td>
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<td>TC</td>
<td>Third Country</td>
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1 **Introduction**

This mission took place in the Dominican Republic from 8 to 23 November 2010 as part of the FVO's planned mission programme.

The inspection team comprised of one inspector from the Food and Veterinary Office (FVO) and one national expert from a Member State, who were accompanied throughout the mission by a representative from the central competent authority (CCA), the Ministry of Agriculture (MA).

An opening meeting was held on 8 November in Santo Domingo with the MA, during which the objectives, itinerary and the standard reporting and follow-up procedures for the mission were confirmed and additional information required for the satisfactory completion of the mission was requested.

2 **Objectives of the mission**

The objective of the mission was to evaluate the systems in place for the control of pesticide residues in food of plant origin intended for export to the European Union (EU), in order to assess whether these systems offer adequate assurance that the produce concerned is within the residue limits laid down in EU legislation and to follow up the previous mission No 2008-7848.

The implementation and effectiveness of existing pesticide residue control plans was evaluated. The mission included a review of the national legislation in place, the organisation of the competent authorities, their control and enforcement capability, facilities (laboratory capability), and the measures in place to determine pesticide residues in foodstuffs of plant origin. As residue checks are directly related to national rules governing the authorisation, placing on the market and use of plant protection products (PPPs), the control systems in these areas were also covered by the mission. As regards products, the mission team looked specifically at mangoes, aubergines, hot peppers and lauki.

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

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<tr>
<th><strong>Central Competent authorities</strong></th>
<th><strong>Comments</strong></th>
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<tr>
<td>MA (Ministry of Agriculture)</td>
<td>Santo Domingo (capital)</td>
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<th><strong>Competent authorities</strong></th>
<th><strong>Comments</strong></th>
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<tr>
<td>Regional MA Office, North Central</td>
<td>La Vega</td>
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<tr>
<td>Staff of MA Office, North West</td>
<td>During on-site visits</td>
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<tr>
<td>Staff of MA Office, South West</td>
<td>During on-site visits</td>
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<tr>
<th><strong>Laboratories visited</strong></th>
<th><strong>Comments</strong></th>
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<tbody>
<tr>
<td>Central Veterinary Laboratory (LAVECEN)</td>
<td>Operational for official controls of pesticide residues and pesticides</td>
</tr>
<tr>
<td>Dominican Agribusiness Board (JAD) Laboratory</td>
<td>Not currently operational for official controls of pesticide residues</td>
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<tr>
<td>---------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Institute for Innovation in Biotechnology and Industry (IIBI)</td>
<td>Not currently operational for official controls of pesticide residues</td>
</tr>
</tbody>
</table>

**Inspection visits**

- Visits to 3 exporters of fresh vegetables to the EU
  - La Vega region
- Visit to 4 exporters of mangoes to the EU
  - Bani, including farms and packing house
- Visit to 4 growers in La Vega
- Visit to 6 retailers (including 2 importers) of PPPs
  - La Vega region and Constanza

### 3 LEGAL BASIS FOR THE MISSION

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

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

### 4 BACKGROUND

According to data from EUROSTAT for the year 2009, the Dominican Republic exported approximately 240 000 tonnes of food of plant origin in that year, of which approximately 228 000 tonnes were banana. The Dominican Republic is also an exporter of fresh and leguminous vegetables to the EU (approximately 8 800 tonnes exported to the EU annually).

The CA stated that all PPPs are included in a list of 1533 commercial products, with 472 authorised active ingredients. PPPs are not produced in the Dominican Republic, so import volumes are an indication of the volumes used. Figures provided by the Dominican Republic MA indicated that some 5 811 tonnes were imported in 2009.

For the commodities of concern in terms of pesticide residues (legumes and oriental vegetables), most production is on small farms of between 0.25 and 15 hectares. The main region is the north central region in the centre of the island in a valley between two mountain ranges. The majority of farms are less than 2 hectares. Other large crops in the area are rice, cassava, tobacco and fruit.
Most mangoes are produced by similar-sized farms but operating together under a cooperative system. The main mango regions are in the south, south central, and south west of the country.

