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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
HUNGARY
FROM 04 TO 08 JUNE 2012
IN ORDER TO EVALUATE CONTROLS OF PESTICIDES

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Hungary, carried out between 04 and 08 June 2012, under the provisions of Regulation (EC) No 882/2004 on official food and feed controls and Regulation (EC) No 1107/2009.

The objective of the audit was to evaluate the controls on pesticides and to follow-up recommendations of the report of a previous inspection DG(SANCO)/2008-7849.

Hungary has a well developed and organised system for the authorisation of Plant Protection Products (PPPs) in place. The high number of authorisations under emergency rules gives cause for concern.

The controls on marketing and use are performed by highly qualified and experienced staff and control programmes are in place. The lack of important elements like the controls on producers of PPPs and risk criteria reduces the effectiveness of the official controls. Some shortcomings concerning the Competent Authorities' (CAs) co-operation on budgets, documented procedures for staff, impurity checks on PPPs and verification of the effectiveness of controls weaken the control system.

Of the three recommendations from the previous audit DG(SANCO)/2008-7849 evaluated by the audit team, two have not been satisfactorily addressed. One official laboratory is not accredited. The recommendation concerning the identification of old stocks of obsolete PPPs has not been addressed.

The report makes a number of recommendations to the 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 Organization of the United Nations and World Health Organization
DG (SANCO)	Health and Consumers Directorate-General
EU	European Union
EU-PT	European Proficiency Test
EURL	European Union Reference Laboratories
FVO	Food and Veterinary Office
GC	Gas Chromatograph
GC-MS	Gas Chromatograph coupled to Mass Spectrometer
GC-FID	Gas Chromatograph coupled to Flame Ionization Detector
GC-MS/MS	Gas Chromatograph coupled to Tandem Mass Spectrometer
GC-PFPD	Gas Chromatograph coupled to Pulsed Flame Photometric Detector
GCO	Government County Office
GCO-DPPSC	Government County Office – Department of Plant Protection and Soil Conservation
GPS	Global Positioning System
HPLC-DAD	High Performance Liquid Chromatography coupled to Diode Array-Detector
HPLC-UVD	High Performance Liquid Chromatography coupled to Ultra Violet Detector
IPM	Integrated Pest Management
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatograph coupled to Tandem Mass Spectrometer
MRD	Ministry of Rural Development
MPAJ	Ministry of Public Administration and Justice
MRL	Maximum Residue Level
MRM	Multi Residue Method
MS(s)	Member State(s)
MSD	Mass Selective Detector
MU	Measurement Uncertainty

NFCSO	National Food Chain Safety Office
NFCSO-DPPSCA	National Food Chain Safety Office - Directorate of Plant Protection, Soil Conservation and Agri-environment
NRL	National Reference Laboratory
PHI	Pre Harvest Interval
PPP(s)	Plant Protection Product(s)
PT	Proficiency Test
QuEChERS	Multi Residue Method - European Standard 15662
SRM	Single Residue Method

1 INTRODUCTION

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

The audit took place from 04 to 08 June 2012. The team comprised of two auditors from the FVO and one expert from a European Reference Laboratory (EURL).

Representatives from the Central Competent Authority (CAA) accompanied the FVO team for the duration of the audit. An opening meeting was held on 04 June 2012 with the Competent Authorities (CAs) at the Ministry of Rural Development (MRD). 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 CAs.

2 OBJECTIVES AND SCOPE

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

- the implementation of requirements for the authorisation of Plant Protection Products (PPPs) and official controls on the marketing and use of PPPs under Regulation (EC) No 1107/2009 and Directive 2009/128/EC;
- the implementation of requirements for official controls of the use of PPPs at growers under Regulation (EC) No 882/2004;
- follow-up recommendations of the Health and Consumers Directorate-General DG(SANCO)/2008-7849 report, which had focussed on the implementation of official controls on pesticide residues under Regulations (EC) No 396/2005 and 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, controls of the growers, and follow-up of recommendations regarding the control programmes and laboratories for pesticide residues.

