EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2008-7848 - MR FINAL

FINAL REPORT OF A MISSION CARRIED OUT IN

THE DOMINICAN REPUBLIC

FROM 03 JUNE TO 12 JUNE 2008

IN ORDER TO

EVALUATE CONTROLS OF PESTICIDES IN FOOD OF PLANT ORIGIN INTENDED FOR EXPORT TO THE EUROPEAN UNION

Please note that factual errors in the draft report have been corrected. A clarification provided by the Competent Authority is given in an endnote.

EXECUTIVE SUMMARY

The objective of the mission was to evaluate the control system in place for pesticides in food of plant origin intended for export to the European Union. It was decided to carry out a mission to in view of the volume of its vegetable and fruit exports to the European Union (EU). There were also notifications of unacceptable levels of pesticide residues in food of plant origin from The Dominican Republic within the EU Rapid Alert System for Food and Feed (RASFF), and of MRL exceedances in the combined pesticide monitoring report.

Marketing and Use

The authorisation system for plant protection products (PPP) in the Dominican Republic is entirely based on an administrative check of rather limited data submitted by applicants without risk assessment. There is no official list of authorised products and uses which makes effective control difficult.

Marketing and use of PPPs is not regularly monitored while the lack of an official list of authorised products creates a lot of problems to technicians on the correct advice to be given to the farmers. Regular advice is given to use pesticides not authorised in Europe for products to be exported to Europe.

The lack of a formulation analysis laboratory reinforces the problem of controls on the market, raising serious concerns about the quality of plant protection products been marketed and used.

Pesticide Residues

There are no MRLs established.

As a control system is dependant upon access to a pesticide residue laboratory, and none is yet equipped in The Dominican Republic there is no monitoring of products exported to the EU.

Overall conclusion

There is a very poor control system is place, PPP use is extensive and not effectively controlled in authorisation, marketing or use. Many pesticides not authorised for marketing and use in the EU are regularly used in products for export. The control system does not provide guarantees equivalent to EU standards. There is no analytical capability and therefore further residues with toxicological risks in exported products remain highly likely.

The report contains recommendations to The Dominican Republic to address identified shortcomings.

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ABBREVIATIONS

Abbreviation	Explanation
CA	Competent Authority
CEDAF	Centre for Agro-Forest Development (*Centro para el Desarrollo Agropecuario y Forestal*)
CEI-RD	Centre for Export and Investments of the Dominican Republic
DIA	Department of Food Safety (*Departamento de Inocuidad Agroalimentaria)*
DSV	Department of Vegetable Health (*Departamento de Sanidad Vegetal)*
ECD	Electron Capture Detector
EU	European Union
EUROSTAT	Statistical Office of the European Communities
FID	Flame Ionisation Detector
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GC	Gas Chromatograph
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points

HPLC	High Performance Liquid Chromatography
IIBI	Institute for Innovation in Biotechnology and Industry
ISO	International Organisation for Standardisation
LAVECEN	Central Veterinary Laboratory (*Laboratorio Veterinario Central)*
MRL	Maximum Residue Level
MSD	Mass Selective Detector
NPD	Nitrogen Phosphorous Detector
PIP	Pesticides Initiative Programme
PPP	Plant Protection Product
PROMEFRIN	Programme for Refrigeration and Greenhouses (*Programa de Mercado Frigorífico e Invernaderos)*
PROVOFEX	Programme for Export of Fruits and Vegetables (*Programa de Vegetales y Frutas Frescas de Exportación)*
RASFF	Rapid Alert System for Food and Feed
SEA	Ministry of Agriculture (*Secretaría de Estado de Agricultura)*
UV	Ultraviolet

1 INTRODUCTION

The mission took place in The Dominican Republic from 03 to 12 June 2008. The mission team comprised one inspector from the Food and Veterinary Office (FVO) and two Member State National experts.

The mission was undertaken as part of the published inspection programme and was the first mission to The Dominican Republic dealing with pesticide residues in produce of plant origin.

The inspection team was accompanied during the mission by representatives from the central competent authority, the Secretary of Agriculture (SEA).

An opening meeting was held on 03 June 2008 with representatives of the SEA, Department of Food Safety (DIA) and the Department of Plant Health (DSV). At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team.

