EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2015-7475 - MR

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
GREECE
FROM 14 SEPTEMBER 2015 TO 22 SEPTEMBER 2015
IN ORDER TO
EVALUATE CONTROLS ON THE MARKETING AND USE OF PLANT PROTECTION PRODUCTS

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 audit in Greece, carried out between 14 and 22 September 2015, 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 system for official controls on the marketing and use of plant protection products.

There is a system of controls on the use of Plant Protection Products (PPPs). However, there is a lack of information, and hence controls, on users not claiming funds under the basic payment scheme. The risk assessment for the prioritization of controls does not take into account all the different users of PPPs and the frequency for controls has not been established based on risk. These weaknesses reduce the effectiveness of the controls. In addition, the majority of staff are not adequately trained in PPP-specific issues and therefore, controls conducted on growers are not effective to verify that only authorised PPPs are used in accordance with their conditions of authorisation.

There are regular, risk-based official controls on retailers of PPPs. The control of labels and revoked PPPs at this level are not effective. The absence of risk based routine inspections on manufacturers, packers and re-packers of PPPs for product destined for the national market also compromises the effectiveness of the control system to ensure that authorised PPPs for marketing in Greece comply with their conditions of authorisation.

Although there are weaknesses in controls for product destined for the domestic market, there are comprehensive controls on the manufacture and re-packing of PPPs intended for use in other Member States or Third Countries. These controls are enhanced by the excellent co-operation with relevant Competent Authorities (CAs) and there is an effective system in the fight against illegal PPPs.

Growers have sufficient information and tools available to guide them in the implementation of Integrated Pest Management (IPM) and the CA has a pest monitoring system in place. However, there is no functioning system for sprayer testing so as to ensure that all pesticide application equipment in professional use can be inspected before the EU legal deadline on 14 December 2016. The systems for pest monitoring and controls on IPM provide assurances on the safe use of PPPs.

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
BPS	Basic Payment Scheme
CA(s)	Competent Authority(ies)
CC	Cross Compliance
CCA(s)	Central Competent Authority(ies)
CNA	Coordinating National Authority
DAA	Decentralised Agency of Attika
DG (SANCO)	Health and Consumers Directorate-General
DG (SANTE)	Health and Food Safety Directorate-General
DGSPP	Directorate-General of Sustainable Plant Production
DPPPB	Directorate of Plant Produce Protection and Biocides
DREV	Directorate of Agriculture Economy and Veterinary of Regional Unit
EFET	Greek Food Authority
ESYD	Hellenic Accreditation System
EU	European Union
FTE	Full Time Equivalent
FVO	Food and Veterinary Office
ha	Hectare
IPM	Integrated Pest Management

Abbreviation	Explanation
Km	Kilometre
MRDF	Ministry of Rural Development and Food
MS(s)	Member State(s)
NAP	National Action Plan
OPEKEPE	Payment and Control Agency for Guidance and Guarantee Community Aid
PHI	Pre-Harvest Interval
PPP(s)	Plant protection product(s)
PTP	Parallel trade permit
RCPPQC	Regional Centres for Plant Protection and Quality Control
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 14 to 22 September 2015. The team comprised three auditors from the FVO and one expert from a European Union (EU) Member State (MS).

A representative from the central competent authorities (CCAs) accompanied the FVO team for the duration of the audit. An opening meeting was held on 14 September with the Directorate-General of Sustainable Plant Production (DGSPP), the Customs, the Greek Food Authority (EFET), the Benaki Phytopathological Institute (BPI), and the Payment and Control Agency for Guidance and Guarantee Community Aid (OPEKEPE). 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 official controls of plant protection products (PPPs) under Regulation (EC) No 1107/2009 and Regulation (EC) No 882/2004;

- the implementation of requirements for the sustainable use of pesticides under Directive 2009/128/EC.

In terms of scope, the audit reviewed the designation of competent authorities (CAs) for official control of pesticides, their co-operation and resources for performance of controls, as well as the organisation of the controls on PPP distributors (manufacturers, importers, re-packing facilities, wholesalers) and professional users.

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

Table 1: Audit visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	2	Opening and closing meeting with DGSPP, Directorate of Customs Procedures, EFET, BPI and OPEKEPE. EFET and BPI present at opening meeting only.
Regional	4	DREVs of Thessaloniki, Xanthi, Attika, and Regional Centre for Plant Protection and Quality Control of Pireaus (RCPPQCP).
On-Site-Visits		
Controls of professional users:		
Growers	2	Arable farm in Xanthi and vegetable grower in Attika.
Seed treatment plant	1	
Controls of PPP distributors:		
Packers and/or re-packers	2	
Distributor	1	

3. LEGAL BASIS FOR THE AUDIT

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 I.

4. BACKGROUND

4.1. AUDIT SERIES

This audit is part of the fifth series of FVO audits in EU MS on controls of pesticides. The general overview reports of the previous audit series can be found on the DG (SANTE) internet site: http://ec.europa.eu/food/fvo/specialreports/index_en.htm.
In the most recent audit series, carried out in the period January 2012 – June 2014 with regard to official controls on the marketing and use of PPPs, the main weaknesses identified were related to the coverage of operators by official controls, labelling checks of PPPs, formulation analysis and measures in place for the control of illegal/counterfeit pesticides. The report of the previous audit to Greece (2012-6285), conducted as part of the series, can be found at http://ec.europa.eu/food/fvo/ir_search_en.cfm.

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 previous FVO audit reports. The country profile can be found at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm. The follow-up of actions taken in response to recommendations from audit 2012-6285 was reviewed as part of the present audit (see section 5.5).

4.3. PLANT PROTECTION PRODUCTS IN GREECE

PPPs containing approximately 14 850 t of active substances, with a value of 183 million euros were sold in Greece in 2014 comprising 35 % fungicides, 35 % herbicides and 23 % insecticides. This places Greece as a medium scale user of PPPs in an EU context. Compared to the figures in 2013, the amount of active substances used has almost doubled in one year. Despite the significant increase in the quantity compared to 2013, the increase in value was only 11%.

No active substances are manufactured in Greece. In 2014, 691 tons of active substances were imported from third countries (TCs).

The total agricultural area reached 3.3 million hectares (ha) in 2013, of which 49.6 % was annual crops, 25 % arboreal crops, 2.4 % vineyards and 23 % other crops.

5. FINDINGS AND CONCLUSIONS

5.1. RELEVANT NATIONAL LEGISLATION

Legal Requirements

Article 291 of the Treaty on the Functioning of the EU

Findings

1. Regulation (EC) No 1107/2009 is directly applicable and different pieces of national legislation have been approved laying down implementing powers. The CA stated that Directive 2009/128/EC was transposed into Greek legislation by law 4036/2012 and the National Action Plan (NAP) for sustainable use of plant protection products was adopted with the Common Ministerial Decision No. 8197/90920 on 22 July 2013. All legislation is published in the official journal and is publicly available at http://www.minagric.gr/index.php/en/farmer-menu-2/plantprotection-menu/control-distr-useplantprotprod-menu.

