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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

GREECE

FROM 02 TO 09 MAY 2012

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 Greece, carried out between 2 to 9 May 2012, 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 of the report of a previous audit, DG(SANCO)/2009-8162.

The audit team found that the system for authorisation of plant protection products (PPPs) follows European Union legislation, and there is good co-operation with other authorities and stakeholders for the adequately targeted control of illegal pesticides.

Although retailers of PPPs are registered and official inspections are carried out, there are deficiencies in the planning of controls and a lack of clear procedures, which reduce the effectiveness of controls.

The control on the use of PPPs at growers is ineffective, due to the lack of legal powers of the competent authority to ensure access to premises, the absence of risk-based planning, insufficient numbers of controls, and insufficient verification of information. Further obstacles to effective controls of growers are the lack of access to training and the lack of access to calibration of equipment for PPP application.

The lack of measures for the safe disposal of the significant stocks of pesticides with expired shelf-life, as well as leftovers and packaging, poses a risk to health and to the environment.

Of the three recommendations of the previous audit DG(SANCO)/2009-8162 evaluated by the audit team, one has not been satisfactorily addressed. Because of the inadequate management of the available resources in the network of official control laboratories, the majority of analyses are carried out in laboratories using instruments with insufficient scope and sensitivity, and do not ensure efficient and effective controls of pesticide residues.

The report makes a number of recommendations to the competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation	
BPI	Benaki Phytopathological Institute	
CA(s)	Competent Authority(ies)	
CCA(s)	Central Competent Authority(ies)	
DG (SANCO)	Health and Consumers Directorate-General	
DPPP	Directorate of Plant Produce Protection	
DREVM	Directorate of Rural Economy and Veterinary Medicine	
ESYD	National Accreditation Body (Hellenic Accreditation System)	
EU	European Union	
EURL	EU Reference Laboratory	
FAO	Food and Agriculture Organisation of the United Nations	
FVO	Food and Veterinary Office	
GC	Gas Chromatograph	
GC-ECD/NPD	Gas Chromatograph coupled to Electron Capture Detector and Nitrogen Phosphorus Detector	
GC-FID	Gas Chromatograph coupled to Flame Ionisation Detector	
GC-MS	Gas Chromatograph coupled to Mass Spectrometer	
GC-MS/MS	Gas Chromatograph coupled to Tandem Mass Spectrometer	
GCSL	General Chemical State Laboratory	
HPLC-UV	High Performance Liquid Chromatograph coupled to Ultra-Violet Detector	

IPM	Integrated Pest Management		
ISO	International Organisation for Standardisation		
LC-MS/MS	Liquid Chromatograph coupled to Tandem Mass Spectrometer		
MRDF	Ministry of Rural Development and Food		
MRL	Maximum Residue Level		
MS(s)	Member State(s)		
NAP	National Action Plan		
ОРЕКЕРЕ	Greek Payment and Control Agency for Guidance and Guarantee Community Aid		
PPP(s)	Plant Protection Product(s)		
PT(s)	Proficiency Test		
RASFF	Rapid Alert System for Food and Feed		
RCPPQC	Regional Centre for Plant Protection and Quality Control		

1 Introduction

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

The audit took place from 2 to 9 May 2012. 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 2 May 2012 with the CCA, the Directorate of Plant Produce Protection (DPPP) of the Ministry of Rural Development and Food (MRDF). 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 authorities.

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 the requirements for official controls of PPPs at growers, as specified in Regulation (EC) No 882/2004;
- follow-up recommendations of report Health and Consumers Directorate-General DG(SANCO)/2009-8162, which had focussed on implementation of official controls on pesticide residues under Regulations (EC) No 396/2005 and No 882/2004.

In terms of **scope**, the audit assessed the performance of Competent Authorities (CA), as well as the organisation of the controls including the authorisation procedures, controls of the retailers of PPPs, controls of the growers, and follow-up of recommendations regarding the control programmes and laboratories for pesticide residues.

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

Table 1: Mission visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	1	MRDF, DPPP
Regional	1	RCPPQC in the Kavala region
Prefectures	3	DREVM from the prefectures Kavala, Drama and Viotia
Laboratories		
Public	3	Formulation laboratory of the BPI, Laboratory of Chemical Control of Pesticides;
		RCPPQC of Kavala, laboratory of pesticide

		residues; RCPPQC of Piraeus, laboratory of pesticide residues (Lykovrisi)
On-Site-Visits		
Controls of growers	1	Observation of an inspection of a grower of fruit in the prefecture of Drama
Controls of retailers of PPPs	2	Observation of inspections of retailers of PPPs in prefectures Viotia and Drama

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

Additionally, the Guideline SANCO/12495/2011 on Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed was relevant for this audit.

