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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

POLAND

FROM 28 MAY TO 05 JUNE 2013

IN ORDER TO EVALUATE CONTROLS OF PESTICIDES

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Poland, carried out between 28 May to 5 June 2013, under the provisions of Regulation (EC) No 882/2004 on official food and feed controls and Regulation (EC) No 1107/2009.

The objective of the audit was to evaluate the controls on pesticides.

An adequate and effective control system is in place for the marketing and use of Plant Protection Products (PPPs). It is based on centrally coordinated control plans, documented procedures, communication between authorities, training of staff and proportionate enforcement measures. There are controls to identify illegal or counterfeit pesticides, supported by an effective programme of PPP formulation testing.

National legislation for the transposition of Directive 2009/128/EC on sustainable use of pesticides is in place and implementing measures have been taken regarding the training of professional users of PPPs and technical checks of pesticide application equipment. Adequate provisions are allowed for in national legislation to facilitate full implementation of future measures contained in the Directive (e.g. integrated pest management) in a timely manner.

The system for the authorisation of PPPs is transparent and well developed, however, it is weakened somewhat by significant delays.

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
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CIPAC	Collaborative International Pesticides Analytical Council
CODEX	Codex Alimentarius Commission of the Food and Agriculture Organisation of the United Nations and World Health Organisation
DG (SANCO)	Health and Consumers Directorate-General
EU	European Union
FTE	full time equivalent
FVO	Food and Veterinary Office
GC	Gas Chromatograph
GC-MS	Gas Chromatograph coupled to Mass Spectrometer
GC-ECD	Gas Chromatograph coupled to Electron Capture Detector
GC-FID	Gas Chromatograph coupled to Flame Ionization Detector
GC-FPD	Gas Chromatograph coupled to Flame Photometric Detector
GC-MS/MS	Gas Chromatograph coupled to Tandem Mass Spectrometer
GC-NPD	Gas Chromatograph coupled to Nitrogen Phosphorus Detector
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatograph coupled to Tandem Mass Spectrometer

LOQ	Limit of Quantification
MARD	Ministry of Agriculture and Rural Development
MRL	Maximum Residue Level
MS(s)	Member State(s)
NIR	near-infrared
NRL	National Reference Laboratory
PHI	Pre-Harvest Interval
PPP(s)	Plant Protection Product(s)
PT	Proficiency Test
RASFF	Rapid Alert System for Food and Feed
RR	Rapid Resolution
SSI	State Sanitary Inspectorate
SPHSIS	State Plant Health and Seeds Inspection Service
TLC	Thin Layer Chromatography
VSPHSIS	Voivodship State Plant Health and Seeds Inspection Service

1 Introduction

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

The audit took place from 28 May to 05 June 2013. The team comprised two auditors from the FVO and one expert from a European Union (EU) Member State (MS).

Representatives from the central competent authority (CCA) accompanied the FVO team for the duration of the audit. An opening meeting was held on 28 May 2013 with the Competent Authorities (CAs). 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 on the use of PPPs 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	MARD and SPHSIS
Regional	1	VSPHSIS in Krakow and Radom
Laboratories		
Public	1	Laboratory of formulation analysis of PPPs in Sośnicowice
On-Site-Visits		

Controls of growers	2	Visits to a vegetable grower in Małopolska region and a fruit grower in Radom district of Mazowieckie region
Controls of wholesalers and retailers of PPPs	2	Visits to a wholesaler in Małopolska region and a retailer in Radom district of Mazowieckie region

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 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 MS subject to audit outlined in action plans how the recommendations would be addressed. These action plans are also published on the DG(SANCO) internet site together with the reports.

In the framework of the last series, the FVO carried out a audit to Poland in 2010. The report 2010-

8593 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 comprehensive systems are in place for the control of the use of PPPs and for the control of pesticide residues in domestic and imported produce. Deficiencies were identified regarding the control programme for pesticide residues, sampling and the analytical scope (number of pesticides sought) of official laboratories.