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

Table 1: Mission visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	2	MRD, NFCSO
Regional	3	GCO-DPPSCs of the Counties Fejér, Komárom-Esztergom and Szabolcs-Szatmár-Bereg
Laboratories		
Public	2	NFCSO laboratories in Velence and Miskolc
On-Site-Visits		
Controls of growers	2	Grower of cereals, peas, rape seed and sunflowers in County Komárom-Esztergom and

Controls of wholesalers and retailers of PPPs	2	a grower of cereals, peppers and apples in County Szabolcs-Szatmár-Bereg Wholesaler in County Komárom-Esztergom and a retailer in the County Fejér
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3 LEGAL BASIS AND STANDARDS

3.1 LEGAL BASIS

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

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

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

3.2 STANDARDS

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

4 BACKGROUND

4.1 MISSION SERIES

This audit is part of a series of FVO missions in Member States (MSs) of the EU on controls of pesticides. Prior to the current audit series, the FVO carried out three series of missions to MSs covering controls on the marketing and use of PPPs and pesticide residues. The general overview reports of the former mission series can be found on the DG (SANCO) internet site: http://ec.europa.eu/food/fvo/specialreports/index_en.htm

During the 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 mission series. Weaknesses were identified in particular regarding the assessment of self-control systems, the place of sampling, and enforcement measures taken in cases 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 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.

In the framework of the last audit series, the FVO carried out a mission to Hungary in 2008. The report DG(SANCO)/2008-7849 of this mission can be found at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm.

The overall conclusion of the mission report was that there was a satisfactory system for the controls of PPPs in place with some weaknesses regarding the control systems, equipment and procedures of the official laboratories. The report also describes deficiencies concerning the identification of obsolete PPPs and makes several recommendations.

4.2 COUNTRY PROFILE

The FVO has published a country profile for Hungary, 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/last5_en.cfm?co_id=HU.

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) 1107/2009

The Regulation is directly applicable in MSs. Fines and penalties for infringements in the scope of the audit are described in the Government Decree 194/2008. A Ministerial Decree is in preparation to regulate plant protection methodologies and PPP authorisation.

Directive 2009/128/EC

The CA stated that the obligations of the Directive are included in Ministerial Decree 43/2010 with the exception of the obligation to establish a National Action Plan in accordance with Article 4 of the Directive.

Competent Authorities

Government Decrees 328/2010 and 22/2012 establish the National Food Chain Safety Office (NFCSSO) and the Government County Offices (GCOs) as the CAs within the scope of the audit.

Legislation is available on the website: www.nebih.gov.hu.

Conclusions

Measures to implement Regulation (EC) No 1107/2009 are in place. Directive 2009/128/EC has been transposed into national legislation with the exception of Article 4 concerning the National Action Plan. The legislation is publicly available.

5.2 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS

5.2.1 Designation of Competent Authorities

Legal Requirements

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

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

Findings

At the MRD, the Deputy State Secretary for food chain control and agriculture administration supervises three departments, one for Food Processing, one for Forestry, Fishery and Game and one for Food Chain Control. The latter has four units and is responsible for strategy, reporting and supervision in the scope of the audit. The National Food Chain Safety Office was created as a back-office to support the Department for Food Chain Control of MRD. They are the CCA in the scope of this audit.

Since March 2012, the Agricultural Office's name has changed to National Food Chain Safety Office (NFCSO). The NFCSO is headed by a president with three deputy presidents, one for financial affairs, one for food chain control and one for plant, soil and forest protection. The NFCSO's Directorate of Plant Protection, Soil Conservation and Agri-environment (NFCSO-DPPSCA) is designated to develop, maintain and supervise control systems for the authorisation, marketing and use of PPPs and checking the level of the residues of PPPs. For controls in the regions the NFCSO-DPPSCA is responsible to provide the GCOs with control programmes, check-lists and working procedures. The NFCSO-DPPSCA supervises the implementation on technical issues and collects the control results from the GCOs.

The GCOs, and in particular their Directorates for Plant Protection and Soil Conservation (GCO-DPPSC) are responsible for the implementation of controls in the regions. Their staff, sites, facilities and equipment were transferred from the Agriculture Office of MRD to the Ministry for Public Administration and Justice (MPAJ) in 2011. They now report to the MPAJ on administrative issues. Technical issues are reported to the NFCSO-DPPSCA.

The four official laboratories within the scope of the audit are part of the NFCSO.

The CAs declared that there is no delegation of tasks to external control bodies within the scope of the audit.

Conclusions

CAs are clearly designated for the authorisation, marketing and use of PPPs. There is no delegation of tasks to private bodies within the scope of the audit as described in Article 5 of Regulation (EC) No 882/2004.

5.2.2 Resources for Performance Controls

Legal Requirements

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

Article 4 of Regulation (EC) No 882/2004 requires 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

At the NFCSO-DPPSCA 12 staff deal with the authorisation of PPPs. There are six experts for the evaluation of dossiers and three staff members work part-time on PPP efficacy evaluation. The CA stated that there is a considerable backlog of applications for re-registration of PPPs since the accession of Hungary in 2004.