2 OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the control systems for pesticide residues in foodstuffs of plant origin intended for export to the European Union (EU). The facilities and measures in place for the determination of such residues in foodstuffs of plant origin intended for export to the EU were assessed to ensure that the produce is within specified limits laid down in EU legislation. As residue controls are related to the placing on the market and use of plant protection products, the control system for the latter functions was also evaluated. The mission formed part of a wider series of missions to Third Countries to evaluate control systems and operational standards in this sector.

The mission was carried out in the framework of:

– Regulation (EC) No 178/2002 of the European Parliament and of the Council

– Regulation (EC) No 882/2004 of the European Parliament and of the Council;

– Regulation (EC) No 852/2004 of the European Parliament and of the Council;

– Council Directive 76/895/EEC;

– Council Directive 90/642/EEC;

– Council Directive 86/362/EEC;

– Regulation (EC) No 396/2005 of the European Council and of the Parliament.

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

Table 1: Mission visits and meetings

Central Competent authorities	**Comments**
SEA (Ministry of Agriculture)	Santo Domingo (The capital)
DIA (Food Safety Department)	Santo Domingo
DSV (Plant Health Department)	Santo Domingo
Competent authorities	**Comments**

Regional SEA Office North Central	La Vega
Staff of SEA Office North West	During on site visits
Staff of SEA Office South West	During on site visits
Laboratory visited	**Comments**
Institute for Innovation in Biotechnology and Industry(IIBI)	Not currently operating for official controls of pesticide residues
Central Veterinary Laboratory (LAVECEN)	Under refurbishment, not currently operating for official controls of pesticide residues
Inspection visits	**Comments**
Visits to 4 exporters of fresh vegetables to the EU	3 in La Vega region, one in Jarabacoa region.
Visit to 2 exporters of mangoes to the EU	San Jose de Ocoa
Visit to Co-operative and exporter of organic bananas, Mao, North west region	Including farms and packing house
Visit to growers in La Vega, Jarabacoa and San Jose de Ocoa	
Visit to 5 retailers of PPPs in La Vega and Jarabacoa Regions	

3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation, in particular under Article 46 of Regulation (EC) No 882/2004, and in agreement with the competent authorities in The Dominican Republic.

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 last amended version.

4 BACKGROUND

According to data from EUROSTAT for the year 2006, The Dominican Republic was the 16th largest exporter of fresh fruit to the EU, and exports amounted to approximately 183,000 tonnes or 1.6 % of the total imports to the EU. The Dominican Republic is also a significant exporter of fresh and leguminous vegetables to the EU (approximately 6,000 tonnes exported to the EU annually).

The competent authorities stated that all plant protection products are contained on a list of 3517 products with 500 authorised active ingredients. PPP are not produced in the Dominican Republic so the import volumes are an indication of the volume used. Figures provided by the Dominican Republic SEA indicated some 5,300,000Kg imported in 2006 and 6,699,000Kg in 2007.

For the commodities of concern (legumes and oriental vegetables) most production is undertaken by small farmers 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 fruits.

Most bananas are produced by similar sized farms but operating together under a co-operative system. The main banana region is in the north west of the island.

Glasshouse production of tomatoes and peppers is concentrated in the Jarabacoa region. Bell peppers are now exported to the EU. Glasshouses are predominately of a standard size (4800 m^2) provided by the Programme for Refrigeration and Greenhouses (PROMEFRIN).

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 (REEFER) containers.

5 MAIN FINDINGS

5.1 LEGISLATION

Legislation for authorisation and control of the marketing and use of pesticides (plant protection products) is laid down in Law 311-68 and the Regulation 322-88 which provides implementing provisions.

Law 311-68 is a framework legislation laying down the general rules for the marketing and use of pesticides while the Regulation 322-88 is describing in detail the procedures and the requirements for granting authorisations as well as marketing and use of pesticides. It includes the requirement for sellers of pesticides to be registered.

There is in addition a Decree of the SEA 217-91 which lists 20 particularly harmful pesticides which are prohibited for importation, production, formulation or sale. Specific legislation is also in place regarding the use of aldicarb (62-97) and paraquat (83-91).

The procedure for registration of exporters is regulated under procedures described in Law 84/99. No legislation was provided for the procedure of the exportation of goods.

