



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6635 - MR FINAL

FINAL REPORT OF AN AUDIT  
CARRIED OUT IN  
CYPRUS  
FROM 05 TO 12 MARCH 2013  
IN ORDER TO EVALUATE CONTROLS OF PESTICIDES

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

### ***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office (FVO) audit in Cyprus, carried out between 05 and 12 March 2013 under the provisions of Regulation (EC) No 882/2004 on official food and feed controls and Regulation (EC) No 1107/2009.*

*The objective of the audit was to evaluate the controls on pesticides and to follow up recommendations from a previous audit, DG(SANCO)/2004-7330 on pesticide controls, which covered pesticide residue controls and, in particular, recommendation 2004-7330-2, on the authorisation of Plant Protection Products (PPPs). Audit objectives were met.*

*A system is in place for the authorisation of PPPs which follows the requirements laid down in EU legislation. Comprehensive inspections take place at both pesticide distributors and growers covering the key aspects with regard to the proper sale, storage and use of PPPs. However, the low number of samples taken for the quality control of pesticides, the limited analytical scope of formulation analysis and the limited number of inspections at growers are considered to be constraints for the identification of illegal and counterfeit pesticides. In addition, the limited number of inspections at growers cannot provide sufficient guarantees that only authorised PPPs are used in compliance with the conditions specified on the labels.*

*The report makes a number of recommendations to the Competent Authorities (CAs), aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.*

# Table of Contents

<b>1</b>	<b><u>INTRODUCTION</u></b> .....	<b>1</b>
<b>2</b>	<b><u>OBJECTIVES AND SCOPE</u></b> .....	<b>1</b>
<b>3</b>	<b><u>LEGAL BASIS AND STANDARDS</u></b> .....	<b>2</b>
	3.1 <u>LEGAL BASIS</u> .....	2
	3.2 <u>STANDARDS</u> .....	2
<b>4</b>	<b><u>BACKGROUND</u></b> .....	<b>2</b>
	4.1 <u>AUDIT SERIES</u> .....	2
	4.2 <u>COUNTRY PROFILE</u> .....	3
<b>5</b>	<b><u>FINDINGS AND CONCLUSIONS</u></b> .....	<b>3</b>
	5.1 <u>RELEVANT NATIONAL LEGISLATION</u> .....	3
	5.2 <u>ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS</u> .....	4
	5.2.1 <u>DESIGNATION OF COMPETENT AUTHORITIES</u> .....	4
	5.2.2 <u>RESOURCES FOR PERFORMANCE CONTROLS</u> .....	6
	5.2.3 <u>AUTHORISATION OF PLANT PROTECTION PRODUCTS</u> .....	7
	5.2.4 <u>CONTROLS ON THE MARKETING OF PLANT PROTECTION PRODUCTS</u> .....	8
	5.2.5 <u>CONTROLS ON THE USE OF PLANT PROTECTION PRODUCTS</u> .....	12
	5.2.6 <u>PESTICIDE RESIDUES LABORATORY</u> .....	16
	5.2.7 <u>PRIORITISATION OF OFFICIAL CONTROLS</u> .....	18
	5.2.8 <u>PROCEDURES FOR PERFORMANCE AND REPORTING OF CONTROL ACTIVITIES</u> .....	19
	5.2.9 <u>CO-ORDINATION AND CO-OPERATION BETWEEN AND WITHIN COMPETENT AUTHORITIES</u> .....	20
	5.2.10 <u>ENFORCEMENT MEASURES</u> .....	21
<b>6</b>	<b><u>OVERALL CONCLUSION</u></b> .....	<b>22</b>
<b>7</b>	<b><u>CLOSING MEETING</u></b> .....	<b>22</b>
<b>8</b>	<b><u>RECOMMENDATIONS</u></b> .....	<b>22</b>
	<b><u>ANNEX 1 - LEGAL REFERENCES</u></b> .....	<b>24</b>
	<b><u>ANNEX 2 – STANDARDS QUOTED IN THE REPORT</u></b> .....	<b>26</b>

**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

<b>Abbreviation</b>	<b>Explanation</b>
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CIPAC	Collaborative International Pesticides Analytical Council
CYSAB	Cyprus Organisation for the Promotion of Quality
DoA	Department of Agriculture
DoE	Department of Environment
DG(SANCO)	Health and Consumers Directorate-General
DMPHS	Department for Medical and Public Health Services
EU	European Union
EURL	European Union Reference Laboratory
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GC	Gas Chromatograph
GC-ECD	Gas Chromatograph coupled to Electron Capture Detector
GC-FPD	Gas Chromatograph coupled to Flame Photometric Detector
GC-MS	Gas Chromatograph Mass Spectrometer
GC-NPD	Gas Chromatograph coupled to Nitrogen Phosphorus Detector
GLC-FID	Gas-Liquid Chromatograph coupled to Flame Ionization Detector
HPLC-UV	High Performance Liquid Chromatography- Ultra Violet (HPLC-UV)
IPM	Integrated Pest Management
LC-MS/MS	Liquid Chromatograph coupled to Tandem Mass Spectrometer
LOQ	Limit of Quantification
MANRE	Ministry of Agriculture, Natural Resources and Environment
MoH	Ministry of Health
MRL	Maximum Residue Level
MRM	Multi-Residue Method
MS(s)	Member State(s)
NAP	National Action Plan
NRL	National Reference Laboratory
PHI(s)	Pre-Harvest Interval(s)
PPP(s)	Plant Protection Product(s)
PPPBB	The Plant Protection Products and Biocides Board

PPRMP	Preventive Pesticide Residue Monitoring Programme
PT	Proficiency Test
SGL	State General Laboratory
SOP	Standard Operating Procedure
SRM(s)	Single Residue Methods
TC(s)	Third Country(ies)

## 1 INTRODUCTION

The audit formed part of the Food and Veterinary Office's (FVO) planned programme.

The audit took place from 05 to 12 March 2013. The team comprised two auditors from the FVO and one expert from a European Union (EU) Member State (MS).

Representatives from the Central Competent Authority (CCA) accompanied the FVO team for the duration of the audit. An opening meeting was held on 05 March 2013 with the CCA, the Department of Agriculture (DoA) at the Ministry of Agriculture, Natural Resources and Environment (MANRE). The opening meeting was also attended by representatives from the Department of Medical and Public Health Services (DMPHS) and the State general Laboratory (SGL) at the Ministry of Health (MoH). At this meeting, the objectives of, and itinerary for the audit were confirmed by the FVO team and the control systems were described by the Competent Authorities (CAs).

## 2 OBJECTIVES AND SCOPE

The **objectives** of the audit were to evaluate the control systems in place for pesticides, in particular:

- the implementation of requirements for the authorisation of plant protection products (PPPs) and official controls on the marketing and use of PPPs under Regulation (EC) No 1107/2009 and Directive 2009/128/EC;
- the implementation of requirements for official controls on the use of PPPs at growers under Regulation (EC) No 882/2004;
- follow-up of recommendations of report Health and Consumers Directorate-General DG(SANCO)/2004-7330 on pesticide controls, which covered pesticide residue controls and, in particular, recommendation 2004-7330-2, on the authorisation of PPPs.

In terms of **scope**, the audit assessed the performance of CAs, as well as the organisation of the controls including the authorisation procedures, controls of wholesalers and retailers of PPPs, controls of growers, and follow-up of one specific recommendation with regard to the authorisation of PPPs.