Glasshouse production of tomatoes and peppers is concentrated in Jarabacoa town, La Vega province. Bell peppers are now exported to the EU. Glasshouses are mostly of a standard size (4800 m²) provided by the Programme for Refrigeration and Greenhouses.

Export is by air through the main airports in Santo Domingo, Puerto Plata and Punta Cana, with the exception of some fruits such as mangoes, which are shipped in refrigerated containers.

In 2008, a total of four notifications concerning pesticide residues in vegetables were received via the Rapid Alert System for Food and Feed (RASFF). In 2009, no notifications were received. As from the beginning of 2010, oriental vegetables are listed under Regulation EC No 669/2009 with an import control frequency of 50 %. In 2010, thirteen more RASFF notifications have been received concerning pesticide residues in vegetables (peppers, aubergine, lauki and beans). There have been no notifications for mangoes.

5 FINDINGS AND CONCLUSIONS

5.1 RELEVANT NATIONAL LEGISLATION

Legal requirements

Article 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 authorisation and control of the marketing and use of pesticides (plant protection products) is governed by Law 311-68 and by Regulation 322-88, which contains implementing provisions.

The procedure for registering exporters is regulated under Law 84/99. No legislation was mentioned for the export of goods.

The Programme for the Export of Fruits and Vegetables (PROVOFEX) was established by MA resolution 12/2007. The Department for Food Safety (DIA) was established by resolution 18/2005.

Since the last mission, the following new legislation has been put in place (for decrees, the year of entry into force is indicated by the last two numbers).

Decree 52-08 lays down the legal requirements for the application of good agricultural practices (GAP), traceability and keeping records of the use of PPPs.

The legal basis for pesticide residue analysis laboratory and for the formulation laboratory for pesticides is established in Resolution 22-2009 of the Secretaria de Estado de Agricultura.
The CA explained that decree 244-10 in general uses Codex Maximum Residue Levels (MRLs) for establishing national MRLs. If the Codex has no MRLs for specific pesticides, the MRLs published by the Environmental Protection Agency of the United States of America (EPA) are used. If there are no EPA MRLs either, the EU MRLs are used. If no EU MRL exists (except the default MRL of 0.01 mg/kg), the MRL of a country where a PPP is registered for a similar crop will be applied.

However, the mission team was informed that the legislation was to enter into force in 2010, so, at the time of the mission, no MRL list had been drawn up in the Dominican Republic.

Conclusions

Legislation for the authorisation and control of the marketing and use of plant protection products provides an adequate legal base for the control of pesticides on the market and for the registration of retailers.

Since the last mission, new legislation has been put in place for GAP, including keeping records of the use of PPPs, traceability requirements, the tasks of the pesticide laboratory and the establishment of MRLs. There is no legal requirement to label fresh produce.¹

5.2 Competent Authorities

Legal requirements

Article 46(1)(b) of Regulation (EC) No 882/2004 stipulates that EU controls shall have, inter alia, particular regard to the organisation of the TC’s competent authorities, their powers and independence, and the authority they have to enforce the applicable legislation effectively.

Findings

There have been no changes regarding the competent authorities since the last mission.

The competent authority for the authorisation of PPP and the control of such products upon import, distribution, marketing and use is the Department of Vegetable Health (DSV) of the MA. There is a specific division for the authorisation of pesticides. The MA is also the CA for controls of pesticide residues in products of plant origin and the follow-up of EU RASFF notifications.

¹ In their response on the draft report the Competent Authority noted that “There is currently no standard for the labelling of fresh products in the Dominican Republic; in the case of exports, however, the standards of the importing country are taken into account. The Directorate-General for Standards (Dirección General de Normas, DIGENOR) plans to draw up a standard for the labelling of fresh products, to be completed for 2012.”
The MA is represented by eight regional offices around the Dominican Republic. Within this structure is a network of provincial offices and local agricultural technicians who provide advice to farmers. The mission team visited the north central regional office. This office plays a strategic and coordinating role with some 350 technicians situated locally within a specific district, which is their responsibility.