Details of the applicable standard is provided in Annex 2. Reference to specific provisions of this text is provided at the beginning of each section.

4 BACKGROUND

4.1 Mission Series

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

http://ec.europa.eu/food/fvo/specialreports/index en.htm

During the former audit series FVO teams identified that control systems vary considerably between Member States. The control system for pesticide residues was in general better developed than the control system for placing on the market and use of PPPs. Deficiencies in the planning and conducting of inspections for control of 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 mission 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 CAs of the MS subject to audit outlined in action plans how the recommendations would be addressed. These action plans are also published on the DG (SANCO) internet site together with the reports.

In the framework of the last series, the FVO carried out a mission in Greece in 2009, mission DG(SANCO)/2009-8162. The report of this mission can be found http://ec.europa.eu/food/fvo/ir search en.cfm. The overall conclusion of the report was that responsibilities of CAs were clearly defined. There was a system in place for performing official controls within the scope of the mission and the existing annual national control programme was risk based. However, a multi-annual control programme as required by Article 30 of Regulation (EC) No 396 / 2005 was not in place. In most of the official laboratories the range of analytes sought was not sufficient to ensure effective controls.

4.2 Country Profile

The FVO has published a country profile for Greece, 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 of the implementation of recommendations of the previous FVO mission reports The country profile can be found at:

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. With the Law 4036 of 27 January 2012, the fees (Article 6) and penalties (Articles 9-10) for infringements concerning PPPs are defined. The DPPP has prepared a protocol in which the procedure as well as the time frame for processing applications, are defined. At the time of the audit, the protocol was a draft and under discussion with the Benaki Phytopathological Institute (BPI).

In March 2012, the DPPP has issued a circular for record keeping by farmers specifying the

information of the use that has to be recorded in line with Regulation (EC) No 1107/2009.

Directive 2009/128/EC

The DPPP stated that Law 4036 of 2012 transposes Directive 2009/128/EC into national legislation, with Articles 15 to 31 of the Law directly transposing the Articles of the Directive, and Articles 32 to 46 providing national implementation measures. In Article 32 the DPPP of MRDF is defined as the national CA regarding drafting, implementation and amendment of the National Action Plan (NAP). A Committee for the NAP has been established by a Ministerial Decision, which has been adopted on 12 April 2012, but not published at the time of the audit. Once established, the Committee will develop and submit the NAP.

Law 4036 provides for implementing measures for Integrated Pest Management (IPM) under the NAP. Two Ministerial Decisions for IPM in cotton with an annex for mandatory and voluntary measures have been adopted, and a further Ministerial Decision for IPM in other crops has been drafted.

Law 4036 provides for further implementing measures under the NAP regarding the training and certification of professional users, distributors and advisers, the calibration and testing of pesticide application equipment, and the recovery or disposal of pesticide remnants and packaging. No national implementing measures regarding these issues were in place at the time of the audit.

Conclusions

The relevant EU legislation has been transposed and the process of implementation of Regulation (EC) No 1107/2009 and Directive 2009/128/EC is within the deadlines set in the EU legislation.

5.2 Organisation and Implementation of Official Controls

5.2.1 Designation of Competent Authorities

Legal Requirements

Article 75(1) and (2) of Regulation (EC) No 1107/2009 requires Member States 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.

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies.

Findings

The CAs are as described in the country profile, with two changes:

- The Directorates of Rural Economy and Veterinary Medicine (DREVM) of the regional units have taken over the responsibility of the Prefecture Rural Development Directorates, with the same staff as before
- Law 4036 designates the BPI as the only body for the evaluation of data submitted by

applicants for the authorisation of PPPs.

Law 4036 designates the DPPP as national coordinating CA under Regulation (EC) No 1107/2009, and designates the DREVM and the Regional Centres for Plant Protection and Quality Control (RCPPQC) for the implementation of controls on the marketing and use of PPPs. The CAs for the implementation of controls on pesticide residues are the same, according to Joint Ministerial Decision No 4011/45391/10-4-2012. The same Ministerial Decision designates the BPI and three regional laboratories for analyses of the formulations of PPPs, and the existing network of laboratories for analyses of pesticide residues.

Conclusions

The CAs are clearly designated. There is no delegation of tasks to private bodies as described in Article 5 of Regulation (EC) No 882/2004.

5.2.2 Resources for Performance of Controls

Legal Requirements

Article 75(3) of Regulation (EC) No 1107/2009 requires Member States 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 the CAs to ensure that they have access to a sufficient number of suitably qualified and experienced staff; 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, six staff are involved in controls within the scope of the audit in the DPPP. At regional level, 81 staff work in the RCPPQC, and at local level, 294 staff work in the DREVM.

Staff have been designated at BPI for the evaluation of data for the authorisation of PPPs.