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

**Table 1: Mission visits and meetings**

Visits/meetings		Comments
<b>Competent Authorities</b>		
Central	1	DoA, Agrochemicals Section
Regional	2	Regional Offices in Larnaca and Limassol

<b>Laboratories</b>		
Public	2	Laboratory for pesticide residues and formulation laboratory at the DoA
<b>On-Site-Visits</b>		
Controls of growers	2	One vegetable grower in the region of Larnaca and one citrus fruit grower in the region of Limassol
Controls of wholesalers and retailers	2	One pesticide wholesaler in the region of Larnaca and one pesticide retailer in the region of Limassol

### **3 LEGAL BASIS AND STANDARDS**

#### **3.1 LEGAL BASIS**

The audit was carried out under the general provisions of EU legislation, in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.
- Article 68 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

EU legal acts quoted in this report refer, where applicable, to the last amended version. Full references to the EU acts quoted in this report are given in Annex 1.

#### **3.2 STANDARDS**

A list containing details of the applicable standards is provided in Annex 2. Reference to specific provisions of these texts is provided at the beginning of each section.

### **4 BACKGROUND**

#### **4.1 AUDIT SERIES**

This audit is part of a series of FVO audits in MSs of the EU on controls of pesticides. Prior to the current audit series, the FVO carried out three series of audits to MSs covering controls on the marketing and use of PPPs and pesticide residues. The general overview reports of the former audit series can be found on the DG(SANCO) internet site:

[http://ec.europa.eu/food/fvo/specialreports/index\\_en.htm](http://ec.europa.eu/food/fvo/specialreports/index_en.htm)

During the previous audit series FVO teams identified that control systems vary considerably between MSs. The control system for pesticide residues was better developed than the control

system for placing on the market and use of PPPs. However, deficiencies in the planning and conducting of inspections for control on the marketing and use of PPPs were frequently identified. The operation of formulation laboratories to test PPPs was generally considered to be satisfactory.

The planning and reporting of controls for pesticide residues in food of plant origin has improved significantly since the first audit series. Weaknesses were identified, in particular, regarding the assessment of self-control systems, the point of sampling, and enforcement measures taken in case of non-compliance. The main deficiencies found in pesticide residue laboratories related to the lack of adequate equipment and implementation of quality control procedures.

The Competent Authority (CA) from the MS subject to audit outlined in an action plan how the recommendations would be addressed. These action plans are published on the DG(SANCO) internet site together with the reports.

Within the framework of the last series, the FVO carried out an audit to Cyprus in 2009. The report DG(SANCO)/2009-8143 of this audit can be found at:  
[http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm).

In 2009, the main focus of the specific audit in Cyprus was on the official controls of pesticide residues. The main conclusions of the audit report were that comprehensive annual sampling programmes for pesticide residues were in place, sampling for pesticide residues followed the requirements as set out in Commission Directive 2002/63/EC, risk-based official controls of pesticide residues in fruit and vegetables were performed with imports from Third Countries (TCs) and the domestic market, SGL that was designated as an official and also a National Reference Laboratory (NRL) for pesticide residues followed the European Commission Guideline on method validation and quality control procedures and the scope of accreditation covered a wide range of parameters.

## **4.2 COUNTRY PROFILE**

The FVO has published a country profile for Cyprus, which describes in summary the control systems for food and feed, animal health, animal welfare and plant health and gives an overview on the state of play on the implementation of recommendations of previous FVO mission reports. The country profile can be found at: [http://ec.europa.eu/food/fvo/country\\_profiles\\_en.cfm](http://ec.europa.eu/food/fvo/country_profiles_en.cfm)

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 RELEVANT NATIONAL LEGISLATION**

#### **Legal Basis**

Article 291 of the Treaty on the Functioning of the EU establishes that MSs shall adopt all measures of national law necessary to implement legally binding Union acts.



## **Findings**

### **Regulation (EC) No 1107/2009**

The Regulation is directly applicable. At national level, a new Plant Protection Products Law was adopted on 27 October 2011 establishing the implementing rules with regard to Regulation (EC) No 1107/2009. The Law provides the legal framework for the official controls on the marketing and use of PPPs and empowers inspectors from the DoA to access premises of pesticide distributors and growers for the purposes of official controls. In addition, the Plant Protection Products Law lays down the procedures and actions to be undertaken for the purposes of enforcement, including administrative sanctions and fines to be imposed in the case of infringement.

The Plant Protection Products Fee Regulations of 2011 (published on 04 November 2011) sets out the fees to be paid by applicants regarding the authorisation of PPPs.

The Plant Protection Products Sales, Manufacturing and Storage Regulations of 2003 lay down the requirements for registration of premises and licensing of salespersons, including the requirements to be met in order for premises to be registered and for salespersons to obtain a license. These Regulations also set out the fees to be paid for the purposes of registration and licensing.

### **Directive 2009/128/EC**

Representatives from the CCA stated that the Directive has been transposed into national legislation by the Sustainable Use of Pesticides Regulations of 2012 (published on 01 June 2012).

The Plant Protection Products National Action Plan Decree of 2013 (published on 08 February 2013) establishes the National Action Plan (NAP) under Article 4 of Directive 2009/128/EC. This is a Decree adopted by MANRE. The NAP covers the period 2013 – 2017.

## **Conclusions**

National legislation within the scope of the audit is in place and Directive 2009/128/EC was transposed within the deadlines set out in the Directive.

## **5.2 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS**

### *5.2.1 Designation of Competent Authorities*

#### **Legal Requirements**

Articles 75(1) and (2) of Regulation (EC) No 1107/2009 require MSs to designate a CA or CAs to carry out the obligations laid down in this Regulation, and to inform the European Commission of the details concerning its CAs.

Article 4(1) of Regulation (EC) No 882/2004 requires MSs to designate the CAs responsible for official controls.

## **Findings**

The Plant Protection Products and Biocides Board (PPPBB) is responsible for the implementation of the Plant Protection Products Law. The PPPBB also has the main role in the case of new legislation in the area of PPPs and biocides being approved. The Director of the DoA, who is also the Chairman of the PPPBB, was given the power to grant authorisation certificates, issue licenses for pesticide retailers and salespersons, as well as to withdraw authorisations and licenses on behalf of the PPPBB. The PPPBB is a body appointed by the Council of Ministers for a period of three years. It has ten members made up as follows: four representatives from the DoA, two representatives from the MoH (one from the Pharmaceuticals Service and one from the SGL), one representative from the Department of Labour Inspections at the Ministry of Labour and Social Insurance, one representative from the Department of Environment (DoE) and one representative from the Council of Agronomists working in the public sector.

Since 01 January 2011, a re-structuring within the DoA at the MANRE has taken place. As a result, control activities and advisory services, both of which are within the responsibilities of the DoA, have been divided and they are currently executed by two different sections belonging to two different divisions of the DoA. The Agrochemicals Section at the Division of Legislation is in charge of official controls on the marketing and use of PPPs. This section is also responsible for the evaluation of applications and drafting the certificates for the purposes of the authorisation of PPPs. In addition, the Agrochemicals Section is involved in drafting legislation in the area of PPPs, planning and co-ordination of control activities, supervision of Regional Offices and communication with other CAs, MSs and the European Commission.

The laboratory for pesticide residues and the formulation laboratory at the DoA belong to the Analytical Laboratories Section of the Division of Horizontal Sections. The laboratory for pesticide residues performs analysis of samples taken at growers under the Preventive Pesticide Residue Monitoring Programme (PPRMP) and, in addition, analysis for pesticide residues in organic products of plant origin (prior to their placing on the market) and in animal feed. The formulation laboratory performs analysis of PPPs for the purposes of quality control.