The Programme for Export of Fruits and Vegetables (PROVOFEX) was established by the SEA resolution 12/2007 and the DIA by Resolution 18/2005.

There is no legislation establishing MRLs for pesticide residues in the Dominican Republic. The mission team was informed that for the purpose of official controls the SDA make reference to international CODEX MRLs, or those of the countries receiving the exported commodities.

5.2 COMPETENT AUTHORITIES

The competent authority for authorisation of plant protection products and controls of such products at import, distribution, marketing and use is the DSV of the State Secretary for Agriculture (SEA). There is a specific Division for the registration of pesticides. The SEA is also the competent authority for controls of pesticide residues in products of plant origin and the follow up of EU Rapid Alert notifications.

The SEA 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. The central office plays a strategic and co-ordinating role with some 350 technicians situated locally with a specific sub-zone which is their responsibility.

The State Secretary for Agriculture, Sub-secretary of extension and agricultural education also has a Division for Food Safety (DIA) which is based centrally. The division is responsible for the promotion and certification of GAP and GMP, concentrating on packing houses. It also contributes to the development of the national sampling plan.

The Export of Fruit and Vegetables for export programme (PROVOFEX) is established by Resolution 12/2007. The programme is supported by the DIA, DSV and industry, funded by the US Inter-American Funding Programme, with the aim of promoting food safety export requirements of the importing countries.

The programme for refrigerated distribution and greenhouses (PROMEFRIN) is part of the SEA and has provided funding for glasshouse construction. It also provides specific technical advice regarding what pesticides to use for each crop and pest or what fertilizer to use.

The Mango Cluster is a joint initiative between the SEA, industry and research bodies. It provides GAP guidance which was found in operation in the visited farms. This includes some advice on the application period of fungicides and recommends which fungicides to use, but does not include details on insecticide use or application.

There is no comprehensive routine training programme undertaken for agricultural technicians and only ad hoc training for agricultural managers. Nevertheless, there was in the past some training of agricultural managers on pesticide use and control, in neighbouring countries (such as Costa Rica and Cuba), and under the PROVOFEX and PROMEFRIN programmes.

There was no evidence of a training programme for pesticide sales managers, while qualifications of the staff varies considerably (i.e. it was found on one occasion that staff had a diploma in agriculture but in all other cases that were visited the staff did not

possess any such qualifications). Some had received training from the manufacturers of pesticides, and some had qualified as agricultural technicians.

5.3 CONTROLS OF THE MARKETING AND USE OF PLANT PROTECTION PRODUCTS

5.3.1 Authorisation of plant protection products

All PPPs require prior authorisation before placing on the market and use. Requirements are very limited and these are mostly statements from applicants on the hazardous properties of the products they intend to be placed on the market. On the basis of the sample dossiers that were shown to the team during the visit, it was noted that no studies are submitted by applicants to enable a comprehensive risk assessment by the competent authority of the physical and chemical properties, the toxicological profile, the residues, the eco-toxicology or the environmental fate and behaviour of the products.

Staff of the SEA are only making a completeness check of the documentation provided by applicants while no risk assessment is conducted for the proposed uses. The final decision for granting an authorisation is taken by the Director of the SEA upon recommendations made by the staff on the completeness check made.

Despite the fact applicants provide a list of intended uses and a draft label, the competent authority does not keep track of authorised uses for each product.

Besides this problem, it was also noted that in the legislation there is a formal requirement that all pesticides be classified into four marketing categories based on the intrinsic toxicity properties of the substances they contain. This classification is based on the World Health Organisation toxicity classification, proposed by the applicant, and is reflected on the label of the product by different colours (green (less toxic), yellow, blue, red (most toxic)), but there is no formal confirmation by the competent authority.

It was noted that different sources for the same substance are authorised but no answer was given as to how an equivalence check is conducted.

From the visits to retail shops it was noted that it is common that PPPs marketed in the Dominican Republic are imported from other Central American countries. In some cases imported products were found without bearing on the label the Dominican Republic authorisation number while it was not understood on the basis of what information the GAP from another country fits to the national GAP. On the other hand in the procedures and data requirements for granting authorisations there do not exist any provisions concerning the mutual recognition of authorisations from other countries.