All staff performing official controls on PPPs and pesticide residues have university degrees as agronomists. The CA stated that from 2006 to 2010 they have completed a full training cycle for inspectors from every region. This scope of the training programme included Regulation (EC) No 396/2005 and the repealed Directive 91/414/EEC. Since publication of the new Law 4036, the CA are planning a new programme for controls on marketing and use of PPPs and for this reason have contacted the Public Education Institute of the National Center for Public Administration. The training programme for national inspectors is an obligation specified in Law 4036.

Most staff met by the FVO team have received appropriate training, but the inspector responsible for controlling PPP retailers in one region was not aware of important international principles for safe storage of pesticides (see section 5.2.4).

Conclusions

Suitably qualified and experienced staff is available. The training system has overall ensured the proper channelling of information. Further training in principles for safe storage of pesticides would increase the effectiveness of controls.

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

The central CA keeps a database for the authorisation status of PPPs. This information is made publicly available in Greek and English at: http://www.minagric.gr/syspest/syspest_menu.aspx, and includes complete information regarding the authorised uses of PPPs, such as time and dosage, number of applications and pre-harvest interval. The CA stated that the register is updated on a daily basis. At the time of the audit, a total of 1 622 PPPs was authorised, containing 270 active substances.

The audit team checked and found that EU approvals and non-approvals of active substances were implemented within the deadlines foreseen in EU legislation, with the minor oversight to withdraw an authorisation for a PPP containing serricornin, which according to the CA has not been marketed in Greece in the last years.

During the controls of retailers observed by the FVO, the audit team found that the authorised labels complied with Regulation (EC) No 547/2011.

Under the provisions for mutual recognition of Regulation (EC) No 1107/2009, the DPPP has issued two provisional and eight full authorisations. Under the respective provisions of the repealed Directive 91/414/EEC, the DPPP had issued 9 provisional and 38 full authorisations.

Decisions for emergency authorisations under Regulation (EC) No 1107/2009 have been made publicly available on the website of the MRDF, and the European Commission was informed. In 2011, 20 emergency authorisation were granted for 120 days, mostly for the control of the quarantine pests *Tuta absoluta* in tomato and *Rhynchophorus ferrugineus* in palm trees. In 2012, four emergency authorisations of 120 days for pheromone products have been granted, restricted to the control of *Lepidoptera* in peaches and apples.

Conclusions

The authorisation procedures of PPPs follow the requirements of EU legislation.

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 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 PPP 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 measure 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

Manufactures and repackaging facilities for PPPs are registered in the official registry of pesticide plants. This registry was established by Law 721/1977 and reiterated by Law 4036. For registration, every pesticide plant is inspected by a special committee which checks all facilities, production lines and ability for formulation and packaging. Also retailers and wholesalers of PPPs need registration since 1977. The total number of registered PPP retailers and wholesalers is 1 386. The total number of in-land manufacturers, including re-packaging facilities, is 27.

Article 35 of Law 4036 reiterates the legal obligation of Law 220 of 1973 for retailers and wholesalers of PPPs to employ at least one staff member with a university degree as agronomist. A revised Presidential Decree regarding specifications for retailers and wholesale shops has been drafted and sent to stakeholders for comments. Access of retailers and wholesalers to additional training in order to update their knowledge is a requirement in Article 5(1) of Directive 2009/128/EC, but DPPP stated that implementation of it is not currently foreseen.

During inspections of retailers and wholesalers, the DREVM inspectors check the registration details of the shop, the presence of an agronomist, storage conditions of PPPs such as ventilation, and the expiry date of products on stock. The inspections follow the standardised report format, which is a check-list with 15 points.

There are further inspections and standardised forms for detailed label checks and for sampling for formulation analyses. For a detailed label check, the product is taken to the DREVM office, unless the inspector has internet access to the MRDF website through the retail or wholesale store.

The inspector in Drama also had updated lists of authorised and recently withdrawn PPPs available. The products on stock were compared with the inventory of the retailer. The authorisation status of selected PPPs was checked on the DPPP website through internet access of the retailer.

In the inspection observed in Viotia, the business operator did not follow some of the main principles of the Pesticides Storage and Stock Control Manual of the Food and Agriculture Organisation (FAO), i.e. the requirements for pesticides not to be directly placed on the floor, and doors to be locked. These facts were not noted by the inspector. Also, herbicides were not always separated from other types of pesticides. Although this point was part of the check-list, the inspector did not make a remark.

According to the 2010 report sent by DPPP to the European Commission, a total of 328 inspections at sale points were carried out, with 26 infringements identified (including 12 unauthorised products). A total of 125 samples were taken for formulation analysis.