For official control of marketing and use of PPPs there are eight staff members at NFCSO-DPPSCA and 148 inspectors in the GCO-DPPSCs.

Some GCOs stated that the tasks emerging from the eradication programme for rag-weed over-stretches their staff capacity between July and September every year.

All staff performing official controls on PPPs and pesticide residues have at least university education with special teaching for PPPs. Most of the inspectors followed e-learning training on authorisation of PPPs in Hungary and in the EU, introduced in 2010. It includes a test which was passed by most inspectors. The audit team obtained training records of inspectors carried out by the NFCSO-DPPSCA and by the GCOs.

The inspectors accompanied by the audit team during controls had a service car for their controls. They had laptops, GPS tools and protective equipment.

Conclusions

The CAs have suitably qualified and experienced staff available. An efficient training system is in place. The necessary equipment for controls is 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 official PPP authorisations are published on the website of the NFCSO. This information is available in Hungarian at the following link:

http://www.nebih.gov.hu/szakteruletek/szakteruletek/noveny_talajvedelmi_ig/kozerdeku_adatok.

The examples of PPP authorisations verified by the audit team were complete regarding the conditions of use of PPPs, as, *inter alia*, application time and concentration, number of applications and Pre-Harvest Intervals (PHIs). Reproductions of the labels for PPPs authorised within the last two years are available on the intranet of NFCSO. The labels checked by the team complied with Regulation (EC) No 547/2009. The CA stated that the register is updated weekly.

In Hungary, PPPs are approved in three categories according to their risk they pose. Categories I and II, with the most risky PPPs, may only be marketed, purchased or used by certified licence

holders. Licences for marketing, purchasing and using PPPs are given by the GCOs depending on the education level of PPP operators and the training courses followed. These training courses are provided by the Chamber of Professionals and Doctors of Plant Protection. The licences are subject to renewal every five years. Category III PPPs may be sold by licensed retailers to the public without restriction. The audit team observed that the categorisation is inconsistent in some cases, as higher toxic PPPs were found in category III and lower toxic in category II.

There were no mutual recognitions granted under Article 40 of Regulation (EC) No 1107/2009 since the Regulation came into force. There is one application for mutual recognition pending. No applications were rejected. The CA stated that there is excellent co-operation between the CAs of MSs in zone B – Centre -as required by Annex I of Regulation (EC) No 1107/2009.

A total of 263 active substances together with 779 PPPs are authorised in Hungary. They are EU approved and listed in Regulation (EC) No 540/2011. 14 active substances are pending approval.

A total of 75 PPP authorisations for emergency situations were granted since the coming into force of Regulation (EC) No 1107/2009. Ten authorisations concerned PPPs containing active substances currently not authorised in Hungary as, *inter alia*, *diflovidazin*, *kasugamycin*, *chlorophazinone* and *penoxsulam*. These active substances of the PPPs are not approved in the EU. For 65 PPPs extensions were given for the use on other crops already authorised in Hungary. The CA stated that this measure was considered as an emergency authorisation. A time-limit for the authorisations was put in place, but the scope of the PPPs is very broad concerning the crops. Two thirds of them are considered as minor uses by the CA.

The European Commission was not yet informed about the 75 authorisations at the time of the audit.¹ The audit team verified examples confirming that all these authorisations were granted for a maximum of 120 days.

Conclusions

An official register for PPP authorisation is publicly available and updated frequently. The system for PPP authorisation follows EU legislation. However, the emergency authorisations are defined too broadly, which is not an adequate application of Article 53 of Regulation (EC) No 1107/2009.

The European Commission and other MSs were not informed about the authorisations under emergency rules in contrary with Article 53 of the same Regulation.

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,

¹ In their answer to the draft report the CA noted that the information was sent after the time of the audit, but within the dead-line foreseen in the EU legislation. However, there is no dead-line set in the EU legislation. The other MSs and the Commission should be informed immediately as required by Article 53 of Regulation (EC) No. 1107/2009.

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.

Manual for Pesticide Storage and Stock Control of the Food and Agriculture Organisation of the United Nations (FAO) was also relevant for this audit.

Findings

Controls on PPP producers

Before starting to operate, all FBOs must apply for an operating and/or establishment permit issued by the competent notary. The notary requests consent from the local GCO-DPPSCs. The GCO-DPPSCs give their consent after a safety assessment. The CA stated that producers are not controlled after approval.