4.2 Country Profile

The FVO has published a country profile for Poland, which describes in summary the control systems for food and feed, animal health, animal welfare and plant health and gives an overview of 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

Law of 8 March 2013 on Plant Protection Products implements that Regulation (EC) No 1107/2009. A number of orders of the Chief Inspector of the State Plant Health and Seeds Inspection Service (SPHSIS) provide for further implementing measures regarding controls on marketing and use of PPPs.

Directive 2009/128/EC is transposed primarily by the Act of 8 March 2013 on Plant Protection Products. A number of regulations of the Ministry of Agriculture and Rural Development (MARD) have been put in place to ensure implementation.

Conclusions

As far as the audit team could ascertain, adequate legislation to enforce controls within the scope of the audit is in place.

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

There has been a slight change to the country profile: the Research Institute of Horticulture in Skierniewice and a private company have been empowered to evaluate dossiers for authorisation of PPPs.

In addition, the SPHSIS currently has 261 field unit.

Conclusions

The CAs are designated and tasks are clearly allocated.

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

There are 10 full time equivalents (FTEs) at the MARD directly involved in the coordination of PPP authorisation and active substance review. A further 151 FTEs (affiliated to governmental and non-governmental institutes and private contractors) are available for evaluation work.

For official control of marketing and use, there are five staff at the Main Inspectorate of SPHSIS and 513 staff at Voivodship State Plant Health and Seeds Inspection Service (VSPHSIS).

The laboratory has adequate facilities, recent equipment and 10 staff.

Most staff performing official controls of PPPs have third level education and are civil servants. New staff have to complete the so called state inspector exam. After the exam, a certificate is issued which is valid for five years. For renewal, staff attend further training every five years where a test needs to be completed in the specific field of responsibility. In addition, civil servants are subject to periodic appraisal every two years.

Staff met by the audit team are adequately trained to perform their job. Inspectors had a service car, laptop and necessary tools for their controls.

Conclusions

Suitably qualified and experienced staff are available. An appropriate training system is in place. The necessary equipment for controls are present.

5.2.3 Authorisation of Plant Protection Products

Legal Requirements

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

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

Findings

The MARD is responsible for the administration of the system for the evaluation and authorisation of PPPs and, when required, the evaluation and review of active substances. Before authorisations are finally issued, they are referred to the “Commission for Plant Protection Products” (advisory body to the MARD).

On the 1 of June 2013, there were 1 141 PPPs authorised, containing 251 active substances.

An electronic register of authorised PPPs is available on the website of MARD. The CA stated that it is updated whenever changes are made:

http://www.minrol.gov.pl/pol/Informacje-branzowe/Wyszukiwarka-srodkow-ochrony-roslin

The active substances are all included in the annex to Commission Implementing Regulation (EC) No 540/2011. Only 13 products were identified as being for amateur use and 252 products were identified as being for use by professional users.

A system is in place allowing for adherence to the requirements set out in Commission implementing regulations following the approval of active substances ("step 1 and step 2"). This is true for both active substances approved under Regulation (EC) No 1107/2009 and active substances historically approved under Directive 91/414/EEC. This system is effective and makes good use of work completed by CAs in other MSs (data matching checks).

The audit team evaluated a randomly chosen authorisation file for a PPP containing epoxiconazole. Commission Directive 2008/107/EC required the evaluation and re-authorisation of this product by the 30 April 2013. This product had successfully completed the "step 1" process on the 29 October 2009 (data matching check completed by another MS). In agreement with the applicant concerned, a dossier was received and deemed complete (after requests for some additional information or letter of access to other registrants' files) some 16 months before the re-registration deadline. The evaluation of this dossier commenced in December 2011 and was completed in March 2012. The registration number of the authorisation was not amended as the original evaluation (conducted in 2008) was found to be still valid and no changes were required to approval conditions. The evaluations conducted were in the prescribed formats and were in accordance with the "uniform principles". However, the authorisation for this product had not been issued at the time of the audit.

Between 14 of June 2012 and 1 May 2013, 107 applications were received, requesting the MARD to mutually recognise authorisations issued in other MSs (Article 40, Regulation (EC) No 1107/2009). To date, 21 such requests have resulted in Polish authorisations, three such requests have been refused (procedural and formal reasons) and 83 requests remain under consideration.

Two applications granted under Article 40 of Regulation (EC) No 1107/2009, were examined by the audit team. One application requested the mutual recognition of a German authorisation and was in the system for 18 months. The other example was an application for the mutual recognition of a Dutch authorisation and was in the system for 19 months. In both instances there were undue delays by both the applicants and MARD and both files were deemed to be deficient in environmental information appropriate to specific Polish conditions. The audit team noted that MARD could have considered refusal of these applications and required the applicants to reapply. It is also noted that where additional country specific information is submitted, the evaluation of such information is completed quite quickly, however there appear to be periods of time where little progress is made with the applications.

In 2012, there were five applications approved for emergency authorisation under Article 53 of Regulation (EC) No 1107/2009. In 2013, there were 12 applications approved for emergency authorisation under the same provisions. An overview of these applications was carried out by the audit team and while at first it appeared that in some instances the same PPP, crop and target pest were the subject of application, MARD explained that the applicant and the location were different. The information on such authorisations are disseminated via the MARD website/database. It should be noted that where emergency use authorisations were granted, authorisations for those products already existed for other uses, therefore comprehensive risk assessments were available. Polish law requires significant information to accompany the application.

With regard to Article 65 of Regulation (EC) No 1107/2009, several PPP labels (6) were examined by the audit team during the course of a wholesale inspection and these were compared to the approved labels on the MARD website/database. The classification present on each of these product labels was also checked against the classification contained on the MARD website/database. The labels of the above mentioned PPPs were checked by the audit team for compliance with both the provisions of Commission Regulation (EC) No 547/2011 and Commission Directive 1999/45/EC. No anomalies were identified.

An examination of the register of applications was carried out. This register contains a record of all applications to MARD, for either authorisation of a PPP (national authorisation, zonal authorisation or mutual recognition) or an amendment of the approval conditions of an existing authorisation. The records indicate that MARD operate a totally transparent system and ensure that authorisations and amendments are finalised and issued in accordance with the time of application. However, it is apparent that the time lines prescribed in Regulation (EC) No 1107/2009 for the processing of certain applications, are not adhered to.

A number of applications for "new" authorisations in Poland were received after the entry into force of Regulation (EC) No 1107/2009. At least 10 of these applications were already 18 months old, with no conclusion reached. An example of such an application was a product containing fluazinam, where application was made in September 2011, but no authorisation had issued at the time of the audit.

A further number of applications had been received by MARD in the context of authorisation by "zonal" approval. An example of one such case was a product containing glyphosate which was approved by Germany as the Zonal Rapporteur MS, but remained unapproved at the time of the audit.

Conclusions

The system for the authorisation of PPPs is well developed and transparent. An electronic register is available and regularly updated.

Significant delays are apparent in the mutual recognition stream largely due to both incomplete data sets provided by the applicant companies and delays in the evaluation of the application. Such delays are not in line with Article 42 of Regulation (EC) No 1107/2009, which requires that a decision on the application is taken within 120 days.

The re-registration process, as assessed by the audit team, complies with the legislatively prescribed time lines for "step 1" and "step 2". However, some delay was observed in the authorisation of epoxiconazole which requires re-registration within time frames prescribed in Directive 2008/107/EC.

Delays in the authorisation process are also apparent for new applications (PPPs not previously on the market) which is not in line with Regulation (EC) No 1107/2009. Article 37 of the Regulation requires the MS to decide on the application within 12 months. An additional period of six months maximum can be granted in the cases where additional information is needed.

A responsible approach is taken by MARD on the issuance of emergency authorisations pending applications as required by Article 53 Regulation (EC) No 1107/2009.

The labels of PPPs checked by the audit team followed the requirements of Regulation (EC) No 547/2011.

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 sale of PPPs to professional users shall be restricted to persons holding a certificate.