Conclusions on Legal Requirements

2. Relevant legislation within the scope of the audit is in place.

5.2. ORGANISATION OF OFFICIAL CONTROLS

Legal Requirements

Article 75(1) of Regulation (EC) No 1107/2009 and Article 4(1) of Regulation (EC) No 882/2004 on designation of CAs

Article 75(3) of Regulation (EC) No 1107/2009 and Article 4(2) of Regulation (EC) No 882/2004 on the qualification and experience of staff who carry out official controls

Article 68 of Regulation (EC) No 1107/2009 on the monitoring and controls, in particular, annual reports to the Commission on the scope and the results of controls

Chapter I of Regulation (EC) No 882/2004 on the general obligations with regard to the organisation of official controls of PPPs used at all stages of production of food

Chapter II of Regulation (EC) No 882/2004 on CAs and, in particular, designation of CAs, staff performing official controls, control procedures and reporting

Findings

Designation of Competent Authorities:

3. Within the Directorate-General of Sustainable Plant Production (DGSPP) of the Ministry of Rural Development and Food (MRDF) (former Ministry of Reconstruction of Production, Environment and Energy), the Directorate of Plant Produce Protection and Biocides (DPPPB) is the Coordinating National Authority (CNA) for the implementation of Regulation (EC) No 1107/2009 and Directive 2009/128/EC. DPPPB is responsible for authorisation of PPPs and the Directorate maintains the register of authorised PPPs http://wwww.minagric.gr/syspest/.
4. At regional level, the CAs are the eight Regional Centres for Plant Protection and Quality Control (RCPPQC) of the MRDF. Their responsibilities are to implement controls on the marketing and use of PPPs; controls on sustainable use of PPPs; to manage the Early Warning System for pests and the internal audit system.
5. The local government structure is established by the Kallikratis Law (3652/2010). The Decentralised Administration is supervised by the Ministry of Interior and thirteen regions were established where Governors of the Regions are elected in regional elections. Within the General Directorates of Regional Agriculture and Veterinary of each region, there are a total of 59 Directorates of Agriculture Economy and Veterinary Regional Units (DREVs) which conduct controls on marketing and use of PPPs.
6. The Laboratory of Chemical Control of Pesticides of Benaki Phytopathological Institute (BPI) is responsible for formulation analyses of PPPs in the country. Two other official laboratories at Thessaloniki and Piraeus also carry out some formulation analyses.
7. The Customs is the CA responsible for conducting controls on imports of PPPs and active substances for use in PPPs in Greece.
8. The Greek Payment and Control Agency for Guidance and Guarantee Community Aid (OPEKEPE) is responsible for controls on farmers receiving payments under the EU basic payment scheme (BPS).

Resources for Performance Controls

9. The assessment of applications for authorisation of PPPs is conducted in the BPI where 30 people are involved. Within the DGSPP, the DPPPB has 4.2 full time equivalents (FTE) dealing with authorisation of PPPs. DPPPB has 5 FTE dealing with controls and for the management of the PPP website. Three DREVs were visited during the audit where controls on PPPs were conducted by 2 FTE in Thessaloniki, 1.5 FTE in Xanthi and 1.6 FTE in Attika. In all DREVs visited the inspectors conducted a wide range of activities in addition to controls on PPPs. RCPPQC staff conduct specific ad-hoc investigation tasks on the use and marketing of PPPs as requested by the CNA.
10. DREV inspectors are required to be agronomists with University degrees or have technical third level qualifications in agriculture. There is no system for initial PPP-specific training for staff, despite the very technical nature of the area and the plan for

on-going training for inspectors designed by the CNA was not fully implemented in the last year due to the recent economic restrictions.

11. Controls on users are conducted in teams with two or three inspectors involved. This facilitates the specific on-the-job training for new entrants. However, no training has been arranged before staff start to conduct inspections on PPP in cases where new staff were allocated to DREVs where no experienced inspectors were on duty and supervision activities have not highlighted the needs for training. This situation has occurred more frequently in recent years due to the high number of staff retirements. This lack of training is not in line with Article 6 of Regulation (EC) No 882/2004.
12. Due to economic restrictions, the number of trips for inspections has been limited. For the next year 2016, a maximum of 220 Km per month will be allocated to each inspector. Responsible staff for the visited DREVs highlighted that this would require a significant reorganisation of the works in order to be able to conduct the same number of inspections.
13. The Presidential decree 159/2013 states that inspections to retailers of PPPs shall be conducted by commissions of three inspectors. Other inspections to users are usually conducted by two inspectors, although there is no legal requirement for that. This practice decreases the time available for conducting inspections. Evidence was provided that the numbers of inspections planned in all 3 DREVs is dictated by staff resources plus working practices, rather than identified risks. This is not in line with Article 3.1 of Regulation (EC) 882/2004.

Prioritisation of Controls

14. The CNA defines the scope of the official controls. The risk assessment for 2015, and consequently, the official control plan did not cover routine inspections to packers, re-packers and producers of PPPs or to seed treatment plants. This is not in line with Article 3.1 of Regulation (EC) No 882/2004. The 2015 control plan adopted by the CNA covered marketing and use of PPPs including official controls to professional users on farms, retailers of PPPs (i.e. sale to end users), specific controls on parallel trade packagers and producers of PPPs for other MS or TC, when such PPPs are not authorised in Greece. There is an annual monitoring plan for formulation analysis of PPPs.
15. From the 750 000 farms claiming funds for the BPS, controls cover only the applicants receiving more than €1 200. OPEKEPE stated that 3 900 farms were inspected in 2014. However, these controls are not reported by the Greek CNA as official controls to enforce compliance with Regulation (EC) No 1107/2009.
16. Prioritisation of the controls in the regions is conducted by the DREVs in line with the instructions established by the CNA. For the controls on users, the risk assessment takes into consideration the type of crop and its relevance within the region, previous maximum residue level (MRL) exceedances, information from pesticide residue monitoring programme, previous non compliances (non-compliant operators are always inspected within a year of the infringement) and the size of the farms.

17. There is no information available on the number of farms not claiming funds under the BPS or on users of PPPs other than farms. This compromises the organisation of official controls accordingly to an appropriate risk basis as required by Article 3.1 of Regulation (EC) No 882/2004.
18. For controls conducted by the DREVs on professional users, a minimum frequency or annual inspection rate has not been established. The CNA does not prescribe the number of planned controls to be conducted in each region. The number of inspections is determined by economic resources available and not the outcome of the risk assessment. This is not in line with Article 3.1 of Regulation (EC) No 882/2004. It was noted that in some important agricultural areas such as Larissa and Kavala no inspections on marketing and use of PPPs were conducted by DREVs in 2014.
19. Ad-hoc inspections are arranged for 100 % of cases where the residue analysis programme detects the use of authorised PPPs not approved for the specific crop or the use of non-authorised PPPs in Greece. Under the residue analysis programme, approximately 2 300 samples are taken each year.
20. In 2014, the DPPPB launched a specific survey of professional users of PPP. This survey is anonymous and 2 815 answers were collected. Information on the use of illegal pesticides, implementation of Integrated Pest Management (IPM) and other questions on PPP have been taken into consideration for risk assessment.
21. The DREVs are responsible for planning and conducting the official controls on operators placing PPPs in the market. The frequency of inspection of PPP retailers has been increased from 25 % annual inspection to 33% in 2015 onwards. Therefore, the CA stated that every retailer is to be inspected at least once every 3 years. All Retailers are registered on a website operated by DPPPB http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/elenxoifitoprostateytikonmenu/529-mhtroa.
22. Since 1 January 2014, retailers must record electronically every sale of PPP to end users. The specific products sold and the customer details are recorded. This data is only accessible to DPPPB staff. The CNA informed the FVO audit team that the data will be used to monitor trends in PPP use and to identify emerging risks, which DREVs can incorporate into their control programmes.
23. The absence of risk based controls at manufacturers, packers and re-packers of authorised PPPs means that the system to ensure that authorised PPPs for use in Greece comply with their conditions of authorisation under Articles 29(1) of Regulation (EC) No 1107/2009 is not effective. Although there is not a programmed plan for the control of manufacturers, packers and re-packers of PPPs, targeted inspections are conducted based on intelligence provided by other CAs, other MS and PPP industry.
24. For companies manufacturing, packing or re-packing PPPs which are not authorised in Greece but destined to be delivered to other MS or exported to third countries (TC), the CAs have established a comprehensive control system conducted on 100% of deliveries. The same comprehensive control system is in place for producers granted with a parallel trade permit (PTP). This system provides assurances that these products comply with their conditions of marketing.
25. There is a formulation analysis program in place. The BPI conducts the majority of the analyses. There are two other laboratories conducting official formulation analyses with

a reduced scope of substances that can be analysed. An annual risk assessment is conducted for the selection of the active substances to be included within the annual plan taking into consideration previous infringements, parallel trade authorisations and the most used PPPs in the country. The decision of the CA to allocate a certain number of analyses to the two laboratories which can only analyses a very limited scope of formulated PPPs compromises the risk assessment process for the annual plan. This is not in line with Article 3.1 of Regulation (EC) No 882/2004.