A case that demonstrates the extent of control on marketing was paraquat. This substance was banned with the Decree of the SEA 217-91 but it was reintroduced the same year following requests from farmer's organisations and without any risk assessment justifying such decision.

Finally, a list of authorised active substances has been provided. This list contains 500 substances. From the list of 500 active substances that are currently authorised in Dominican Republic only 88 have been included in the EU positive list (Annex 1 of Council Directive 91/414/EEC), with 125 (25%) of them withdrawn or not authorised for use in the EU. Others on The Dominican Republic list are currently being evaluated or have not been in use in the EU since the review began in 1991. It was also noted that in the list of plant protection products that have been imported in the last 3 years in the Dominican Republic there exist a number of products that contain substances that are not on the list of authorised substances (e.g. fenamidone and thiacloprid).This raises some concerns about the accuracy of the list of authorised substances that has been provided.

The mission team was also informed that there are 3517 authorized PPPs. No list of authorized plant protection products has been provided and a data base of the decisions taken for authorisations granted does not exist.

5.3.2 Controls of the marketing of plant protection products

There are numerous small retail shops scattered all around the country mainly in the agricultural areas but there is no register of them. There are no formal requirements for setting up a business and there is no licensing system.

Legislation states that retail shops of plant protection products must be run by persons that possess a diploma in agronomy and that the enterprise must be registered but this was not the case in the visited retailers. A central list of registered retailers was provided, indicating there were 229 retailers in the country. The status of this was not clear as the majority were listed as requiring renewal; the premises visited by the mission team were not on the list and no evidence could be provided of them being either authorized or inspected. The list includes only one premises for the visited town of Jarabacoa where the mission team were informed there were six retailers.

The safety standards within the visited retailers were poor. PPPs were displayed on shelves without any precaution (e.g. closed cabinets) for those that are very toxic or toxic. Storage places are not equipped with ventilation systems putting in danger the health of the staff.

Advice and recommendations to farmers on the most appropriate product to be used for the specific problem they are facing is mostly given by the retailers based upon the recommendations of producing companies as these are stated on the label.

In one occasion the mission team observed repackaging of PPP from big drums to smaller containers, conducted by the staff of a co-operative, without any precautionary measures (such as protective clothing) or license for that.

The mission team was informed that Category 1 pesticides or those of concern such as monocrotophos and endosulfan are not sold in vegetable production areas. The mission team visited a number of retailers in the main vegetable production region of La Vega where monocrotophos, methomyl, endosulfan, amitraz, malathion, chlorfenapyr, dichlorvos, diazinon, paraquat and other Category 1 or toxic/harmful pesticides were

found on sale without restriction. None of these are authorised for use in the EU. The three retailers in the La Vega region stated that there was no requirement for registration but that visits were made by the local DSV inspectors. Two companies did not have a qualified agricultural technician, but had previous experience in selling pesticides.

The mission team also visited retailers in the Jarabacoa region where monocrotophos, methomyl, endosulfan, malathion, methiocarb, dichlorvos, diazinon, paraquat and other Category 1 or toxic/harmful pesticides were found on sale. No examples of registration with the DSV were found in any of the visited sellers in this region, and one seller had only a trainee agricultural engineer.

5.3.3 Controls of users of plant protection products

Controls of the users of plant protection products are not carried out. Standardization and specifications of spraying equipment does not exist. Knapsack sprayers are widely used because of the small size of the majority of farms but also because of the low economic power of farmers that can not afford to acquire more expensive spraying equipment, thus dosage of pesticides is not consistent. The use of this method for harmful pesticides such as paraquat was observed which poses a high risk to the user.

In two cases the application of paraquat was observed in the field and it was found in all retailers and in the stores of 3 users. Glyphosate and paraquat are the most widely used herbicides in the country.

Due to the lack of a central list of uses for pesticides varying advice is given by agricultural technicians and sellers of pesticides on suitable PPP. For example in relation to the control of thrips in oriental vegetables a number of operators, sellers and DSV technicians informed the mission team they advised the use of endosulfan, methomyl, monocrotophos, malathion, chlorpyrifos, imidacloprid, methiocarb, and fenturon (the first 4 of which are not registered for use in the EU). Several lists of pesticides were found: from importing companies, from agricultural organisations and from PROMEFRIN. It was stated that a different list would be used dependant upon the destination country. In all cases however, these lists contained recommendation for use of pesticides that are withdrawn in Europe, including a list provided by an importing company in the Netherlands and a large supermarket retail chain in the UK.

