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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SLOVENIA

FROM 08 TO 12 OCTOBER 2012

IN ORDER TO EVALUATE CONTROLS OF PESTICIDES

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Slovenia, carried out between 08 and 12 October 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.

Slovenia already implemented the large majority of the requirements of Directive 2009/128/EC on the sustainable use of pesticides, which provides for adequate training and controls of growers and distributors of Plant Protection Products (PPPs). The Competent Authority is well organised and staff are well trained. A good system is in place for authorisation of PPPs and detailed information on PPPs is available on the internet. Guidelines for Integrated Pest Management (IPM) are available and IPM is promoted.

Weaknesses were found in meeting the deadlines for re-authorisation of PPPs, in the coordination of controls on use of PPPs between the CAs and the quality controls of PPPs.

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

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation	
AIS	Agricultural Institute of Slovenia	
CA(s)	Competent Authority(ies)	
CCA(s)	Central Competent Authority(ies)	
DG (SANCO)	Health and Consumers Directorate-General	
EU	European Union	
FBO(s)	Food Business Operator(s)	
FVO	Food and Veterinary Office	
IPM	Integrated Pest Management	
IRSAFFE	Inspectorate of the Republic of Slovenia for Agriculture, Forestry, Food and the Environment	
MAE	Ministry of Agriculture and the Environment	
MRL(s)	Maximum Residue Level(s)	
MS(s)	Member State(s)	
PARS	Phytosanitary Administration of the Republic of Slovenia	
PPP(s)	Plant Protection Product(s)	

1 Introduction

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

The audit took place from 08 to 12 October 2012 The team comprised 2 auditors from the FVO and one expert from a European Union (EU) Member State (MS).

Representatives from the Central Competent Authority (CCA), the Inspectorate of the Republic of Slovenia for Agriculture, Forestry, Food and the Environment (IRSAFFE), accompanied the FVO team for the duration of the audit. An opening meeting was held on 08 October 2012 with representatives of the Ministry of Agriculture and the Environment (MAE), IRSAFFE, the Phytosanitary Administration of the Republic of Slovenia (PARS) and the laboratory of the Agricultural Institute of Slovenia (AIS). 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 requirements for official controls of the use of PPPs at growers under Regulation (EC) No 882/2004;

In terms of **scope**, the audit assessed the performance of CAs, as well as the organisation of the controls including the authorisation procedures, controls of the wholesalers and retailers of PPPs, and controls of the growers.

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

Table 1: Mission visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	1	MAE, PARS.
Regional	2	Regional units of the IRSAFFE in Ljubljana and Nova Gorica.
Laboratories		
Public	1	Laboratory of the AIS.

On-Site-Visits		
Controls of growers	2	A grower in Ljubljana and one in Miren.
Controls of wholesalers and retailers	2	A wholesaler of PPPs in Ljubljana and a retailer of PPPs in Vipava.

3 LEGAL BASIS AND STANDARDS

3.1 LEGAL BASIS

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

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

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

3.2 STANDARDS

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

4 BACKGROUND

4.1 AUDIT SERIES

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

http://ec.europa.eu/food/fvo/specialreports/index_en.htm

During the previous audit series FVO teams identified that control systems vary considerably between MSs. The control system for pesticide residues was better developed than the control system for placing on the market and use of PPPs. However, deficiencies in the planning and conducting of inspections for control on the marketing and use of PPPs were frequently identified. The operation of formulation laboratories to test PPPs was generally considered to be satisfactory.

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

The CAs of the MSs subject to audits 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.

The FVO carried out an audit on the controls of pesticides in Slovenia in 2005. The report DG (SANCO)/7668/2005 of this audit can be found at http://ec.europa.eu/food/fvo/ir_search_en.cfm The overall conclusion of the audit report was that the control system for pesticide residues had improved significantly but further improvement was necessary. The control system for marketing and use of PPPs needed to be strengthened particularly in the areas of training, planning and numbers of controls at both marketing and users levels.

4.2 Country Profile

The FVO has published a country profile for Slovenia 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 is implemented by the Regulation implementing Regulation (EC) concerning the placing of plant protection products on the market (Official Gazette of the Republic of Slovenia, No 86/2011).