In addition to these routine checks, the CAs perform controls on illegal or counterfeit pesticides. They co-operate with the CAs of other Member States, the European law enforcement agency Europol, the financial police against fraud, the Customs, and the police traffic corps. Several examples were given by DPPP of their co-operation with these institutions at central level. Also the DREVM Drama provided evidence of their co-operation with the police. Thus, the DREVM participated in 14 joint border inspections in 2012, together with the traffic police services.

At both visited retailers, a considerable amount of PPPs had exceeded the shelf-life of two years. At one of the retailers these pesticides amounted to 400 kg. These products were locked in a separated room. The CA stated that the owner is responsible for the disposal of authorised products, which exceed the shelf-life. As there are no facilities for disposal in Greece, the owner can only send the products for incineration abroad, but this was stated to be extremely expensive and therefore economically unrealistic.

A sampling instruction for formulation analyses is prepared annually by DPPP. The 2012 instructions identifies parallel trade products to be sampled, and additionally specifies active substances and the four laboratories, to which samples should be sent. It does not mention numbers or formulated products to be sampled.

The laboratory for Chemical Control of Pesticides at BPI is accredited to ISO 17025 for formulation analysis of PPPs by the national accreditation body Hellenic Accreditation System (ESYD) from 2009. The accredited methods are focussed on the determination of active ingredients of PPPs by HPLC-UV and GC-FID and determination of emulsion characteristics, according to the Collaborative International Pesticides Analytical Council (CIPAC). In 2010, a total of 125 official samples were analysed. The laboratory identified non-compliances with the FAO specifications. For example, 20 % of the abamectin samples were non-compliant.

The laboratory has extended the methods to the determination of targeted impurities by GC-MS/MS and LC-MS/MS. In 2011, the laboratory started to apply a GC-MS and LC-MS screening method to detect unexpected active substances and co-formulants. These analyses are performed for parallel trade products and suspected illegal pesticides. A non-compliant parallel trade product was identified and enforcement measures taken.

Conclusions

Controls on the marketing of PPPs take place as laid down in Article 68 of Regulation (EC) No 1107/2009. In one of the two visited regions, the controls include effective checks of the authorisation status of PPPs and adequate spot-checks of the labels. The observed deficiencies in the controls carried out in the second region can be explained by horizontal shortcomings, i.e. insufficient training (see section 5.2.2), the lack of risk-based planning (see section 5.2.7) and insufficient procedures (see section 5.2.8).

The targeted checks to control illegal or counterfeit pesticides are effective, because they are carried out in co-operation with institutions in Greece and other Member States, and supported by innovative formulation analysis of PPPs in the well equipped laboratory for Chemical Control of Pesticides of BPI.

No measures are currently foreseen regarding additional training of PPP distributors to update the knowledge, in contrary to the requirement laid down in Article 5 of Directive 2009/128/EC.

The practice of the CA to take products with expired shelf-life from the market without measures to ensure their safe recovery and disposal is contrary to Article 13 of Directive 2009/128/EC, and leads to the accumulation of substantial stocks of obsolete pesticides.

5.2.5 Controls on the Use of Plant Protection Products

Legal Requirements

Article 4(1) of Regulation (EC) No 852/2004, 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, as referred to in Article 14 of Annex III to Directive 2009/128/EC, which shall apply at the latest by 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 integrated pest management on a voluntary basis.

Article 67(1) of Regulation (EC) No 1107/2009 requires that professional users, for at least 3 years, keep 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 measure 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

Measures have been undertaken to promote IPM (see section 5.1). Representatives of DREVM at the Regional Unit in Drama explained that guidelines were provided to local growers on the IPM in cotton, wheat and potatoes, as well as five additional quality guides for other crops. According to data provided by the local inspectors, there are currently 160 IPM cotton growers (total cultivated area 1 600 ha), 45 IPM potato growers (total cultivated area 600 ha) and 450 IPM wheat growers (total cultivated area 3 000 ha) in Drama and Nevrokopi. In the second region (Livadia prefecture), an IPM programme has been launched by a private company in co-operation with the Regional Unit. Funding is provided for advising growers and a percentage of these funds are allocated to IPM growers. At the time of the audit the total plots for IPM production covered 5 000 ha.

A standard check list for inspection at growers was developed by DPPP. Inspections at growers are announced two to three days in advance. Inspectors have no legal power for the access to growers' premises except when a criminal investigation has been launched.

In the Drama region, the total number of agricultural holdings is 7 283 and the average cultivated area is 6.5 ha. Most of the farms are small scale holdings with total cultivated area of up to 0.2 ha.

Also in the region Livadia most of the farms were stated to be small. The CA did not have statistical information available regarding the numbers and size of farms.