At regional level, there are two offices (one in Larnaca and one in Limassol) whose staff is involved in official controls on the marketing and use of PPPs and biocides in four regions (Larnaca, Ammochostos, Limassol and Paphos). Official controls in the Nicosia region are the responsibility of the CCA. Staff members from both regional offices belong to the Agrochemicals Section of the DoA, which allows direct communication and co-ordination with staff members at central level.

Regarding the CAs in charge of official controls for pesticide residues, there have been no changes since the last FVO audit to Cyprus in 2009. More detailed information on their structure and allocation of responsibilities can be found in the Country Profile for Cyprus.

## **Conclusions**

CAs in charge of official controls on the marketing and use of PPPs have been designated and their responsibilities are clearly defined, as required by Article 75(1) of Regulation (EC) No 1107/2009 and Article 5 of Regulation (EC) No 882/2004.

## 5.2.2 Resources for Performance Controls

### Legal Requirements

Article 75(3) of Regulation (EC) No 1107/2009 requires MSs to ensure that CAs have a sufficient number of suitably qualified and experienced staff to carry out their obligations efficiently and effectively.

Article 4 of Regulation (EC) No 882/2004 requires CAs to ensure that they have access to a sufficient number of suitably qualified and experienced staff; and that they have appropriate and properly maintained facilities and equipment. Article 6 requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

### Findings

At central level (Agrochemicals Section at the DoA), there were two officials and one technician, who were involved in the authorisation of PPPs, planning and co-ordination of official controls on the marketing and use of PPPs. In addition, they also had responsibilities related to the authorisation and official controls of biocides. One staff member at central level also performed inspections at pesticide retailers and growers in the Nicosia region.

At regional level, there were four staff members who performed inspections at pesticide distributors and growers. In Larnaca Regional Office, there were two inspectors. They were both involved in the official controls of biocides. They estimated that they spend 50% of their time on pesticide related issues. In Limassol the situation was similar; there were two inspectors who stated they spend 70% of their time on pesticide related activities and 30% on biocide controls.

Both officials at central level had a university degree in agriculture. In the regions, two out of the four staff members had a background related to agricultural science; one is an agronomist and the other has graduated from a college of agriculture.

For pragmatic reasons, there was no annual training programme in place. However, all inspectors met by the audit team at both central and regional level confirmed that regular meetings took place (every two months) where problems faced during routine inspections were discussed, as well as issues related to the implementation of the legislation in place. Minutes of meetings were provided to the audit team as documentary evidence. Requirements were in place for staff at central level to hold a degree in agronomy. For staff members in the regions, no requirements were in place with regard to their background. When appointed as inspectors they had to attend an initial training, which was stated to cover legal aspects (legislation in place in the area of PPPs), procedures for performance of official controls and other related topics. There was also practical training where newcomers attended inspections as observers. In addition, during their first inspections newly appointed staff members were accompanied by an experienced inspector.

### Conclusions

Suitably qualified and experienced staff are available for the authorisation of PPPs and official controls on the marketing and use of PPPs which is in compliance with the requirements laid down in Article 75(3) of Regulation (EC) No 1107/2009 and Article 4 of Regulation (EC) No 882/2004.

### 5.2.3 Authorisation of Plant Protection Products

#### Legal Requirements

Article 29 of Regulation (EC) No 1107/2009 requires that a PPP shall only be authorised if it complies with specified requirements. The required contents of the authorisation are specified in Article 31. Article 57 requires that an updated electronic register must be publicly available.

Articles 40 - 42 of Regulation (EC) No 1107/2009 lay down the requirements and procedures for mutual recognition of authorisations between MSs. Article 53 of the Regulation provides for the authorisation of PPPs for limited and controlled use in emergency situations.

#### Findings

Under the Plant Protection Products Law, the PPPBB was empowered for the authorisation of PPPs. These powers had been delegated to the Director of the DoA with the exception of some specific and delicate cases where additional restrictions were needed or sensitive issues are involved.

In 2004, an FVO audit on controls of pesticides in food of plant origin took place in Cyprus. At the time, there was one member of the Pesticide Authorisation Board who was a representative of a private organisation. For this reason, the following recommendation was made in report DG(SANCO)/2004-7330:

*“The competent authorities of Cyprus should clearly allocate the competency for the authorisation of plant protection products and ensure that authorisations are granted and MRLs are set fully in accordance with Council Directive 91/414/EEC.”*

Actions have been undertaken by the CAs of Cyprus to address this recommendation. Currently, most of the PPPBB members are civil servants and one of them is a representative from a public organisation. More detailed information is available in Chapter 5.2.1 of *Designation of Competent Authorities*.

The Agrochemicals Section of the DoA kept a register of PPPs authorised for placing on the market and use in Cyprus. The list of authorised PPPs provided information on the trade name, active substance(s) contained, authorisation number, group of product, authorisation holder, local distributor in the country and type of formulation. In addition, a list of PPPs withdrawn was available. Both lists were to be found on the web-site of the DoA and were up-dated on a regular basis (every two months). Authorisation certificates for all PPPs were also to be found on the web providing extensive information on the conditions for use, risk mitigation measures, if any, Pre-Harvest Interval (PHIs), conditions for handling and storage, authorised packaging etc. At the time of the audit, there were 497 PPPs authorised for marketing and use in the country containing 187 active substances.

Representatives from the Cypriot CA stated that before entry into force of Regulation (EC) No 1107/2009 and even before the accession of Cyprus to the EU, most of the PPPs were authorised under the procedure for mutual recognition. The reasons behind this were stated to be the following: there is a limited number of staff dealing with authorisation, Cyprus is a small country and therefore a small market for PPPs.

After the entry into force of Regulation (EC) No 1107/2009, a total of 80 applications were submitted to the CCA for the authorisation of PPPs. The break-down is as follows: 35 cases of parallel trade, 31 applications for mutual recognition and 14 applications for authorisation of identical PPPs (known in Cyprus as “me too” authorisations). At the time of the audit, authorisation certificates had already been granted for 53 PPPs and the remaining 27 were still pending.

In the case of authorisation of an identical PPP, the manufacturer and the source of active substance(s) must be the same for both the reference and the identical PPP, as well as the content of the active substance, their technical specifications and all the relevant aspects. The only difference is the applicant and respectively the authorisation holder. They are usually two or even three local distributors selling the same PPP, but under different trade names and different authorisation numbers which are to be clearly indicated on the label. Labels with identical PPPs should also list the name of the original (first) authorisation holder.

In 2012, two requests were submitted for the authorisation of three PPPs to be used in emergency situations under Article 53 of Regulation (EC) No 1107/2009. The active substances concerned were 1, 3 *dichloropropene* and *deltamethrin*. In both cases of emergency use being authorised, the Cypriot authorities informed the European Commission and the other MSs in due course. There were no cases of applications being rejected.

## **Conclusions**

Procedures are in place for the authorisation of PPPs which comply with the requirements set out in EU legislation.

Actions have been undertaken by the CAs of Cyprus to address recommendation 2004-7330-2.

### *5.2.4 Controls on the Marketing of Plant Protection Products*

## **Legal Requirements**

Article 28 of Regulation (EC) No 1107/2009 lays down that a PPP shall not be placed on the market unless it has been authorised in the MS concerned.

Article 29(1) of Regulation (EC) No 1107/2009 sets out the requirements to be met in order for PPPs to be authorised and placed on the market.