The Act on Plant Protection Products (Official Gazette of the Republic of Slovenia, No 35/2007-consolidated version) contains the main points of Directive 2009/128/EC. The new Act on Plant Protection Products is in the process of adoption in the Parliament which is foreseen at the end of 2012. The CA stated that this Act fully transposes Directive 2009/128/EC.

Controls on marketing and use are regulated by the Decree on the implementation of certain Regulations (EC) concerning official control and obligations of food business operators in primary production of foodstuffs and feed (Official Gazette of Republic of Slovenia, No 120/2005)

The most important parts of the secondary legislation regarding the placing on the market of PPPs are the rules concerning the conditions to be met by natural and legal persons for placing plant protection products on the market (Official Gazette of RS, No. 68/2002, 73/2005), the rules concerning the entries into and removals from the register of natural and legal persons for trading in plant protection products (Official Gazette of RS, No. 58/2001, 64/2005, 66/2007), and rules on the

designation of border crossing points for marketing plant protection products and inspection procedures for their import (Official Gazette of RS, No. 68/2002, 73/2005).

Secondary legislation regarding the use of PPPs contains rules concerning the conditions and procedures to be met and followed by supervisory bodies authorized to carry out regular examinations of application techniques for plant protection products (Official Gazette of RS, No. 12/2000, 18/2002, 97/2005) and rules on the responsibilities of users of plant protection products (Official Gazette of RS, No. 62/2003, 5/2007, 30/2009).

The legislation is available on the internet.

Conclusions

Most elements of Directive 2009/128/EC had already been part of the Slovenian legislation before the existence of this Directive. The full transposition is expected in the near future. Requirements regarding marketing and use of PPPs are implemented in secondary legislation.

5.2 Organisation and Implementation of Official Controls

5.2.1 Designation of Competent Authorities

Legal Requirements

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

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

Findings

In May 2012 a reorganisation between two ministries took place. The Ministry of Agriculture, Forestry and Food took over the responsibility for the environment dossier from the Ministry of Environment and Spatial Planning. Within the MAE PARS is the CA for the authorisation of PPPs. The Inspectorate for agriculture, forestry and food is the IRSAFFE from May 2012. The IRSAFFE is the CA for official controls on the marketing and use of PPP's, and because of the transfer of environment also for controls on obsolete PPPs. The inspectorate comprises eight regional units and their local branches.

More details are available in the country profile of Slovenia.

Conclusions

The CAs are adequately designated.

5.2.2 Resources for Performance Controls

Legal Requirements

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

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

Findings

Four staff of PARS are involved in authorisations of PPPs and two staff are involved in training and inspection of equipment. The assessment of PPPs is performed by 11 appointed assessors.

The IRSAFFE is the CA for official controls on the use of PPP's with 1 senior inspector at head quarters and 34 local inspectors of AIS at regional/local level.

Staff for marketing controls: 1 senior inspector at head quarters of the IRSAFFE and 7 local inspectors of the Agricultural Inspection Service at the regional/local level.

To ensure that personnel are qualified, the PPP Act determines that inspectors have to have adequate education and at least 4 years work experience. Staff are regularly trained. A training programme was presented to the FVO team. The head of the Agricultural Inspection Service carries out personal interviews with the inspectors and regularly joins inspections for supervision.

An inter-regional Working Group on control of marketing and use of PPPs meets 3-4 times per year to discuss the annual working programme, the changes in legislation and other relevant issues. This working group also developed manuals for controls to standardise the work of the inspectors in control of marketing and use of PPPs.

Conclusions

Suitably qualified and experienced staff were available; Staff have received appropriate training.

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

There were a total of 347 PPPs authorised in August 2012, containing 206 active substances. The assessment of PPPs is co-ordinated by the Phytosanitary Administration, and performed by

appointed assessors in the Slovenian Institute for Hop Research and Brewing, the Agricultural Institute of Slovenia, the Institute for Public Health of the Republic of Slovenia and the Agricultural Institute Nova Gorica. All data and evaluation reports are entered in an on-line database, containing comprehensive and transparent information about the authorisation process. The CA prepares a proposal on possible authorisation for an opinion of the PPP Commission, who meets monthly. The CA adopts a decision on authorisation, based on the opinion of the Commission, and on consent of the Ministry of Health.