Similar advice was also given in relation to the use of pesticides in greenhouses. In the Jarabacoa region dichlorvos, chlorfenapyr, malathion and endosulfan were recorded as being applied to sweet peppers, and were advised by the SEA through the PROMEFEX staff. The same substances were noted in the records of application for the visited greenhouse and difocol, endosulfan and methomyl were noted in the pesticide store.

5.3.4 Formulation laboratory

There is at present no operating formulation laboratory within the Dominican Republic. The LAVECEN (described under section 5.3.8) has established a formulation laboratory that is currently being equipped with HPLC, GC-NPD/ECD/FID/FPD and UV and IR

spectrophotometers although no MSD for confirmation purposes. The mission team was informed that staff would be recruited in 2-3 weeks and it is anticipated that full analytical capability would be in place at the end of the year. It is planned to recruit 5 staff.

The laboratory is not accredited to any international standard.

5.4 CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN ON THE DOMESTIC MARKET

There is extensive pesticide use in the Dominican Republic. Figures provided indicate that there are large volumes (6,698,938 Kg) of pesticides being imported into the country. The pesticides imported include many that are not permitted for use in Europe for reasons of human health. For example some 447,479 litres of paraquat were imported in 2006 (about 8% of the total) and similar imports were noted up to April 2008.

There are cases reported of intoxication from pesticides, either by workers, accidentally or suicides. In 2006 this resulted in 49 cases of intoxication linked to pesticides and 12 deaths being reported to regional intoxication centres, with a lower figure of 11 cases and 1 death in 2007.

5.5 CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN TO BE EXPORTED

5.5.1 Organisation of controls

There is no official export control system for pesticide residues in place. The competent authorities focus on the provision of advice to farmers, and with the PROVOFEX programme on the provision of GAP/GMP for registered exporters.

All exporters have to be registered by the CEI-RD. A comprehensive list was provided to the mission team that includes details of the exporter and the products exported.

The DIA have undertaken inspection of the exporting companies for the application of GMP. All the visited pack houses/ exporters of oriental vegetables had received two inspections. DIA inspections had not been carried out in the banana packing or mango packing facilities.

Commodities for export require a phytosanitary certificate from the DSV inspectors at the airport of dispatch. The phytosanitary certificate is only issued if the lot is accompanied by a certificate from the DSV inspector at the packing house. This DSV certificate is a list of commodities in the lot on a pro-forma carbon copy sheet

5.5.2 Communication of EC MRLs

There are no national MRLs and thus these are not communicated to the local offices or the farmers. The SEA at the time of the mission did not have an up to date list of EU MRLs, or MRLs from any other source, and were using information from a variety of sources, including the internet and lists provided by pest manufacturers and companies who were exporting to the EU.

In the La Vega region the mission team were shown a list of pesticides that they were informed was used by technicians locally to inform farmers on suitable applications for export crops. The list was dated 2005 and included a column for 'Dutch MRLs' and was provided by an exporting company. It contained outdated or invalid MRLs..

A second list was provided electronically for the control of application in greenhouses under the PROMEFRIN programme. This list contained recommendations on what PPP to use in either tomatoes, peppers or cucumbers although substances not authorised in the EU were repeatedly mentioned, such as methomyl, endosulfan and malathion for all three commodities. The use was not checked for compliance with EU MRLs.

A third list was provided by an exporting company for mangoes which was provided by an importing UK supermarket chain. It also contained a column of EU/UK/Codex MRLs although some, such as malathion had been withdrawn for use in the EU.

5.5.3 Approval and control of exporters

Under the Dominican Republic Law 84-99 all exporters are registered with the CEI-RD. The mission team was provided with a list from this database that includes details of the commodities that the company exports. For the export of new groups of commodities the SEA has to grant approval.

Law 84-99 establishes the requirement for exporters to be registered. A list of 80 exporters to the EU was provided from the central database. The mission team was informed that DIA have inspected for GMP about 60 of these under the PROVOFEX programme. Evidence was provided of two visits in each of the three pack houses visited in the La Vega region. The inspection included application of GMP, based on a GMP guide for pack houses, and hygienic conditions and resulted in a report in each case. The inspection does not cover controls over pesticides.