Article 5 of Directive 2009/128/EC requires MSs to ensure that all distributors of PPPs have access to appropriate training by bodies designated by the CAs. Certification systems have to be established by 26 November 2013.

Article 6 of Directive 2009/128/EC lays down that, by 26 November 2015, the sales of PPPs to professional users shall be restricted to persons holding a certificate.

Article 67(1) of Regulation (EC) No 1107/2009 requires that producers, suppliers, distributors, importers and exporters of PPPs shall keep records for at least 5 years.

Article 68 requires MSs to carry out official controls in order to enforce compliance with this Regulation.

Article 13 of Directive 2009/128/EC requires MSs to adopt the necessary measures to ensure that handling and storage of pesticides and handling, recovery or disposal of their packaging and remnants do not endanger human health or the environment.

## **Findings**

At the time of the audit, there were 143 pesticide retailers, three re-packing facilities and three local manufacturers (formulators); nine applications for registration of pesticide retailers were pending. Registration and control of pesticide retailers, re-packing facilities and manufacturers are the responsibility of the DoA. In order to operate, establishments dealing with PPPs must be registered with the PPPBB. For the purposes of first time registration, on-the-spot inspections have to be performed at the premises prior to granting the registration. These are usually joint inspections performed by representatives from the CCA and the Regional Offices. The registration is valid for a period of 20 years. At central level, a register of pesticide dealers was kept and up-dated on a regular basis.

The Plant Protection Products Sales, Manufacture and Storage Regulations requires the premises of pesticide dealers to have appropriate facilities for storage and handling of PPPs and the facilities need to meet the requirements set out in the Regulations.

Annual Programmes were in place for official controls on the marketing and use of PPPs. These were developed by representatives at central level and provided the minimum number of inspections at both pesticide retailers and growers to be performed in all regions, as well as providing advice on any particular aspects to be looked at and identifying priorities. In addition to the Annual Programme, further instructions were provided on the sampling of PPPs for the purposes of quality control. At regional level, monthly programmes were drafted following a standard template which provided detailed information (listing the names of the inspectors, dates of inspections and premises to be visited). These regional programmes were sent to the CCA where a national monthly programme is compiled and transmitted back to the Regional Offices.

According to data provided by the DoA, a total number of 173 inspections at pesticide retailers were performed in 2011 and 160 in 2012. Regarding frequency of controls, pesticide retailers are inspected at least once a year. According to information provided by the CA in charge, manufacturers and re-packing facilities were subject to inspection once every three years by representatives from the CCA.

In both regions visited it was confirmed that most of the registered premises were inspected two to three times a year. Routine inspections covered all aspects to be checked. Additional inspections could also be performed focusing on specific issues. These were performed at the request of the CCA, as a follow-up on irregularities identified or based on complaints and/or suspicion. All types of controls were unannounced.

Two routine inspections were observed by the audit team in both regions visited, one at a pesticide wholesaler and one at a retailer. Both inspections were performed by a team of two inspectors, without prior warning. Standard check-lists were used during the inspections and both teams followed a uniform approach with slight deviations in the first region visited. Both inspections started with documentary checks (registration of the premises and salespersons certificates). These were followed by checks of PPPs in stock (in both the display and storage areas). All PPPs available at the time of inspection were checked for their authorisation status, date of manufacture and expiry date. To confirm the authorisation status of PPPs, inspectors checked the authorisation number on

the label; cross-checks were also performed against the register of PPPs authorised for placing on the market (print-outs available) and the list of PPPs withdrawn from the market (for PPPs recently withdrawn or close to the date of withdrawal). In both regions, print-outs of five authorisation certificates were prepared prior to the inspection, which were used for a detailed labelling check of these specific PPPs, covering crops, targeted pests, timing of application, application rates, PHIs.

Storage facilities and display areas were also subject to inspection in order to check compliance with national legal requirements in place; the main focus was on the following: ventilation, floors, availability of materials to be used in the case of spillage, no direct access of customers to PPPs, no direct exposure of PPPs to sun light, separate storage of pesticides from different groups, separate storage of expired pesticides in clearly indicated areas etc. The last item checked related to records on sales kept at the premises. For this purpose, in both regions a check was performed for two randomly chosen PPPs to confirm if stocks available comply with the quantities indicated in the records.

After completion of all the checks, inspectors finalised the check-lists by listing the irregularities (if any) in the Comments section. The check-lists were signed by both inspectors and the salesperson. In both cases, one copy of the check list was left at the premises inspected. Two more copies were always produced; one was kept at the Regional Office and the second one was provided to the CCA.

Quality checks of PPPs were part of the official controls on the marketing of PPPs. These were performed at the request of the CCA for specific PPPs. The main focus was on PPPs from parallel trade or identical (“me too”) PPPs. In 2011 and 2012, the total number of samples taken and analysed was 16 and 20 respectively. In 2011, there was one case of irregularity identified with regard to the content of the active substance. The PPP in question was an import from a TC, via another MS.

### Record-keeping

In the national legislation in place, reference is made to EU Regulation (EC) No 1107/2009 on record keeping at pesticide distributors for a period of 5 years. Documentary evidence was provided to the audit team about official communication with pesticide distributors regarding their obligations under the Plant Protection Products Law, including record-keeping. In addition, representatives from pesticide distributors were involved in the consultation procedure prior to adoption of the Plant Protection Products Law.

### Training and Certification of Pesticide Distributors

Since 2006, following the entry into force of the Plant Protection Products Sales, Manufacturing and Storage Regulations, a system has been established for the licensing of pesticide dealers (salespersons). At pesticide retailers and wholesalers, a salesperson has to be appointed who has either a university degree in agronomy or has successfully passed an exam to carry out these activities. In cases where no permanent staff member has been appointed with a degree in agronomy, the licensed salesperson should be supervised by an agronomist. At the time of the audit, neither initial nor on-going training was required in order for a salesperson to be granted a license. Licenses were issued by the PPPBB on the basis of their background/education or results from the exam. At the time of the audit, 230 salespersons were licensed and 36 further applications were pending. The licence for a salesperson is subject to renewal every five years.

Training of pesticide dealers was introduced as a legal obligation after the adoption of the Plant Protection Products National Action Plan Ministerial Decree. According to the requirements set out in the Ministerial Decree, by 26 November 2016 all pesticide dealers must have completed specialised training organised and provided by the DoA in order to obtain a certificate. This certificate will be subject to renewal every five years. At the time of the audit, there were no specific arrangements and clarity on the content of training to be provided, duration of training sessions, time schedules etc.

### Sale of pesticides

At the time of the audit, there were no requirements in place for PPPs to be sold to professional users only. The NAP introduced this requirement with a deadline starting on 26 November 2015. Restrictions were in place only for sales of PPPs containing the following active substances: *methomyl*, *aluminium phosphide* and *magnesium phosphide*. In addition, a general restriction was in place for PPPs not to be sold to persons under the age of 18 or those who do not appear to be competent.

### Handling, storage and safe disposal of packaging and remnants of plant protection products

In 2003, a Code for Proper Handling of Pesticides was developed and issued by the DoA as instructions for pesticide retailers and growers where all main aspects related to proper storage, handling, transport and use of PPPs were covered, also including issues related to personal safety of end-users, proper handling of expired and obsolete pesticides and actions to be undertaken in the case of leakage and/or spillage of PPPs. In the NAP, 26 November 2013 is fixed as a final deadline in the NAP for Codes of Good Agricultural Practice (GAP) to be developed and published by the DoA in order to address issues related to handling, storage and safe disposal of packaging and remnants of plant protection products.