The State Secretary for Agriculture, sub-secretary of extension and agricultural education, is also in charge of the Department for Food Safety (DIA), which is based centrally. The Department is responsible for the promotion and certification of GAP and Good Manufacturing Practice (GMP), concentrating on packing houses. It also contributes to the development of the national sampling plan for pesticide residues.

The mission team was informed by the MA that it imposes sanctions on farmers that use banned pesticides. However no evidence was provided on sanctions for the use of unauthorised pesticides. The laboratory report on a rejected consignment showed the use of chloropropylate, which is not registered in the Dominican Republic and the EU, indicating the illegal import/use of PPPs. No action was taken by the CA before the mission team discovered the case. At the closing meeting, the CA stated that an investigation had been opened into the case.  

The CA informed the FVO team that DSV, through the Pesticide Registry Division, runs an ongoing agro-medicine programme aimed at specialists, producers, labourers, persons applying plant protection products and medical staff in hospitals at national level.

The mission team was informed by the MA that there is an ongoing training programme for farmers on the safe use of pesticides. A training initiative on the safe use of pesticides, conducted jointly by AFIPA, PATCA, PROVOFEX, DIA, IDIAF, ADEXVO, JAD, and Croplife (international association of PPP producers) for 2160 participants (farmers, technicians and pesticide spraying providers), will start in January 2011.

However, there is no comprehensive routine training programme for agricultural technicians and only ad hoc training for agricultural managers.

Conclusions

The competent authorities for the authorisation, marketing and use of PPPs and for controls on pesticide residues are clearly defined. The CA did not demonstrate its authority to enforce the

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2 In their response on the draft report the Competent Authority noted that: “As a result of the DG SANCO report and the RASFF notification the appropriate investigations were carried out, focusing on three fundamental aspects:

The results of the field investigation indicate that the producer in question did not apply any pesticide with the active ingredient chloropropylate.

None of the dossiers for pesticides, covering both the molecules registered in the country and the statistics compiled for imports of pesticides, include any product with the active ingredient chloropropylate.

It is important to note that chloropropylate is an original molecule and that bibliographical research found no indication that the substance in question is a final metabolite of the pesticides used on the farm (propine, propiconazole, trifloxystrobin and abamectin).”
applicable legislation effectively in terms of sanctions for use of unauthorised PPPs.

5.3 Controls on marketing and use of plant protection products

Legal requirements

Article 46(1)(e) and (b) of Reg. (EC) No 882/2004 stipulates 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. Evaluation, marketing and use of PPPs in the EU are regulated under Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

Findings

5.3.1 Authorisation of plant protection products

The CA informed the mission team that there had been no changes in the procedure for authorising pesticides since the last mission.

All PPPs require prior authorisation before placing on the market and use. The MA requires evidence of authorisation for placing on the market and use in the country of origin and, if PPPs are formulated in another country, also the authorisation for marketing and use in that country.

MA staff check only the completeness of the documentation provided by applicants. The CA informed the mission team that they carry out a risk assessment for the proposed uses based on documentation from the manufacturer in the country of origin, provided by the party registering the product. The final decision on granting an authorisation is taken by the Director of the MA upon recommendations made by staff following the completeness check.

From the visits to retail shops, the mission team noted that PPPs marketed in the Dominican Republic were commonly imported from China, India and other Central American countries. In some cases, imported products were found without the Dominican Republic authorisation number on the label.

A list of authorised active substances was provided. This list contains 472 substances.

Of the 472 active substances currently authorised in the Dominican Republic, only 136 are included or are pending inclusion in the EU positive list (Annex 1 of Council Directive 91/414/EEC), while 189 (40 %) are not included and the remaining 147 (31 %) substances have never been authorised for use in the EU.

The mission team was also informed that there are approximately 1533 authorised PPPs and the
official list was provided.