Controls on PPP wholesaler

The audit team observed a control on a wholesaler in County Komárom-Esztergom. The wholesaler has a market share around 15% for PPPs in Hungary. The inspection was done with a checklist provided by the NFCSO intranet. No rules of procedures were in place. The inspector of the GCO-DPPSC did not use a register or database to verify the label content against the official authorisation. The storage was suitable with sealed floors, sufficient ventilation and was securely closed. PPPs of all categories were stored together. The CA stated that there were no requirements in place for separate storage of herbicides.

Controls on PPP retailers

The audit team visited County Fejér for a control on a PPP retailer and the only official Hungarian laboratory for formulation analysis in Velence. There are no producers, importers and re-packing establishments in the county. There are around 10 wholesalers and 90 retailers.

The audit team observed an inspection of a retailer for farmer produce. All retailers are visited twice a year. The control frequency is not linked to previous results of the official controls or the company's own-checks. Retailers for the general public may only sell PPPs of category III. The inspector checked if the retailer's staff members had a valid licence to sell PPPs of this category and if PPPs were stored on a separate shelf not accessible to the public. He verified the licence documents and the stock records and observed that they were up-to-date. They were kept for five years by the retailer, as required by the legislation. Inspectors requested bills of the last delivery. He checked authorisations of the present PPPs against a commercial database on a laptop. Expiry dates were also checked. Inspector verified labels for their completeness but he did not verify them against the database in particular concerning PHIs, formulations or concentrations. The inspector followed a check-list, but there were no rules of procedures for inspections in place.

To verify the correctness of the commercial database the audit team compared several products to the official authorisation and found some differences, e.g. for the PHIs and crops to be applied on. For the controls on marketing and use at all levels, the inspectors use the commercial database in an offline version on their laptop or the "green book", a printed version of the same commercial database with annual updates.

Waste management of PPP remnants and empty containers

Remnants and empty containers of PPPs must be kept by professional users and collected by the

wholesalers for incineration. The wholesaler explained that twice a year the users bring their PPP waste to his premises where they are collected and transported to the nearest incinerator in Győr. Users must keep proof of collection.

Counterfeits and illegal PPPs

Inspectors are duty bound to observe and report suspicious PPPs. Checklists for inspectors have questions regarding counterfeits e.g. are manufacturer seals present on PPP packages. A public awareness campaign is broadcasted on Hungarian Television during the main season for PPP use. Since 2009, however, there were no suspicious samplings out of the scope of the annual control program or other direct actions conducted to detect illegal pesticides or counterfeits. The CA stated that an inter-ministerial special team has been formed to combat counterfeits and illegal pesticides. It is awaiting final approval by the responsible Ministers.

Pesticide Analytical Laboratory in Velence

The laboratory visited was the Pesticide Analytical Laboratory in Velence, County Fejér. This is the only authorised laboratory in Hungary that performs formulation analysis on PPPs. The numbers of official samples performed in 2010 and 2011 were 441 and 462, respectively. In 2012, 475 samples are programmed to be analysed, 25 for each of the 19 Counties. Analyses for concentration of active substances in PPPs are reported within two weeks after reception of the sample. In 2011, the laboratory also analysed 713 samples for private customers. A third of the private analyses was conducted on expiry dates of PPPs. If active substances are not degraded, the shelf life can be extended for one year.

The laboratory was accredited to ISO/IEC 17025:2005 in 2009. A total of 181 substances are accredited under the standard methods of the Collaborative International Pesticides Analytical Council (CIPAC). In Hungary there are 263 active substances authorised together with 779 PPPs; distributors are obliged to provide standards during the application for authorisation. Although the laboratory did not have all of them in stock, they have access to them upon request. The laboratory estimates to have evaluated 80% of PPPs commercialised in Hungary.

There are two staff members allocated to PPP analysis. They are both highly qualified and experienced. Both received appropriate training to conduct the tasks programmed by the quality control office of the laboratory. One person is dedicated to the programming.

The laboratory dedicated exclusively two GC-FIDs and one HPLC-UVD to determine the active substances, the concentration of active substances and seven other parameters such as, *inter alia*, pH and density. The analyses do not include unexpected active substances, co-formulants and impurities due to a lack of equipment, i.e. no MSD is available.

Since 1999 the laboratory has routinely participated in collaborative trials organised by private companies where the active substance and the concentration must to be reported. They have participated annually in a proficiency test organised by CAs of MSs since 2009. The laboratory had acceptable z-scores in all PT tests verified by the audit team.