The audit team observed an inspection in the Drama region. The farmer visited grows mainly apples (1.5 ha) and pears (1.0 ha). In addition, cherries, nectarines, peaches and plums are grown on a plot of 0.4 ha. Before starting to operate as an agricultural holding, the grower had attended an introductory training of 300 hours for young farmers. During this training, pest control and pesticide related issues have been covered. He stated that he did not participate in any further training to update his knowledge. No bodies have been designated for this task by the DPPP.

A previous inspection at this farmer was carried out in September 2008 and no irregularities were found. The inspection observed by the audit team was performed by one member of staff from the DREVM in Drama who followed the standard check list. The inspection took place on the field. During the inspection, the farmer was interviewed on the main aspects listed in the check list. The inspector asked whether records of pesticide applications were kept. These were not available during the inspection, and the inspector asked the farmer to submit them later. They were later made available to the FVO team, and the audit team noted that the list of records contained only some of the data required by Regulation (EC) No 852/2004. In the pesticide storage, the inspector checked the shelf-life of the PPPs available, the storage conditions and the personal protective equipment. The visual inspection of the sprayer was a check for apparent leakages and whether nozzles and manometers appear to be operational. Neither the inspector nor the grower were aware of any facilities in the region for calibration of the equipment. The grower usually collects and burns the empty containers directly on the field. The inspector did not classify this as infringement, but advised the grower to rinse the empty pesticide containers three times and to send them for household waste recycling. No documentary checks were done on-the-spot. The check-list was signed by the inspector and the grower. One copy was left with the grower.

No routine inspections of users are carried out in the visited Viotia region, but controls were performed in the follow-up to exceedances of Maximum Residue Levels (MRLs), or when complaints are received.

Conclusions

The lack of documentary checks during the inspections at growers does not ensure the proper use of pesticides to be verified. In particular, the records of PPP applications was not checked. Due to this reason, the effectiveness of official controls can not be ensured, in contrary to Article 4(2) of Regulation (EC) No 882/2004.

Inspections at growers are announced and this is in contradiction with the requirements laid down in Article 3(2) of Regulation (EC) No 882/2004.

The lack of provisions in the national legislation allowing MRDF inspectors to access growers' premises and check documentation is in contradiction with the requirements set out in Article 4 (2) (e) of Regulation (EC) No 882/2004.

Professional users of PPPs do not have access to appropriate initial and additional training, and to facilities for the calibration of pesticide application equipment. No measures have been taken to ensure the safe handling, recovery and disposal of pesticide packaging and remnants. These requirements must be implemented under Directive 2009/128/EC, Articles 5(1), 8(5) and 13(1). Certification systems for training must be established by November 2013, Article 5(2), and all application equipment inspected by November 2016, Article 8(2).

At central level and in the regions visited, measures were in place to promote IPM, in line with Article 14 of Directive 2009/128/EC.

5.2.6 Control Programmes for Pesticide Residues

Legal Requirements

Article 10 (2) (a) of Regulation (EC) No 882/2004 requires that official controls on food and feed include, *inter alia*, examination of any control systems that feed and food business operators have put in place and the results obtained.

Commission Directive 2002/63/EC establishes methods of sampling for the official control of pesticide residues.

Article 12 of Regulation (EC) No 882/2004 requires that competent authorities only designate laboratories that operate and are assessed and accredited in accordance with the standards EN ISO/IEC 17025 and EN ISO/IEC 17011. Article 28 of Regulation (EC) No 396/2005 lays down requirements for the methods of analysis and quality control procedures for pesticide residue analysis.

Guidance Document (SANCO/12495/2011) on Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed was also taken into account for this audit.

Findings

The audit team followed up on three recommendations of the audit DG(SANCO)/2009-8162:

Recommendation No 4: ensure that a documented procedure is in place in the case of sampling for pesticide residues as laid down in Article 8 (1) of Regulation (EC) No 882/2004.

A documented procedure regarding sampling for pesticide residues analyses was established by DPPP in March 2012.

Recommendation No 6: take account of the reliability of food business operators' own checks, especially when carrying out official controls on non – processed food of plant origin, as stipulated in Article 3 (1) (c) of Regulation (EC) No 882/2004.

A documented procedure for taking account of the reliability of food business operators' own checks, especially when carrying out official controls on non – processed food of plant origin, was established and distributed by DPPP in March 2012.

Recommendation No 7: substantially increase the number of analytes including metabolites covered by their analytical methods for pesticide residues in food of plant origin; guarantee the effectiveness and appropriateness of official controls as required by Article 4 (2) (c) and 4 (2) (d) of Regulation (EC) No 882/2004, ensure implementation of Regulation (EC) No 396/2005 and take account of the provisions laid down in Commission Regulation (EC) No 1213/2008.

The audit team requested updated information on the number of analytes sought in each of the ten designated pesticide residues laboratories, about their available equipment and results in EU Proficiency Tests (PTs). The audit team visited the two designated laboratories in Kavala and Lycovrisi (Piraeus).

There were 10 official laboratories designated for pesticide residue analysis. Only the BPI and the General Chemical State Laboratory (GCSL) have LC-MS/MS and GC-MS/MS equipment, which is necessary to analyse for all pesticides included in the annual EU Control Programme under Regulation (EC) No 396/2005 with the required precision and sensitivity. The Thessaloniki laboratory has LC-MS/MS and GC-MS equipment, which allows the required analysis with some restrictions. The remaining seven laboratories do not have LC-MS/MS equipment. Nevertheless,

57 % of official control samples in 2011 were analysed in these seven laboratories with inadequate equipment. Only 19 % of samples (597) were analysed at BPI which has the necessary instrumentation to substantially increase the number of analyses. In most of the EU PTs since 2008 all laboratories except BPI, GCSL and Thessaloniki were in category B because of the insufficient scope.

Peripheral Centre of Plant Protection and Quality Control of Kavala

The laboratory has been accredited to ISO 17025 by the national accreditation body ESYD since 2009. The accredited scope of the laboratory covers 31 GC amenable residues in fruits and vegetables with high water content. The laboratory has extended the scope of the residues by adequate validations following the EU Guidance Document (SANCO/12495/2011) on Method Validation and Quality Control Procedures for pesticide residues analysis to 150 GC amenable residues.

The pesticide residue laboratory employs 6 staff: 4 agronomists, 1 chemist and 1 technician. Adequate training records of these staff were on file. During 2011 a total number of 323 pesticide residues analyses were performed without any MRL exceedance detected.

The laboratory participates regularly in the EU PTs for multi-residue methods organised by the EU Reference Laboratory (EURL) for Pesticide Residues in Fruit and Vegetables. During the last seven years, the scope has been unsatisfactory, and therefore the laboratory has been classified in category B in all PTs. In only two of the seven years the combined Z-score obtained was satisfactory.

For sample preparation the aggregate sample is divided in sub-samples of 15g each after adequate homogenisation at room temperature. One of the sub-samples is analysed following the Dutch multi-residue method (see for details: www.eurl-pesticides.eu). The analysis is performed by using GC-ECD/NPD. Additionally the laboratory has a GC-MS system with single quadrupole and one liquid chromatograph with a N-methylcarbamate post-column derivatisation system coupled to a fluorescence detector. However, both need repair and are not in use. The audit team observed that in many cases the limits of quantification obtained are higher than the EU MRLs. This fact is a consequence of the lack of sensitivity of the equipment.

Regional Center of Plant Protection and Quality Control of Piraeus (Lycovrisi)

The laboratory in Lycovrisi is accredited to ISO 17025 for pesticide residue analyses by ESYD since 2009. The accredited scope of the laboratory covers 22 GC amenable residues in fruiting vegetables and citrus. The laboratory has extended the scope of the residues by adequate validations following the EU Guidance Document (SANCO/12495/2011) to 92 GC amenable residues.

The pesticide residue laboratory employs three agronomists. Adequate training records of these staff were on file. During 2011 a total number of 247 of pesticide residues in fruits and vegetables and olive oil samples were performed with seven samples exceeding MRLs.

The laboratory participates regularly in the EU PTs for fruits and vegetables with multi-residue methods, and in some cases for cereals, organised by the EURLs. Additionally the laboratory participates in the PT for olive oil organised by the Italian National Health Institute. In the case of the PTs for fruit and vegetables all of the results during the last seven years have been unsatisfactory due to the insufficient scope. In two cases of the seven the combined Z-score obtained was satisfactory. Similar results have been obtained in the case of EU PTs for cereals.

The laboratory follows the same method as Kavala. It has one GC with ECD/NPD detector, and another GC with an NPD detector operational.

The results obtained in both laboratories are not corrected for recovery. Calibration curves are constructed daily, recovery is checked daily and samples are run together with the calibration curve

and recovery checks. The uncertainty factor applied is 50 %, as specified in point 91 of the Guidance Document (SANCO/12495/2011). However, the application of this value without proving its correctness in the laboratory is not in line with the Document, in consequence of the often unsatisfactory results obtained by the laboratory during the EU PTs.

Conclusions

Recommendations 4 and 6 of the previous report have been satisfactorily addressed. However, recommendation 7 has not yet been satisfactorily addressed. Because of the inadequate management of the available equipment and staff in the network of official control laboratories, the majority of analyses do not ensure efficient and effective controls of pesticide residues. The laboratories in Kavala and Lycovrisi have sufficient staff and operate quality control procedures which mostly follow the EU Guidance Document. However, their available equipment is totally inadequate to achieve correct identification, as well as scope and sensitivity of analyses required by Regulations (EC) Nos 396/2005 and 1274/2011. In the BPI, on the other hand, adequate equipment is available to substantially increase the number of samples.