Procedures for Performance and Reporting of Control Activities

26. For the inspections conducted by DREV under the annual control plan at retailers and users of PPPs, the CNA has issued several internal circulars with instructions for conducting the controls and specific checklists are in place for the inspections. A report form is used and a copy is provided to the operator, either on site, or by post, when the inspection report is finalised at the office. The same checklist and report forms are used for non-planned inspections such as visits triggered by results of the residue monitoring plan.
27. For ad-hoc inspections at formulators, packers holding parallel trade permits, packers and re-packers, there are no specific checklists in place but general report forms. Operators are always provided with a copy of the report.
28. Article 8 of the National Law 4036/2012 lays down the obligation of operators to co-operate and supply any requested information during controls. This addresses recommendation No 7 of the previous audit 2012-6285.
29. The annual report on the scope, and results, of official controls under Article 68 of Regulation (EC) No 1107/2009 is provided to the Commission by the due date. The FVO audit team reviewed the compliance with the submission deadlines for the years 2013 and 2014.

Co-ordination and co-operation between and within Competent Authorities

30. There is active, ongoing co-operation between the control and the authorisation unit within the DPPPB, responsible for co-ordinating the enforcement and authorisation of PPPs respectively. Co-ordination and co-operation between the DPPPB and the DREVs, Customs and laboratories is excellent. There is continuous two-way exchange of information between these services. The annual control programme is devised taking the views of all authorities into account. High priority work can be undertaken at short notice, e.g. targeted controls on suspected use of illegal PPPs in cotton, involving the CCA, DREVs and the BPI, due to this close working relationship.
31. There is limited co-operation with OPEKEPE, and while the DPPPB cross reports the outcomes of inspections to OPEKEPE, this is not reciprocated since DPPPB has not access to information relevant to the use of PPPs and IPM implementation issues such as type of infringement. DPPPB have not access to a format allowing the data to be useful for prioritising controls.

32. There are numerous examples of co-operation between the DPPPB, other MS, TCs and industry for example controls on imports are targeted based on intelligence provided by other MS.

Conclusions on the Organisation of Official Controls

33. Although there is nominally training programme for official controls on marketing and use of PPPs, the lack of implementation of the programme and the absence of systematic initial PPP-specific training for inspectors is not in line with Article 6 of Regulation (EC) No 882/2004 and compromises the effectiveness of the controls.

34. The absence of defined lists of all professional users of PPPs, the risk assessment which does not cover all types of users and the absence of a defined risk based inspection frequency on users is not in line with Article 3 of Regulation (EC) No 882/2004 and compromises the effectiveness of the official controls.

35. The absence of regular inspections of manufacturers, packers and re-packers of PPPs limits the effectiveness of the control system to ensure that authorised PPPs for marketing in Greece comply with their conditions of authorisation.

36. There is a comprehensive control system in place for manufacturers, packers or re-packers of PTP PPPs, and for operators producing PPPs not authorised in Greece but intended for use in another Member State (MS) or Third Country (TC). These controls coupled with the excellent co-ordination and co-operation between the CNA and Customs enhances the effectiveness of controls of PPPs traded within the EU.

37. The BPI provides analytical services to give assurances that PPPs placed on the market comply with their conditions of authorisation/parallel trade permit as required by Articles 29(1) and 52 of Regulation (EC) No 1107/2009. However, the formulation analysis programme is weakened, in both its risk based planning and execution, by the use of two laboratories with very limited analytical scope.

38. Co-ordination and co-operation between and within competent authorities and between the CAs and relevant external stakeholders is excellent, which contributes greatly to the efficiency and effectiveness of controls, as required by Articles 4(3) and (5) of Regulation (EC) No 882/2004, with the exception of co-ordination and co-operation with OPEKEPE.

39. The decision on the number of inspections driven by the availability of resources coupled with the allocation of resources in two or three inspector teams compromises the organisation of risk based controls with appropriate frequency as required by Article 3 of Regulation (EC) 882/2004.

5.3. IMPLEMENTATION OF OFFICIAL CONTROLS

5.3.1. Controls on the Marketing of Plant Protection Products

Legal Requirements

Article 28 of Regulation (EC) No 1107/2009 on the authorisation of PPPs for placing on the market and use

Article 29 of Regulation (EC) No 1107/2009 on the requirements for the authorisation of PPPs

Article 52 of Regulation (EC) No 1107/2009 on parallel trade of PPPs (where applicable)

Article 65 of Regulation (EC) No 1107/2009 and Regulation (EU) No 547/2011 on the labelling of PPPs

Article 67(1) of Regulation (EC) No 1107/2009 on record-keeping

Article 68 of Regulation (EC) No 1107/2009 on the monitoring and controls

Article 6 (2) of Directive 2009/128/EC on the sale of pesticides by staff holding a certificate

Article 13 of Directive 2009/128/EC on the adoption of measures to avoid endangering human health or the environment by specific operations and the storage of pesticides for professional use

Findings

General information

40. The official register of PPPs and biocides is located at http://wwww.minagric.gr/syspest/syspest_menu_eng.aspx. It is updated daily and contains all PPPs that can be marketed and used, including emergency authorisations. At the time of the audit, there were 1 307 authorised PPPs, (including products in their sell out phase), and 199 PTP PPPs that could be marketed and used, containing 336 active substances. There are just 10 amateur use PPPs authorised in Greece. The website provides information on each product including *inter alia*, the authorisation number, trade name, name and quantity of the active substance(s), function, rate of use, pre-harvest interval (PHI) and classification. Artwork versions of product labels are not approved at the time of authorisation. The CA stated that authorisation numbers do not change, even in cases where significant changes are made to the authorisation e.g. the loss of approved crops. Lists of revoked PPPs are available on the website, with the last day for sale and use clearly stated, permitting 6 months for sale and 18 months for storage and use of revoked PPPs. Own use PTPs are granted by DPPPB, but to date, no requests to grant permits have been received.
41. There are 21 registered PPP manufacturers and eight registered re-packers in Greece. However, 75 % of these manufacturers are, in fact, re-packers. There are 2 530

wholesalers and retailers of PPPs. All operators involved in manufacture, re-packing and marketing PPPs must be registered. Operators are inspected by the relevant DREV before business activity starts to determine if facilities are suitable. This includes storage standards in the case of retailers. Lists of registered operators are published on the Ministry's website at http://www.minagric.gr/images/stories/docs/agrotis/Georgika_Farmaka/elenxoi/FP_Mhtrwo_Biomhxaniwn_160315.pdf (manufacturing, re-packing and re-labelling facilities) and http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/elenxoifitoprostateytikonmenu/529-mhtroa (wholesalers and retailers). The number of retailers has increased significantly in recent years, due to an increased focus on agriculture related industries as a result of the economic difficulties.