Control is concentrated on the visits to farmers by local agricultural technicians of the DSV who advise on ad-hoc GAP.

5.5.4 Traceability and record-keeping

During the mission the mission team was informed there was no legislation in force in the Dominican Republic requiring the traceability and record keeping of pesticides applications.(see Endnote) Records of application were not found in the majority of retailers or users. However, this was observed in some of the visited companies where they were certified by private certification bodies.

With the exception of the PROMEFRIN project regarding greenhouse application, records of recommended application from the DSV were not kept by the farmers, and no record of actual applications was made, as is required by Article 4 (1) of Regulation EC (No) 852/2004.

Supply to the packing houses/exporters from the farm level is from three sources; their own production, farmers with a verbal agreement to produce and products purchased from intermediate suppliers. The use of the latter in particular makes traceability impossible. In most of the premises visited the majority of supply is from contracted farmers.

Records of applications were found in the visited organic banana producer and in the mango producer, and in both cases traceability was possible and was demonstrated to the mission team.

5.5.5 Sampling programme for pesticide residues

There are no sampling plans for official pesticide residue analysis due to the lack of analytical capability. Thus there are no current procedures for sampling.

In 2006 a consultant produced a document on the production of a national sampling programme. This included information on pesticides that should be examined in certain commodities following the identification of exceedances of these compounds by the USA. Pesticides included those found in commodities exported to the EU such as methiocarb, methomyl and monocrotophos were noted.

This paper was used as the basis of the establishment of a national plan. A 'National Residue and Food Hygiene Commission' has been established with representatives of the SEA, DSV, DIA, Department of Animal Health and LAVECEN to integrate the MOVEHIRA plan. The programme started in 2006 and at the time of the mission this programme was in its third version but still on a draft stage although ready to be finalised. It includes a list of 80 fruit and vegetable commodities and the total list of 500 authorized PPPs. There is not at present a defined monitoring plan with an identified range of analytes to be analysed in each commodity, nor analytical methods defined.

It was stated that after the finalisation of the programme on an annual basis, sampling plans would be elaborated.

Sampling and analysis for a small number of commodities exported to the USA (including long bean, aubergines, peppers, snow peas and fuzzy squash) require that five samples from the same harvest are sent for private analysis at FDA approved US laboratories for certain harmful pesticides such as monocrotophos, acephate, dicrotophos and profenofos. Once the five samples do not indicate presence of the pesticides, export can proceed.

5.5.6 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 issuance of a phytosanitary certificate. There is no link between this and any checks or controls on pesticide use or application.

5.5.7 Follow-up of notifications in the EU RASFF

The mission team visited a number of packing houses that had been involved in RASFF messages from the EU. These had all received notification of this from the SEA and been asked to take corrective actions. In one case the manager had to attend a meeting at the SEA in the capital to discuss the issue. In all cases an elevated level of inspection and control was described although additional official monitoring was not possible due to the lack of laboratory capability.

Despite this action there is no response sent to the Commission on the actions taken by the SEA in relation to RASFF messages notified.

5.5.8 Laboratory for pesticide residue analysis

5.5.8.1 Organisation

At present, there is no official monitoring program for pesticide residues in plant produce, whether for domestic use or for export. The mission team visited the Central Veterinary Laboratory (LAVECEN), which is part of the SEA, which is presently undergoing refurbishment and re-equipping for use as a pesticide residue laboratory. It also visited IIBI (Institute for Innovation in Biotechnology and Industry), an institute responsible to the Ministry of Higher Education.

LAVECEN which belongs to the SEA was being restructured to provide adequate facilities to analyse pesticide residues in fruit and vegetables. Private and public analyses are currently being done on other matrices and analytes. They are to become the National Reference Laboratory for the analysis under the Monitoring Plan in agrochemicals and veterinary residues in food (MOVEHIRA).

The second laboratory the Institute of Innovation in Biotechnology and Industry (IIBI) was mainly focused on research sponsored by the Ministry of High Education. Analysis is mainly performed on microbiology, pesticides in waste water, infant milk, oil and alcoholic drinks and some in fruit although no evidence was shown.