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

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

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

Findings

Act of 8 March 2013 on Plant Protection Products requires that distributors, retailers and re-packers of PPPs be registered with the VSPHSIS. This was also required by previous legislation. The registration data are entered by the VSPHSIS into the central database of the SPHSIS.

As of 31 December 2012, there were 6 801 entities (333 wholesalers and 6 468 retailers) selling PPPs registered with SPHSIS. The number of PPP packaging sites and PPP manufacturers was 27 and six, respectively.

Record Keeping

Record keeping of the batch number and the expiry date of the purchased and sold PPPs is required by Act of 8 March 2013 on Plant Protection Products.

Entities involved in marketing of PPPs have to keep records for five years according to the Polish Law and as required by EU provisions. This is a recent requirement under the new Plant Protection Products Act.

Training and Certification of Pesticide Distributors

Employees of distributors, retailers and/or re-packers of PPP must be trained and hold a certificate, which is valid for 5 years. The certificate is issued after having passed an examination.

Training on marketing and packaging of PPPs is provided by 175 operators registered by SPHSIS. In 2012, 244 such training sessions were provided to 4 531 participants.

MARD Order of 8th of May 2013 on training on plant protection products sets out the requirements for registered operators providing training, as well as the topics to be covered.

Evidence was provided that the training providers are regularly checked by the VSPHSIS.

Controls of PPP manufacturers

There are 6 manufacturers of PPPs in Poland They are required to be registered with the SPHSIS. Inspections regarding the production of PPPs under the new Plant Protection Products Act were due the commence.

Sale of Pesticides

VSPHSIS inspectors carry out controls at packaging entities, wholesalers and retailers of PPPs registered with them. The CA stated that in addition, locations where illegal trade of PPPs may take place, e.g. markets, are also inspected. The CA further stated that they monitor the internet and media regarding advertisements and sales offers of PPPs.

There were over 6 300 and more than 6 800 inspections on marketing of PPPs performed in 2011 and 2012, respectively. Some 1 % of the checks involved non-compliances. The main irregularities identified were in relation to the use of unauthorised PPPs, labelling, packaging and expiry date of PPPs, and lack of training.

Order No 5/2013 of the Chief Inspector of SPHSIS specifies the conditions, including check-lists, for the performance of official controls of marketing of PPPs. Official controls on the quality of PPPs are set out in Order No 9/2012.

The audit team observed inspections carried out by the VSPHSIS at marketing level in both of the two regions visited. The inspectors followed the check-list specified in the relevant Order of the Chief Inspector of SPHSIS. The inspections covered the following aspects:

- documentary checks (registration of the wholesaler with the VSPHSIS, the training certificates of the staff of the warehouse, invoices of purchased and sold PPPs, disposal of collected empty packages of PPPs);
- detailed verification of the authorisation status and shelf life of registered PPPs (whether they comply with the authorisation document in force),
- detailed label check in the pesticide store,
- sample taking for formulation analysis and
- verification whether action has been taken as a consequence of the deficiencies identified at the previous inspection.

The audit team noted that the inspection had been announced. The announcement letter indicated that the inspection would take place within 7-30 days. This is required by Polish legislation. No announcement is required if the inspection is a preventive measure against an offence.

Handling, Storage and Safe Disposal of Packaging and Remnants of Plant Protection Products

The collection of obsolete pesticides and pesticide packaging waste is regulated by the Act of 14 December 2012 on Waste and Act of 11 May 2001 on Packaging and Packaging Waste.

Wholesalers and retailers of PPPs facilitate the collection of empty PPP containers. A collection facility was available at both the wholesaler and retailer visited by the audit team.

For remnants and obsolete pesticides see 5.2.5.

Illegal and Counterfeit Pesticides

Targeted controls of illegal and counterfeit pesticides are performed by the SPHSIS in co-operation with customs, State Sanitary Inspectorate (SSI), the border control authority and CAs in other MSs. PPPs are sampled at wholesalers and retailers. Where necessary, PPPs are also sampled during the course of investigations. Additional inspections are carried out at manufacturing and packaging establishments where illegal trade is suspected. Inspectors of VSPHSIS took 40 and 79 “intervention” samples in 2011 and 2012, respectively. Around 50% of these samples were found to be non-compliant.