5.2.7 Prioritisation of Official Controls

Legal Requirements

Article 3 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 food business operators' 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 formulation analysis a national control programme is drawn up annually by DPPP. In 2012, it identifies parallel trade products and products with certain identified active substances to be sampled and analysed, based on the risk of non-compliance identified in previous controls.

A total of 43 inspections were carried out of the 31 licensed retailers in Drama in the last eight years. Notably, 13 of these 31 retailers were not inspected at all in this period. In Viotia, two of the 42 registered retailers were inspected in 2010, and five in 2011.

In the visited prefecture of Drama, on average 15 inspections per year were carried out of the 7 283 growers. It was noted that the farms were generally small, and only 11.5 % of farms had over 6 hectares of land. No routine checks at growers are carried out in Viotia.

No control plans, risk criteria nor target frequencies to prioritise inspections of retailers or growers have been documented. The CA in Drama stated that decisions on which growers to be inspected are taken at local level following an internal discussion where all staff members in the Regional Units take part. According to explanations provided by representatives of the DREVM in Drama, they take into account the resources available and additional tasks falling within their responsibilities. However, there were no clear criteria to be followed so as to ensure that official controls are risk based and performed regularly and with appropriate frequency.

Conclusions

Except formulation analysis, the controls are not sufficiently based on risk and not carried out with

appropriate frequency in line with Article 3 of Regulation (EC) No 882/2004.

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 their 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 business operator concerned.

Article 68 of Regulation 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

Report formats in the form of check-lists for inspections of retailers and users have been distributed by DPPP, and were followed by the DREVM visited by the audit team. The CA stated that new descriptive procedures are planned to be issued taking into account Law 4036. The check-lists verified during the inspections of growers and retailers did not provide guidance for inspectors to allow judgement of compliance.

Reports are drawn up following the inspections, and signed by both parties. A copy is left with the grower or retailer, in Viotia on request.

A summary of the controls is sent to the European Commission. The report for 2010, under the repealed Directive 91/414/EEC, was sent in October 2011.

Conclusions

The documented procedures do not contain sufficient information and instructions for staff to perform effective official controls, in contrary to Article 8 of Regulation (EC) No 882/2004.

Reports are drawn up following all inspections as required by Article 9 Regulation (EC) No 882/2004. Reports are sent to the Commission as required by EU legislation.

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

The responsibilities for DPPP, RCPPQC and DREVM are clearly defined. Regular vertical communication takes place for the promulgation of Ministerial Decisions, DPPP instructions, new legislation, the central sampling plan for formulation analysis, and the follow up of infringements.

Controls at growers for the purposes of cross-compliance are the responsibility of the Greek Payment and Control Agency for Guidance and Guarantee Community Aid (OPEKEPE). OPEKEPE perform cross-compliance checks of pesticide use in 1 % of the 800 000 growers who receive EU funding. DPPP stated that information on non-compliances regarding the use of PPPs is communicated to OPEKEPE. However, DPPP, RCPPQC and DREVM were not aware of any pesticide controls carried out by OPEKEPE.

Conclusions

There was regular and effective vertical communication in place. Horizontal co-operation between the CAs performing controls of pesticide use is not sufficiently effective, in contrary to Article 4(3) of Regulation (EC) No 882/2004.

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

Administrative penalties and criminal sanctions relating to infringements of Regulation (EC) No 1107/2009 and Directive 2009/128/EC are specified in Law 4036. Fines range from EUR 300 to EUR 100 000, and Courts can decide on imprisonment of up to one year. Administrative fines and sanctions are applied by the MRDF, after notifications by the DREVM and a relevant proposal of the DPPP.

The audit team evaluated the documentation of three cases in the prefecture of Drama, where illegal pesticides were detected: the police made arrests, and the Court forwarded the files to DPPP. MRDF applied sanctions, which were implemented by DREVM. The audit team evaluated further cases where sanctions were applied in the region Viotia. In cases of repeated unauthorised uses of pesticides sanctions of up to EUR 15 000 were applied, and notified to the public prosecutor. Sanctions were also applied for non-compliances detected in the formulation laboratory.

The keeping of record of PPP applications has been a legal obligation under Regulation (EC) No 852/2004. However, until Law 4036 entered into force, the keeping of records was promoted by DPPP, but no sanctions could be applied due to a legal loophole: enforcement of Regulation (EC) No 852/2004 falls under the responsibility of the Greek Food Safety Authority (EFET), who is not

responsible for control in primary production. Since entry into force of Law 4036 of 2012, the legal obligation for growers to keep records of PPP applications can be enforced by the DPPP.