The audit team checked two files for re-authorisations of PPPs containing the active substances mancozeb and dimethoate, respectively. The authorisations were granted on 4 and 13 September 2012. The deadline for re-authorisation of PPPs containing mancozeb stipulated in Commission Directive 2005/72/EC, Article 3, was 30 June 2010 and for PPPs containing dimethoate it was 30 September 2011, as stipulated in Commission Directive 2007/25/EC, Article 3. The CA stated that the Implementing Decree 86/2011 has abolished the PPP Commission, which is expected to speed up the authorisation procedure. The Decree will apply once the draft Act on Plant Protection Products will be adopted. The audit team made a spot check and found that authorised labels comply with Regulation (EC) No 547/2011.

An electronic register with details of the authorisations is publicly available on the internet and updated on a daily basis.

There were 49 authorisations of PPPs granted under mutual recognition as provided by Directive 91/414/EEC. Under Regulation (EC) No 1107/2009, twelve applications have been received. One of these applications has been approved, and the remainder are under evaluation.

A total of four emergency authorisations have been granted in 2012 for PPPs containing active substances, which are included in Regulation (EC) No 540/2011. The authorisations are limited to four months, and the requirements for use are clearly defined - there are special risk mitigation measures, the use is allowed in risk areas only, and there are special requirements for recording the use.

Permits for extension of use can be granted. These permits are published on the internet and available for all users.

Conclusions

The authorisation process complied with the provisions of Directive 91/414/EEC and Regulation (EC) No 1107/2009, except for the deadlines to amend authorisations after inclusion of active substances in Annex I to Directive 91/414/EEC.

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 PPPs shall keep records for at least 5 years.

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

Article 13 of Directive 2009/128/EC requires MSs to adopt the necessary 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

One wholesaler was visited in the Region of Ljubljana. The inspector had prepared herself prior to inspection which included checking the reports from her last inspection at this company in 2007; checking the training certificate of the responsible person and also whether the data in the register concerning the company were still valid.

At the on-the-spot inspection, the audit team noted that the inspector verified the registration and the training certificate of the responsible person. She also checked the records and whether the amount of traded PPPs in 2011 was notified to PARS within the deadline; the storage conditions of the PPPs were also checked.

In the region of Nova Gorica a PPP retailer was inspected. The inspector had prepared herself, prior to the inspection, by checking the registration of the establishment and the training of the staff in the databases. These were verified on the spot. She also checked the results of previous inspections. The last inspection took place on 12/04/2011. A non-compliance from this inspection was that the container for empty packages was too small. This non-compliance was rectified. The storage of PPPs with expired authorisations was checked. Authorisation and labels were checked for two PPPs. The retailer had submitted a list with the yearly turnover of pesticides to the CA as required. No non-compliances were found.

The audit team visited a laboratory of the AIS. In 2010 and 2011, 11 formulation samples were analysed for content of active substances only. No further parameters were analysed.

Customs are checking imports of PPPs together with the phytosanitary inspection service for compliance. As a result of a tip-off from a distributor, the IRSAFFE identified an illegal PPP based on formulation analysis. This PPP was taken from the market.

Marketing controls cover wholesalers and retailers, but not manufacturers of PPPs.

Conclusions

Controls on marketing are carried out as required. Training and certification of PPP distributors is in place. The distributors visited kept records and the handling and storage of PPPs, packages and remnants was in line with the requirements. Quality control of PPPs takes place, however only the content of active substances is checked. Controls are carried out for illegal pesticides.

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 (IPM), 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 IPM on a voluntary basis.

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

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

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

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

Article 13 of Directive 2009/128/EC requires MSs to adopt the necessary 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

Provisions for training and certification of professional users and distributors of PPPs, testing and certification of spraying equipment, record keeping of PPP uses, the storage of pesticides, treatment of their packaging and remnants and Integrated Pest Management (IPM) have already been included in the Act on Plant Protection Products and are implemented.