42. The CAs treat formulated products and active substances, in both bulk and packaged form, as falling under the scope of Regulation (EC) No 1107/2009. All imports of both formulated product and active substances from TCs must be notified to the DPPPB prior to import, and an import licence granted. Similarly, if the material is intended for manufacturing a PPP for placing on the market in another EU MS or TC, all deliveries of formulated products and active substances from other EU MS must be notified to the DPPPB prior to arrival. This notification includes an explanation of what specific PPPs will be made using the active substance. Finally, all deliveries of PPPs for sale under PTPs must be notified to the DPPPB ten days before entering into the country. The CA restricts re-packing of parallel trade permit PPPs within Greece.
43. From 26th November 2015 the electronic recording system for sales of PPPs will require a prescription completed by a registered agronomist, for the purchase of all professional use PPPs. This will specify the crop and the target pest/justification for use. The prescription number will be recorded in the electronic sales system, thus linking the product to the grower and crop on which the PPP is intended for use.
44. There are 2 530 retailers of professional use PPPs. In 2013 and 2014, DREVs conducted 818 and 847 routine inspections on retailers, and 72 and 155 investigations on wholesalers and retailers of PPPs. In 2014, 41 out of 59 DREVs conducted controls on wholesalers and retailers. All controls are unannounced. It is planned that all controls take place with three inspectors working in a team. The control focuses on the expiration status of PPPs and records of sales. The product authorisation status is not checked. Storage facilities and storage practices (e.g. storage of powders above liquids) are not addressed. These controls resulted in 55 and 129 infringements being detected in 2013 and 2014 respectively. In 2013, the main offences related to the sale of expired PPPs. In 2014, more than 60 % of offences were related to the electronic recording of PPP sales. The remaining offences largely related to sale of expired PPPs and sale of PPPs by non-registered premises. In the three DREVs visited by the audit team, there are 132, 62 and 30 wholesalers/retailers respectively. In 2014, 26, 24 and 20 of these were controlled. To date in 2015, 3, 5 and 8 were controlled. In the first two cases, the DREVs explained that other work has taken priority in 2015.
45. Detailed label checks are only conducted on PPPs taken for formulation analysis. This is done in the office, using a checklist and the product's authorisation details on the

Ministry website. Under national law 4036/2012, expired (i.e. greater than two years old) PPPs cannot be marketed or used. All details on the label are checked, including name, active substance level, formulation type, classification, risk and safety phrases, authorisation number, authorisation holder, approved crops, rates of use and pre-harvest interval. The CNA informed the FVO audit team that 358 label checks were conducted in 2014.

46. The lack of detailed label checks on PPPs during onsite inspections, coupled with the system of keeping the same authorisation number even when significant changes are made to the authorisation compromise the controls on the compliance with Article 46 of Regulation (EC) No 1107/2009.
47. The annual formulation analysis programme is drawn up by the DPPPB, in consultation with the laboratories and the DREVs. Samples are taken by DREV inspectors at re-packers and retailers of PPPs. Specific active substances are selected for analysis each year, 14 in 2013 and 15 in 2014. Sample numbers are not defined.
48. Four laboratories conducted formulation analysis on PPPs in 2013 and three in 2014. A total of 364 samples were analysed in 2014 comprising 244 for the annual program for market control. The BPI is accredited for formulation analysis with a flexible scope covering the determination of active ingredients in PPPs by HPLC-UV and GC-FID techniques. The Regional Centre for Plant Protection and Quality Control (RCPPQC) of Thessaloniki is accredited for the determination of only two active substances (Chlorpyrifos and Lambda-cyhalothrin). The RCPPQC of Pireaus which is only analysing dimethoate is not accredited according to the information available at the website of the Hellenic Accreditation System (ESYD) http://esyd.gr/portal/p/esyd/en/pinakestop.jsp. The BPI can conduct a range of analysis including quantification of active substances, impurities and profiling to verify if PPPs sold under PTPs are compliant. The RCPPQC laboratories of Thessaloniki and Pireaus can only test PPPs containing a very limited number of active substances, three (*tebuconazole, pyraclostrobin* and *boscalid* which do not fall under the scope of the accreditation) and one (*dimethoate*) respectively, for the level of active substance. The number of formulation analysis conducted in the laboratories of Thessaloniki and Pireaus were 21 and 15 respectively in 2014. The RCPPQC laboratories of Thessaloniki and Pireaus are not accredited to the scope of the official formulation analysis conducted. This is not in line with Article 12 of Regulation (EC) No 882/2004. Samples are generally batched to increase laboratory efficiency, meaning that turnaround times can routinely extend to a number of months, however, priority samples can be processed promptly.

Controls observed by the audit team:

Controls at manufacturers:

49. The audit team visited a manufacturer of PPPs with DREV staff. While the operator is registered as a manufacturer, and manufactured PPPs in the past, they now only purchase formulated PPPs in 200 – 1 000 l containers and re-pack them into smaller packs, for sale

under their own trade names. The company stated that it cannot afford the high costs of generating data to comply with EU PPP legislation, and hence all authorisations are based on access to data owned by research and development companies. In addition, they sell a small number (<10 % turnover) of PTP PPPs. All PPPs marketed are sold on the Greek market. Notifications are provided to the DPPPB when PTP PPPs are imported for re-packing.

50. The DREV conducts announced controls on all notified PTP imports, focusing on that product only. There are no routine controls on the plant to verify that the authorised PPPs for sale in Greece comply with the condition of authorisation, and there are no controls on the manufacturing process e.g. traceability or cross contamination. The operator has separate packing lines for herbicides and other products. In addition, they flush the packing lines between products and the efficacy of this process has been verified using analysis.

Controls at Importers:

51. The audit team met with officials of the Customs staff involved in controls on imported PPPs. Customs stated that they conduct documentary checks on 15 %, and physical checks on 5 %, of all imports through ports and airports. All PPP imports from TCs (both formulated product and active substances) must be notified to the DPPPB and an import licence granted. In cases of suspicion, the DPPPB highlights the consignment to Customs, and in these cases, documentary checks are conducted. Physical checks are conducted if required. There is co-operation with DREVs and the DPPPB, in cases where clarification is required.

52. Customs conduct controls at the land borders with Turkey, Former Yugoslav Republic of Macedonia and Albania. The illegal introduction of PPPs is common along these borders and the CA estimates that up to 50 % of PPPs used in some border regions are illegal. The trade is driven by farmers purchasing PPPs for their own use and small distribution networks selling direct to the end user. From 1 January 2014 to date, over 1 000 small packages of illegal PPPs, containing approximately 120 kg in total, were detected entering Greece from Albania, while in 2014 approximately 20 consignments, comprising 500 kg in total, were detected entering from Turkey. These small consignments are generally hidden, making detection difficult. The products typically contain active substances approved in the EU. In all cases, products are seized and a fine imposed by Customs. The CAs suspect that many Turkish PPPs are entering Greece via Bulgaria, but there are no Greek border controls in this case. Furthermore, Greek farmers purchase PPPs authorised in Bulgaria for use in Greece. In many cases, virtually identical PPPs are authorised in Greece, but as PPPs are authorised at the MS level, this practices of purchasing authorised PPPs in one MS for use in another is illegal. The illegal trade is driven by the price differential between Greece and neighbouring countries. PPPs are 50 % more expensive in Greece than Bulgaria on average, and it is estimated that the price differential in the case of Turkey and Albania is similar, or even greater.

Controls at re-packers:

53. The audit team visited a re-packer of PPPs with DREV staff. The operator purchases formulated PPPs in 200 – 1 000 l containers and re-packs them into smaller packs, for sale in Greece, other MS and TCs. Notifications are provided to the DPPPB when PTP PPPs and formulated PPPs for sale in other EU MS and TCs are imported for re-packing. The DPPPB firstly consults the database of PPPs authorised in the EU http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN, to verify, using the information in the notification, that the PPP is authorised in that MS. In cases of suspicion, further contacts are made with the CA in the destination MS. For PPPs for export to TCs, the DPPPB contacts the CA is that country to check that the PPP may be marketed in that country.
54. The DREV conducts controls in response to all notifications, focusing on that product only. The purpose of the control is to verify that all stocks of the PPP imported, are exported to the relevant MS or TC. As with manufacturers, there are no routine controls on re-packers to verify that the authorised PPPs for sale in Greece, comply with the condition of authorisation and there are no controls on the manufacturing process e.g. traceability or cross contamination.
55. Re-packing of PTPs for marketing in Greece must be undertaken in Greece. All PTPs must bear the date of manufacture, the date of re-packing and a batch number allocated by the re-packer. The label must state the product is marketed under a PTP, with the name and authorisation number of the reference product stated on the label.

Controls at wholesalers and retailers:

56. The audit team observed a DREV inspection at a retailer of PPPs, conducted by a team of three inspectors. All PPPs in store were checked for expiry date. All PPPs placed on the Greek market must bear the date of manufacture plus the date of expiry, usually two years later. However, by this practice of checking solely the stated expiry date, it is not feasible to identify revoked PPPs after the date of production and the compliance with the grace period (up to 18 months including marketing and use) as per Article 46 of Regulation (EC) No 1107/2009.
57. The DREV inspectors seized the found expired (as distinct from revoked) PPPs. The expired PPPs were placed in a sealed plastic bag and left at the operators premises, for disposal as hazardous waste at some point in the future. The inspectors checked that all sales of PPPs were being recorded on the central electronic sales recording system. There were no checks on purchase records of PPPs, the authorisation status of PPPs in store, PPP labels or storage conditions, e.g. bunding and segregation of liquids and powders. All three inspectors failed to detect storage of at least three cases of liquid PPPs being stored above wettable powder products in the store which is not in line with the main principles of the Pesticides Storage and Stock Control Manual of the Food and Agriculture Organisation (FAO). When questioned, the lead inspector stated that none of the three

inspectors were trained in controls on marketing of PPPs and their role in this context is to give guidance on storage standards. This lack of training is not in line with Article 6 of Regulation (EC) No 882/2004. Controls are always un-announced and a copy of the inspection report, and seizure notice, if relevant, is provided to the operator.

58. Records are kept by producers, suppliers, distributors, importers and exporters as required by Article 67(1) of Regulation (EC) No 1107/2009.

Conclusions on Controls on the Marketing of Plant Protection Products

59. The publicly available official product register contains all relevant details on all PPPs that can be marketed and used in Greece, as required by Article 57 of Regulation (EC) No 1107/2009, thereby providing a foundation for controls.

60. The practice of inspections focusing solely on stated expiry date, rather than the legal authorisation status of the product, means that the system for enforcing the deadline for sale of revoked PPPs, to ensure compliance with Article 46 of Regulation (EC) No 1107/2009, is not effective.

61. The practice of retaining the same authorisation number when there are changes in the authorised conditions of use (e.g. loss of crops), coupled with the reduced number and limited nature of label checks, means that the system for enforcing the deadline for sale of existing stocks, to ensure compliance with Article 46 of Regulation (EC) No 1107/2009, is not effective.

62. The system of controls on PPP labels is hampered by the absence of approved artwork labels and the limited number and scope of label checks.

63. Use of non-accredited laboratories for official formulation analyses is not in line with Article 12 of Regulation (EC) No 882/2004 and compromises the effectiveness of the official controls on formulated PPPs.

5.3.2. Controls on the Use of Plant Protection Products

Legal Requirements

Article 49 of Regulation (EC) No 1107/2009 on placing on the market and use of treated seeds

Article 55 of Regulation (EC) No 1107/2009 on the proper use of PPPs, in particular, compliance with the conditions of use specified on the labelling

Article 67(1) of Regulation (EC) No 1107/2009, Article 4(1) of Regulation (EC) No 852/2004, and Annex I, Part A.III of the same Regulation on keeping records of the PPP use

Article 68 of Regulation (EC) No 1107/2009 on monitoring and controls and, in particular, PPP use in compliance with the authorised conditions specified on the label

Article 13 of Directive 2009/128/EC on the adoption of measures to avoid endangering human health or the environment by specific operations and the storage of pesticides for professional use

Commission Implementing Regulations (EU) No 485/2013 and No 781/2013

Findings

General information

64. There is no information available regarding the total number of users of PPP in Greece. Accordingly to OPEKEPE there are approximately 750 000 farms in Greece that claim Common Agricultural Policy subsidies. There is no defined list or lists of other PPP end users.
65. The DREVs conducted a total of 942 controls on professional users in 2014. DREVs inspectors declared that they used a range of sources (internet search, local knowledge of the sector) to select these operators for inspection.
66. Two growers were visited during the audit in two different regions, a 55 ha farm in Xanthi and a 30 ha unit in Attika. In the region of Xanthi, DREVs have access to the information provided to OPEKEPE on 10 000 growers. In 2014, a total of 30 growers were inspected and the 2015 plan is to inspect the same number of growers. At the time of the audit, ten growers had already been inspected in 2015. In the region of Attika, there is no information for CC since the crops are not subject to aid from the single payment. The DREV of Attika estimates a total number of 2 500 growers, most of them producing vegetables for local market in small quantities. The target set by the DREV of Attika for 2014 was to inspect 20 growers but only 6 were inspected. For 2015, the target was 12 growers, and at the time of the audit 16 growers had been inspected, mainly due to the requirement from the CNA to inspect growers with residue breaches detected in the previous year.
67. Checklists are used when conducting inspections and the operator receives a copy of the report in all cases. The FVO audit team was informed that all DREV controls are unannounced. Controls focus on the PPPs in store and records of PPP purchased and used, combined with some elements of Directive 2009/128/EC, such as handling of empty PPP containers. In both regions, inspectors brought to the attention of the grower several issues related to the implementation of the Directive (EC) 2009/128, such as the need to attend and pass the exam for professional users of PPP, which will be required for buying PPPs for professional use from 26 November 2015.
68. In both regions, the DREVs inspectors informed the FVO audit team that controls are conducted in teams with some rare exceptions when only one inspector was allocated. When queried about the training received, all the inspectors at the region of Attika informed the FVO audit team that they had not received training for the control of use of PPPs. This is not in line with Article 6 of Regulation (EC) No 882/2004.
69. In the region of Xanthi, the grower was producing cotton, soya, sunflower, pomegranate and olives. The inspection focused mainly in the cotton crop which comprised 10% of the total production of the grower. On site, the inspectors questioned the grower about

the plant protection methods used and the adherence to the early warning system for taking decisions on PPP applications. The inspectors also checked the storage area dedicated to PPPs. The area was locked and appropriately bunded. Inspectors queried the grower to demonstrate his knowledge in dealing with PPPs at all stages from storage, to use and disposal and use of personal protective equipment.

70. Inspectors reviewed the records of PPP application for the cotton crop only, and checked the information of purchase and use, however during the inspection, the inspectors did not have access to the information of the authorisation of the PPP to verify that the adequate dose was applied and they did not take sufficient notes related to the application records to verify this information later.
71. The other inspection took place in Attika. The grower supplied fresh vegetables (salads, tomato, cucumber, courgette, mint and other aromatic herbs) to national supermarket chains. The farm comprised 10 ha of plastic greenhouses and 20 ha of open field production. The grower was certified in private quality assurance schemes. The inspectors checked that the PPP store was locked and bunded and that powder PPPs were stored above liquids. All products in the store were checked to ensure that all of them had an authorisation number, and were not expired. The inspectors found two containers of expired PPPs. This control was not sufficient to identify any PPP still not expired but exceeding the grace period for use as per Article 46 of Regulation (EC) No 1107/2009. The inspectors did not check that the authorisation number on the PPPs containers matched with the actual authorisation number. No further information from the stored PPPs was noted. These expired PPPs were placed in a sealed plastic bag and left at the operator's premises, for disposal as hazardous waste at some point in the future.
72. The inspectors sought the PPP purchase records and the application records for one of the crops as per the CNA documented procedures and instructions. Information on records was gathered to be reviewed at a later stage at the DREV office, however, the FVO audit team noted that the information available did not include the actual size of the different fields treated. Therefore, the CA could not verify that the grower has used the PPP as indicated in the authorisation as required by Article 55 of the Regulation (EC) No 1107/2009. The FVO audit team requested records of previous inspections conducted by the inspectors during 2015 and related documents such as pictures of PPP labels and other information needed to check appropriate use of PPPs by the growers. The documented information available was not sufficient to demonstrate the appropriate use of PPPs in any of the four files checked.

Seed coating and drilling:

73. The DPPPB stated that there were four seed treatment plants in the country as published on the Ministry's website: http://wwww.minagric.gr/e-icide/e-icide_comp_crops_estab.aspx. However, the industry operator met by the audit team stated that there were three large plants and five or six newer, smaller scale operators that started in the last year. These new operators were not known to the CA.

74. The authorisations of relevant seed treatment PPPs had been revised, or revoked, as required by Regulations (EU) No 485/2013 and 781/2013, and the official product register updated. The CA stated that, to date, no emergency authorisations have been granted for neonicotinoid seed treatments, since these restrictions came into force.
75. Until recent years, seed treatment in Greece focused largely on cotton, and cotton was the only seed treated with neonicotinoid seed treatments. Farmer demand for treated seeds of other crops (wheat, barley, maize etc.) was largely supplied by imported seeds. There is no seed treatment at farm level in Greece, as certified seed must be used, and labels provided, to claim EU BPS payments.
76. While there is no programme of routine controls on seed treatment operators, at the request of the audit team, a seed treatment contractor was visited. This operator treats cotton and cereal seeds, using four non-neonicotinoid seed treatments. Although the central plan for official controls do not cover seed treatment plants, the local DREV took the initiative to conduct inspections to this operator to verify that some old stocks of revoked neonicotinoid seed treatments were still in store. The inspection did not address the authorisation status of PPPs in use, their storage conditions, if they were authorised on the specific seed being treated, the rates of use, etc. While there is no programme of routine controls covering the labelling of treated seed, labels of treated seed seen by the audit team stated the active substances and PPPs used in the treatment, the safety phrases, and gave guidance on safe use, including dust reduction.
77. Both farmers visited by the audit team purchased and used treated seeds. The treatment was determined by their advisor and/or supplier and was tailored to the expected pest challenge in accordance with Integrated Pest Management (IPM). Following the restrictions on neonicotinoids, there are now no insecticidal seed treatments authorised in cotton, so the cotton grower visited now uses alternative PPPs to control pests, including soil incorporated *chlorpyrifos* granules at sowing and subsequent foliar treatments in years of high pest pressure. The representative of the seed treatment plant confirmed that following the restrictions on neonicotinoids, alternative PPP treatments are now used by the majority of growers.
78. Although there is no specific monitoring plan on bee health as the CA stated that no neo-nicotinoids seed treatment are currently used in Greece, the CA investigates any incident involving bee health. The CA does not have information regarding the use of seeds of cereals treated with neonicotinoids brought from other MS.

Conclusions on Controls on the Use of Plant Protection Products

79. In general, records on PPP use are kept by professional users as required by Article 67(1) of Regulation (EC) No 1107/2009 allowing CAs to conduct proper controls on the use of PPPs.

80. Not all categories of PPP end users, including seed treatment plants, fall under the scope of official controls as required by Article 68 of Regulation (EC) No 1107/2009.

81. Documented controls conducted on growers by DREVs are not sufficient to verify that only authorised PPPs are used in accordance with their conditions of authorisation as

required by Article 55 of Regulation (EC) No 1107/2009.

82. The practice of controls focusing solely on stated expiry date of the product, but not on the legal authorisation, means that the system for enforcing the deadline for use of existing revoked stocks to ensure compliance with Article 46 of Regulation (EC) No 1107/2009, is not effective.

83. The authorisations of relevant seed treatment PPPs have been revised, or revoked, as required and the official product register updated. There are currently no authorised neo-nicotinoids seed treatments PPPs for the crops which the CA stated are treated in Greece.

84. There is a bee incident investigation system in place as required by Regulations (EU) No 485/2013 and 781/2013, based on reported incidents.

5.3.3. Aerial spraying

Legal Requirements

Article 9(2) and (3) of Directive 2009/128/EC on the conditions to be met for approval of aerial spraying and designation of CAs for establishing these specific conditions

Article 9(4) and (5) of Directive 2009/128/EC on the procedure for approval of aerial spraying and monitoring

Findings

85. Aerial spraying of PPPs has been prohibited in Greece since 1995 and there are no pesticides authorised for aerial spraying. Law 4036/2012 provides for the possibility of granting derogations for aerial spraying and describes the procedure to be undertaken for granting, and monitoring compliance with the derogation, in line with Directive 2009/128/EC. No derogations have been granted since the entry into force of Directive 2009/128/EC.

Conclusions on Aerial Spraying

86. Aerial spraying is prohibited in Greece and there is no record of any derogatioin being granted, thus satisfying the requirements of Article 9 of Directive 2009/128/EC.

5.3.4. Integrated Pest Management

Legal Requirements

Article 55 of Regulation (EC) No 1107/2009 on the proper use of PPPs

Article 14 of Directive 2009/128/EC on IPM

Findings

87. At the time of the audit, voluntary IPM guidelines for cherry, cotton and tobacco were completed and publicly available and included both compulsory and voluntary measures. These were drawn up by expert working groups under the guidance of the MRDF. A total of 43 guidelines are planned, the majority of which are in the final stages of approval. There were early warning systems in place designed and run by the MRDF, in collaboration with the RCPPQC and the DREVs. In all 8 regions, the warning systems cover the main crops. The systems are tailored to use the relevant data e.g. metrological data, traps, visual inspections, data from previous year, modelling, etc to predict pest outbreaks. There are three largest monitoring programmes focused on cotton bollworm (*Heliverpa armigena*), and pink bollworm (*Pectinophora gossypiella*) on cotton, western corn rootworm (*Diabrotica virgifera*) on maize, and olive fruit fly (*Bactrocera oleae*) on olive trees. These programmes are funded or co-funded by the MRDF with an annual budget of €82 000, €6 500 and 24 million euros, respectively. All growers of cotton and maize use certified treated seeds.
88. IPM is a legal requirement in the EU. Forty five thousand growers in Greece have received official training, which includes an IPM component. This addresses recommendation No 2 of the previous audit 2012-6285.
89. The annual survey of the professional use of PPPs was completed by 2 815 growers in 2014 and had been used for a better understanding of the current implementation of the Directive 2009/128/EC on sustainable use of pesticides and the IPM in the country. Controls on users also include questions related to the appropriate implementation of requirements of the Directive 2009/128/EC.
http://www.minagric.gr/images/stories/docs/agrotis/Georgika_Farmaka/Symplhrwmatika_Apotelesmata_230914.pdf
90. Triple rinsing of empty used containers is mandatory. The label of PPPs includes the information for this procedure and it is also required by the NAP. There is a trial recycling program in place specifically for empty pesticide containers, with the initiative of the Greek Plant Protection Association. The programme is offered free of charge and currently is implemented as a pilot project covering 5 % of the waste containers. The results of the survey on professional use showed that 60 % of growers declared that empty containers are rinsed and recycled. The actions taken in response of recommendation No4 of the previous audit (2012-6285) are in progress.
91. Both growers met by the audit team were aware of IPM good practices. The cotton grower used inter-row cultivations, crop rotation and resistant varieties, where feasible. Furthermore, the grower declared the use of reduced dosages, and products with