5.5.8.2 Resources and training

The LAVECEN laboratory is not currently being operated for pesticide residue analysis, space has yet to be allocated to conduct pesticide residue analysis under GLP (good laboratory practice). Two rooms are to be shared with analysis of veterinary residues in

meat. There is no clear allocation of resources regarding equipment and staff for each purpose.

Six new staff have been hired and training is being carried out in quality system and pesticide analysis, although no specific task has been assigned within the workers of the laboratory. The laboratory has no previous experience in analysing pesticide residues in fruit and vegetables, although some of the staff had worked in the previous laboratory that undertook pesticide analysis between 1978 and 1986.

The IIBI is operating in a research capacity but claims to have undertaken some pesticide residue analysis in products of plant origin. There are only 3 staff in the pesticide residue laboratory.

5.5.8.3 Analytical spectrum and methods

Within LAVECEN there is not at present an established operating pesticide residue laboratory. Some equipment is present (mainly GC) that had previously been used for veterinary residue analysis. New equipment has been delivered and is being installed (GC- ECD/NPD/FID/FPD and HPLC-UV/DAD although no confirmation method of MSD is available. No clear pesticide scope has been fixed, nor clear analytical methods to be used and validated when equipment is working.

The IIBI is equipped with HPLC-UV and HPLC-FLD and GC-MS which could not be seen working as it is switched off every day. Reports of analysis did not show evidence of performing mass spectrometry. No analytical methods are validated although they use the Association of Official Analytical Chemists Methods (AOAC Methods) and Quechers Method (EN 15662). They have standard mixtures that summed up a scope of approximately 38 pesticides, but with no list of standard controls.

5.5.8.4 Quality assurance systems

There is no Quality Control System implemented in LAVECEN, there is no quality manual or SOP's, although they have experience in working under general quality requirements for analysis. The laboratory is not accredited to any international standard, although this described as an objective.

The IIBI are being accredited under ISO 9001 for general quality procedures by a Mexican accreditation body. They have no ISO 17025 accreditation.

5.5.9 Additional Private Controls

The growers and exporters met by the mission team had established systems for food safety and traceability where part of private standards bodies. The growers had

established systems for keeping records of PPP applications where part of the same scheme, or in the case of production under the PROMEFRIN.

Private agricultural technicians were recruited by some of the larger exporting companies (one for mangoes and one for oriental vegetables) and they were responsible for the advice and supervision of the farming of land owned by the company or for farms that had a verbal contract for the production of products for them.

6 CONCLUSIONS

6.1 LEGISLATION

(1) Legislation for 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 registration of retailers.

6.2 COMPETENT AUTHORITIES

(1) The competent authorities for PPP authorization, marketing and use, and for control on residues is the SEA. The DSV is responsible for controls on farm and for the control of exported goods regarding phytosanitary controls. The DIA has responsibility for the inspection of pack houses regarding GMP application.

(2) Within the same structure there are a number of programmes run jointly with industry, including one (PROVOFEX) for exported goods.

6.3 CONTROLS OF THE MARKETING AND USE OF PLANT PROTECTION PRODUCTS

(1) The authorisation of PPP is based on an administrative check of limited data provided by applicants without risk assessment.

(2) The central register of authorised products does not contain any description of authorised use or application, this is a considerable drawback in enabling controls on the market. 25% of the products on the list are not authorised for use in the EU and the mission team found products on the Dominican Republic market not on the list.

(3) There is a central register of pesticide retailers, but the status of the list was not clear and the five premises visited by the mission team had no record of any visits, had inadequate training and were not on the central register.

(4) There is no coherent advice on pesticide use, and thus this is often advice from the manufacturers. Advice was provided from the industry, from pesticide sellers, from EU

importers and from the central, regional and local competent authority for use of pesticides on products which when exported to the EU might result in MRL exceedances.

(5) Records of PPP application were not kept by the farmers or required by the Competent Authority, as is required by Article 4 (1) of Regulation EC (No) 852/2004.

(6) PPP use in organic banana production was controlled through a co-operative and the list of products and record of application did not give rise to any concerns regarding variance from EU standards.