A total of 16 bodies have been designated for training of professional users, advisors and distributors. The designated bodies are local units of the Chambers for Agriculture and Forestry, secondary schools for agriculture and the two Agricultural Universities. A total of 65 000 persons have been trained and certified, and their details are included in an on-line database. Requirements for training vary between 15 hours for professional users and 60 hours for advisors, and have to be renewed after 3 to 5 years, respectively.

Records of PPP uses were kept by the growers visited by the audit team. For the testing of spraying equipment, nine bodies have been designated, i.e. secondary agricultural schools and universities. A total of 22 000 pieces of equipment have been tested and certified. Four technological instructions for Integrated Pest Management on Vegetables, Fruit, Arable Crops and Vienyards were available and used by growers and inspectors for reference.

Pesticide remnants and empty packaging of pesticides are collected through distributors, traders, collection centres and mobile collection points and temporarily stored and disposed of by an authorised private company. In 2011, a total of 328 tonnes of pesticides waste was collected, and 122 tonnes were safely disposed. The remainder was temporarily stored.

In addition, in 2011 the IRSAFFE has taken 65 samples of agricultural products before harvest and/or marketing, and analysed them for pesticide residues. The results were checked for unauthorised uses of PPPs.

The audit team observed two inspections of growers by inspectors of the IRSAFFE. The inspectors checked records of the farmers on the use of PPPs, the certificates for training, spraying equipment and certificates of the private certification bodies for IPM. The certificates of the spraying equipment were verified by checking the certification labels on the equipment. The records of use were verified in one region by checking the invoices of the growers. The inspectors used the respective IPM manuals to verify whether the recorded uses were authorised, but in one case the IPM manual was out of date. The inspectors also checked the storage conditions for PPPs and recorded the products on stock. The inspectors did not have access to approved labels of authorised PPPs to identify any counterfeit labels. In 2011 a total of 1 082 inspections were made out of a total of 43 000 growers who had identity codes for agricultural holdings.

Conclusions

Records are kept by end users of PPPs as required by Article 67(1) of Regulation (EC) No 1107/2009, Article 4(1) of Regulation 852/2004, and Annex I, Part A.III of the same Regulation. Controls on the use of PPPs take place as laid down in Article 68 of Regulation (EC) No 1107/2009.

Adequate measures have been taken to address the requirements regarding IPM Guidelines, training and certification of PPP users, inspections on the application equipment, handling and storage of PPPs and treatment of packages and remnants of PPPs as laid down in the legislation listed above.

5.2.6 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 FBOs past record as regards compliance; (c) the reliability of any own-checks that have already been carried out; and (d) any information that might indicate non-compliance.

Findings

Retailers and distributor/repackaging facilities are inspected once a year. When irregularities are found, official controls are repeated. Inspection frequency for PPP users is based on information regarding type, extent and variability of production, irregularities from the past, Maximum Residue Level (MRL) exceedances, tip-offs, agricultural land on vulnerable areas, higher possibility to pollute the environment, emergency authorisations and mutual recognition of authorisations, IPM and organic farming. Own checks of FBOs and other official controls, for example cross-compliance, are not taken into account. Between 2 and 3 % of the users are controlled every year.

Conclusions

Controls are risk-based and carried out with appropriate frequency. However, results of other checks, in particular cross-compliance checks, are not sufficiently taken into account in the planning of controls.

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

Findings

Inspectors use documented procedures and check-lists to carry out controls in marketing and use of PPPs. These documents contain instructions for the performance of controls as well as legal information. A report is drawn up for every inspection containing the results and actions to be taken, including deadlines for these actions. The company controlled receives a copy of the report. In the two regions visited the inspectors used the same procedures and check lists.

The CA stated that a report regarding the controls of 2011 was sent to the Commission in July 2012, as required by Article 68 of Regulation (EC) No 1107/2009.

Conclusions

The procedures for performance and reporting of control activities comply with the legal requirements.

5.2.8 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

An agreement was concluded between the IRSAFFE and the Agricultural Market Agency, the designated body for cross-compliance checks. The Agency is informed of all non-compliances

resulting in fines to growers, and consequently corresponding reductions are made to their subsidies. However, the IRSAFFE receives no information about controls carried out by the Agency.