At the time of the audit, there was an initiative by the Agricultural Research Institute, in co-operation and with the support of the DoE, pesticide wholesalers and retailers for collection of empty packages. This initiative had been undertaken under the transnational programme of European territorial co-operation “MED European Research Project AGROCHEPACK: Design of a common agrochemical plastic packaging waste management policy”. This project represents a partnership between Greece, Cyprus and Southern Italy, thus covering the geographical area of the Eastern Mediterranean countries. The pesticide wholesaler visited in one of the regions was involved in this initiative. Regarding remnants of PPPs, there were three private companies approved by the DoE for collection. These PPPs were sent for incineration abroad and costs were to be covered by the owners of the products.

### Formulation laboratory

The formulation laboratory at the DoA was the only official laboratory for the quality control of PPPs in Cyprus. This laboratory had one staff member (only 0,5 full time equivalent) with a university degree in chemistry and experience of 25 years. The laboratory was not accredited and performed analysis mainly based on Collaborative International Pesticides Analytical Council (CIPAC) methods or methods provided by the manufacturers. Traceability of analytical results was guaranteed by hand-written register books. The laboratory regularly participated in CIPAC collaborative tests.



The premises and the technical equipment were sufficient to perform physical tests (e.g. pH, temperature stability, particle size, viscosity) as well as identification and quantification of the active substances. The available equipment included High Performance Liquid Chromatography-Ultra Violet (HPLC-UV) and GC/FID. All active substances approved in Cyprus could be analysed using certified solid reference standards. The laboratory did not have a Liquid Chromatograph coupled to Tandem Mass Spectrometer (LC-MS/MS). It was stated that when necessary the LC-MS/MS equipment of the pesticide residue laboratory can be used. Distinct profiling for PPPs placed on the market was not performed and the laboratory analysis no longer covered impurities and co-formulants. However, in certain targeted controls, at the request of the Agrochemicals Section the laboratory performed analysis of PPPs for impurities. In the case of positive findings those were documented.

The total number of samples analysed in 2011 was 33 (16 official, 17 private) and 44 samples (20 official, 24 private) for 2012. Analytical results were usually provided within 2-3 days.

## **Conclusions**

A system for training and certification of pesticide distributors has not yet been established. However, 26 November 2015 is fixed in the NAP as the final deadline for pesticide distributors to have completed training and to hold Training Certificates which is in line with the deadline set in Directive 2009/128/EC.

In accordance with the requirements laid down in Article 67 of Regulation (EC) No 1107/2009, pesticide distributors are required to keep records on sales for a period of 5 years. Distributors visited by the audit team complied with this requirement.

A system is in place for official controls on the marketing of PPPs as required by Article 68 of Regulation (EC) No 1107/2009. Comprehensive and well organised inspections at pesticide retailers and wholesalers take place which ensure that PPPs placed on the market comply with the requirements laid down in Article 28 of Regulation (EC) No 1107/2009.

Formulation analysis does not cover co-formulants and relevant impurities which cannot ensure that PPPs placed on the market in Cyprus meet the requirements laid down in Article 29(1) of Regulation (EC) No 1107/2009. Moreover, the limited scope of formulation analysis cannot allow for counterfeit and illegal pesticides to be identified. Although the quality controls of PPPs is targeted, the low number of official samples for formulation analysis cannot ensure compliance with national and EU requirements in place.

Legal requirements are in place and initiatives have been undertaken regarding handling, storage, transportation and safe disposal of packaging and remnants of PPPs in accordance with Article 13 of Directive 2009/128/EC.

### *5.2.5 Controls on the Use of Plant Protection Products*

## **Legal Requirements**

Article 4(1) of Regulation (EC) No 853/2004, and Annex I, Part A.III of the same Regulation, requires that Food Business Operators (FBOs) producing or harvesting plant products are, in particular, to keep records on any use of PPPs.

Article 55 of Regulation (EC) No 1107/2009 requires that the use of PPPs shall comply with the general principles of Integrated Pest Management (IPM), as referred to in Article 14 of Annex III to Directive 2009/128/EC, which shall apply no later than 1 January 2014. Article 14(5) of the Directive specifies that MSs shall establish appropriate incentives to encourage professional users to implement crop or sector-specific guidelines for IPM on a voluntary basis.

Article 67(1) of Regulation (EC) No 1107/2009 requires that professional users keep, for at least 3 years, records of the PPPs they use. Article 55 specifies that PPPs shall be used, *inter alia*, in compliance with the authorised conditions specified on the labels.

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

Article 5 of Directive 2009/128/EC requires MSs to ensure that all professional users have access to appropriate training by bodies designated by the CAs. Certification systems have to be established by 26 November 2013.

Article 8 of Directive 2009/128/EC requires MSs to ensure that pesticide application equipment in professional use is subject to inspections at regular intervals. By 26 November 2016, all equipment shall have been inspected at least once.

Article 13 of Directive 2009/128/EC requires MSs to adopt the necessary measures to ensure that handling and storage of pesticides and handling, recovery or disposal of their packaging and remnants do not endanger human health or the environment.

Article 8(5) of Directive 2009/128/EC requires professional users to conduct regular calibrations and technical checks of the pesticide application equipment.

## **Findings**

Since the beginning of 2012, following the entry into force of the Plant Protection Products Law a system has been established for the official controls on the use of PPPs. Inspections at growers are performed in accordance with the existing annual and monthly control programmes described in more detail in Chapter 5.2.4 of *Controls on the Marketing of Plant Protection Products*.

At the time of the audit, there was no legal obligation for growers to be registered. However, a new Law was in the final stage of approval and will provide for a national register of growers to be established. The total number of growers in Cyprus is estimated to be about 30 000 (20 000 full time farmers). Controls on the use of PPPs mainly focused on large scale and export oriented growers. However, according to statistics provided by the CCA, most of the growers were small family holdings with average plots of 3.5 ha. The biggest plots grown and the highest volumes produced covered the following crops: cereals, vineyards, potatoes and citrus fruit. There was also extensive production of vegetables, including tomatoes, cucumbers, eggplants, courgettes, leafy vegetables and herbs in greenhouses and in the open air.

Inspections at growers were unannounced. They were usually performed by a team of two inspectors. In 2011, 52 inspections at growers were carried out. The total number of inspections in 2012 was 86.

Two inspections at growers were observed by the audit team. In the region of Larnaca, a vegetable grower was visited. Cucumbers, tomatoes and eggplants were grown on a total plot of 3.5 ha. In the Limassol region, a grower of citrus fruit and pomegranates was visited. The total plot was 50 ha. Both growers visited were certified under private schemes.

Inspections performed by the regional inspectors included checks of pesticide storages and records kept on the application of PPPs. Checks in pesticide storages were performed similarly to those at pesticide retailers and wholesalers. At first, all PPPs in stock were checked for their authorisation status, date of manufacture and expiry date. The authorisation status of PPPs was confirmed via a cross-check with the register of authorised PPPs. An additional check was performed against the list of withdrawn PPPs. All PPPs available were also checked to confirm if they are authorised for use in the crops grown. Two PPPs were found which had already expired and the person in charge was required to put them aside, in the section indicated for expired PPPs. After the check of PPPs available, conditions in the storage premises were checked. Although currently there are no legal requirements in place for storage premises at growers, the same aspects were checked as at pesticide retailers. At one of the growers, there was no proper ventilation and the person in charge was advised to fix this issue. Personal protective equipment of staff dealing with the application of PPPs was also checked. During the last part of the inspections, records on the application of PPPs were checked. In-depth checks were performed for two PPPs, randomly picked during the storage check. These checks aimed to verify that the PPPs in question were used in accordance with the instructions on the label, including the crop, pest targeted, timing of application, application rate, maximum number of applications per growing season and PHI. In order to verify that the PHI was respected the inspectors asked for the records of harvesting to be provided. An irregularity was identified relating to one PPP with regard to the application rate. All irregularities identified were clearly listed in the Comments chapter of the check-list and seizure protocol was drafted for the expired products indicating the trade names and the quantities available. These were left at the grower and the person in charge was required to provide documentary evidence that the PPPs in question were returned to the supplier.