alternative modes of action to manage the development of resistance. Low drift nozzles were used where feasible and spraying took place late in the day when bees are not flying. In addition, bee keepers are informed before spraying takes place. The grower of protected crops declared that he used rotation, biological PPPs, pest trapping measures and soil solarisation in addition to chemical PPPs to control pests. Both growers used specialist advisors employed by PPP distributors. They claimed that they were using the early warning system in guiding decisions regarding PPP use. Finally, they stated as common practice the triple rinse and disposal of empty PPP containers.

92. A system for sprayer testing and certification is currently being developed by the MRDF. The system will be enforced by a series of private certification/testing stations, but these have yet to be approved. The CA believe that the estimated 40 000 sprayers in the country will all be tested by 26 November 2016 as required by Article 8 of Directive 2009/128/EC, although this target appears ambitious.

Conclusions on Integrated Pest Management

93. Compliance with IPM is a legal obligation and a monitoring system is operational in line with Article 14(4) of Directive 2009/128/EC.

94. Growers have sufficient information and tools available to guide them in the implementation of IPM as required by Article 14(2) of Directive 2009/128/EC.

95. There is no functioning system for sprayer testing so as to ensure that all pesticide application equipment in professional use can be inspected by 26 November 2016, as required by Articles 8(1) and 8(2) of Directive 2009/128/EC.

96. The system for recovery and disposal of pesticide remnants and their packaging by professional users and distributors is not effectively implemented.

5.4. ENFORCEMENT MEASURES

Legal Requirements

Article 72 of Regulation (EC) No 1107/2009 on penalties applicable to infringements of this Regulation

Article 17 of Directive 2009/128/EC on penalties applicable to infringements of the national provisions adopted pursuant to this Directive

Article 54 of Regulation (EC) No 882/2004 on action in the case of non-compliance

Article 55 of Regulation (EC) No 882/2004 on sanctions applicable to infringements of feed and food law

Findings

97. The national law 4036/2009 outlines the sanctions in case of infringement on the use and marketing of PPPs. Ministerial decisions have been issued to define the infringement process for different types of operators. The CNA has been designated as the responsible CA for the proposal of sanctions in case of infringements regarding PPPs and sustainable use which are ultimately signed by the Minister. When fines are not paid within one month, the Greek CA for taxes is informed and actions are taken to recover the fine amount. The legislation on infringements foresees a maximum of €30 000 fine and 1 year in prison for penal cases.
98. Reports on non-compliant cases referred for legal proceedings are required to be submitted by Regions to CNA to activate the sanction procedure.
99. The number of infringements detected at PPP retailers in 2014 was 129. Infringements by users of PPPs were detected mainly by the pesticide residue monitoring system, 186 cases of growers using non-authorised products on the crop or non-authorised products in Greece have been reported in 2014. The FVO audit team reviewed three cases for use of dieldrin, endosulfan and diazuron by small scale growers. In all the reviewed cases the fines were €1 000. The procedure from the detection of the non-compliance to the decision of the CA imposing the fine was two months in one case and up to nine months in the other two cases where the grower appealed the decision.
100. Customs detecting illegal introduction of PPPs may impose a minimum fine of €750 and several examples were reviewed during the audit including one fine of €1 900 due to higher amount of PPPs found.
101. Packers and re-packers are subject to specific intelligence-led controls. Several examples of infringements were reviewed during the audit comprising fines of €1 000 in cases of selling revoked PPPs or incorrect labels, €5 000 in case of PPP composition not matching with the authorisation, €10 000 in case of parallel import not being the same than the declaration to the CNA, and €25 000 in a case where PPP from another MS was brought to Greece without previous notification.

Conclusions on Enforcement Measures

102. The action taken by the CA to address non-compliances was considered to be appropriate and therefore in line with Article 54 of Regulation (EC) No 882/2004.

103. The maximum possible sanctions in the case of non-compliances linked are effective, proportionate and dissuasive as required by Article 55 of Regulation (EC) No 882/2004.

5.5. FOLLOW UP ON PREVIOUS AUDITS

Legal Requirements

Article 45(5)(a) of Regulation (EC) No 882/2004 on the follow-up action in the light of the recommendations from previous EU controls

Findings

104. Actions taken to address the recommendations of the previous related audit 2012-6285 were reviewed during the current audit.

Follow up of Recommendations for Audit 2012/6285		
No	**Recommendation**	**Finding(s)**
No 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.	Although efforts have been made in preparing training material and training session have taken place, the economic restrictions have compromised the on-going training plan. The recommendation **is in progress.** A more specific recommendation on the training of inspectors being a requirement for conducting official controls is made as a consequence of the shortcomings identified in the current audit. (See recommendation 1).
No 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.	The NAP for the sustainable use of plant protection products includes the requirement for all professional users of PPPs to be trained. At the time of the audit the CCA advised that 45,000 users had so far registered for this training or had already been trained. The recommendation has been **satisfactorily addressed**. (See paragraph 67, 88).
No 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.	No inspections of application equipment have taken place as of 14th September 2015 since no test centers have been officially designated yet. The actions planned in response to this recommendation are **in progress.** (See recommendation 7).
No 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	The response to an anonymous survey shows that 60% of the users declare triple rinsing. The actions planned in response to this recommendation are **in progress.** (See paragraphs 69, 90). (See recommendation No 8).
No 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.	Guidelines and other official documentation – checklists, inspection reports, questionnaires and forms have been issued by the CCA to the staff involved in the controls of PPPs. The audit team witnessed the use of this documentation in the field and has received copies of completed checklists and reports of finalised inspections. The recommendation has been **satisfactorily addressed.** (See paragraphs 26).