Infringements with MRLs are notified by the CAs to the IRSAFFE, and the audit team saw evidence of related follow-up at growers. The online IT system within the IRSAFFE allows for coordination of controls, and inspectors have access to data of operators and inspection reports. However, as inspectors have only access to their personal inspection reports, they are not always aware of inspections in their area of responsibility, but which are carried out by colleagues.

There was insufficient co-operation regarding the development of IPM manuals and the required records to be kept by growers. Inspectors warned both growers visited to include the vegetation stage and the time of treatment during the day in their PPP records. These are legal requirements in Slovenia, but the growers had not been aware and such information was not required in the forms for record keeping provided by the IPM certification bodies. In a previous inspection of one of the growers, an unauthorised PPP use had been detected and the grower was fined, but the related recommendation in the relevant IPM manual was not clear. The IPM manuals are developed by the MAE using some proposals from the Phytosanitary Administration.

Conclusions

There were examples for co-operation and co-ordination between and and within CAs, but the provisions for IPM were not sufficiently co-ordinated to reflect the legal requirements. There is insufficient co-ordination between the Agriculture Market Agency and the IRSAFFE regarding controls of growers. The restricted access for inspectors to inspection files limits follow-up actions.

5.2.9 Enforcement Measures

Legal Requirements

Article 72 of Regulation (EC) No 1107/2009 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

Under the Inspection Act the inspector can issue a decision as an administrative act to rectify a non-compliance within a given deadline; can start a procedure according to the Minor Offence Act or the Criminal Act; can propose that the competent authority undertakes legal actions in case of non compliances found on-the-spot. Under the Minor Offence Act, fines can be between 200 Euro for a natural person to 20 000 Euro for a legal entity. Under the criminal act the penalties can be up to imprisonment.

In case of a non-compliant sample, the FBO has to pay for the analysis.

Conclusions

Effective, proportionate and dissuasive enforcement measures are in place.

5.2.10 Verification Procedures and Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 CAs 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

Internal audits are carried out within the IRSAFFE by the Internal Audit Commission. The 2010 audit has also included the work of the pesticide inspector of the region of Ljubljana met by the audit team. A plan for 2012 audits is in place.

Verification procedures are in place including supervision of activities in accordance with instructions and procedures. Superiors perform annual interviews of staff and an internal notice board has been created where inspectors can post their decisions.

Conclusions

Audits are carried out and procedures for supervision are in place.

6 Overall Conclusion

Slovenia already implemented the large majority of the requirements of Directive 2009/128/EC on the sustainable use of pesticides, which provides for adequate training and controls of growers and distributors of PPPs. The CA is well organised and staff are well trained. A good system is in place for authorisation of PPPs and detailed information on PPPs is available on the internet. Guidelines for IPM are available and IPM is promoted.

Weaknesses were found in meeting the deadlines for re-authorisation of PPPs, in the co-ordination of controls on use of PPPs between the CAs and the quality controls of PPPs.

7 CLOSING MEETING

A closing meeting was held on 12 October 2012 with representatives of the CA. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit. The CA made some comments and provided clarifications to the FVO team.

8 RECOMMENDATIONS

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

N°.	Recommendation
1.	Ensure that deadlines for re-authorisations of Plant Protection Products are respected as required by the Commission Directives including the respective active substances into Annex I of Directive 91/414/EEC.
2.	Ensure that official controls on the marketing of Plant Protection Products comply with Regulation (EC) No 1107/2009. In this regard, the Competent Authority should, not withstanding other factors, extend the scope of formulation analyses in order to increase their effectiveness.
3.	Ensure an efficient and effective co-ordination within and between Competent Authorities as required by Articles 4(3) and 4(5) of Regulation (EC) No 882/2004, regarding the provisions for Integrated Pest Management and regarding controls on the use of Plant Protection Products in combination with cross-compliance.

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=2012-6295

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Horizontal Legislati	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
Legislation on Plant	t 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
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

Legal Reference	Official Journal	Title
Dir. 91/414/EEC	OJ L 230, 19.8.1991, p. 1-32	Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market
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