(7) In mango production some advice on fungicide type and application was provided under the 'Mango Cluster', but use of insecticides not authorised in the EU for products for export was still observed.

(8) There is at present no operating formulation laboratory engaged in analysing plant protection product formulations in the Dominican Republic. A laboratory is being equipped within LAVECEN with new analytical equipment, but with no MSD. The laboratory is not accredited and is yet to be staffed.

6.4 CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN ON THE DOMESTIC MARKET

(1) There are no national MRLs and currently no sampling programme for the domestic market so the nature and extent of residues is unknown.

(2) Pesticide use is extensive and not controlled. Many pesticides in regular use raise concerns for their safety regarding users, the environment or in residues in foodstuffs.

6.5 CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN TO BE EXPORTED

(1) All exporters are registered with the CEI and the SEA had an up to date list of exporters which included details of products exported.

(2) There is no official export control system for products being exported regarding pesticide residues, and as there is no laboratory capability there is no residue sampling.

(3) There are no established MRLs in the Dominican Republic and thus these cannot be communicated to regions or to producers.

(4) There is no legal requirement for record keeping of either recommendations for pesticide application, or records of application, as required by Art 4 (1) of Regulation EC (No) 852/2004.

(5) The pack houses for oriental vegetables that are exporting had all been inspected by DIA for the application of GMP principles, but not covering pesticide controls. Pack houses for mangoes and bananas had not been visited.

(6) There is currently no pesticide monitoring programme. There is a draft national programme being developed which includes pesticides but no described scope of pesticides or specific sampling plan.

(7) LAVECEN is not accredited and is not yet ready for providing analytical results. Within six months to one year, with personnel training in analytical methods and validation, a quality system, and a well defined scope, it could be able to report pesticide residue results although with no confirmation technique.

(8) The capability and the aim of the IIBI laboratory are not suitable to perform routine monitoring analysis. They are capable of submitting results, however, without confirming by mass spectrometry. No ISO 17025 quality system is in place. The staff of 3 people for the laboratory is not sufficient for the amount of samples planned to be analysed for pesticides residues in the different matrices.

6.6 Follow up of Rapid Alerts notified within the EU Rapid Alert System

(1) There has been follow up of RASFF messages by the SEA, although there is no reply sent to the Commission.

6.7 Overall conclusion

There is a very poor control system in place; PPP use is extensive and not effectively controlled in authorisation, marketing or use. Many pesticides not authorised for use in the EU are regularly used in products for export. The control system does not provide guarantees equivalent to EU standards.There is no analytical capability and therefore further residues with toxicological risks in exported products remain highly likely.

7 Closing Meeting

A closing meeting was held on the 12th June 2008 with the competent authorities. At this meeting, the main findings and conclusions of the mission were presented by the inspection team. The representatives of the competent authorities offered some initial comments and provisionally accepted the preliminary findings

8 Recommendations

In relation to pesticide residues in food of plant origin intended for export to the European Union, The Dominican Republic should

No.	Recommendation

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.
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.
3	Set up a post-registration control programme for marketing, use and quality of pesticides.
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.
5	Develop a monitoring plan for pesticide residues.
6	Develop an analytical capability for the monitoring of pesticide MRLs, including quality procedure and scope and validated methods, to ensure the equivalence with 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

The competent authorities of The Dominican Republic are invited to send an action plan in response to the recommendations to the Commission within 25 working days of dispatch of the report. This action plan should clearly set out the manner and deadline by which the competent authorities will address each recommendation.

The competent authority's response to the recommendations can be found at:
http://ec.europa.eu/food/fvo/ap/ap_the_dominican_republic_7848_2008.pdf

9. ENDNOTES

Concerning	Detail
Section 5.5.4	The competent authority of the Dominican Republic, in their response to the draft report, stated that there was now a legal requirement in Art10 of Decree 52-08. The date of application of this legislation is not stated.

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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
Directive 90/642/EEC	OJ L 350, 14.12.1990, p. 71–79	Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables
Directive 86/362/EEC	OJ L 221, 7.8.1986, p. 37–42	Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals
Regulation (EC) No 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
Directive 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
Directive 91/414/EEC	OJ L 230, 19.8.1991, p. 1–32	Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market
Directive 76/895/EEC	OJ L 340, 9.12.1976, p. 26–31	Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables