FINAL REPORT OF AN AUDIT
CARRIED OUT IN
ITALY
FROM 31 JANUARY TO 08 FEBRUARY 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 Italy, carried out between 31 January and 8 February 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 on one recommendation of report DG(SANCO) 2007-7194.

Although Directive 2009/128/EC had not been transposed at the time of this audit, there is a system in place for the control on the marketing and use of Plant Protection Products (PPPs) and it is in compliance with EU rules, however, some shortcomings were found in the implementation of the system which undermine the effectiveness of the controls. Despite progress having been made by the two laboratories visited, significant deficiencies still exist with regard to the performance of the official laboratories for pesticide residues in fruit and vegetables and for the formulation of the PPPs.

Recommendation 5 of report DG(SANCO)2007-7194 was adequately addressed.

The report makes a number of recommendations to the Competent Authorities (CA), aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.
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<th>Explanation</th>
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<tr>
<td>AGREA</td>
<td>Regional Agency for Financing in the Agricultural Sector - <em>Agenzia Regionale per le Erogazioni in Agricoltura</em></td>
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<td>ARPA</td>
<td>Regional Agencies for Environment Protection - <em>Aziende Regionali per la Protezione Ambientale</em></td>
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<tr>
<td>AUSL</td>
<td>Local Health Units - <em>Aziende Unità Sanitarie Locali</em></td>
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<tr>
<td>CA(s)</td>
<td>Competent Authority(ies)</td>
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<td>CCA(s)</td>
<td>Central Competent Authority(ies)</td>
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<tr>
<td>CFS</td>
<td>State Forestry Service - <em>Corpo Forestale dello Stato</em></td>
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<tr>
<td>DG(SANCO)</td>
<td>Health and Consumers Directorate-General</td>
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<tr>
<td>DGFHFSN</td>
<td>Directorate-General for Food Hygiene, Food Safety and Nutrition - <em>Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e la Nutrizione</em></td>
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<td>DPR</td>
<td>Presidential Decree</td>
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<td>EU</td>
<td>European Union</td>
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<td>EUPT</td>
<td>European Union Proficiency Test</td>
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<td>FBOs</td>
<td>Food Business Operators</td>
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<tr>
<td>FTE</td>
<td>Full-Time Equivalent</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<tr>
<td>GC-MS</td>
<td>Gas Chromatograph coupled to Mass Spectrometer</td>
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<td>GC-MS/MS</td>
<td>Gas Chromatograph coupled to Tandem Mass Spectrometer</td>
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<tr>
<td>GC-MSD</td>
<td>Gas Chromatograph coupled to Mass Selective Detector</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>ICQRF</td>
<td>Central Inspectorate for Quality Controls and Antifraud of Foodstuff and Agricultural Products - Dipartimento dell’Ispettorato Centrale della Tutela della Qualità e della Repressione Frodi dei Prodotti Agro-alimentari</td>
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<tr>
<td>IPM</td>
<td>Integrated Pest Management</td>
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<td>ISO</td>
<td>International Organization for Standardisation</td>
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<td>ISS</td>
<td>National Health Institute - Istituto Superiore di Sanità</td>
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<tr>
<td>LC-MS/MS</td>
<td>Liquid Chromatograph coupled to Tandem Mass Spectrometer</td>
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<td>LOQ</td>
<td>Limit of Quantification</td>
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<tr>
<td>MANCP</td>
<td>Single Integrated Multi-Annual National Control Plan</td>
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<tr>
<td>MATTM</td>
<td>Ministry of Environment and Protection of Land and Sea</td>
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<td>MH</td>
<td>Ministry of Health</td>
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<td>MIPAAF</td>
<td>Ministry of Agriculture, Foodstuff and Forestry Policy</td>
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<td>MRL</td>
<td>Maximum Residue Level</td>
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<td>MS(s)</td>
<td>Member State(s)</td>
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<td>NAS</td>
<td>Carabinieri Health Protection Unit - Comando Carabinieri per la Tutela della Salute - Nuclei Antisofisticazione e Sanità dei Carabinieri</td>
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<td>NCP</td>
<td>National Control Plan for the Marketing and Use of Plant Protection Products for the five year period 2009-2013</td>
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<td>NRL</td>
<td>National Reference Laboratory</td>
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<td>PPP</td>
<td>Plant Protection Product</td>
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<td>RPHS</td>
<td>Regional Public Health Services - Servizi di Sanità Pubblica delle Regioni</td>
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<tr>
<td>SIAN</td>
<td>Food Hygiene and Nutrition Service - Servizio Igiene degli Alimenti e della Nutrizione</td>
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<tr>
<td>SPSAL</td>
<td>Workplace Prevention and Safety Service - <em>Servizio di Prevenzione e Sicurezza degli Ambienti di Lavoro</em></td>
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1 INTRODUCTION

The audit formed part of the Food and Veterinary Office's (FVO) planned programme and took place from 31 January to 8 February 2012. The audit team comprised 2 auditors, a trainee 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 31 January with the CCA(s), including the Ministry of Health (MH), the Ministry of Environment and Protection of Land and Sea (MATTM), the Ministry of Agriculture, Foodstuff and Forestry Policy (MIPAAF), the Central Inspectorate of Quality Protection and Fraud Prevention (ICQRF - Dipartimento dell'Ispettorato Centrale della Tutela della Qualità e della Repressione Frodi dei Prodotti Agro-alimentari), the Carabinieri Health Protection Unit (NAS), the National Health Institute (ISS) and the Regional Public Health Service (RPHS) of Emilia-Romagna and Puglia. 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 the official controls on the use of PPPs by growers under Regulation (EC) No 882/2004;

In terms of scope, the audit assessed the performance of the Competent Authorities (CA), as well as the organisation of the controls including the authorisation procedures, the controls of the wholesalers and retailers of PPPs, and the controls of the growers and the National Reference Laboratory (NRL) for pesticide residues.

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

Table 1: Mission visits and meetings

<table>
<thead>
<tr>
<th>Visits/meetings</th>
<th>Comments</th>
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<tr>
<td>Competent Authorities</td>
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<tr>
<td>Central</td>
<td>1</td>
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<tr>
<td>MH, MATTM, NAS, MIPAAF, ISS</td>
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<tr>
<td>Regional</td>
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<td>RPHS and AUSLS of Emilia-Romagna and Puglia</td>
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<td>Laboratories</td>
<td></td>
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<tr>
<td>Public</td>
<td>2</td>
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<tr>
<td>ISS Rome and ARPA Bari</td>
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On-Site-Visits

<table>
<thead>
<tr>
<th>Controls of growers</th>
<th>1</th>
<th>Citrus grower in Puglia</th>
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<tbody>
<tr>
<td>Controls of wholesalers and retailers</td>
<td>1</td>
<td>Distribution centre of PPPs Puglia</td>
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</table>

3 **Legal Basis and Standards**

3.1 **Legal Basis**

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


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

3.2 **Standards**

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

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

4 **Background**

4.1 **Audit Series**

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

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

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

The planning and reporting of controls for pesticide residues in food of plant origin have improved significantly since the first mission series. Weaknesses were identified in particular regarding the assessment of self-control systems, the point of sampling, and enforcement measures taken in case of non-compliance. The main deficiencies found in pesticide residue laboratories related to the lack of adequate equipment and the 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) (Health and Consumers
Directorate-General) internet site together with the reports.

In the framework of the last series, the FVO carried out a mission in Italy in 2004 (DG(SANCO)/7318/2004) and in 2007 (DG(SANCO)2007-7194). The reports of these missions can be found on the DG SANCO internet site http://ec.europa.eu/food/fvo/index_en.cfm. The overall conclusion of the mission report from 2004 was that the competent authority had attempted to improve the co-ordination of the controls with the regions but with limited success. The lack of central enforcement powers gave rise to concern. The reliability of analytical results was not ensured due to the lack of accreditation in many laboratories. The 2007 report concluded that further progress had been achieved concerning communication. The structures, plans, and procedures for the controls of pesticide residues on the domestic market and at the point of import were in place. However, the controls suffered as a result of significant deficiencies in the laboratory network, such as the lack of accreditation, analytical equipment, co-ordination and technical support.

4.2 COUNTRY PROFILE

The FVO has published a country profile for Italy, 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 the 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

Art. 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

Presidential Decree (DPR) 290/2001 in conjunction with the Legislative Decree 194/95 transposed Directive 91/414/EEC. At the time of the audit a revised version of the DPR had been adopted in order to align national legislation with Regulation (EC) No 1107/2009.

The fees for the authorisation of PPPs are laid down in the Ministerial Decree of 9 July 1999. Office-VII of the Directorate-General for Food Hygiene, Food Safety and Nutrition (DGFHFSN - Direzione Generale per L'igiene e la Sicurezza degli Alimenti e la Nutrizione) of the MH stated that this Decree will also be revised in order to reflect the actual situation and costs.

A representative of the MATTM stated that Directive 2009/128/EC had not been formally transposed at the time of the audit. The government had been entrusted with the transposition by Law No 217 of 15 December 2011 on "Measures for the fulfilment of obligations deriving from Italy to the European Communities - Community Law 2010". The MATTM provided information on the timetable for the transposition of the Directive into national legislation by April 2012 as well as for the adoption of the National Action Plan referred to in Article 4 of Directive 2009/128/EC before the end of 2012.
Conclusions

The audit team found no discrepancies between the national provisions and Regulation (EC) No 1107/2009. Directive 2009/128/EC had not been formally transposed at the time of the audit. This is not in compliance with EU provisions requiring transposition by 26 November 2011. However, a timetable for the transposition of the EU provisions into national legislation is in place.

5.2 Organisatio
d 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 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.

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

Findings

The competences of the authorities involved in the official system for authorisation and controls on the marketing and use of PPPs have not changed since the 2007 FVO mission. The official control system is described in the country profile.

Office VII of the DGFHFSN is the CCA responsible for the authorisation of PPPs and is in charge of the following areas of activity:

- authorisation and marketing of PPPs;
- co-ordination of official controls on the trade and use of PPPs;
- official controls on pesticide residues in food of plant origin;
- management of the national database for PPPs and publications of general interest concerning PPPs;
- contact point for the European Commission for PPP related issues and co-ordination with other Ministries concerned;
- secretariat of the Advisory Commission on PPPs.

The MATTM is the CCA in charge of drafting the legal provisions for the transposition of Directive 2009/128/EC.

The National and EU legislation concerning the marketing and use of PPPs are implemented by the Regional Public Health Services (RPHSs). The regions have delegated this task to the Local Health Units (AUSLs - Aziende Unità Sanitarie Locali. The Food Hygiene and Nutrition Service (SIAN - Servizio Igiene degli Alimenti e della Nutrizione) and the Workplace Prevention and Safety Service (SPSAL- Servizio di Prevenzione e Sicurezza degli Ambienti di Lavoro) of the (AUSLs) are the services which carry out the controls, The SIAN is responsible for the marketing and use of PPPs at distributor and user levels and the SPSAL deals with issues related to safety at work including spraying equipment. In addition, the regional agencies for financing in the agricultural sector are in
charge of organising cross-compliance controls including controls on the use of PPPs.

Several CAs which have regulatory powers also carry out controls on the marketing and use of PPPs. These are mainly the NAS, the ICQRF of the MIPAAF with their local branches in the regions and the State Forestry Service (CFS - *Corpo Forestale dello Stato*) perform controls on PPPs within their area of responsibility.

The ISS is the NRL for pesticide residues in fruit and vegetables (single and multi-residue methods). It plays a co-ordination role with regard to the network of laboratories for pesticide residues and carries out analysis for supplementary expert opinion (secondary analysis) for pesticide residues and the formulation of the PPPs.

Qualitative analysis on the formulation of the PPPs are performed by 8 regional laboratories mainly from the Regional Agencies for Environmental Protection (ARPAs - *Aziende Regionali per la Protezione Ambientale*), which may also be used by the NAS. ICQRF has its own laboratories for the formulation analysis of primary and secondary samples.

**Conclusions**

CAs are designated and their responsibilities are clearly identified at central and regional level.

**5.2.2 Resources for Performance of 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**

Office VII of the DGFHFSN of the MH has 26 staff. The staff met by the audit team were competent and familiar with EU legislation.

In Puglia one person is assigned part-time to the co-ordination of controls on the marketing and use of PPPs carried out by the AUSL inspectors. The SIAN has more than 18 Full-Time Equivalents (FTEs) assigned to controls on the marketing and use of PPPs. Some of the inspectors were qualified as medical doctors but did not have any educational background in agriculture or areas related to the use of PPPs. The CAs of Puglia stated that the last specific training on the marketing and use of PPPs was organised in 2001 by the University of Bari. A training course held in 2010 was limited to pesticides used in wheat production only. The audit team noted that the AUSL inspectors and the operators visited in Puglia did not know precisely how long PPP records had to be kept.

In Emilia-Romagna 3 training courses addressing aspects relevant to the controls on the marketing and use of PPPs were held in 2011. Participants from the AUSLs organised training courses at provincial level for colleagues who had not attended the courses at regional level. An example of the staffing situation was given to the audit team for the province of Ferrara where 15.5 inspectors were entrusted with the controls on the marketing and use of PPPs. At regional level one person was in charge of co-ordinating the regional control plan for the marketing and use of PPPs.
The audit team were informed by the inspectors they met in Emilia-Romagna and Puglia that during inspections they did not always have access to the database of authorised PPPs, mainly because portable PCs were not always available during inspections. Inspectors in both regions stated that the authorisation of products was checked after return to the office. This check was based only on notes made during the inspection as no photos were taken of the labels and no copies of the records on the use of PPPs were made in order to perform a detailed check in the office later.

The ARPA laboratory in Bari has assigned 3.5 FTEs to the analysis of pesticide residues and the formulation analysis. Staff were trained by experts from the manufacturer of the new analytical equipment purchased in 2011.

The NRL have four technical staff and a director. Documentary evidence of internal training courses held was provided to the audit team.

Conclusions

The staff met were experienced, however, in Puglia inspectors were not sufficiently trained on the marketing and use of PPPs. This is not in compliance with Article 6 of Regulation (EC) No 882/2004.

The staff of the AUSLs of Puglia and Emilia-Romagna did not have the appropriate equipment to ensure that official controls can be performed efficiently and effectively. This is not in compliance with Article 4(2)d of Regulation (EC) No 882/2004.

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.

1 In their response to the draft report the Competent Authority noted that the Puglia Regional Health Department provided guidance to the Directors-General of the local health authorities regarding the allocation and use of the amounts received pursuant to Legislative Decree No 194/2008, including the percentage breakdown for the allocation of these funds to different expenditure items. Specifically, it stipulated that these amounts must be used to finance targeted projects, set up by ASL Prevention Departments at the request of the services responsible, to cover the cost of investing in equipment and training the staff involved in planning official food safety control activities. In its letter ref. 00/153/012 of 4 July 2012, the Taranto ASL, which was involved in the inspection in question, stated that the training plans for 2012 included an interdisciplinary SIAN/SPSAL training event called 'Using plant protection products: direct and indirect risks to human and animal health and environmental protection'. Furthermore, the Prevention Department of the ASL submitted a request to use the funds pursuant to Legislative Decree No 194/2008 to purchase appropriate technical and IT equipment for SIAN's medical and inspection staff with responsibility for this matter in order to increase the effectiveness of controls and compliance with the laws in force.

2 In their response to the draft report the Competent Authority noted that Emilia Romagna pointed out that it is not always possible to establish an internet connection in order to consult the Ministry database in the field due to problems connecting to the internet throughout the region, meaning that IT equipment alone is not enough to ensure the effective and efficient performance of official controls. By 2013, it will therefore provide cameras to the AUSLs that do not already have them, to be used during inspections to document the information on the labels in order to be able to check the Ministry of Health database and confirm whether the label is compliant.
Findings

The MH has established guidelines for applications for the authorisation of PPPs and these are available on its website. A standard operating procedure has been established for mutual recognition authorisation requests. It sets out the documentation to be submitted and the process for issuing such authorisations.

The MH is assisted by the Consultative Committee on Phytosanitary Products established by the Managerial Decree of 18 March 2011. It is made up of representatives of the MH, the MIPAAF, the MATTM, the Ministry of Economic Development and of experts. The MH prepares the Ministerial Decisions on the approval of PPPs based on the Committee's opinion. The national register of authorised PPPs is updated within one to five working days following the publication of the Executive Decree. The register can be accessed via the website of the MH (http://www.salute.gov.it).

Since Regulation (EC) No 1107/2009 entered into force three applications for the mutual recognition of PPPs have been filed and six PPPs have been authorised for emergency situations. The MH provided satisfactory information concerning these files as well as for some other PPPs selected by the audit team. The audit team also noted that the PPPs for emergency situations were authorised for a limited period of less than 120 days.

The national database for PPPs contains more than 15 000 entries, including 351 for authorised active substances and 3574 for authorised PPPs plus information on the PPPs for which authorisation has expired or has been withdrawn. The authorisation of nine active substances was pending at the time of the audit. In 2011 authorisations were granted for 377 PPPs. Between 2009 and 2011 a total number of 761 pesticides were authorised, mainly fungicides (274) and herbicides (209) followed by insecticides (157).

Conclusions

A publicly available national electronic register of authorised PPPs is in place and kept up-to-date in accordance with Article 57 of Regulation (EC) No 1107/2009. Authorised PPPs checked by the audit team were registered in compliance with the provisions of Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 540/2011. PPPs for emergency situations are authorised in exceptional cases and for a limited period of time as required by Article 53 of Regulation (EC) No 1107/2009.

5.2.4 Controls on the Marketing of Plant Protection Products

Legal Requirements

Article 28 of Regulation (EC) No 1107/2009 lays down that a PPP shall not be placed on the market unless it has been authorised in the MS concerned.

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

Article 6 of Directive 2009/128/EC lays down that, by 26 November 2015, the sales of PPPs to professional users shall be restricted to persons holding a certificate.

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

Article 68 requires MSs to carry out official controls in order to enforce compliance with this Regulation.
Article 13 of Directive 2009/128/EC requires MSs to adopt the necessary measure to ensure that handling and storage of pesticides and handling, recovery or disposal of their packaging and remnants do not endanger human health or the environment.

Findings

The premises of the distributors of PPPs must be registered. An application must be sent to the Local Health Units - Aziende Unità Sanitarie Locali (AUSLs), including detailed information on the premises and safety issues. Establishments are approved if they fulfil all the requirements. This is checked on the spot by AUSL inspectors and where necessary by other CAs (e.g. Fire Brigade).

On 8 April 2009 the State-Region Conference adopted the “National Control Plan for the Marketing and Use of Plant Protection Products for the five year period 2009-2013” (NCP). The NCP lays down that controls on the marketing and use of PPPs shall be carried out, based on a risk assessment taking into account all the necessary information (e.g. past records of operators and statistics on the sale of PPPs).

The audit team met the regional and provincial CAs of Puglia and Emilia-Romagna and noted that:

- a multi-annual regional control plan for the marketing and use of PPPs has been established and is complemented by provincial plans;
- implementation of the control plan is co-ordinated and supervised by the RPHS and reports on the results of the controls are submitted by the AUSLs to the RPHS at least once a year;
- results of the inspections are entered by the inspectors into a database;
- inspection guidelines including checklists for controls and report templates have been established at regional level;
- a system for the training and certification of distributors is in place. The licences are valid for five years and are renewed after attendance at a refresher course.

The audit team saw inspection reports and received copies of the inspection guidelines in both regions.

A representative of the Puglia RPHS stated that all points of sale are to be controlled at least once during a three-year period under the regional control plan which also lays down a minimum number of samples of PPPs to be taken for targeted active substances. In Puglia 391 distributors were controlled in 2010 and 13 infringements were found.

The RPHS of Emilia-Romagna informed the audit team that approximately 600 distributors including two producers of PPPs were registered in the region and that according to the planning programme each distributor will be inspected at least once every 5 years and in some cases, based on a risk assessment, checks will be performed annually.

The audit team participated in one inspection of a distribution centre of a PPP producer. The distribution centre executed only orders placed by retailers and wholesalers at the central office of the producer. The authorisations for purchase ("licences") of the customers were checked at the central office. The CAs stated that the distribution centre was open only at set times. For this reason, inspections were announced, whereas in other cases no prior notice was given. The distribution centre was inspected annually and the audit team saw the 2009 and 2010 inspection reports including (one follow-up inspection) a report on a follow-up inspection to address minor shortcomings. The audit team noted that:

- inspections were usually carried out jointly by SIAN and SPSAL;
- the SIAN inspector met checked the facilities, the entry-exit records, a sample of labels and
compared the data in the records with the quantities of the relevant PPPs in stock;

• the entry-exit register of PPPs did not allow retrospective manipulation of entries.

• the inspector entered the national database for PPPs via the internet in order to verify the authorisation and the information on the label;

• the inspector followed the checklist and at the end of the inspection issued a report which was signed by both, the inspector and the representative of the distribution centre.

Inspections on the marketing of PPPs are also carried out by the NAS, ICQRF and the CFS.

The NAS works on its own initiative (routine checks and targeted inspections on the basis of evidence) or on request by the MH (see also section 5.2.10).

In 2010 the ICQRF carried out 403 inspections at points of sale of PPPs and more than 600 controls on labelling and packaging and took 123 samples of PPPs (all samples were compliant). The ICQRF found 36 non-compliances related to the points of sale and 2 with regard to labelling.

The representatives of the RPHS and AUSLs and of the ICQRF stated that data on withdrawn PPPs (whose retention and marketing at retail stores are no longer allowed), are distributed to the inspectors at the local units of these CAs. The audit team saw examples of this communication.

According to the information received from the MH, only eight regions took samples of PPPs for the formulation analysis in 2010. The number of samples was 64. Samples were analysed by the ARPA laboratories and in Sicily, by the ICQRF laboratory. All but one of the laboratories were accredited, nevertheless, the audit team received no information concerning the range of substances covered by the analytical methods. Also, the 13 samples taken by the NAS were analysed by the ARPA laboratories. The audit team visited the ARPA laboratory in Bari and was informed that the laboratory analysed all 15 samples taken by the AUSL inspectors of the Puglia region in 2010 (all of which were compliant). A representative of the laboratory stated that only a qualitative check of the active substance was carried out for substances detectable by Gas Chromatograph coupled to Mass Spectrometer (GC-MS) methods. In 2010 and 2011 no samples of PPPs were taken in Emilia-Romagna.3 The representative of the ARPA laboratory in Bologna stated that, in the past, analysis of PPP samples (both qualitative and quantitative) had shown no non-compliances and that in Emilia-Romagna it was considered unlikely that samples taken from authorised PPPs at authorised points of sale would be non-compliant. The representative of the ICQRF said that their laboratories only carry out analysis targeted at the active substance which is expected to be contained in the PPPs; 123 samples of PPPs were taken in 20104. The ARPA laboratories in Bologna and Bari and the ICQRF laboratories do not analyse PPP samples for all compounds of the PPP formulation or carry out screening for unexpected active substances or formulation agents.

Conclusions

3 In their response to the draft report the Competent Authority noted that Emilia Romagna has stated that it believes that the quantitative analysis of active substances is not sufficient to establish whether the danger level declared by the PPP manufacturer is correct. In order to analyse the formulation in accordance with Article 68 of Regulation (EC) No 1107/2009, a reference structure is required to validate the analytical methods and an interlaboratory arrangement is necessary to check the quality of the analytical data. Until an agreement is reached between the state and the regions establishing methods for checking chemical substances in PPPs, the 2013 annual control plan will be extended to include testing for certain chemical substances based on the higher level of danger they pose, determined by the order of priority that follows the sequence of long-, medium- and short-term toxicological, ecotoxicological and physico-chemical priorities and the quantity used in practice in the areas for which the individual AUSLs are responsible.

4 In their response to the draft report the Competent Authority noted that the Central Inspectorate for Quality Controls and Antifraud of Foodstuff and Agricultural Products (ICQRF) will put in place the type of control requested once it has obtained the information from the Ministry of Health and that EU guidelines and/or criteria for the control of co-formulants would facilitate the analytical controls.
Records on the entry and exit of PPPs were kept by distributors as required by Article 67(1) of Regulation (EC) No 1107/2009 and controls on the marketing of PPPs are performed as required by Article 68 of the same Regulation.

A system for the training and certification of the PPP distributors, as required by Articles 5 and 13 of Directive 2009/128/EC, is in place in the regions visited by the audit team.

With regard to the formulation analysis of PPPs the controls do not ensure that compliance with EU provisions can be enforced as required by Article 68 of Regulation (EC) 1107/2009 as not all regions take samples of PPPs, and the official laboratories entrusted with the formulation analysis do not analyse for all compounds of the PPP formulation and screening is not carried out for unexpected compounds in the formulation for the detection of, for example, counterfeit products.

5.2.5 Controls on the Use of Plant Protection Products

Legal Requirements

Article 4(1) of Regulation (EC) No 852/2004, and Annex I, Part A.III of the same Regulation, requires that Food Business Operators (FBOs) producing or harvesting plant products are, in particular, to keep records on any use of PPPs.

Article 55 of Regulation (EC) No 1107/2009 requires that the use of PPPs shall comply with the general principles of integrated pest management (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 integrated pest management on a voluntary basis.

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

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

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

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

Article 13 of Directive 2009/128/EC requires MSs to adopt the necessary 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 pesticides application equipment.

Findings

With regard to the following issues the same applies for the control system as for the marketing of PPPs (see section 5.2.4):

- The controls on the use of PPPs are an integral part of the NCP for 2009-2013 and of the regional control plans of Puglia and Emilia-Romagna.
- The CAs in charge of the controls on the use of PPPs are the same as those for the marketing
of PPPs except the ICQRF which only inspects the marketing of PPPs.

- Inspections usually take place without prior notice.
- Inspection guidelines in the form of checklists have been established in Puglia and Emilia-Romagna.
- A system for the training and certification of users is in place in Puglia and Emilia-Romagna. The licences are valid for five years and have to be renewed following the completion of a refresher course.

Puglia has a significant area of agricultural land in particular for vegetables grown in the open air (24% of the national production), grapes (25% of the national production), olives (33% of the national production) with more than 275,000 producers. In 2009 the number of controls conducted on the use of PPPs was 230 (31 infringements) and in 2010 the number of controls was 108 (17 infringements).

More than 74,000 agricultural holdings are situated in the region of Emilia-Romagna according to the 2010 census. The main fruit and vegetables grown in the area are pears, nectarines, apples and melons with a total production area of approximately 50,000 ha. The RPHS informed the audit team that in 2010 the number of controls for the use of PPPs — sometimes combined with controls on pesticide residues — was 281, covering 243 agricultural holdings. The number of non-compliances found was 53.

The audit team participated in a joint inspection of the SIAN and the SPSAL to a citrus producer in Puglia. The SIAN inspector (a medical doctor) checked whether or not a spray diary was kept. The audit team noted that the inspector did not verify the entries into the the spray diary (e.g. location and size of the site, crop treated, pre-harvest interval). The inspector did not have access to the information contained in the national database on authorised PPPs (neither printouts nor access to the internet). The SIAN inspector also checked the storage facilities for PPPs and selected four PPPs randomly. For these PPPs he recorded the name on the checklist and stated that the authorisation of these products would be checked on his return to the office. The report was finalised and signed by both, the representative of the farm and the inspector. The farm had been inspected in previous years and the audit team received copies of the inspection reports.

The SPSAL inspector in charge of safety at work checked the protective clothing and the spraying equipment. A visual inspection was carried out and the certificate of calibration was checked. The RPHS and the Agricultural Service informed the audit team that in Puglia the plant protection consortia (made up of semi-state bodies), which also advise farmers on pest management and carry out the monitoring of pests and diseases, are entrusted with the technical checks on the spraying equipment. The CAs stated that no final decision has yet been taken on how to organise the inspections of the spraying equipment in accordance with Directive 2009/128/EC and that consideration was being given to delegating inspection tasks to the consortia. Approximately 50,000 machines are to be inspected in Puglia.

Puglia published measures for pest and disease management — including biological measures and the application of PPPs — in the Official Journal No 33 of 3 March 2011. The Agricultural Service informed the audit team that the information is also used in order to convince retailers to take account of and promote integrated pest management (IPM). In 2011 the regional Agricultural Service published a brochure on the use of PPPs, including some information on IPM. The brochure was handed out to participants at the training courses on PPPs and one citrus farmer met by the audit team was aware of it. This farmer informed the audit team that mass trapping for fruit flies was successfully applied.

In both the Puglia and Emilia-Romagna regions, the CAs stated that controls are not systematically
carried out during the application of PPPs.

The audit team met a representative of the local office of the ICQRF in Bologna. He stated that the main activity of the ICQRF was to control issues related to the quality of agricultural production such as organic farming and geographical indications and that, in addition, controls are also carried out on the marketing of PPPs, in particular on the labelling.

In Emilia-Romagna the audit team was informed that the Regional Agency for Financing in the Agriculture Sector (AGREA) carries out checks on the use of PPPs in the framework of the agricultural support schemes (single payment and agri-environmental scheme). One percent of farms receiving subsidies is checked every year.

Conclusions

A system for the controls on the use of PPPs is in place in accordance with Article 68 of Regulation (EC) No 1107/2009. However, given the high volume of fruit and vegetables produced, the large number of farmers and the relatively high level of non-compliance found in 2010, the frequency of controls on the use of PPPs in Puglia is considered not to be in compliance with Article 3(1) of Regulation (EC) No 882/2004. Furthermore, the audit team observed that the recording of data on the use of PPPs and the labelling of PPPs were not verified by one inspector during the inspection in Puglia, therefore, the control was not considered to be sufficiently effective. This is not in compliance with Article 4(2)(a) of Regulation (EC) No 882/2004.

In Emilia-Romagna the number of controls was relatively low, but this was offset by the link created with the controls carried out in connection with the agricultural support schemes (see section 5.2.7).

Professional users of PPPs met by the audit team kept records on the use of PPPs as required by Article 67 of Regulation (EC) No 1107/2009.

A system for the training and certification of professional users of PPPs as well as a system for the technical check of the spraying equipment is in place.

Both regions visited by the audit team had measures in place to promote IPM.

5.2.6 Control Programmes for Pesticide Residues

Legal Requirements

Article 33 of Regulation (EC) No 882/2004 requires MSs to designate National Reference Laboratories (NRLs) for each EU reference laboratory, 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 the EN ISO/IEC 17025 and EN ISO/IEC 17011 standards. Article 28 of Regulation (EC) No 396/2005 lays down the requirements for the methods of analysis and quality control procedures for pesticide residue analysis.

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

Findings

Recommendation 5 of report DG(SANCO)2007-7194: The CAs should ensure that the NRLs comply with Article 33 of Regulation (EC) No 882/2004 was followed-up by this audit.

The team visited the ISS in Rome, and the ARPA Puglia laboratory in Bari.

The ISS is designated as the NRL for pesticide residues in fruit and vegetables, food of animal origin, and for single residue methods. The NRL maintains an updated register of designated
laboratories in Italy, and organises regular meetings for official laboratories in the network. At the
time of the audit 28 official laboratories for pesticide residues analysis of fruit and vegetables were
registered. On request of the audit team the NRL requested information on the available equipment
from the official laboratories. The CA stated that in 2012 all official laboratories are accredited and
that 16 laboratories are equipped with LC (HPLC)-MS-MS and five with GC-MS-MS. The other
laboratories have GC-MS, GC-ECD, GC-NPD, GC-ECD/ECD, GC with ECD and FPD, LC-MS,
HPLC-DAD or HPLC-FL.

The NRL does not carry out routine analysis, but performs second instance analysis. In 2011, 37
samples were analysed for pesticides for which non-compliances had been detected. The analysis
take a minimum of three months. The facilities are adequate. Since the last audit in 2007, the
laboratory has received LC-MS-MS and GC-MS-MS equipment (both triple quadrupole), and GC-
MSD) ion trap. In addition, Gas Chromatograph coupled to Mass Selective Detector (GC-MSD)
and Gas Chromatograph coupled to Flame Photometric Detector/Gas Chromatograph coupled to
Electron Capture Detector equipment is available. Since 2010, the laboratory is accredited by
ACCREDIA for analysis of 11 pesticides in various matrices. Validation of methods for further
pesticides has been achieved. The total scope covers 161 analyses, but does not include all
substances of the 2012 EU control programme. The laboratory has implemented the QuEChERS
method (EN 15662:2009), together with an in-house method based on acetone extraction and solid
phase partition with dichloromethane in diatomaceous earth cartridges. The laboratory regularly
participates in the European Union Proficiency Test (EUPT). Generally the results have been good
since 2009, however, there was a false negative report in 2011. The SANCO Guidelines for Method
Validation and Quality Control Procedures are followed in principle but with significant deviations:

• Matrix effects are not determined, and calibration curves are prepared in solvent (point 44);
• The recovery studies were performed in non-compliant samples and the spiking level was only
twice the expected concentration, but not a minimum of three times as required (point 63).

The ARPA Puglia laboratories in Bari and Brindisi are the only laboratories designated by the
AUSLs for pesticide residues analysis in Puglia. The authorities in Puglia stated during the audit
that from 2012, all official analysis will be carried out by the Bari laboratory. The laboratory has
carried out analysis of around 1,200 samples in 2011. Analysis take 7 to 20 days. Three staff are
dedicated to pesticide residues analysis, one of whom has a university degree, under the supervision
of the director and the laboratory manager, who are also responsible for other areas. The building
was suitable for the analysis carried out. Since the last mission in 2004 the laboratory has purchased
new equipment, an LC-MS ORBITRAP and a GC-MS-MS (triple quadrupole). For formulation
analysis a GC-MS (Ion trap) in full scan mode is used. Since 2010, the laboratory is accredited by
ACCREDIA for analysis of 15 pesticides in three different groups of matrices. A full validation of
90 substances has been performed by the laboratory, although the total scope is 247. The laboratory
has implemented the Quechers method (EN 15662:2009). The laboratory regularly participates in
different proficiency tests, including EUPT. The results were generally good, although the scope did
not include all substances covered by the EUPT. The laboratory follows, in principle, the SANCO
Guidelines for Method Validation and Quality Control Procedures, however with significant deviations:5

• Stock standards were not correctly stored in tightly closed glass containers but were in
  volumetric flasks (point 18);

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5 In their response to the draft report the Competent Authority noted that on this point, Puglia has specified the
  corrective actions taken by ARPA in relation to the comments on the Sanco/12495/2011 guidelines. As far as the
  number of accredited pesticides is concerned, another 101 active substances analysed using LC/HRMS Orbitrap
  were accredited during the latest inspection by Accredia (20 June 2012). This takes the total number of accredited
  pesticides to 130.
• Standards, stock and working solutions are stored in the same refrigerator as homogenised samples (point 28);

• No bracketing calibration is carried out, and the drift of the determination system has not been studied (point 35);

• The minimum frequency of calibrations for representative analysis is not followed, as calibration curves are established only every two weeks (point 42);

• Matrix effects are not determined, particularly in LC-MS. Calibration curves are prepared in solvent (point 44);

• The ion ratio of the transitions was not determined to verify the correct identification of the analysis (point 80, table 5);

**Conclusions**

Both laboratories visited by the audit team had made progress since the previous FVO audits (2004 and 2007) and both were accredited, although the number of compounds covered by the accreditation is still very low, and significant deviations from the SANCO Quality Control Guidelines were observed.

Adequate equipment for a broad range of analysis and low LOQs is available in the laboratories visited by the audit team. While there is still a lack of adequate equipment in many designated laboratories, the available resources in the NRL allow for a significantly higher number of analysis to make more efficient use of the equipment and to gather more experience with routine samples.

Not all official laboratories for pesticide residues can analyse the full range of pesticides listed in the co-ordinated multi-annual control programme referred to in Article 29 of Regulation (EC) No 396/2005.

The NRL for multi- and single-residue methods for pesticide residues in fruit and vegetables carries out its task in accordance with the EU provisions. Recommendation 5 of report DG(SANCO) 2007-7194 has been addressed.

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 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.

Article 41 of Regulation (EC) No 882/2004 requires that each MS shall prepare a single Integrated Multi-Annual National Control Plan (MANCP) and Article 42 of the same Regulation lays down the principles for the preparation of the MANCP

**Findings**

The NCP 2009-2013 as well as the regional control plans of Puglia and Emilia-Romagna contain criteria for the risk-based planning of controls on the marketing and use of PPPs such as the results of previous controls including irregularities found.

The ICQRF carries out inspections based on an annual plan which is established based on the following risk criteria:
• marketing data;
• commercial preparations with retail price lower than those with similar formulation;
• experience of previous inspections.

The NAS carries out targeted inspections related to criminal activities based on information received from police investigations or other sources of information (e.g. from the MH). Examples of such targeted operation were presented to the audit team (see section 5.2.10).

In Puglia the audit team was informed by the CAs that the AUSLs plan the controls for their jurisdiction and that the results of previous inspections are taken into account. The inspector met at the citrus farm stated that own-controls of the producers are not checked and the audit team noted that this was not included in the checklist. In Emilia-Romagna own-controls are covered by the checklist, but an inspector met stated that this is not taken into account for the planning or performance of controls6.

Distributors of PPPs are checked in Puglia at least once every three years, but in some cases annually. Each of the AUSLs in Puglia must inspect at least 12 producers for the use of PPPs under the regional control plan based on Regional Decision No 788/2011 for the period 2011-2013. The audit team received no evidence that the results of the controls concerning the agricultural support schemes are taken into account for prioritisation of controls on the use of PPPs. In Emilia-Romagna the audit team was informed that an agreement concerning exchanges of data on the controls on use of PPPs between the AGREA and the RPHS had been in place since 2008 and that a joint database was planned by the end of 2012.

Italy has established a MANCP for the period 2011-2014 which can be found on the website of the MH (http://www.salute.gov.it/pianoNazionaleIntegrato/homePianoNazionaleIntegrato.jsp). Chapter 3E provides information on the system for the controls on the marketing and use of PPPs.

Conclusions
Risk criteria are taken into account for planning controls on marketing and use of PPPs. However, own-controls by producers are not taken into account by the CAs of Puglia and Emilia-Romagna and the results of the controls in connection with the agricultural support schemes were not considered by Puglia. This is not in compliance with Article 3(1)(c) and (d) of Regulation (EC) No 882/2004.

5.2.8 Procedures for Performance and Reporting of Control Activities

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

Article 9 of the above Regulation requires CAs to draw up reports on the official controls carried out, including a description of the purpose of the 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.

6 In their response to the draft report the Competent Authority noted that Emilia Romagna has stated that this aspect of the official controls will be addressed at the next regional training event on PPP scheduled for September 2012.
Findings

In Puglia and Emilia-Romagna the audit team received documented evidence that inspection guidelines were established and reports were issued after each control. The audit team observed one inspection of a citrus producer and one inspection of a distribution centre for PPPs and noted that after each inspection, inspectors issued a report which was signed by the inspectors as well as by the representatives of the holdings.

In 2009 and 2010 every region submitted the results of their controls on the marketing and use of PPPs to the MH which compiled the data together with information from the other CAs in a report which was sent to the Commission.

Conclusions

Controls are based on documented procedures and inspection reports are issued in compliance with EU provisions. Italy submitted reports concerning the controls on the marketing and use of PPPs to the Commission as required by EU legislation.

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

Legal Requirements

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

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

Findings

Co-ordination takes place at central level in meetings between the ministries involved. For example, with a view to the establishment of the National Action Plan on the use of PPPs in accordance with Directive 2009/128/EC, the MATTM organised a meeting with the representatives of different ministries from the central level along with representatives of all regions and other CAs in May 2011. The State-Regions Conference provides a forum for nationwide co-ordination of activities. The NCP for 2009-2013 is based on an agreement by the 2009 State-Regions Conference.

Several CAs are involved in the official controls on the marketing and use of PPPs. The audit team noted that there are partial overlaps with regard to the controls on the marketing of PPPs, in particular as regards the activities of the ICQRF which overlap with the controls by the NAS and by regional CAs. No evidence of co-operation between them was provided to the audit team.

In Puglia the audit team was informed that the CFS had found an unauthorised point of sale and had seized suspicious PPPs. The RPHS had not been informed by the CFS. The RPHS had also not been informed by the NAS about its activities in Bari (see section 5.2.10) in 2009 and 2010. At the request of the audit team, the RPHS asked the CFS for information and was told that, due to the ongoing investigations, no detailed information can be provided. The CFS took the opportunity to seek advice from the RPHS concerning the appropriate laboratory capable of analysing the target substance. The CAs of Puglia, including the ARPA laboratory in Bari, did not have this information and had to forward the request to the MH.

The audit team received copies of the communications between the MH and the NAS. At the closing meeting a representative of NAS stated that it is the responsibility of the MH to communicate with the regions as appropriate.
The SIAN and the SPSAL in Puglia have been carrying out joint activities since 2011 and the local Agricultural Services organise and co-ordinate the training courses on PPPs with AUSLs. The audit team also obtained documentary evidence of meetings organised by the RPHS with AUSLs.

The ARPA laboratory in Bari informed the audit team that a network of official laboratories for formulation analysis has not yet been established and that there are no exchanges of information on this issue between the laboratories which carry out such controls.

In Emilia-Romagna the working groups of the CAs have been established at regional and provincial levels and meet at least once a year. Minutes of the meetings were made available to the audit team. A project to establish a joint AGREA/RPHS database for recording official controls was under way at the time of the audit.7

Conclusions

There is good communication and co-operation between CAs at federal level with a view to the preparation of the National Action Plan referred to in Article 4 of Directive 2009/128/EC and between the MH and the regional CAs.

However, the results of the activities of the NAS and the CFS are not systematically communicated to the regions and there is no systematic exchange of information between laboratories performing formulation analysis of PPPs. There is an overlap between the work of the RPHSs and the ICQRF and no evidence of co-operation between them was provided to the audit team. This is not in compliance with Article 4(3) of Regulation (EC) No 882/2004.

5.2.10 Enforcement Measures

Legal Requirements

Article 72 of Regulation (EC) No 1197/2009 states that MSs shall lay down the rules on penalties applicable to infringements and ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive.

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

Article 55 of Regulation (EC) No 882/2004 states that MSs shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings

The audit team was informed that Law 283/62 provides the legal basis for administrative fines of up to EUR 46 481.