5.3.2 Formulation analyses

There is at present no operational formulation laboratory for the routine analysis of PPPs in the Dominican Republic. In 2008, LAVECEN established a formulation laboratory equipped with HPLC-UV, GC-NPD/ECD/FID/FPD and UV and IR spectrophotometers. Even though there are no mass spectrometry facilities for confirmation purposes, this could be resolved by using the GC-MSD installed in the pesticide residue laboratory (PRL). The staff, partially shared with the PRL, comprises four persons with adequate qualifications. The mission team was informed that around 20 samples had been evaluated for purity and physico-chemical properties. The team was also informed that a general protocol for quality control and sample management, including analysis fees, would be ready in January 2011. The laboratory is not evaluated to any international standard.

5.3.3 Controls on marketing and use of plant protection products

There is extensive pesticide use in the Dominican Republic. Figures provided indicate that large volumes (5 811 711 kg) of pesticides are imported into the country. A large percentage (>50 %) are not authorised in the EU. MRL values in the EU are 0.01 mg/kg in the majority of the cases. In many cases, the pesticides imported are not permitted for use in Europe for human health reasons. For example, paraquat and malathion were imported in 2010 in quantities of 730 000 l and 2000 kg of commercial product. The instructions for two different commercial products indicated pre-harvest intervals of between 2 days and 21 days for the same crop. The CA stated that measures were being taken to sort out the problem.

Improvements were observed regarding the inspection of pesticide retailers since the last mission. Legislation stipulates that retail shops selling PPPs must be run by persons who possess a diploma in agronomy and that the enterprise must be registered. This was the case for the retailers visited.

The mission team was informed that the inspection and registration of pesticide retailers was under way throughout the Dominican Republic. At the time of the mission, the CA stated that some 275 out of 600 retailers had been inspected and registered as pesticide retailers. A list was provided. The list of registered retailers indicated that 23 retailers of the 275 had been excluded from selling PPPs.

The recommendations made during the inspection for registration are not followed up systematically, and the CA stated that follow-up inspections are usually not conducted because of a shortage of staff.

The mission team visited two large importers of PPPs that also act as retailers. The safety standards within the visited importers were poor, and one importer had two pallets with an unauthorised (registration not renewed) pesticide in its store. Several PPPs were stored on the floor. One store contained excessive quantities of PPPs (approximately 200 tonnes instead of 150 tonnes) for the size of the premises. PPPs were stored in several cases in three layers of pallets. This had led to broken and leaking bottles of highly toxic pesticides. Safe storage was not guaranteed. The CA did not take immediate action against this importer.
One of the two small retailers of PPPs visited also had excessively high quantities of PPPs in its store. Recommendations for corrective action were made by the MA inspector in charge on the spot.

Two of the three retailers visited unannounced in Constanza showed major deficiencies in terms of the safe storage of PPPs. At present, no produce is exported from Constanza to the EU. Labels were found on PPP containers with fraudulent indications of the nationally determined toxicity level (yellow was used instead of red for ‘highly toxic’, indicating to farmers a lower toxicity). Additionally, PPPs with an expired shelf life were on offer. The CA did not take immediate action against these retailers.

The mission team frequently found amitraz, malathion, dichlorvos, diazinon, paraquat\(^3\) and other Category 1 or toxic/harmful pesticides. None of these are authorised for use in the EU. The CA stated that only small amounts of amitraz, malathion and dichlorvos remained on the market related to the inventory made based on Regulation 50-2009.

The MA explained that produce exported to the EU is grown by three types of producers. One quarter is grown by exporters’ own farms, another quarter by medium-sized and big farms, and approximately half by small growers that sell their produce through intermediaries to the exporters. GAP implementation is about 60 % at exporters, 15-20 % at medium-sized and big farms, and less than 10 % on small farms.

The CA stated that the technical staff directly or indirectly assigned to inspection and/or supervision consists of 102. Thirty-five PROVOFEX technicians are assigned to supervision and inspection in packing areas, twenty PROVOFEX technicians are assigned to supervision and inspection in growing areas, thirty-two plant quarantine inspectors (export unit) at national level, who also carry out inspections in packing areas, and fifteen agrifood safety inspectors are active both in the field and in packing areas.

After the listing of produce from the Dominican Republic under Regulation (EC) No 669/2009, the MA has allocated 20 technicians to support growers and exporters involved in exports to the EU in the La Vega region. Its advisory service at present reaches all exporters, approximately 80 % of medium-sized and big farms and approximately 45 % of small farms.

Recommendations to farmers on the most appropriate product to be used for the specific problem they are facing are mostly based on lists of pesticides registered for the specific crop in the EU. The lists consist of 30 to 40 active ingredients per crop, EU MRLs and pre-harvest intervals. In the case of mango, the list did not contain information about pre-harvest intervals. In 7 out of 13 cases, RASFF notifications concerned PPPs that are not included in the MA list for EU exports.

Controls of the users of PPPs are only carried out after RASFF notifications and rejected consignments (see chapter 5.4.6). The mission team obtained evidence during four field visits that small farmers in particular did not always follow the recommendations given. The records of the CA showed at one of the visited farmers that was involved in a RASFF notification related to dicofol that he continued to use dicofol. Dicofol is an active ingredient that is registered in the Dominican Republic but is restricted to certain crops (Resolution 50-2009). The recommendations in the protocol of the RASFF investigations showed that he should not use it but the records of the follow-up visit showed that he continued to use dicofol.

\(^3\) In their response on the draft report the Competent Authority noted that: “Paraquat was declared a product for RESTRICTED USE in accordance with the provisions of Law 311 of 24 May 1968 and with Regulation 322/88.”
Conclusions

Progress was observed regarding the inspection and registration of pesticide retailers, but the recommendations made are not followed up systematically.

The majority of PPPs authorised in the Dominican Republic cannot be marketed and used in the EU, and their use in the Dominican Republic could lead to residues exceeding EU MRLs.

The CA inspects the use of PPPs by farmers when MRL exceedances are found and provides advice, but the recommendations regarding PPP use are not followed up systematically and small growers in particular do not always follow the advice given.

The implementation of GAP is low, especially at small farmers, and the majority of them are not reached by the official extension service of the CA.

Small producers account for half of the imports of fresh vegetables from the Dominican Republic and there are not sufficient assurances that they produce in line with EU MRLs.

There are not enough technicians to inspect all farmers involved in EU exports and provide them with technical advice.

The CA did not demonstrate its authority to enforce the applicable legislation effectively in terms of marketing and use of PPPs.

5.4 Controls of pesticide residues in food of plant origin

Legal requirements

Article 46(1)(e), (b) and (h) of Regulation (EC) No 882/2004 stipulates 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 authority to enforce the applicable legislation and the assurances which the third country can give regarding compliance with, or equivalence to, EU requirements.

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 food business operators producing or harvesting plant products to keep records of any use of PPPs.

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

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

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

Findings

5.4.1 Communication of EU MRLs

At the time of the mission, the MA had up-to-date lists of EU MRLs and pre-harvest intervals for the main crops (aubergines, banana, pepper, beans and mango [no pre-harvest intervals listed]) for export to the EU. The CA stated that the lists had been forwarded to all exporters (29) and farmers involved in exports to the EU.

The mission team was shown those lists at all the exporters and farmers visited.

5.4.2 Traceability and record-keeping

There is legislation in place requiring traceability of produce and record-keeping of PPP use.

The farmers visited generally kept records of pesticide applications. In the case of illiterate farmers, the MA inspectors keep records of the recommendations they make. They showed a list to the mission team concerning the use of pesticides. However, this list did not provide details of which pesticides were used on which crop.

During the follow-up investigations regarding RASFF notifications in 2010, the exporters were able to trace back the produce in question to the producer. They demonstrated that traceability was possible only by getting information regarding the date of delivery and the type of produce.

5.4.3 Control of packing houses

Since the last mission, DIA has developed comprehensive check-lists for the inspection of mango exporters and farmers. The mission team visited 4 mango growers/exporters in Bani region, representing approximately 90 % of mango exported to the EU. The mission team was informed that the pack houses of the mango exporters are inspected on an annual basis. The inspection does not cover control of the use of post-harvest pesticides.

However, the copies of inspection reports provided to the mission team showed that there is no follow-up of corrective actions recommended during inspections. The templates are usually not filled out properly.
Regarding inspections of mango farmers, the requested reports were provided after the mission.

5.4.4 Sampling and monitoring programmes for pesticide residues

A copy of a monitoring programme was provided to the mission team during the closing meeting. There are still no sampling plans for official pesticide residue analysis due to the lack of analytical capability. However, the CA stated that plans would be finalised in about 6 months and that they had started taking some 12 samples for initial tests. The mission team observed one sampling exercise in an aubergine field one day before harvest of the crop. In the sampling procedure, no details of the quantity/size of the samples for the sampling of different crops were defined.

5.4.5 Certification of exports

All exported consignments of food of plant origin must be certified by the local agricultural technician of the DSV. This is required at the point of export for the issuing of a phytosanitary certificate. There is no certification of plant produce intended for export to the EU as free of pesticide residues, as EU legislation does not require certification for pesticide residues in food of plant origin.

5.4.6 Follow-up of notifications in the EU RASFF

Investigations to follow up RASFF notifications are always conducted systematically and the sources of exceeded MRLs are in general identified. The MA forwards the notifications received from the RASFF to all exporters and the violating company. The MA sends a team of at least 2 inspectors to the company to investigate the reasons for the MRL exceedance and to initiate corrective actions, including penalties established by the Minister of Agriculture.

The CA stated that for a first RASFF notification, the exporter concerned receives an official warning from the MA. In the case of a second RASFF notification, the exporter is suspended from exporting for 21 to 45 days. The mission team was informed about one case of an exporter suspended in 2010 for 15 days following RASFF notifications.

Farmers that have sold produce with MRLs over the limits are investigated by the MA team, along with the intermediary and exporter, if any. Where produce remains in the field, it is destroyed. In minor cases, however, all exporters receive an order that they are not allowed to buy produce from this farmer for export.

MA has developed and implemented a fast-response system following rejection of produce from the Dominican Republic at the EU borders. This system is based on tracking the Common Entry Documents (CED).

The Minister of Agriculture authorised the MA by a circular of 14 June 2010 to request CEDs from exporters. CEDs must be forwarded to the MA not later than 5 days after the produce left the Dominican Republic. The MA is thus very quickly informed of rejected produce and can promptly
launch investigations and corrective actions. Where exporters do not provide the CEDs to the MA, they are excluded from export by not being issued phytosanitary certificates.

5.4.7 Additional private controls

The mango growers and exporters met by the mission team had established systems for food safety and traceability. They were inspected and certified by private standards bodies.

The growers and exporters of oriental produce visited were not inspected by private standards bodies. However, they generally kept records of PPP use and had established traceability systems that were shown to be effective in RASFF follow-up investigations.

Conclusions

Packing houses exporting fresh fruit and vegetables are officially registered in line with Regulation (EC) No 852/2004. Effective traceability systems were implemented in the packing house visited by the mission team. The producers met by the mission team kept records of the use of PPPs in line with Regulation (EC) No 852/2004.

There were no sampling plans for official pesticide residue analysis.

There was evidence that recent EU RASFF notifications on pesticide residues in vegetables from the Dominican Republic had been followed up.

The comprehensive auto-control systems for pesticide residues operated by mango producers and exporters provide some assurance of compliance with EU MRLs for pesticides in the case of mango.

5.5 Laboratories for pesticide residue analysis

Legal requirements

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


Commission Directive 2002/63/EC establishes 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).

Findings

5.5.1 Organisation

At present, there is no official monitoring programme for pesticide residues in plant produce, whether for domestic consumption or for export. The mission team visited the Central Veterinary Laboratory (LAVECEN), which is part of the MA. The mission team also visited the laboratories run by JAD (Junta Agroempresarial Dominicano), which is the farmers association of the Dominican Republic, and IIBI (Institute for Innovation in Biotechnology and Industry), an autonomous, decentralised State research and service institution governed by an Advisory Council, presided over by the Ministry of Higher Science and Technological Education.

LAVECEN has been restructured and has adequate facilities to analyse pesticide residues in fruit and vegetables. It has improved its laboratories since 2008 in terms of personnel, facilities and analytical equipment like GC-MS. It is intended to become the National Reference Laboratory for analysis under the monitoring plan for agrochemicals and veterinary residues in food.

The second laboratory belongs to JAD. It started pesticide residue analysis in 1992 with basic or classical analytical instrumentation. In 2009, as a consequence of the requirements of its associates, it invested in a new laboratory with GC-MS to be operational in 2011.

The third laboratory belongs to the Institute of Innovation in Biotechnology and Industry (IIBI). It was stated that it mainly focuses on research. A pesticide residue analysis laboratory has been developed. However, the director of the Institute and the head of the laboratory considered information on this matter to be confidential, so no documentation about organisation and capabilities was provided.

5.5.2 Resources and training

The LAVECEN laboratory has acceptable facilities with rooms for sample reception, sample treatment, analysis and quality control activities. The laboratory staff comprises four people with adequate qualifications and two observers or collaborators from the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA) programme. Over the past year, the staff have been receiving training from international consultants on the main aspects of analysis and quality control procedures. They have developed basic SOPs with a view to obtaining ISO 17025 in 2011. The LAVECEN laboratory has received support for investment in equipment from the MA’s agrifood support programme (Proyecto de Apoyo para la Transición Competitiva Agroalimentaria). In addition there is an institutional support programme for regional integration (ISPRI) with EU funding.

The JAD laboratory has adequate facilities. It has started with one chemist with basic qualifications in pesticide residue analysis. The laboratory aims to start analysing PPP residues in the field in 2011.
5.5.3 Analytical spectrum and methods

LAVECEN is on the way to establishing routine pesticide residue analysis. The new equipment installed is a Gas Chromatograph Mass Spectrometer (GC-MS) and a High Performance Liquid Chromatograph with Ultraviolet Diode Array Detector (HPLC-UV/DAD). The multi-residue method in place covers 22 compounds. It is based on the Quechers extraction procedure. However, some difficulties have been observed in achieving detection limits in the range of 0.01 mg/kg, the default value for official EU controls. No Liquid Chromatograph Mass Spectrometer (LC-MS) facilities are to be acquired in the coming months. Furthermore, there is no single residue method (SRM) in place or under study, which also represents a limitation considering the intensive use of the fungicide Mancozeb.

5.5.4 Quality assurance systems

LAVECEN has not implemented a full quality control system, a quality manual or adequate SOPs, but it has experience in working under general quality requirements for analysis. The laboratory is not evaluated or accredited to any international standard. LAVECEN has contracted a consultant in October 2010 to support ISO 17025 implementation. Basic SOPs have already been developed.

The mission team was informed by JAD staff that the JAD laboratory will be visited by ENAC (Spanish accreditation agency) in 2011 to start the process of accreditation to ISO 17025.

The CA informed the mission team after the mission that the IIBI has ISO 17025 accreditation (16 accredited tests), in areas such as mineralogy (7 tests), microbiology (2 tests), chemistry (5 tests), physics (1 test), chromatography (1 test). IIBI obtained ISO 9001 recertification in 2008.

Conclusions

The pesticide residue laboratories visited are not evaluated regarding the application of internationally recognised quality assurance systems and are not accredited to ISO 17025.

The current methods of analysis and the equipment used in the laboratories do not cover the range of pesticides used by farmers in the Dominican Republic and the majority of active substances monitored in the EU.

The LAVECEN laboratory has started the procedure to validate a GC-MS, multi residue method (MRM) method with a very limited scope. LC-MS and some SRMs are missing. This represents a serious limitation for the monitoring programme, as more than 50% of the pesticides currently used in the Dominican Republic are only LC-amenable.

4 In their response on the draft report the Competent Authority noted that: "With the assistance and advice of the United States Food and Drug Administration and the installation of a GC/MS detection method, the laboratory has increased its capacity so that 516 compounds can now be identified with their metabolites, and the 22 mentioned above can be quantified."
The JAD laboratory has started basic practical GC-MS work. But no clear plans for methodology and method validation have yet been developed. There are no plans to acquire LC-MS.

All laboratories visited invested in new GC-MS equipment.

The IIBI laboratory could not be adequately evaluated due to the lack of information provided.

5.6 Follow-up of the recommendations of the previous mission

Out of the seven recommendations made in 2008, three recommendations have been fully addressed, three have been partly addressed and one was not addressed at the time of the mission.

<table>
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<tr>
<th>No.</th>
<th>Recommendation</th>
<th>Evaluation</th>
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| 1   | Improve 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. | Partly addressed
At present, no PPP residue analysis is performed to control residues and formulations of PPPs                                                                                                         |
| 2   | Ensure that producers keep records of applications of plant protection products in relation to produce exported to the EU as required by Art 4 (1) of Regulation (EC) No 852/2004 in connection with Annex 1 and Article 10 of that Regulation. | Addressed                                                                                                                                                                                                 |
| 3   | Set up a post-registration control programme for marketing, use and quality of pesticides.                                                                                                                                                  | Partly addressed
Inspections are not followed up, pesticides are only analysed to a small extent                                                                                                                     |
| 4   | Establish MRLs in relation to produce exported to the EU and ensure that EU MRLs are communicated to local CA and to producers/exporters.                                                                                                   | Addressed                                                                                                                                                                                                 |
| 5   | Develop a monitoring plan for pesticide residues.                                                                                                                                                                                             | Addressed                                                                                                                                                                                                 |
| 6   | Develop an analytical capability for the monitoring of pesticide MRLs, including quality procedure and scope and validated methods, to ensure the equivalence with                                                                 | Not addressed                                                                                                                                                                                             |
Article 18 of Regulation (EC) No 2076/2005, and to ensure that the laboratory provides reliable analytical results. Equivalence to Art 12 (2) of Regulation (EC) No 882/2004 should be demonstrated by 1 January 2010

| 7 | Consider setting up a system of authorisation based on risk assessment, a register of authorised products and their uses, and to ensure this information is disseminated to regional offices, growers, pack houses and exporters | Partly addressed

No risk assessments are being conducted yet, but decree 244/2010 provides the legal basis for risk assessments

6 **OVERALL CONCLUSIONS**

There were some improvements since the previous mission in particular regarding new legislation, advice for producers and exporters, follow-up of border rejections and laboratories.

However the legislation is not yet fully implemented and enforced, while the majority of small growers exporting to the EU are not covered by official supervision and do not have good agricultural practices (GAP) in place. The laboratories are not fully operational yet. The majority of authorised PPPs may not be used in the EU and some of these have led to RASFF notifications.

Compliance with EU MRLs for pesticides is partly ensured for mangoes by the comprehensive auto-control systems.

7 **CLOSING MEETING**

A closing meeting was held with the MA on 23 November 2010. At that meeting, the inspection team presented its main findings and preliminary conclusions. The representatives of the CA offered some initial comments and provisionally accepted the preliminary findings and conclusions.

8 **RECOMMENDATIONS**

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion (‘action plan’), to address the recommendations set out below, within 25 working days of receipt of this report.
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<td>The CA of the Dominican Republic should consider setting up a post-registration control programme for the marketing, use and quality of PPPs.</td>
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<td>4.</td>
<td>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.</td>
</tr>
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<td>5.</td>
<td>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).</td>
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<td>6.</td>
<td>The CA of the Dominican Republic should consider expanding the range of analyses for pesticide residues for example by acquiring LC-MS equipment.</td>
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<td>7.</td>
<td>The CA of the Dominican Republic should consider a practical training programme for laboratory staff to reach the international standards within a reasonable time.</td>
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The competent authority's response to the recommendations can be found at: [http://ec.europa.eu/food/fvo/ap/ap_do_2010-8588.pdf](http://ec.europa.eu/food/fvo/ap/ap_do_2010-8588.pdf)
### Annex 1 - Legal References

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<th>Legal Reference</th>
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