In addition to inspections at growers, the DoA runs the PPRMP. This programme aims at verifying if the general principles of GAP and the conditions on the use listed on the label were followed. In 2011, a total number of 145 samples were taken at growers, including the following crops: spinach, lettuce, tomatoes, potatoes, cucumbers, green beans, grapes, strawberries, peaches, pome fruit and citrus fruit. In 2012, the total number of samples was 100 and the products covered included strawberries, green beans, potatoes, cucumbers, tomatoes, mandarins and grapes. All non-compliances identified in 2012 were related to grapes.

### Record-keeping

Legal reference is made in the national legislation to Regulation (EC) No 1107/2009 with regard to record keeping on the application of PPPs for a period of three years.

After entry into force of the Plant Protection Products Law when record keeping became an obligation for all growers, a manual developed for the purposes of cross-compliance was used as a tool for advising growers who are not subject to EU payment schemes. In accordance with this manual, the minimum aspects to be covered in the records kept on the application of PPPs are the following: trade name of the PPP used, crop, application rate, timing of application and area covered. Records seen at growers visited covered this minimum and contained, in addition, information on the active substance contained, target pest, method of application and PHI.

## IPM

Since February 2013, legal requirements have been adopted via the Ministerial Decree of 2013 for growers to follow the general IPM principles. This obligation will be applicable after 01 January 2014. Several measures were outlined in the NAP. This included establishing an Expert Committee to assist drafting IPM Guidelines for specific crops or groups of crops, producing a list of private advisers, providing a list of practices available and alternative methods for pest controls and initiating an extensive information campaign for promoting IPM.

### Training and Certification of Professional Users

Training and certification became obligatory for growers after entry into force of the Sustainable Use of Pesticides Regulations of 2012. According to the NAP established in the beginning of 2013, the final deadline for professional users and advisers to have completed training and obtained a Training Certificate is 26 November 2015. The training is to be provided by the Plant Protection and Apiculture Section of the DoA. Although it was practice within the DoA in the past to provide training to growers (covering issues related to plant pests and diseases, safe use of pesticides, GAP and IPM), with the new legislation in place there is an obligation for them to establish a system for training and certification of growers. Currently discussions are on-going on the content of training to be provided and all related details with regard to the organisation, duration and design of training session.

### Handling, storage and safe disposal of packaging and remnants of plant protection products

More details with regard to the legal aspects related to handling, storage, transport and disposal of empty packages and remnants of PPPs were provided under Chapter 5.2.4 of *Controls on the Marketing of Plant Protection Products*. Currently, growers are advised to apply a triple rinsing of empty packages. Empty containers then go to urban waste. There is also an option for growers to send the empty packages to specialised collection centres that were established under an initiative run by the Agricultural Research Institute. One of the growers visited was aware of this and has used this option.

### Application Equipment

According to the NAP, a register of application equipment is to be established and kept at the DoA commencing 01 January 2014. By the end of 2013, procedures should be set out for the licensing of Stations which will be delegated to perform the technical checks of the application equipment. The final deadline for application equipment to be certified is fixed as 26 November 2016. At the time of the audit, technical checks and calibration of the equipment was not required. One of the growers visited stated that he has his equipment checked by a private company. The second grower had a staff member who was in charge of calibration of application equipment which was stated to be carried out twice each growing season.

### Illegal Pesticides

Following targeted joint inspections performed by the DoA and the Police, an information campaign had been launched by the CCA with regard to counterfeit and illegal pesticides. However, illegal pesticides of non-clarified origin were still found at growers. It was suspected that these PPPs originate from the territories which are not under the control of the government of the Republic of Cyprus. At the time of the audit, controls on the green line were weak, which made possible the

smuggling of small quantities of PPPs into the Republic of Cyprus by small scale growers.

## **Conclusions**

Requirements are in place for growers to keep records on the application of PPPs for a period of three years as provided for in Article 4(1) of Regulation (EC) No 852/2004 and Article 67 of Regulation (EC) No 1107/2009. Records were kept by the growers visited during the audit.

Since 2012, a system has been established for official controls on the use of PPPs which is in accordance with Article 68 of Regulation (EC) No 1107/2009. Comprehensive inspections take place at growers covering all relevant issues with regard to the application of PPPs.

The number of inspections is low in comparison with the total number of growers in the country. This is a constraint for providing sufficient guarantees that PPPs are used in compliance with the authorised conditions specified on the labels, as required by Article 55 of Regulation (EC) No 1107/2009, including identification of illegal pesticides. This could result in EU Maximum Residue Levels (MRLs) being exceeded.

The NAP in place provides for specific measures to be undertaken with regard to training and certification of growers, handling, storage and safe disposal of packaging and remnants of PPPs, promoting and encouraging IPM and inspections of application equipment, which is in accordance with the requirements laid down in Directive 2009/128/EC. Deadlines fixed in the NAP of Cyprus are in compliance with those established in the same Directive.

The current system of controls on the green line does not provide sufficient guarantees that small quantities of illegal pesticides cannot enter the Republic of Cyprus. Thus no guarantees could be provided that only authorised PPPs are used at grower level, so as to ensure that the requirements of Article 28 of Regulation (EC) No 1107/2009 will be fully complied with.

### *5.2.6 Pesticide Residues Laboratory*

#### Organisation

The FVO team visited the Pesticide Residue Laboratory at the DoA. This is the laboratory in charge of pesticide residue analysis of fresh fruit and vegetables under the PPRMP. Samples are usually taken before or after harvesting at growers or warehouses and prior to the placing of the products on the market. In addition, they perform pesticide residue analysis of organic products sampled at grower level, as well as animal feed samples. In the laboratory, samples are also analysed which were taken as a follow-up on non-compliances notified by the Department of Medical and Public Health Services. In 2011, the total number of samples, including private samples, Proficiency Test (PT) samples and organic products was 178. 125 samples were analysed in 2012. Time lapse is 3-30 days depending on the workload of the laboratory. All samples are analysed covering the full analytical scope.

#### Resources and training

There are four staff members in the laboratory for pesticide residues, including three analysts and one laboratory assistant. Two of the analysts have a university degree in chemistry. The third analyst graduated from a chemistry high school and has more than 25 years of experience. Regular training

has been provided over the years for the staff in charge of quality management. An external training for one week at the EU Reference Laboratory (EURL) for SRMs (training on the QuEChERS method) has been passed by some staff. Although there have been continuous training activities on analytical issues for the staff members in the past, due to the current budgetary restrictions no additional training has been organized in the last two years. Representatives from the laboratory stated that there is communication with the official NRL (SGL) on specific issues and specific training was provided by the NRL in accreditation-related issues over the last years.