Conclusions

Where non-compliance is detected, the CA takes appropriate action to ensure that the operator remedies the situation. Sanctions provided for are effective, proportionate and dissuasive.

5.2.11 Verification Procedures and Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 competent authorities are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed.

Findings

No procedures for verification of the effectiveness of controls, and no system for internal or external audit was in place. The DPPP stated that they plan to implement these requirements after adoption of the draft law concerning the reorganisation of the central government, which has been tabled for discussion in the parliament.

Conclusions

In contrary to Articles 4 and 8 of Regulation (EC) No 882/2004, no procedures for verification of the effectiveness of controls, and no systems for internal or external audit were in place.

6 Overall Conclusion

The system for authorisation of PPPs follows EU legislation, and there is good co-operation with other authorities and stakeholders for the adequately targeted control of illegal pesticides.

Although retailers of PPPs are registered and official inspections are carried out, there are deficiencies in the planning of controls and a lack of clear procedures, which reduce the effectiveness of controls.

The control on the use of PPPs at growers is ineffective, due to the lack of legal powers of the competent authority to ensure access to premises, the absence of risk-based planning, insufficient numbers of controls, and insufficient verification of information. Further obstacles to effective controls of growers are the lack of access to training and the lack of access to calibration of equipment for PPP application.

The lack of measures for the safe disposal of the significant stocks of pesticides with expired shelf-life, as well as leftovers and packaging, poses a risk to health and environment.

Of the three recommendations of the previous audit DG(SANCO)/2009-8162 evaluated by the audit team, one has not been satisfactorily addressed. Because of the inadequate management of the

available resources in the network of official control laboratories, the majority of analyses are carried out in laboratories using instruments with insufficient scope and sensitivity, and do not ensure efficient and effective controls of pesticide residues.

7 CLOSING MEETING

A closing meeting was held on 9 May 2012 with representatives of the CCA. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit.

The representatives of the CA offered initial comments and clarifications, which were considered for the drafting of this report.

8 RECOMMENDATIONS

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

N°.	Recommendation
1.	Ensure that staff receive appropriate training, and are kept up-to-date in their competencies, as required by Article 6 of Regulation (EC) No 882/2004. This applies in particular to the safe storage of pesticides.
2.	Ensure that professional users and distributors of PPPs have access to appropriate training by bodies designated by CAs. This shall consist of both initial and additional training to acquire and update knowledge as appropriate, as required by Article 5(1) of Directive 2009/128/EC.
3.	Ensure that professional users shall conduct regular calibrations and technical checks of the pesticide application equipment as required by Article 8(5) of Directive 2009/128/EC. Pesticide application equipment in professional use shall be subject to inspections, and be inspected at least once by 26 November 2016, as required by Articles 8(1) and 8(2) of the same Directive.
4.	Ensure that the recovery and disposal of pesticide remnants and their packaging by professional users and distributors do not endanger human health or the environment, as required by Article 13(1)(e) of Directive 2009/128/EC.
5.	Include documentary checks in the inspections of users of PPPs to ensure the effectiveness of official controls, as required by Article 4(2)(a) of Regulation (EC) No 882/2004.
6.	Ensure that official controls of users of PPPs are carried out without prior warning, as

Recommendation		
laid down in Article 3(2) of Regulation (EC) No 882/2004.		
Ensure that staff have access to premises of and documentation kept by users of PPPs, as required in Article 8(2) of Regulation (EC) No 882/2004.		
Ensure that all designated pesticide residue laboratories have LC-MS/MS and GC-MS/MS equipment to ensure that staff can perform official controls efficiently and effectively, as required by Article 4(2)(d) of Regulation (EC) No 882/2004.		
Ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, as required by Article 3(1) of Regulation (EC) No 882/2004.		
Ensure that documented procedures contain sufficient information and instructions for staff to perform effective official controls, as required by Article 8 of Regulation (EC) No 882/2004.		
Ensure effective co-operation between the authorities performing controls on pesticide use, as required by Article 4(3) of Regulation (EC) No 882/2004.		
Ensure that procedures are put in place to verify the effectiveness of controls that they carry out, as required by Article 8(3)(a) of Regulation (EC) No 882/2004.		
Carry out internal audits or have external audits carried out, as required by Article 4(6) of Regulation (EC) No 882/2004.		

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=2012-6285

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Horizontal Legislation	on	
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		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	p. 1, Corrected and	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
Legislation on Plant	Protection Products	
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

Legal Reference	Official Journal	Title
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
Legislation on Pesticion	de Residues	
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 $2-S{\scriptsize \mbox{tandards}}$ Quoted in the report

Reference number	Full title	Publication details
SANCO/12495/20 11	Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed, Document SANCO/10684/2009.	ection/resources/qualcontrol_en.p