Conclusions

Controls on the marketing and use of PPPs take place in accordance with Article 68 of Regulation (EC) No 1107/2009 with the exception of producers of PPPs. The safety rules for storage are insufficient as there are no requirements in place to store herbicides separately from other PPPs as described in the Manual for Pesticide Storage and Stock Control of the FAO (<http://www.fao.org/docrep/V8966E/V8966E00.html>).

The checks on the authorisation status of PPPs were satisfactory, however, labels were not verified in all regions for the correctness of the PHIs. The records of operators were checked with the

exception of those of PPP producers. The deficiencies of the controls observed are due to shortcomings at a horizontal level, i.e. the lack of risk-based control programmes (see section 5.2.7) and the lack of rules of procedures (see section 5.2.8).

Adequate measures are taken to dissuade the public from using illegal and counterfeit pesticides. No coordinated inter-service actions against counterfeits has been conducted since 2009.

The analytical controls on PPP formulation are in place and sufficient in number but not fully effective because there is no check on unexpected active substances, co-formulants and impurities. There is a system in place to train and certify PPP retailers and wholesalers. An efficient waste-management system is in place.

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 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 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 measures to ensure that handling and storage of pesticides and handling, recovery or disposal of their packaging and remnants do not endanger human health or the environment.

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

Findings

Integrated Pest Management

To date, Integrated Pest Management (IPM) has not been promoted by the NFCSO. However, there are elements of IPM included in the legal obligations for users and a voluntary National Environmental Programme is in place with incentives to avoid the use of environmentally harmful PPPs.²

² In their answer to the draft report the CA noted that the principles of integrated pest management has already been

Aerial spraying was restricted recently by legislation and can only be used with special approval by the CO-DPPSC for spraying in emergency cases. Requests for approval were submitted recently to the CA.

Controls of PPP user

The same system of licence documents as for marketing is in place for professional users of PPPs. The Chamber of Professionals and Doctors of Plant Protection organises the training courses. All users visited during the audit had a valid licence document.

The inspectors used a standard checklist distributed by the NFCSO for inspection at growers. There are two kinds of inspections: on-the-spot checks during spraying in the fields and so called 'technical checks' at the farms. On-the-spot checks are not announced to the operators. They focus on the use of PPPs and mainly consist of documentary checks, spray equipment and the storage of PPPs. 'Technical checks' are announced.

The number of holdings in the County Komárom-Esztergom is circa 3,700. About 200 farms are larger than 100 ha. The main crops are corn, wheat and sunflowers. In a field the team observed an on-the-spot demonstration of inspection of spring barley. It was performed by the inspector from the GCO-DPPSC of the Komárom-Esztergom County. The inspected field belonged to a co-operative with 3,300 ha. It produced mainly cereals. A team of five PPP specialists dedicated to the use of PPPs was employed by the co-operative. The inspector checked if all staff involved had valid licence documents and completed training. The staff stated that all spraying equipment underwent an annual check and calibration by an external contractor. There was no documented evidence available about the calibration of the spray-equipment. The inspector followed a check list during the controls. The 'green-book' was used to verify the authorisation of the PPP and the concentrations allowed to be used. The plot was identified on the spray scheme. The spray-equipment was controlled for a type-approval. As the approval is only obligatory since 2004 and the sprayer was older than 2004 no further checks were carried out on the equipment. The inspector did not check if sensitive environmental zones neighboured the plot. The PPP was checked for its toxicity for apicultures.

The audit team observed control at a grower in County Szabolcs-Szatmár-Bereg. There are several co-operatives with more than 400 ha. Around 2,000 family run farms have an average size of 45 ha. 28,000 farms in the County have an average size of 2.9 ha. The main crops are corn, cereals and sunflowers.

The farm visited was made up of 180 ha with cereal, apple and pepper production. The inspector conducted a 'technical check'. He used a checklist and controlled licences, PPP bills, proof of waste collection and spray schemes. The spray scheme for apple orchards contained, *inter alia*, the plot number, the PPP used, the concentration, the date of application and the PHI. The inspectors used a laptop with the private PPP database but did not verify the PHIs. An incorrect PHI was recorded in the spray diary with half the waiting time required by the official authorisation. This was not noticed by the inspectors. The PPP storage of the operator was inspected. The stocks were compared with the stock-list, labels were checked by the inspector. The storage for PPPs was insufficiently ventilated, which was not noted by the inspector. The grower stated that he recently contracted an external company for the calibration of spray-equipment.