#### Analytical spectrum and methods , status of accreditation

Since 05 April 2011, the laboratory has been accredited by the national accreditation body, Cyprus Organisation for the Promotion of Quality (CYSAB). A follow-up audit by CYSAB was performed in 2012. There is no general accreditation for types of testing (flexible scope) in Cyprus as CYSAB requires accreditation for every single method. Thus the scope of accreditation covers one multi-residue method (MRM) (Determination of residues of the active substances *chlorpyrifos* and *alpha-cypermethrin* in citrus fruits and of the active substances *chlorpyrifos*, *cypermethrin* and the *strobilurine group* in berries and small fruit by gas chromatography/mass spectrometry (GC-MS)). Six further methods (most of them in-house methods) are not included in the scope of accreditation. However, the laboratory is planning to extend their scope with regard to analytical methods in the near future, in particular to include LC-MS/MS technique (using the QuEChERS method). Currently, the laboratory does not analyse for compounds requiring SRMs.

The laboratory is equipped with Gas Chromatograph coupled to Electron Capture Detector (GC-ECD), Gas Chromatograph coupled to Nitrogen Phosphorus Detector (GC-NPD), GC-MS and one UPLC-MS/MS. Although LC-MS/MS equipment has been in use since mid 2012, only general training has been provided by the supplier so far. A representative from the laboratory stated, that specific training will be required and provided once they have gained more experience using this technique. Currently, the analytical scope covers 162 active substances. The scope does not fully cover metabolites included in the specific residue definitions.

#### Quality assurance systems

According to the standard operating procedure (SOP) in place samples are delivered to the laboratory within 36 hours by the sampling inspector or staff members from the CCA. In the summer, cooling boxes are used for the transportation of the samples. Sampling, sample preparation and processing of the laboratory sample are performed in accordance with the requirements of Commission Directive 2002/63/EC. However, for the homogenisation of the frozen sample neither dry ice or liquid nitrogen are used.

For the accredited method, validation was performed following Document No SANCO/12495/2011 “Method Validation and Quality Control Procedures for pesticide residue analysis in food and feed”. However, no validation has been performed yet for methods outside the scope of accreditation, as well as for the purposes of the extension of the accreditation planned<sup>1</sup>. The quality control procedures included regular calibration and recovery checks with mixtures of the pesticides used. Representatives from the laboratory stated that in the case of MRL exceedance samples are subject to repeated analysis using a different analytical method. Recovery for all analytes in a routine analysis has to be within the range of 60 – 140%. The default value of 50% for measurement uncertainty is only applied when the accredited method has been used. Analytical standards

---

<sup>1</sup> According to the comments on the the draft report provided by the CAs, validation of methods has been planned for the purposes of extension of the accreditation scope.

(certified standards already in organic solvent) are bought, labelled in consecutive serial numbers and documented in electronic as well as printed form to guarantee traceability. The standards were stored properly at  $-20^{\circ}\text{C}$  and they were checked and replaced in regular intervals. Working solutions were tested against newly prepared solutions.

Most of the Limits of Quantification (LOQs) are too high to meet the criteria set out in Regulation (EC) No 396/2005 for food of plant origin and does not fulfill the criteria for organic products where a default MRL is set at 0.01 mg/kg. The FVO audit team was informed that the stated LOQ is not set as the lowest possible validated spike level during the validation procedure but rather determined at 50% of the MRL. It was also stated that in cases where it is necessary to achieve a lower LOQ (e.g. organic products with an LOQ of 0.02 mg/kg) this is practically done by simultaneous recovery experiments at the respective level.

The laboratory continuously participates in PTs. In 2012, the laboratory participated in two Food Analysis Performance Assessment Scheme (FAPAS) PTs and one PT organized by the EURL for Cereals and Feeding stuff. The z-Scores for the analysed compounds in the FAPAS-PTs were within  $\pm 2$ ; however, the laboratory could not fulfil the scope of the PT due to the limited analytical scope covered. For the EU PT the number of identified compounds was again quite low (only 10 out of 18 pesticides within the test matrix have been detected) and *propiconazole* was found as false negative for the same reason as listed above. The overall performance of the laboratory was classified into Category B.

## **Conclusions**

The laboratory staff have the educational background and experience to perform their tasks.

The methods used in the laboratory do not allow for the covering of the entire range of PPPs authorized for use in the country or to identify illegal pesticides.

The laboratory is accredited to ISO 17025, but the current scope of accreditation is limited and covers only one MRM. The planned extension of the accreditation scope and the use of LC-MS/MS equipment for routine analyses will allow the broadening of the analytical scope, achieving lower LOQs and thus improving the effectiveness of pesticide residue analyses performed.

Document No SANCO/12495/2011 “Method Validation and Quality Control Procedures for pesticide residue analysis in food and feed” is generally followed. However, validation is not performed for methods outside the scope of accreditation.

### *5.2.7 Prioritisation of Official Controls*

## **Legal Requirements**

Article 3(1) of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency, taking account of (a) identified risks; (b) the FBOs past record as regards compliance; (c) the reliability of any own checks that have already been carried out; and (d) any information that might indicate non-compliance.

## **Findings**

For the marketing of PPPs, there is a requirement in place regarding the minimum frequency of

official controls. Pesticide retailers and wholesalers are subject to inspection a minimum of once a year and up to two or three times. The large wholesalers as well as those premises where irregularities were identified during previous visits are also usually subject to more than one inspection per year.

Official controls on the use of PPPs are risk based. In the planning stage, the following criteria are taken into account: volume of production, pesticide use depending on the crops grown, previous history and non-compliances found by the SGL under the existing national control programme for pesticide residues. However, this approach generally results in large scale and export-oriented growers being subject to inspection instead of small scale growers who are in the majority in Cyprus. In addition, the number of inspections at growers is quite limited in comparison to the total number of growers in the country.

## **Conclusions**

Official controls on the use of PPPs are risk-based as required by Article 3(1)(a) of Regulation (EC) No 882/2004. However, the number of inspections at growers is limited in comparison with the total number of growers in the country.

### *5.2.8 Procedures for Performance and Reporting of Control Activities*

## **Legal Requirements**

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the above Regulation requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the FBO concerned.

Article 68 of Regulation (EC) No 1107/2009 requires MSs to transmit to the Commission a report on the scope and the results of controls to enforce compliance with this Regulation within six months of the end of the year.

## **Findings**

A Manual of Procedures was developed by the CCA and was published in August 2012. The Manual was available in both Regional Offices visited by the audit team. The Manual included SOPs for performance of inspections at both pesticide distributors and growers as well as standard check lists to be followed during inspections. Procedures for enforcement measures to be undertaken, administrative sanctions and fines to be imposed in the case of irregularities identified were also covered as well as reporting of results.

The standard check-lists available were also used as inspection reports. They contained a Comments section so that in the case of shortcomings identified they could be described in more detail. One copy was always provided to the person in charge at the premises visited, the second copy was retained by the inspectors and a third copy was always sent to the CCA. The shortcomings



identified during the inspections observed by the FVO team were listed in the Comments section of the check-lists. However, corrective actions to be undertaken were only mentioned orally and not listed in writing. No deadlines were fixed for corrective measures to be undertaken.

In one of the regions visited, an own electronic system was developed to enter the key inspection related data including dates of inspections, operators visited and the outcome. A similar data base was kept at central level for all inspections performed at national level. Individual files were kept at both regions visited for every single pesticide distributor and grower. Results of inspections were reported by the regional inspectors to the CCA on either a weekly or fortnightly basis.

At central level, summary information on the number of inspections performed on the marketing and use of PPPs, the number of PPPs authorised and the type of authorisation was prepared and included in the annual report on the activities performed by the DoA. However, a report on the scope and the results of the controls on the marketing and use of PPPs has not been provided to the European Commission so far.