In Puglia the audit team noted from the reports of previous inspections that irregularities were recorded and corrective action was followed up. The RPHS informed the audit team of a case where a distributor had not kept the entry-exit register of PPPs accurately and an administrative fine of EUR 700 was imposed.

7 In their response to the draft report the Competent Authority noted that Emilia Romagna has stated that the data from the findings of the controls performed by NAS are automatically included in the annual report prepared by ARPA and sent each year to the Ministry of Health and other parties with an interest or involvement in the subject.
In Emilia-Romagna the audit team checked the file on a non-compliance case where a farmer had not properly recorded the use of PPPs in the spray diary. The farmer was notified about the non-compliance and the corrective action to be taken (which was followed up) and fined EUR 250.

Between 2009 and 2011 nearly 3 200 inspections were carried out by the NAS and 1 135 administrative or criminal offences were found. Nearly 50 people were arrested and more than 577 000 kg of PPPs seized. At the opening meeting a representative from the NAS gave examples of targeted operations in the regions, including two in Bari. Both had targeted criminal organisations linked to robbery and theft, including illegal trade in PPPs with a value of EUR 60 million in the 2010 case.

**Conclusions**

Appropriate action is taken in cases of non-compliance and corrective measures are followed-up by inspections. Sanctions applied are effective, proportionate 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 the official controls, to ensure the effectiveness of the corrective action and to update documentation where needed.

**Findings**

The MH informed the audit team that an audit on pesticide residues and marketing and the use of PPPs to Sardinia and Toscani is planned for 2012. The representatives of the RPHS of Puglia stated that so far no internal audit on PPPs was organised nor was such an audit planned. The region of Emilia-Romagna provided documentary evidence of an audit carried out in 2008. It addressed the implementation of the regional control plan for PPPs 2004-2008. The audit covered the activities of all 11 AUSLs of the region.

**Conclusions**

The system for audits does not ensure adequate coverage of the control system for the marketing and use of PPPs and all relevant competent authorities within the sector at an appropriate risk-based frequency as required by Article 4(6) of Regulation (EC) No 882/2004 in conjunction with Commission Decision 2006/677/EC.

### 6 Overall Conclusion

Although Directive 2009/128/EC had not been transposed at the time of this audit, there is a system in place for the control on the marketing and use of PPPs and it is in compliance with EU rules. However, some shortcomings were found in the implementation of the system which undermine the effectiveness of the controls. Despite progress having been made by the two laboratories visited, significant deficiencies still exist with regard to the performance of the official laboratories for pesticide residues in fruit and vegetables and for the formulation of the PPPs.

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8 In their response to the draft report the Competent Authority of Puglia noted that one of the commitments set out in the regional prevention plan adopted with Decision No 2994/2010 of the Regional Council qualifying the regional and ASL health staff responsible for performing official controls through a specific audit training plan.
Recommendation 5 of report DG(SANCO) 2007-7194 was adequately addressed.

7 CLOSING MEETING

A closing meeting was held on 8 February 2012 with representatives of the CCAs and representatives of the CAs of Emilia-Romagna. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit.

The CAs provided some clarifying comments.

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 the translated draft audit report. The CA should:

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<td>1.</td>
<td>Ensure that laws, regulations and administrative provisions necessary to comply with Directive 2009/128/EC are brought into force as required by Article 23 of the same Directive.</td>
</tr>
<tr>
<td>2.</td>
<td>Ensure that staff performing official controls on the marketing and use of PPPs, receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner as required by Article 6 of Regulation (EC) No 882/2004.</td>
</tr>
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<td>3.</td>
<td>Ensure that staff have the appropriate equipment for the verification of the details of the authorisation of PPPs during inspections in order to ensure that official controls on the marketing and use of PPPs can be performed efficiently and effectively as required by Article 4(2)(d) of Regulation (EC) No 882/2004.</td>
</tr>
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<td>4.</td>
<td>Ensure that all regions take samples of PPPs and that analysis of the formulation of the PPPs include expected and unexpected active substances, co-formulants and impurities in order to comply with Article 68 of Regulation (EC) No 1107/2009.</td>
</tr>
<tr>
<td>5.</td>
<td>Ensure that controls on the use of PPPs are effective and appropriate as required by Article 4(2)(a) of Regulation (EC) No 882/2004 and in particular that information on the labels of PPPs and entries into the records on the use of PPPs are verified.</td>
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<tr>
<td>6.</td>
<td>Ensure that controls on the use of PPPs are carried out with an appropriate frequency as required by Article 3(1) of Regulation (EC) No 882/2004.</td>
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<td>7.</td>
<td>Ensure that all official laboratories designated for pesticide residues are able to analyse the full range of pesticides listed in the co-ordinated multi-annual Community control programme referred to in Article 29 of Regulation (EC) No 396/2005.</td>
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| 8.  | Ensure that all official laboratories designated for pesticide residues take account of the “Method Validation and Quality Control Procedures for pesticide residues analysis in
<table>
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<td>9.</td>
<td>Ensure that official controls on the use of PPPs are carried out on a risk basis as required by Article 3 of Regulation (EC) No 882/2004 and in particular that the reliability of any own checks of users of PPPs as well as information indicating non-compliance, including results from controls carried out in the framework of the agricultural support schemes, are taken into account.</td>
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<tr>
<td>10.</td>
<td>Ensure efficient and effective coordination between all the competent authorities involved in the official controls on the marketing of PPPs as required by Article 4 of Regulation (EC) No 882/2004 and in particular as regards the coordination of the activities of the NAS, the CFS and the ICQRF with the RPHSs.</td>
</tr>
<tr>
<td>11.</td>
<td>Ensure that internal or external audits are carried out in accordance with Article 4(6) of Regulation (EC) No 882/2004 in conjunction with Commission Decision 2006/677/EC and in particular that the audit system ensures adequate coverage of the control system for the marketing and use of PPPs and all relevant competent authorities within the sectors at an appropriate risk-based frequency.</td>
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### ANNEX 1 - LEGAL REFERENCES

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<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
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<tbody>
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<td><strong>Legislation on Plant Protection Products</strong></td>
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**Legislation on Pesticide Residues**

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# Annex 2 – Standards Quoted in the Report

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