In one particular case, inspections were carried out by the SPHSIS and SSI as a result of information provided by the German authorities at Hamburg port. A PPP active substance

originating from China was in question. The inspections carried out at the manufacturer who purchased this material, did not identify any irregularities.

Formulation Laboratory

The audit team visited the laboratory of formulation analysis of PPPs in Sośnicowice, which is part of the Institute of Plant Protection – National Research Institute.

The laboratory is not accredited according to ISO 17025 but it is certified as compliant with Good Laboratory Practice (GLP). The accreditation is planned for 2014. The laboratory stated that all methods used are validated. The laboratory has adequate facilities, modern equipment and trained staff. They carry out a broad range of analysis for the determination of the identity and content of the active substance, determination of impurities, and checks of physical-chemical properties. In 2012, the laboratory analysed 354 formulated products containing 115 active substances. A number of significant discrepancies of the quality parameters were detected by the laboratory (see section "Illegal and Counterfeit Pesticides" above).

The laboratory is equipped with GC using FID, ECD and HEAD SPACE, GC using MS, HPLC with UV, DAD and RR, LC with MS/MS and TLC-SCAN and NIR detectors.

The laboratory uses well-defined in-house methods, which are mainly based on Collaborative International Pesticides Analytical Council (CIPAC). Quality control procedures are in place.

The laboratory had not participated in comparative tests yet. Such participation is planned once the accreditation according to ISO 17025 has been obtained.

Conclusions

Records regarding PPPs at marketing level are kept wholesalers retailers as required by Article 67(1) of Regulation (EC) No 1107/2009.

Detailed controls on the marketing of PPPs take place as laid down in Article 68 of Regulation (EC) 1107/2009.

A well established system is in place regarding training and certification of PPP distributors as laid down in Article 5 of Directive 2009/128/EC.

Provisions on handling and storage of PPPs and treatment of packages and remnants of PPPs as laid down in Article 13 of Directive 2009/128/EC are in place.

A substantial sampling programme is implemented for formulation analysis with adequate capabilities and knowledge in the laboratory of formulation analysis. It allows for identifying illegal and counterfeit pesticides.

5.2.5 Controls on the Use of Plant Protection Products

Legal Requirements

Article 4(1) of Regulation (EC) No 852/2004, and Annex I, Part A.III of the same Regulation, requires that food business operators (FBOs) producing or harvesting plant products 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

The MARD stated that there is an estimated 2 million farmers in Poland. About 800 000 farmers sell their products on the market, but not all of them may cultivate crops. The average farm size is 6.8 ha with significant regional variations. Some 1 360 000 farmers are registered for the purpose of direct payments.

In 2012, the SPHSIS through the VSPHSISs carried out more than 27 000 controls on the use of PPPs including about 9 800 inspections on cross-compliance and about 2 700 on Integrated Production. In addition to these controls, about 3 000 samples of farm produce are taken annually at farm level, to test them for pesticide residues to check the lawful use of PPPs. As of January 2013, cross-compliance checks are carried out by the Agency for Restructuring and Modernisation of Agriculture (ARMA).

Non-compliances were identified in the case of 9.2% of the controls on use of PPPs and about 1% of residue samples were found to be non-compliant. The main irregularities identified were in relation to lack of training, record keeping, testing of sprayers, illegal use of PPPs and the use of unauthorised PPPs.

Order No 5/2013 of the Chief Inspector of SPHSIS specifies the conditions for the performance of official controls on the use of PPPs. The order specifies check lists for the control of the use of PPPs by producers. Order No 6/2013 of the Chief Inspector of SPHSIS specifies sampling for pesticide residues to verify the use of PPPs.

Based on the annual guidelines issued by the SPHSIS, the VSPHSIS carries out inspections on the use of PPPs at least once every year at:

- all producers registered for Integrated Production and
- producers contained in the phytosanitary register (e.g. potato producer, nurseries) if they are producing for the market;

All farmers where non-compliances were found in the previous year are re-inspected. The remaining inspections, which are estimated by the VSPHSIS to amount to one third of their inspections on the use of PPPs, are targeted on other farms producing for the market. The inspectors of the Field Units select the farms based on the register of trained farmers and operators with certified application equipment. The CA stated that inspectors also assess the area in order to select

additional farms for inspection. The VSPHSIS inspectors met also stated that they take local knowledge and their experience regarding the type of crop production and risks related to PPP use in certain areas into consideration when planning inspections. (See also 5.2.6 for Prioritisation of Official Controls).

In some cases the inspections on the use of PPPs and the visits to farmers for the purpose of taking product samples for pesticide residue testing are combined. Inspections at farms are carried out by the VSPHSIS inspectors unannounced.

The audit team observed inspections carried out by the VSPHSIS at producer level in both of the two regions visited. The inspectors followed the check-list specified in Order No 5/2013 of the Chief Inspector of SPHSIS. The inspections covered the following aspects:

- documentary checks (the training certificate of the producer and the certificate of the technical check of the spraying equipment);
- verification of the records regarding the use of PPPs against the authorisation of the applied products by consulting the official PPP register;
- the storage facilities of PPPs and the verification of products in stock against the producer's records and the official register of PPPs;
- check of the spraying equipment in order to verify that the label on the equipment and spray number correspond with the certificate of the technical check;
- availability of protective clothing and
- proof of disposal of empty containers of PPPs.

The audit team noted that the spray records of the farmer contained basic information (PPPs used, dates of application, land parcel, treated surface area and crop). The crop growth stage at the time of PPP application and harvest date are recorded. However, these are not specifically required by EU provisions.

Record Keeping

Professional users of PPPs have to keep records for three years according to Polish Law and as required by EU provisions. This was confirmed and verified at the farmers visited by the audit team.

Training of and Certification of Professional Users of PPPs

Since 1996, professional users of PPPs have to be trained on the use of PPPs and have to pass an exam before a training certificate, valid for five years, is issued. Article 28 of the new Act March 2013 on Plant Protection Products stipulates that professional producers who wish to purchase PPPs have to hold such a training certificate. At the time of the audit only persons purchasing toxic and highly toxic PPPs had to provide evidence of a specific training certificate at the sales point. The new Plant Protection Products Act stipulates that PPPs for professional use can only be purchased upon presentation of a valid training certificate. This provision applies as of 26 November 2015 in line with Article 6 (4) of Directive 2009/128/EC. Trained producers are registered with the VSPHSIS. At the time of the audit about 360 000 trained producers were registered in the SPHSIS database. The training courses are organised by trainers who are approved by and registered with the VSPHSIS. The VSPHSIS supervises the training activities of the entities performing such training and VSPHSIS are members of the examination boards. The previous national provisions on plant protection contained requirements on training of professional users of PPPs. The new Plant Protection Products Act introduced the requirement that advisors on the use of PPPs must also be trained. Specific provisions on the training on the use of PPPs are given in the MARD Regulation of 8 May 2013 on PPP training.

Pesticide application equipment

The MARD stated that more than 600 000 checks of sprayers have been carried out in Poland since 1999. The new Plant Protection Products Act and the MARD Regulation of 5 March 2013 on technical requirements for sprayers and MARD Regulation of 7 of March 2013 on testing technical conditions of sprayers lay down provisions for the regular check of spraying equipment. The technical checks are carried out by entities with specific expertise. Inspectors testing the technical condition of sprayers are certified by one of the five institutes authorised for this purpose. The entities performing technical checks are registered and supervised by the VSPHSISs. Each spraying device passing inspection is labelled. The technical check is valid for three years. Poland exempts hand-held sprayers from the technical checks which is in accordance with EU provisions.

Handling, Storage and Safe Disposal of Packaging and Remnants of Plant Protection Products

The SPHSIS stated that where during an inspection of a producer remnants or obsolete pesticides are found, the products can be seized and the Inspectorate for Environment of the Voivodship is informed.

Integrated Pest Management

The MARD Regulations of 16 December 2010 and of 18 April 2013 make provisions on integrated production and integrated plant protection. Based on the Order of 2010, the Chief Inspector of the SPHSIS has issued methodologies for the integrated production of 27 crops. The MARD stated that in order to ensure that all farmers implement the general principles of integrated pest management (IPM) by 1 January 2014, a specific awareness raising campaign will be launched in 2013 including dissemination of leaflets to producers, participation of the CAs in agricultural fairs, meeting with farmers at local level, incorporation of IPM in obligatory training for professional users of PPPs and training of advisers of the extension services.

The MARD stated that the National Action Plan (NAP) as referred to in Article 4 of Directive 2009/128/EC had been signed by the Minister, but has not been officially published.

The audit team noted that the Laboratory of Pesticide Residue Analysis in the Regional Experimental Station in Trzebnica which performs official controls on pesticide residues is not accredited to ISO 17025. This was confirmed by the CA.

Conclusions

A well established system for the control on the use of PPPs including the training of producers, certification of application equipment and record keeping is in place and is largely in accordance with EU provisions.

There are appropriate measures in place to promote IPM in line with EU legislation.

There are sufficient measures in place regarding the handling, storage, transportation and safe disposal of packaging and remnants of PPPs as required by EU legislation.

The NAP under Article 4(1) of Directive 2009/128/EC has been finalised and submitted to the European Commission. However, it has not yet been endorsed by MARD as the publication of the NAP in the official journal is outstanding.

One of the pesticide laboratories is not accredited to ISO 17025, which is not in line with Article 12 of Regulation (EC) No 882/2004.

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

The Main Inspectorate of SPHSIS issues guidelines (work programme) for official controls on marketing and use of PPPs annually. These guidelines include the priorities for the controls, the number of inspections which are centrally decided and an indication of tasks to be planned by the regions alone. Wholesalers of PPPs must be inspected once a year and retailers at least once every two years. Growers in the integrated production scheme are inspected annually. Establishments where irregularities are detected, including via RASFF notifications, must be controlled in the following year.

Based on these guidelines, controls on the use of PPPs are planned by the field units and incorporated into the regional plan. The VSPHSIS largely rely on the field units.

The inspectors of the field units met, stated that the following aspects are considered:

- past records,
- local knowledge of production and related risks with respect to PPP use and
- other information that indicates a risk of unlawful use of PPPs in certain areas (e.g. finding a sales point of unauthorised PPPs at a farmer market may trigger inspections of farmers in that area).

The SPHSIS do not have a complete database with all farmers available when planning PPP controls. The VSPHSIS inspectors stated that additional inspections of farms outside their system are carried out, but that this is not planned in a structured way. However, as admitted by the CAs, there is no evidence that the planning and prioritisation process takes all professional users of PPPs into account.

A sampling plan for pesticide residues to verify the use of PPPs and a sampling plan for formulation analysis of PPPs are also prepared by the Main Inspectorate of SPHSIS annually. A statistical model for pesticide residue testing to verify whether PPPs are lawfully used has been developed and is used to prepare the sampling plan.

A statistical model is in preparation in order to improve planning and prioritisation of inspections of PPP users in 2014.

The CA does not have knowledge of own control system in place by farmers and consequently cannot take this into consideration for the planning of controls.

Conclusions

Controls are carried out based on risk except for controls on use of PPPs. In this case, it cannot be guaranteed that all professional users of PPPs are taken into account while planning controls, which is not in line with Article 3 (1) of Regulation (EC) No 882/2004.

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

A range of Orders of the Chief Inspector of SPHSIS are in place specifying procedures and inspection report forms to perform controls of marketing and use of PPPs.

Reports are drawn up following all inspections. The results of the inspections are entered into the database of the SPHSIS.

An annual national report required by Article 68 of Regulation (EC) No 1107/2009 on controls of the marketing and use of PPPs was under preparation at the time of the audit.