## **Conclusions**

Documented procedures are in place for official controls on the marketing and use of PPPs and inspection reports are always left at the premises visited which is in compliance with the requirements of Article 8 and Article 9(3) of Regulation (EC) No 882/2004. However, neither the corrective measures to be undertaken nor deadlines for their implementation were listed in the check-lists when irregularities were found which is not in line with the requirements of Article 9(2) of Regulation (EC) No 882/2004.

A report on the scope and the results of controls on the marketing and use of PPPs was not transmitted to the Commission within six months of the end of the year contrary to Article 68 of Regulation (EC) No 1107/2009.

### *5.2.9 Co-ordination and co-operation between and within Competent Authorities*

## **Legal Requirements**

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination between CAs.

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a CA, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

## **Findings**

Regular communication takes place between the Regional Offices and the CCA in charge of official controls on the marketing and use of PPPs. Documentary evidence was also provided for the effective communication and co-operation between the DoA and the DMPHS, in particular, in the case of illegal use of PPPs or illegal pesticides used as well as in the context of the follow-up of non-compliances identified under the national control programme for pesticide residues in food of plant origin placed on the market. Evidence was also provided for communication and co-operation between the DoA and Police Forces to identify illegal pesticides at growers and between the DoA

and Customs in the case of import of pesticides from TCs. However, representatives from the DoA stated there was no communication, co-operation or exchange of information with the Paying Agency who perform the cross-compliance checks at growers.

## **Conclusions**

Regular communication and co-operation within the DoA takes place as well as with most of the CAs involved in official controls within the scope of the audit as required by Article 4(5) of Regulation (EC) No 882/2004. However, the lack of communication with the Paying Agency undermines the effectiveness and efficiency of controls at growers.

### *5.2.10 Enforcement Measures*

## **Legal Requirements**

Article 72 of Regulation (EC) No 1197/2009 states that MSs shall lay down the rules on penalties applicable to infringements and ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive.

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

Article 55 of Regulation (EC) No 882/2004 states that MSs shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

## **Findings**

The Plant Protection Products Law provides the legal framework for administrative sanctions and fines to be imposed in the case of irregularities identified at pesticide distributors and growers. The Manual of Procedures provides detailed instructions for inspectors on actions to be undertaken when shortcomings are found during inspections.

Several cases of irregularities found were provided to the FVO team. A uniform approach was followed by inspectors in both regions visited. In all cases where irregularities were found a follow-up inspection was carried out within a reasonable time frame. Non-compliant cases were reported to the CCA and all supporting documents were also submitted. A decision on the sanctions to be imposed is taken by the Director of the DoA, based on proposals provided by representatives from the Agrochemicals Section. The minimum fine is 50 Euros and the maximum fine which can be imposed by the DoA is 2 000 Euros depending on the seriousness of the non-compliance. If a non-compliant operator fails to pay the fine within the fixed deadline (75 days) the case is brought to Court. The maximum amount of fines to be imposed by the Court is up to 20 000 Euros and/or two years imprisonment.

## **Conclusions**

National legal requirements are in place for administrative sanctions and fines to be imposed in the case of infringement as required by Article 72 of Regulation (EC) No 1107/2009. Sanctions to be

imposed are effective, proportionate and dissuasive which is in line with Article 55 of Regulation (EC) No 882/2004.

## 6 OVERALL CONCLUSION

A system is in place for the authorisation of PPPs which follows the requirements laid down in EU legislation. Comprehensive inspections take place at both pesticide distributors and growers covering key aspects with regard to the proper sale, storage and use of PPPs. However, the low number of samples taken for quality control of pesticides, the limited analytical scope of formulation analysis and the limited number of inspections at growers are considered to be constraints for the identification of illegal and counterfeit pesticides. In addition, the limited number of inspections at growers cannot provide sufficient guarantees that only authorised PPPs are used in compliance with the conditions specified on the labels.

## 7 CLOSING MEETING

A closing meeting was held on 12 March 2013 with representatives from the central and regional CAs. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit. The Cypriot CAs were given the opportunity to provide their preliminary comments.

## 8 RECOMMENDATIONS

The CAs are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of the draft translated report. The CA should:

Nº.	Recommendation
1.	Ensure strengthening the quality control of pesticides in order to provide guarantees that PPPs placed on the market meet the requirements laid down in Article 29(1) of Regulation (EC) No 1107/2009.
2.	Ensure that only authorised PPPs are used as required by Article 28 of Regulation (EC) No 1107/2009. In this regard, the CA should, for example, notwithstanding other existing control measures, extend the scope of formulation analysis and undertake all the necessary actions in order to avoid illegal pesticides entering the Republic of Cyprus.
3.	Ensure strengthening official controls on the use of PPPs, in particular, increasing the number of inspections at growers, so as to provide sufficient guarantees that PPPs are applied in accordance with the conditions specified on the labels as required by Article 55 of Regulation (EC) No 1107/2009.
4.	Ensure broadening the analytical scope of the pesticide residue laboratory at the DoA in order to ensure that the full range of PPPs authorised for use in Cyprus are covered

N°.	Recommendation
	as well as relevant illegal pesticides, i.e those that have been withdrawn recently or which were widely used in the past, in order to guarantee effectiveness of controls on the use of PPPs as provided for in Article 4(2)(a) of Regulation (EC) No 882/2004.
5.	Ensure that in the case of irregularities identified measures to be undertaken by the operator are described in the inspection report as required by Article 9(2) of Regulation (EC) No 882/2004.
6.	Ensure that annual reports on the scope and the results of official controls on the marketing and use are transmitted to the Commission within the deadline fixed as laid down in Article 68 of Regulation (EC) No 1107/2009.
7.	Ensure that efficient and effective co-ordination takes place between all relevant CAs as required by Article 4(3) of Regulation (EC) No 882/2004 and, in particular, with the Paying Agency in order to take account of and exchange information on results of official controls performed at growers by both CAs.

The competent authority's response to the recommendations can be found at:

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2013-6635](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6635)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
<i>Horizontal Legislation</i>		
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 16/2011	OJ L 6, 11.1.2011, p. 7-10	Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed
<i>Legislation on Plant Protection Products</i>		
Reg. 1107/2009	OJ L 309, 24.11.2009, p. 1-50	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
Dir. 2009/128/EC	OJ L 309, 24.11.2009, p. 71-86	Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Reg. 540/2011	OJ L 153, 11/06/2011, p.0001-0186	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances
Reg. 547/2011	OJ L 155, 11/06/2011, p.0176-0205	Commission Regulation (EU) No 547/2011 of 08 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products
<i>Legislation on Pesticide Residues</i>		
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Reg. 1274/2011	OJ L 325, 08/12/2011, p.0024-0043	Commission Implementing Regulation (EU) No 1274/2011 of 7 December 2011 concerning a coordinated multiannual control programme of the Union for 2012, 2013 and 2014 to ensure compliance with maximum residue levels of pesticide residues and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

**ANNEX 2 – STANDARDS QUOTED IN THE REPORT**

Reference number	Full title	Publication details
SANCO/12495/2011	Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed	<a href="http://ec.europa.eu/food/plant/plant_protection_products/guidance_documents/docs/qualcontrol_en.pdf">http://ec.europa.eu/food/plant/plant_protection_products/guidance_documents/docs/qualcontrol_en.pdf</a>
	FAO Pesticide Storage and Stock Control Manual	<a href="http://www.fao.org/docrep/V8966E/V8966E00.htm">http://www.fao.org/docrep/V8966E/V8966E00.htm</a>