Conclusions

A voluntary environmental programme is in place to promote IPM measures. The controls on users are comprehensive but there is a lack of verification on PHIs and PPP labels which reduces their effectiveness. Professional users of PPPs are trained and certified. An effective waste-management

included in national legislation from 1990 onwards.

system for PPPs users is in place. The deficiencies of the controls observed are due to shortcomings at a horizontal level, i.e. the lack of risk-based control programmes (see section 5.2.7) and the lack of procedures (see section 5.2.8).

5.2.6 Control Programmes for Pesticide Residues

Legal Requirements

Article 33 of the Regulation (EC) No 882/2004 requires MSs to designate National Reference Laboratories (NRL) for each EURL and specifies tasks for the NRL.

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

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

Findings

The audit team followed up on three recommendations of audit DG(SANCO)/2008-7849:

Recommendation No 3: *“ensure that all designated laboratories comply with Article 12(2)(a) of Regulation (EC) No 882/2004, or are availing of the derogation foreseen in Article 18 of Commission Regulation (EC) No 2076/2005. The quality control system in the laboratories availing of Article 18 should be based on the SANCO Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed (SANCO 2007/3131)”*.

The CA stated that the official laboratory in Hódmezővásárhely is not accredited. The CA stated that the accreditation is in preparation. The other three official laboratories for residue analysis are accredited.

Recommendation No 5: *“ensure that the laboratory equipment and methodology are adequate for measuring the limit values laid down under Community legislation, as required by Article 16(3) of Regulation No 882/2004.”*

The CA provided information on the equipment and methodology of the official residue laboratories. The audit team visited one laboratory.

Miskolc Pesticide Residue Analytical Laboratory

This laboratory is designated as the NRL for pesticide residues in fruit and vegetables and for Single Residue Methods (SRMs). The NRL gives assistance to the network of official laboratories. It disseminates information provided by the EURLs and the feedback of workshops attended.

The premises were built in 2004 and are adequate. The laboratory has been accredited since 2009 to ISO/IEC 17025:2005 with a fixed scope. The total number of active substances accredited are 266 for Multi Residue Method (MRM) and 10 for SRM. 770 and 573 official samples were analysed for 2010 and 2011 respectively and 500 are planned for 2012. The laboratory conducts analyses for periodical field trials prior to the authorisation of PPPs (14 trials in 2011).

Six staff, including three technicians and three higher level educated analysts (two chemical engineers and one biologist), are involved in the pesticide residue analysis.

QuEChERS citrate method is used for cereals, fruit and vegetables extraction using three internal standards. Ethyl acetate method is used in oil samples and for the confirmation of some GC analysis. The laboratory is equipped with GC-MS/MS and LC-MS/MS, both triple quadrupoles for

routine MRM analysis. A HPLC-DAD and a GC-PFPD are designated for SRM method analysis. The laboratory conducts its analysis based on the SANCO Guideline 12495/2011 for Method Validation and Quality Control Procedures for Pesticide Residues Analyses in Food and Feed.

Measurement Uncertainty (MU) is reported in two different ways. 50% MU is used if the result is at or above the MRL. If it is below, standard deviation of the long term routine recovery is used for SRM.

The laboratory routinely participates in the European Proficiency Tests (EU-PTs) organised by the EURLs for cereals, SRMs and fruit and vegetables. The results were satisfactory. For EU-PT-SRM5 (2010) two z-scores > 3 were reported but the reasons for the unacceptable results were found and followed up.

The audit team noticed that for stone fruit samples, the results were not recalculated taking the stone into account.

Recommendation No 7: *“consider identifying the exact quantities of obsolete pesticides and arranging for their safe destruction, in order to avoid possible contamination of food, feed and the environment”*.

The CA stated that investigations are still ongoing in 14 of the 19 counties in order to assess the stocks of PPPs which became obsolete by accession to the EU.

Conclusions

Recommendation No 3 has not yet been addressed. Recommendation No 5 is addressed adequately. The NRL visited follows the SANCO Guidelines 12495/2011 on Method Validation and Quality Control Procedures for Pesticide Residues Analyses in Food and Feed and has adequate equipment. Recommendation number 7 is not satisfactorily addressed by the CA.

5.2.7 Prioritisation of Official Controls

Legal Requirements

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

Findings

Since 2012 there is a control programme in place for use and marketing of PPPs. It stipulates that 25 samples and controls must be made by each County. The programme is available as an excel sheet on the intranet. Parameters like, for example the total PPPs use in Hungary, are not taken into account.

In Hungary, around 200 000 farms with a minimum size of 0.3 ha are beneficiaries to agricultural subsidies. A minimum of 1% is checked annually for cross-compliance in the framework of the EU Common Agriculture Policy.

There are no criteria for the programming of controls, e.g. the identified risks, the operator's past record as regards compliance or the reliability of own checks by operators. Retailers and wholesalers are checked in most Counties twice a year without taking into account the results of previous controls. Professional users not receiving subsidies are mainly selected for controls by their size and the fact that they have a warehouse for PPPs on their site. 3,600 controls on users are planned for 2012 which represents an annual control frequency of 85% to 100% for the selected

group of professional users. Small and medium-sized growers outside the cross-compliance checks are controlled only in exceptional cases. There are 475 official samples taken for formulation analyses, they are, however, not controlled for impurities. At marketing level, there were 3,852 inspections in 2009 and 3,491 in 2010 with a non-compliance rate of 10% in 2009 and 5.6% in 2010.

Conclusions

The programming on the controls of marketing and use of PPPs are not risk based and prioritised in contrary to the principles of Article 3 of Regulation (EC) No 882/2004. The frequency for formulation sampling is appropriate. There is absence of impurity testing. The frequency of controls on marketing and use is adequate.

5.2.8 Procedures for Performance and Reporting of Control Activities

Legal Requirements

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

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

Article 68 of Regulation 1107/2009 requires MSs to transmit to the Commission a report on the scope and the results of controls to enforce compliance with this Regulation within six months of the end of the year.

Findings

There are standard checklists available on the intranet for use by the inspectors for controls at marketing and user level. However, no rules procedures are in place. An official report was drawn up after each inspection and a copy given to the operators. There is a comprehensive manual available to inspectors for pesticide residue controls. Reports are provided to operators after inspections. A summary report of the controls is sent annually to the European Commission. The last report under the repealed Directive 91/414/EEC was sent in August 2011.

Conclusions

There are no documented procedures for the controls on marketing and use of PPPs for staff to perform effective official controls contrary to Article 8 of Regulation (EC) No 882/2004.

Official reports were drawn up following all inspections as required by Article 9 of Regulation (EC) No 882/2004. Annual reports are sent to the European Commission as required by EU legislation.

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

Legal Requirements

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

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

shall be ensured between the different units.

Findings

Minutes of formal meetings between the NFCSO and the GCO-DPPSCs at Director and Head of Unit level were presented to the team. There is a regular informal exchange of information between NFCSO and GCO-DPPSC. Relevant technical information from the NFCSO is available on the intranet for the GCO-DPPSC including, *inter alia*, control programmes, check-lists and legislation. Results of the GCO controls were available at the NFCSO.

The audit team observed, however, that co-operation concerning the financial budgets did not work smoothly. Technical decisions of the NFCSO have an immediate impact on the budgets of GCO-DPPSC. But there is no cooperation on this issue between the responsible Ministries MRD and MPAJ. Cars for the inspectors are leased by NFCSO, but the fuel costs are paid by MPAJ. A letter from an electricity provider was presented to the audit team with the threat of closing down electricity supply of one of the visited GCO-DPPSC due to unpaid bills. The recommendation is open since accession and should therefore be monitored concerning its progress and completion in 2014.

Conclusions

There is established co-operation between the CAs concerning technical issues. The co-operation between the MRD and MPAJ is not entirely effective, contrary to Article 4(3) of Regulation (EC) No 882/2004.

5.2.10 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

Fines

The audit team verified follow-up measures taken by the inspectors in cases of non-compliance. In County Fejér a retailer had separated two packages of a PPP. The PPP, however, was only authorised as a twin-pack for combined use. The inspector notified the non-compliance to the operator, the NFCSO and the PPP producer. The responsible operator rectified the situation. A fine of HUF 1 123 000 (approximately EUR 3 900) was imposed and paid.

Another case of non-compliance at a retail shop concerned the distribution of professional spray-equipment without type-approval. The producer was requested by the inspector to obtain the type-

approval for the equipment and was fined the minimum amount of HUF 15 000 (approximately EUR 52).

Conclusions

Enforcement measures are in place for non-compliances detected. Appropriate follow-up measures are taken by the CAs. Sanctions are appropriate, effective and dissuasive.

5.2.11 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

The NFCSO (and its predecessor the Agricultural Office) has audit plans in place since 2010. Three audits were done in the field on the use of PPPs in 2010. One recommendation required that a risk-based control programme for the marketing and use be introduced. The recommendations were only partially followed-up, as risk-based criteria were missing in the programme for 2012. In 2011 there were no audits for controls of PPPs. In 2012 there are three internal audits planned concerning on-the-spot checks of the PPP Cross-Compliance checks.

There are no procedures for verification of the effectiveness of controls in place with the exception of Cross Compliance checks at the GCOs.

Conclusions

An internal audit system is in place but not always followed-up as the control programmes for marketing and use are not risk based (see section 5.2.7).

Procedures for verification on the effectiveness of controls are not in place for controls outside the scope of Cross Compliance checks which is in contradiction with the requirements of Article 8 of Regulation (EC) No 882/2004.

6 OVERALL CONCLUSION

Hungary has a well developed and organised system for the authorisation of PPPs in place. The high number of authorisations under emergency rules gives cause for concern.

The controls on marketing and use are performed by highly qualified and experienced staff and control programmes are in place. The lack of important elements like the controls on producers of PPPs and risk criteria reduces the effectiveness of the official controls. Some shortcomings concerning the CAs co-operation on budgets, documented procedures for staff, impurity checks on PPPs and verification of the effectiveness of controls weaken the control system.

Of the three recommendations from the previous audit DG(SANCO)/2008-7849 evaluated by the audit team, two have not been satisfactorily addressed. One official laboratory is not accredited. The

recommendation concerning the identification of old stocks of obsolete PPPs has not been addressed.

7 CLOSING MEETING

A closing meeting was held on 08 June 2012 with representatives of the CAs. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit. The CAs provided some preliminary comments and all documents requested by the audit 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 Directive 2009/128/EC is fully transposed into Hungarian legislation.
2.	Ensure that a National Action Plan is prepared and submitted to the European Commission before 26 November 2012 in line with Article 4 of Directive 2009/128/EC.
3.	Ensure that the national system applied for the authorisation of PPPs for emergency situations is in line with Article 53 of Regulation (EC) No 1107/2009.
4.	Ensure that control on producers of PPPs take place in accordance with Article 68 of Regulation (EC) No 1107/2009.
5.	Ensure that the safety rules for storage foresee the separate storage of herbicides as described in the Manual for Pesticide Storage and Stock Control of FAO.
6.	Ensure that analysis of the formulation of PPPs include unexpected active substances, co-formulants and impurities in order to comply with Article 68 of Regulation (EC) No 1107/2009.
7.	Ensure that the Recommendation No 3 of audit DG(SANCO)/2008-7849 is addressed:“ensure that all designated laboratories comply with Article 12(2)(a) of Regulation (EC) No 882/2004, or are availing of the derogation foreseen in Article 18 of Commission Regulation (EC) No 2076/2005. The quality control system in the laboratories availing of Article 18 should be based on the SANCO Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed (SANCO 2007/3131)”.
8.	Ensure that the Recommendation No 7 of audit DG(SANCO)/2008-7849 is addressed:“consider identifying the exact quantities of obsolete pesticides and

N°.	Recommendation
	arranging for their safe destruction, in order to avoid possible contamination of food, feed and the environment”.
9.	Ensure that control programmes for the authorisation, marketing and use of PPPs are risk based according to Article 3(1) of Regulation (EC) No 882/2004.
10.	Ensure that documented procedures for staff are in place for the controls on PPP marketing and use to perform effective official controls as required by Article 8 of Regulation (EC) No 882/2004.
11.	Ensure that there is effective cooperation between the MRD and MPAJ for the implementation of official controls in accordance with Article 4(3) of Regulation (EC) No 882/2004.
12.	Ensure that recommendations of internal audits are followed-up and the CAs take appropriate measures in the light of their results in line with Article 4(6) of Regulation No (EC) 882/2004.
13.	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.

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=2012-6287

ANNEX 1 - LEGAL REFERENCES

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

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
<i>Legislation on Pesticide Residues</i>		
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Reg. 1274/2011	OJ L 325, 08/12/2011, p.0024-0043	Commission Implementing Regulation (EU) No 1274/2011 of 7 December 2011 concerning a coordinated multiannual control programme of the Union for 2012, 2013 and 2014 to ensure compliance with maximum residue levels of pesticide residues and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

ANNEX 2 – STANDARDS QUOTED IN THE REPORT

Reference number	Full title	Publication details
SANCO/12495/2011	Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed, Document SANCO/10684/2009.	http://ec.europa.eu/food/plant/protection/resources/qualcontrol_en.pdf
	Manual for Pesticide Storage and Stock Control of the FAO.	http://www.fao.org/docrep/V8966E/V8966E00.html