Conclusions

Documented procedures and provisions for reporting have been implemented in line with EU legislation.

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

A number of examples of adequate co-operation between and within CAs were provided to the audit team.

Cooperation agreements between the SPHSIS and other authorities (e.g. the border guards) are in place at central and regional level. International co-operation exists to fight counterfeit pesticides (see also 5.2.5). Evidence was also provided of Police involvement in a case where illegal pesticide was the issue. Customs regularly inform SPHSIS where they detect illegal pesticides.

Conclusions

There was overall efficient and effective co-ordination and co-operation between and within competent authorities for controls on the marketing and use of PPPs.

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

Administrative procedures can be initiated, fines imposed and sanctions issued under the Act of 8 March 2013 on Plant Protection Products in the case of irregularities identified at pesticide distributors and professional users.

Evidence was provided that non-compliances are followed-up in order to ensure that the operator remedies the situation. As an example, in consequence of a non-compliant sample for pesticide residues to verify the use of PPPs, a fine was imposed and a detailed inspection was performed on the use of PPPs at the farm of origin. A complex case regarding the marketing of an illegal PPP involved a number of follow-up actions including sampling of PPPs and follow-up inspections at marketing and user level.

Conclusions

In the case of non-compliance, the CA has taken appropriate action to ensure that the operator remedies the situation.

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

MARD controls the activities of the Main Inspectorate of SPHSIS. The Main Inspectorate performs verification controls regarding the implementation of inspection procedures at the VSPHSIS. The Main Inspectorate also has an internal auditor to centrally check procedures implemented by SPHSIS. The VSPHSISs verify the inspection procedures implemented by their field units. Verification within the SPHSIS is based on an annual plan.

Conclusions

Verification procedures and an audit system is in place in line with the EU legislation.

6 Overall Conclusion

An adequate and effective control system is in place for the marketing and use of PPPs. It is based on centrally coordinated control plans, documented procedures, communication between authorities, training of staff and proportionate enforcement measures. There are controls to identify illegal or counterfeit pesticides, supported by an effective programme of PPP formulation testing. National legislation for the transposition of Directive 2009/128/EC on sustainable use of pesticides is in place and implementing measures have been taken regarding the training of professional users of PPPs and technical checks of pesticide application equipment. Adequate provisions are allowed for in national legislation to facilitate full implementation of future measures contained in the Directive (e.g. integrated pest management) in a timely manner. The system for the authorisation of PPPs is transparent and well developed, however, it is weakened somewhat by significant delays.

7 Closing Meeting

A closing meeting was held on 5 June 2013 with representatives of the CA. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit. The CA provided initial comments and clarifications.

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 the re-evaluation and authorisation of PPPs containing epoxiconazole, in accordance with the Uniform Principles, and within the deadlines specified in the Commission Directive 2008/107/EC.
2.	Ensure that for the purpose of mutual recognition, a decision on applications is taken within 120 days as required by Article 42 of Regulation (EC) No 1107/2009.
3.	Ensure that for PPP applications submitted under Regulation (EC) No 1107/2009 a decision is taken within the time line specified in Article 37 of the Regulation.
4.	Ensure that all designated pesticide residue laboratories comply with Article 12 of Regulation (EC) No 882/2004.
5.	Ensure that the planning of control on use of PPPs takes into account all professional users in line with Article 3 (1) of Regulation (EC) No 882/2004.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6640

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
Reg. 16/2011	OJ L 6, 11.1.2011, p. 7-10	Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed
Legislation on Plant Protection Products		
Reg. 1107/2009	OJ L 309, 24.11.2009, p. 1-50	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
Dir. 2009/128/EC	OJ L 309, 24.11.2009, p. 71-86	Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides

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

Annex 2 – Standards Quoted in the report

Reference number	Full title	Publication details
SANCO/12495/2011		http://ec.europa.eu/food/plant/protection/resources/qualcontrol_en.pdf
	FAO Pesticide Storage and Stock Control Manual	http://www.fao.org/docrep/V8966E/V8966E00.htm