Follow up of Recommendations for Audit 2012/6285		
No	**Recommendation**	**Finding(s)**
No 6	Ensure that official controls of users of PPPs are carried out without prior warning, as laid down in Article 3(2) of Regulation (EC) No 882/2004.	The documented procedures state that controls are conducted without prior warning. The audit team received confirmation of this being the case from all DREVs visited and from growers and retailers that were visited for the audit. The recommendation has been **satisfactorily addressed.** (See paragraphs 44, 57, 67).
No 7	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	Article 8 of the National Law 4036/2012 lays down the obligation of operators to co-operate and supply any requested information during controls. The audit team witnessed such access being given during inspections at growers and retailers. The recommendation has been **satisfactorily addressed.** (See paragraph 28).
No 8	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.	This recommendation falls out of the scope of this audit. The actions planned in response to this recommendation are **in progress.** However, the number of analytes being tested (that can be analysed with appropriate equipment) at 8 of the 10 designated laboratories remains a matter of concern. The continued designation of laboratories that do not provide full, adequate analysis should be further addressed.
No 9	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	The recommendation has been **satisfactorily addressed** with regard to retailers of PPPs. However there remain **inadequate controls** on manufacturers and packers of PPPs, and users of PPPs. (See recommendations 2).
No 10	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	The CCA has issued documented procedures, circulars, guidelines, control forms, checklists and standardized inspection reports to all staff involved in the controls of PPPs. The recommendation has been **satisfactorily addressed**. (See paragraph 26).
No 11	Ensure effective co-operation between the authorities performing controls on pesticide use, as required by Article 4(3) of Regulation (EC) No 882/2004	The audit team observed effective co-operation between the CCA and the regional authorities (DREVs) conducting the PPP controls. Excellent co-operation with customs was observed during the assessment. The recommendation has been **satisfactorily addressed.** Only general information has been provided to DPPPB regarding the controls conducted by OPEKEPE which does not detail PPP or IPM related issues. Despite the desirable synergy between both CAs, the CNA does not consider the controls conducted by OPEKEPE as official controls to enforce compliance with Regulation (EC) No 1107/2009 or with Directive 2009/128/EC.
No 12	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	This recommendation falls out of the scope of this audit. However, an update on the situation was provided by the CA and no implementation of the planned internal audit system yet. The audits will include internal audit of the DREVs and inspections and controls carried out. The actions planned in response to this recommendation are **in progress.**

Follow up of Recommendations for Audit 2012/6285		
No	**Recommendation**	**Finding(s)**
No 13	Carry out internal audits or have external audits carried out, as required by Article 4(6) of Regulation (EC) No 882/2004	This recommendation falls out of the scope of this audit. However, an update on the situation was provided by the CA. Timetable of audits set to begin in 2015 and to be completed at all CAs in 5 years' time. The actions planned in response to this recommendation are **in progress.**

6. OVERALL CONCLUSION

There is a system of controls on the use of Plant Protection Products (PPPs). However, there is a lack of information, and hence controls, on users not claiming funds under the basic payment scheme. The risk assessment for the prioritization of controls does not take into account all the different users of PPPs and the frequency for controls has not been established based on risk. These weaknesses reduce the effectiveness of the controls. In addition, the majority of staff are not adequately trained in PPP-specific issues and therefore, controls conducted on growers are not effective to verify that only authorised PPPs are used in accordance with their conditions of authorisation.

There are regular, risk-based official controls on retailers of PPPs. The control of labels and revoked PPPs at this level are not effective. The absence of risk based routine inspections on manufacturers, packers and re-packers of PPPs for product destined for the national market also compromises the effectiveness of the control system to ensure that authorised PPPs for marketing in Greece comply with their conditions of authorisation.

Although there are weaknesses in controls for product destined for the domestic market, there are comprehensive controls on the manufacture and re-packing of PPPs intended for use in other Member States or Third Countries. These controls are enhanced by the excellent co-operation with relevant Competent Authorities (CAs) and there is an effective system in the fight against illegal PPPs.

Growers have sufficient information and tools available to guide them in the implementation of Integrated Pest Management (IPM) and the CA has a pest monitoring system in place. However, there is no functioning system for sprayer testing so as to ensure that all pesticide application equipment in professional use can be inspected before the EU legal deadline on 14 December 2016. The systems for pest monitoring and controls on IPM provide assurances on the safe use of PPPs.

7. GOOD PRACTICES

A number of good practices were noted in the course of this audit. These included:

- The system of notification and restricting re-packing of parallel trade license for PPPs provides assurances that these products comply with their conditions of marketing. (Paragraph 24, 49)
- Comprehensive controls are in place on the manufacture and re-packing of PPPs intended for use in another Member State (MS) or Third Country (TC) as required by EU legislation. These systems could be identified as good practice in the fight against illegal PPPs. (Paragraph 24, 42)
- Co-ordination and co-operation with customs is excellent, which contributes greatly to the efficiency and effectiveness controls. (Paragraph 30, 32)
- There is an electronic recording system in place for PPP retailers allowing the CA access to accurate information on the trade and marketing of PPPs in the country. (Paragraph 43)
- Pest and disease monitoring and early warning system providing valuable tools to growers for a sustainable use of PPPs. (Paragraph 87)

8. CLOSING MEETING

A closing meeting was held on 22 September 2015 with representatives of DGSPP, DSCCO, and OPEKEPE. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit.

9. 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:

No.	Recommendation
1.	Ensure that inspectors performing official controls on the use of PPPs, receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner as required by Article 6 of Regulation (EC) No 882/2004. *Conclusions upon which this recommendation is based: 33, 81* *Associated findings upon which this recommendation is based: 11, 57, 68*
2.	Ensure the planning of controls is reviewed, taking into account risks specifically those relating to manufacturers, packers and re-packers of professional use PPPs, seed treatment plants and PPP users so as to ensure that official controls are carried out in line with an appropriate pre-determined frequency as required by Article 3 of Regulation (EC) No 882/2004. *Conclusions upon which this recommendation is based: 34, 35, 39, 80* *Associated findings upon which this recommendation is based: 14, 17, 18, 23, 64*
3.	Ensure that the system of controls is revised so that controls on end users examine if PPPs are used in accordance with the conditions of authorisation, as required by Article 55, Paragraph 1, of Regulation (EC) No 1107/2009. *Conclusions upon which this recommendation is based: 81* *Associated findings upon which this recommendation is based: 70, 72*
4.	Ensure that the official product register of PPP is enhanced to provide a solid foundation for the programme of controls by: Ensuring that the authorisation number changes when authorisations are amended or to implement other measures to facilitate controls under Article 46 of Regulation (EC) No 1107/2009. *Conclusions upon which this recommendation is based: 60, 61, 82* *Associated findings upon which this recommendation is based: 41, 46, 56, 71* Considering approval of artwork labels in line with Articles 31(4) of Regulation (EC) No 1107/2009 to facilitate more effective controls on PPPs placed on the market. *Conclusions upon which this recommendation is based: 62* *Associated findings upon which this recommendation is based: 40*

No.	Recommendation
5.	Ensure that the programme of official controls on formulation analysis is risk based to provide assurances that PPPs placed on the market comply with their conditions of authorisation/parallel trade permit, and as laid down in Articles 29(1) and 52 of Regulation (EC) No 1107/2009. *Conclusions upon which this recommendation is based: 37* *Associated findings upon which this recommendation is based: 25*
6.	Ensure that only laboratories that are accredited in accordance with the EN ISO/IEC 17025 for the scope of formulation analysis are used for the relevant official controls as required by Article 12 of Regulation (EC) 882/2004. *Conclusions upon which this recommendation is based: 63* *Associated findings upon which this recommendation is based: 47, 48*
7.	Ensure that the programme for testing pesticide application equipment is in place to achieve that equipment has been inspected at least once by 14 December 2016 as required by Article 8 of Directive 2009/128/EC *Conclusions upon which this recommendation is based: 95* *Associated findings upon which this recommendation is based: 92*
8.	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 *Conclusions upon which this recommendation is based: 96* *Associated findings upon which this recommendation is based: 90*

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=2015-7475

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Horizontal Legislation		
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
Legislation on Plan 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
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

Reg. 485/2013	OJ L 139, 25.5.2013, p. 12-26	Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances
Reg. 781/2013	OJ L 219, 15.8.2013, p. 22-25	Commission Implementing Regulation (EU) No 781/2013 of 14 August 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance
Reg. 1272/2008	OJ L 353, 31.12.2008, p. 1-1355	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
Dir. 1999/45/EC	OJ L 200, 30.7.1999, p. 1-68	Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations