FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

POLAND

FROM 15 TO 23 NOVEMBER 2010

IN ORDER TO ASSESS THE OFFICIAL CONTROL SYSTEMS IN PLACE FOR PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN

IN THE CONTEXT OF A GENERAL AUDIT

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) specific audit in Poland, carried out between 15 to 23 November 2010, as part of the general audit of Poland undertaken under the provisions of Regulation (EC) No 882/2004 on official food and feed controls. The objective of the specific audit was to check that official controls are carried out in accordance with the principles of that Regulation and in line with the multi-annual national control plan (MANCP) as specified in Article 41 of the above Regulation. In order to achieve the overall objective the specific audit evaluated the implementation of the EU legislation in the area of pesticide residues and plant protection products (PPPs).

Competent Authorities (CAs) are designated and their responsibilities at all levels are clearly defined. Efficient and effective co-ordination between and within the CAs takes place. Regular and risk-based controls are performed in accordance with annual control programmes. However, shortcomings were identified, relating to the content of the MANCP, contingency plans and the evaluation of auto-control systems.

Comprehensive systems are in place for the control of the use of PPPs and for the control of pesticide residues in domestic and imported produce. Deficiencies were identified regarding the control programme for pesticide residues, sampling and risk-based import controls.

The designated laboratories are accredited and the quality control systems generally follow the SANCO Guidelines. However, the analytical scope (number of pesticides sought) in most of the official laboratories is not sufficiently broad for an effective control of all PPPs authorised and the pesticide residues included in the EU control programme.

Illegal uses of PPPs are notified to the national contact point of the Rapid Alert System for Food and Feed (RASFF), but MRL infringements in domestic products are only notified to the EU if the product was distributed to other MSs.

Recommendations made in the report of the previous mission have been addressed, but the destruction of obsolete pesticides is not finalised yet.

The report makes a number of recommendations to the Polish competent authorities aimed at rectifying the shortcomings identified and enhancing the implementation of the control measures in place.
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<th>Explanation</th>
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<tr>
<td>BSES</td>
<td>Border Sanitary Epidemiological Station</td>
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<tr>
<td>CA</td>
<td>Competent Authority</td>
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<td>CCA</td>
<td>Central Competent Authority</td>
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<tr>
<td>CSI</td>
<td>Chief Sanitary Inspectorate</td>
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<tr>
<td>DG (SANCO)</td>
<td>Health and Consumers Directorate-General</td>
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<tr>
<td>EC</td>
<td>European Community</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>FBO</td>
<td>Food Business Operator</td>
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<td>FNAO</td>
<td>Food of Non – Animal Origin</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<td>GA</td>
<td>General Audit</td>
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<tr>
<td>GC/ECD</td>
<td>Gas Chromatography / Electron Capture Detector</td>
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<td>GS/MS</td>
<td>Gas Chromatography / Mass Spectrometry</td>
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<td>GC/NPD</td>
<td>Gas Chromatography / Nitrogen Phosphorous Detector</td>
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<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
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<tr>
<td>HPLC/UV-VIS</td>
<td>High Performance Liquid Chromatography / Ultraviolet Visible Detector</td>
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<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<td>LOD</td>
<td>Limit of Detection</td>
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<td>LOQ</td>
<td>Limit of Quantification</td>
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<tr>
<td>LC/MS</td>
<td>Liquid Chromatography / Mass Spectrometer</td>
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<td>LC/MS-MS</td>
<td>Liquid Chromatography / Tandem Mass Spectrometry</td>
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<td>MANCP</td>
<td>Multi Annual National Control Plan</td>
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<td>MARD</td>
<td>Ministry of Agriculture and Rural Development</td>
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<td>MIPHSI</td>
<td>Main Inspectorate for Plant Health and Seed Inspection</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>NIPH - NIH</td>
<td>National Institute of Public Health – National Institute of Hygiene</td>
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<td>NRL</td>
<td>National Reference Laboratory</td>
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<tr>
<td>PCA</td>
<td>Polish Centre for Accreditation</td>
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<td>PLN</td>
<td>Polish Zloty</td>
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<td>PPA</td>
<td>Plant Protection Act</td>
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<td>PSES</td>
<td>Poviat Sanitary Epidemiological Station</td>
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<td>PT</td>
<td>Proficiency Tests</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>SPHSIS</td>
<td>State Plant Health and Seed Inspection Service</td>
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<td>SSI</td>
<td>State Sanitary Inspectorate</td>
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<tr>
<td>TC</td>
<td>Third Country</td>
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<tr>
<td>UV-VIS</td>
<td>Ultraviolet Visible</td>
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<td>VPHSIS</td>
<td>Voivodship Plant Health and Seed Inspection Service</td>
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<td>VSES</td>
<td>Voivodship Sanitary Epidemiological Stations</td>
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1 INTRODUCTION

The specific audit formed part of the FVO's planned mission programme and was carried out as a component of a General Audit (GA), as prescribed in Article 45 of 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.

The specific audit took place in Poland from 15 to 23 November 2010. The audit team comprised three inspectors from the Food and Veterinary Office (FVO) and one expert from a Member State (MS).

Representatives from the central competent authorities (CCAs), namely the State Sanitary Inspectorate (SSI) within the Ministry of Health (MoH) and the State Plant Health and Seed Inspection Service (SPHSIS) within the Ministry of Agriculture and Rural Development (MARD) accompanied the mission team for the duration of the mission. An opening meeting was held on 15th November 2010 with the above CCA. The objectives of, and itinerary for, the specific audit were confirmed by the mission team and the control systems were described by the authorities.

2 OBJECTIVES OF THE MISSION

The objectives of the specific audit were to:

- verify that official controls are organised and carried out in accordance with relevant provisions of Regulation (EC) No 882/2004, and the multi-annual national control plan (MANCP) prepared by Poland in the sector currently under evaluation;
- evaluate the implementation of:
  - 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,
- follow-up recommendations of mission DG(SANCO)/7665/2005, on the evaluation of official controls within the context of the above objective.

The table below lists sites visited and meetings held in order to achieve that objective:
### MEETINGS/Visits

<table>
<thead>
<tr>
<th>Competent Authorities</th>
<th>nr</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central</td>
<td>2</td>
<td>State Sanitary Inspectorate (SSI) at MoH State Plant Health and Seed Inspection Service (SPHSIS) at MARD</td>
</tr>
<tr>
<td>Regional</td>
<td>2</td>
<td>Voivodship Sanitary Epidemiological Stations (VSESs) in Warsaw and Lodz Voivodship Plant Health and Seed Inspection Services (VIPHSISs) in Warsaw and Lodz</td>
</tr>
</tbody>
</table>

| Laboratories          | 3  | Regional Laboratory at VSES Warsaw Regional Laboratory at VSES Lodz Laboratory at the Research Institute of Pomology and Floriculture in Skierniewice |

| Farms                | 2  | Observing an inspection on the use of PPPs |

| Establishments       | 1  | Importer of plant produce – sampling for pesticide residues |

| Other Sites          | 1  | Supermarket – sampling for pesticide residues |

### 3 Legal Basis for the Mission

The audit was carried out under the general provisions of Community legislation, and in particular: Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

A full list of the legal instruments referred to in this report is provided in the Annex and refers, where applicable, to the last amended version.

### 4 Background

#### 4.1 Contribution to the General Audit

Article 45 of Regulation (EC) No 882/2004 requires the Commission to carry out general and specific audits in MSs. The main purpose of such audits is to verify that, overall, official controls take place in MSs in accordance with the MANCPs referred to in Article 41 and in compliance with Community law.

This specific audit was carried out as a component of a GA to Poland and it is the second pesticides audit undertaken to this MS after accession. It forms part of a series of audits to MSs with similar objectives concerning the evaluation of the implementation of EU legislation on official controls for pesticide residues in and on food of plant origin. Section 5 below contains findings and conclusions relating to the implementation of Regulation (EC) No 882/2004 and Section 6 below contains findings and conclusions relating to sector specific issues.
4.2 Background to the series of missions on pesticide residues

Prior to this mission series, the FVO carried out two series of missions to all MSs concerning pesticides in food of plant origin. The final reports of these missions can be found on the DG Health and Consumer Internet site:

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

During these missions, a number of deficiencies in control systems were identified such as deficiencies in the planning and conducting of inspections for control of the marketing and use of plant protection products, the technique of sampling, assessment of risk to consumers and operation of the EU Rapid Alert System for Food and Feed (RASFF), the follow-up of infringements and the range of analysis in pesticide residue laboratories. Action Plans outlining how the recommendations would be addressed were submitted by the competent authorities.

In addition, the FVO has published a country profile for MSs, which describe in summary form the control systems for food and feed safety, animal health, animal welfare and plant health. The country profile for Poland (DG(SANCO)/8112/2009) can be found at:

http://ec.europa.eu/food/fvo/follow_up_en.cfm?co_id=PL

Findings during missions to third countries have shown deficiencies in control systems for pesticide residues in plant produce exported to the European Union (EU). As a result, the assessment of controls at the point of import from third countries is included in the current series of missions.

5 Findings and Conclusions related to implementation of Regulation (EC) No 882/2004

5.1 Competent Authorities

5.1.1 Designation of Competent Authorities

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls.

Findings

There are two competent authorities (CAs) within the scope of the mission – MoH and MARD. Both Ministries are responsible for transposition of EU legislation and policy development within their areas of competence. MARD is also responsible for the authorization of plant protection products (PPPs) for placing on the market and use.

The SSI at MoH is responsible for the official controls in the area of food safety, including controls for pesticide residues in and on food of non-animal origin (FNAO). At central level, the Chief Sanitary Inspectorate (CSI), headed by a Chief Sanitary Inspector, deals with planning and co-ordination of controls, as well as reporting of results. The CSI is also the national contact point for RASFF. The Department for Food Safety and Nutrition at CSI is in charge of the activities listed above.

At regional level, there are 16 Voivodship Sanitary Epidemiological Stations (VSESSs). The VSESSs are responsible for planning, co-ordination and supervision of official controls within the regions.
At district level, 318 Poviat Sanitary Epidemiological Stations (PSES) are established. They are directly involved in the performance of official controls on pesticide residues and report results to the VSES. In addition, there are 10 Border Sanitary Epidemiological Stations (BSES) that perform border sanitary inspections. From the beginning of 2010 they are directly subordinated to the CSI and report to the Chief Sanitary Inspector.

The Main Inspectorate for Plant Health and Seed Inspection (MIPHSI) at MARD is the CCA responsible for official controls on marketing and use of PPPs. The MIPHSI headed by a Chief Inspector for Plan Health and Seeds, and in particular the Plant Protection and Technology Department, is also responsible for planning and co-ordination of and reporting on official controls and for supervision of the activities performed by the regional CAs. In addition, the MIPHSI is involved in developing guidelines and providing written instructions to the regional and district CAs.

At regional level, 16 Voivodship Plant Health and Seed Inspection Services (VPHSIS) are established, and they deal with planning, co-ordination and supervision of official controls performed on the territory of the respective region. The VPHSIS are also involved in reporting of results to the MIPHSI, as well as planning and providing of trainings for their own staff and for the inspectors from the Poviats.

At district level, there are 271 field units. The field units are responsible for performance of the official controls on the use of PPPs. They report results of the controls to the relevant VPHSIS.

There are also 12 Border Inspection Posts (BIPs) where phytosanitary controls of plans and plant products are performed.

As from 01 January 2010, VSESs should provide reports on activities performed to both the central CAs (CSI) and the Voivods of the Voivodships. Funds for performing their activities are allocated by the Voivodship administration. This practice, known as "the integrated service", has been applied by SPHSIS since January 1999.

There are 359 inspection units (institutes or private companies) that are authorised by the SPHSIS to perform controls on the equipment for application of PPPs.

5.1.2 Co-operation between Competent Authorities

Legal Requirements

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

Findings

There is an agreement on co-ordination and co-operation between SSI and Customs Service. This agreement covers mainly the responsibilities of both authorities related to controls on imported food, including plant produce. The legal basis for this agreement is a Regulation of the Minister of Health and the Minister of Finance of 18 February 2008. Similar formal or informal agreements also exist at regional and district level. Border sanitary inspectors met during the mission confirmed that regular, close and effective communication with customs officers takes place in their daily work.

A similar bilateral agreement is in place between Customs Service and SPHSIS, but it is mainly related to plant health issues, including phytosanitary border controls.
Even though there is no official bilateral agreement between SSI and SPHSIS within the scope of the mission, effective communication and co-operation was demonstrated, in particular in the cases of Maximum Residue Levels (MRL) being exceeded or illegal uses of PPPs identified by either of the two CAs. Joint ad-hoc inspections indicate a good co-operation, and documentary evidences of these inspections were provided to the mission team.

The pesticide residue laboratories at the Plant Protection Institute in Poznan and the Institute for Horticulture and Floriculture in Skierniewice perform analyses in the frames of the existing pre-harvest monitoring. Both of them are Research Institutes and their activities within the scope of the mission are regulated by Multiannual Framework Programmes for co-operation with SPHSIS. These Multiannual Framework Programmes cover the period 2006 – 2010 (for the Institute in Poznan), and the period 2008 – 2013 (for the Institute in Skierniewice). The new Multiannual Framework Programme for co-operation with the Plant Protection Institute in Poznan for the period 2011 - 2015 has already been drafted and its adoption is expected soon. Both programmes were adopted by a Resolution of the Council of Ministers. Their activities related to official controls are financed by the MARD.

5.1.3 Co-operation within Competent Authorities

Legal Requirements

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a competent authority, 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

Effective co-operation and communication within both CAs – SSI and SPHSIS at all levels is ensured either by organising meetings or by exchange of official letters, circulars, e-mails, and by phone and fax messages.

Good co-operation was observed within both CAs and between laboratories, CAs and the NRL in the case of MRL exceedances identified and the following risk assessment, as well as in cases of misuses of PPPs or illegal pesticides used.

Documentary evidences were provided regarding regular and ad-hoc meetings organised at central level by the CSI where representatives of all the 16 VSESs are present. Pesticide related issues were also listed in the agenda. The same approach is followed by the VSESs, who organise meetings for their staff and invite representatives from all PSESs. These meetings are organised on a regular basis, every three months. In the case of necessity ad-hoc meetings are organised as well.

Similar practice exists at SPHSIS, where the MIPHSI organises either regular or ad-hoc meetings at central level. The VPHSISs organise meetings at regional level, where their staff and the field units' representatives are present. In addition, when considered as necessary, meetings out of the schedule could take place.

5.1.4 Delegation of specific tasks related to official controls

Legal Requirements

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. Where such delegation takes place, the delegating competent authority must organise audits or inspections of the control bodies as necessary. The Commission must be notified about any intended delegation.

Findings

No tasks have been delegated to control bodies within the scope of the mission.

5.1.5 Contingency planning

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 also requires that competent authorities have contingency plans in place, and are prepared to operate such plans in the event of an emergency. Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.

Findings

The CCAs confirmed that there is no contingency plan in place related to food safety, and specifically for FNAO. The representatives of the SSI stated that a contingency plan is to be established mid 2011.

Conclusions on Competent Authorities

CAs are designated and their responsibilities are clearly identified at national, regional and district level for both – controls on the use of PPPs and controls on pesticide residues in and on food of plant origin, as required by Article 4(1) of Regulation (EC) No 882/2004.

In accordance with the requirements of Article 4(3) of Regulation (EC) No 882/2004, efficient and effective co-ordination between CAs within the scope of the mission takes place.

Adequate co-ordination and co-operation within the CAs are in place, as required by Article 4(5) of Regulation (EC) No 882/2004.

A contingency plan related to food safety is still not in place, contrary to the requirements laid down in Articles 4 and 13 of Regulation (EC) No 882/2004.

5.2 Resources for performance of controls

5.2.1 Legal basis for controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on food business operators to undergo inspection
by the competent authorities. Article 8 of the above Regulation requires that competent authorities have the necessary powers of access to food business premises and documentation.

Findings

The legal provisions for SSI inspectors to undertake official controls are laid down in Articles 73 to 78 of the Food Safety and Nutrition Act dated on 25 August 2006. In addition, their competences and responsibilities are set out in the State Sanitary Inspectorate Act, dated on 14 March 1985 (last amended in 2009).

The inspectors of SPHSIS are empowered to perform official controls, and their responsibilities are defined in the PPA dated on 18 December 2003 (last amended in 2010) and Article 78 and in the Food Safety and Nutrition Act. In accordance with Art 92 of the PPA, SPHSIS inspectors are allowed to access premises and grounds, to perform documentary checks, to interview the persons in charge and to take samples.

The Institute for Industrial Agricultural Machinery is in charge of performing controls at the inspection units listed under point 5.1.1. The legal basis for this activity is to be found in Article 85 (7) (c) of the Plant Protection Act (PPA). The Institute for Industrial Agricultural Machinery was selected to perform these controls after a tender organised in accordance with the provisions of the Public Procurement Law of 29 January 2004 (last amended in 2010). Criteria to be met were listed in the tender documentation.

5.2.2 Staffing provision and facilities

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Findings

According to data provided in Section 2.2 of the MANCP for the period 2010-2014, the total number of staff of SSI is 3288, or 3196 full time equivalents (FTEs). The number of staff directly involved in official controls is 2338 FTEs, and 858 FTEs are laboratory staff.

The total number of staff of SPHSIS is 2248; 1569 of them are inspectors, 263 deal with laboratory analyses, and the rest are supporting staff.

There are appropriate facilities and sufficient staff in both CAs (VSES and VPHSIS) to implement their activities within the scope of the mission in both regions – Warsaw and Lodz, as well as in the official laboratories visited by the mission team.

Most of the staff involved in official controls are civil servants. In order to become a civil servant every candidate should pass an exam in general administrative procedures. In accordance with the requirements laid down in the Code of Administrative Proceedings and the Act on Civil Service dated on 21 November 2008, civil servants are obliged to act free from any conflict of interests. Additional requirements to avoid any conflict of interest for SSI members of staff, who are not civil servants, are laid down in Article 29 (a) of the SSI Act.
The SSI Act and the Regulation of the Minister of Health of 22 March 2010 set out the requirements for appointment of managerial staff. SSI inspectors are appointed in accordance with the requirements listed in the job description for the vacancy they apply for.

5.2.3 Staff qualifications and training

Legal Requirements

Article 6 of Regulation (EC) No 882/2004 requires competent authorities to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

At SSI, training for the staff performing controls is mainly organized by the VSESs for their staff and for the staff from PSESs. The CSI is involved in organising and performing training at central level, if requested by the VSESs and mainly in the case when additional clarifications are needed regarding interpretation of specific pieces of legislation. A cascade system is applied to transmit information to colleagues after attendance at both internal and external training by staff members.

Organising specific training on pesticide related issues is one of the main tasks of the National Institute for Public Health – National Institute of Hygiene (NIPH-NIH). Training on pesticide residue controls have not been organised by the NIPH-NIH since 2008.

There is a written procedure in place at VSES Warsaw providing for assessment of training needs and describing the process of organising training, related documentation and reporting. A special project has been run by the Human Resources Department for the last 2 years looking for additional external financial sources, and 3 Mio PLN (around 750,000 Euros) have been spent on staff training. In 2009 and 2010, two training sessions were organised on RASFF for both VSES and PSESs staff.

In VSES Lodz, 7 training courses on pesticide related issues were organised in 2009 and 2010; 4 of them covered topics related to the annual sampling programme and reporting of results, and 3 related to the operation of the national RASFF system. In addition, inspectors from this VSES took part in 3 external trainings in the area of pesticide residues in the period 2009 – 2010.

Specific training on sampling for pesticide residues was organised in 2007 within the frames of a Transitional Facilities Project. Inspectors from both regions visited attended this training session. This training was provided by German experts.

The CSI and all VSESs are accredited to ISO PN-EN 9001:2009 and have a quality assurance system in place, requiring them to keep training records. Every member of staff has a personal training file.

In accordance with the requirements of Article 91 (2) of the PPA, in order to be appointed as state inspectors, candidates should have a university degree in agriculture, horticulture or other related areas. In addition, every candidate should pass an exam on the legislation in force in the area of plant protection, seed and planting materials and phytosanitary issues.

At SPHSIS, an annual training programme is developed at central level by the MIPHSI. This programme is then transmitted to the regional CAs to nominate participants. In addition, based on assessment of training needs, further in-house group training sessions and individual training are organised. Apart from the regular training courses listed in the training programme, ad-hoc trainings may be organised in the case of specific problems arising in the course of the year.
Conclusions on Resources for Performance of Controls

Legal requirements are in place, providing for inspectors to carry out official controls and to have access to Food Business Operators’ (FBO) premises and documentation, as required by Articles 4 and 8 of Regulation (EC) No 882/2004.

In accordance with the provisions of Article 4 of Regulation (EC) No 882/2004, there are appropriate facilities, trained and experienced staff in both CAs to implement their activities within the scope of the mission in both regions visited Warsaw and Lodz. Adequate provisions are in place to avoid conflict of interest.

Training systems are established in both CAs, and the staff receive training in their areas of competence enabling them to carry out official controls within the scope of the mission as required by Article 6 of Regulation (EC) No 882/2004.

5.3 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS

5.3.1 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. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the Community, imports into the Community and to product placed on the Community market.

Findings

An annual control programme for pesticide residues is in place. The programme is based on a risk assessment and results from previous years. Further criteria taken into account are the EU control programme, consumption data, intended use, data on use of PPPs and toxicity of pesticides.

Due to the fact, that the auto-control systems of FBOs are not evaluated (see section 5.3.2), their reliability can not be taken into account when the frequency of official controls is considered, as required by Article 3 (1) (c) of Regulation (EC) No 882/2004.

Samples for pesticide residues are taken at retailers, wholesalers, supermarkets and at points of entry.

In parallel to the annual control programme for pesticide residues, the SPHSIS is running a pre-harvest monitoring before the plant produce is placed on the market. The pre-harvest monitoring is also risk based taking account of results from previous years. Depending on the risk identified and the consumption data, plant products are divided into three groups, and sampling is performed respectively every year, every two years or every four years.

Controls on the use of PPPs at growers are also risk based taking account of their previous performance, the crops grown, size of the farm, intensity of PPPs application and statistical data provided by the National Statistical Institute. These controls are performed within annual control programmes drafted at regional and district level, based on the Guidelines developed by the MIPHSI and provided in the beginning of the year.
All the inspectors met during the mission stated that inspections are performed without prior warning. This was also confirmed by the FBOs and growers visited.

5.3.2 Control activities, methods and techniques

Legal Requirements

Article 10 of Regulation (EC) No 882/2004 specifies the control activities, methods and techniques that should be deployed.

Findings

The main methods used for control on pesticide residues in and on FNAO include sampling and analyses. The SSI inspectors met by the mission team stated that checks of the auto-control systems in place and traceability are performed during general hygiene inspections at FBOs. Nevertheless, the standard check list followed does not contain a specific section or point on FBOs’ own controls, and no clear evidence was provided by the SSI, that FBOs' own control systems in place for pesticide residues are examined, as required by Article 10 (2) (a).

Controls on the use of PPPs are performed at growers by checking the premises and the application equipment, documents and log books, interviewing the person in charge, sampling and analyses.

5.3.3 Sampling and Laboratory analysis

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires competent authorities to have, or to have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the competent authority to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for laboratories so designated.

Findings

A laboratory network has been established comprising 1 NRL at the NIPH-NIH and 16 regional laboratories for pesticide residue analyses. These regional laboratories are established at the VSESs, so that the CA responsible for official controls of pesticide residues is able to ensure access to adequate laboratory capacity. All designated laboratories are accredited to ISO 17025. A decision has been taken to limit the number of the regional official laboratories to 5 at the beginning of 2011.

The designation of a new NRL is in progress. The process was initiated 18 months ago.

Amendments of the existing legislation are needed for both limiting the number of official laboratories and designation of a new NRL. This process is in an advanced stage.
5.3.4 Procedures for performance and reporting of control activities

Legal Requirements

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities 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 competent authorities 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.

Findings

A written procedure on official controls is developed by the CSI and provided to all VSESs. Then VSESs transmitted the written procedure to all PSESs on their territory. This is a general procedure for all types of controls in the area of the food safety, outlining inspectors’ responsibilities and describing the steps to be followed and documents to be drafted. However, specific requirements for pesticide residue controls are not listed in this document. All inspection related documents are enclosed as Annexes, including a working instruction on planning of controls, general procedure for sampling, templates of sampling protocols, inspection protocols and check-lists.

This general procedure on official controls is followed by the sanitary inspectors in VSES Warsaw and the PSESs on the territory of the Voivodship. In addition to the existing general procedure at the VSES in Lodz an internal written procedure on inspection controls has been developed providing more detailed instructions for the sanitary inspectors.

Written instructions on sampling for pesticide residues are provided by Regulation of the Minister of Health dated on 17 October 2007 (OJ 207). Information on number of primary samples, minimum weight of the sample and number of units is listed in the Annex to the regulation.

At SPHSIS a written procedure on sampling is in place, adopted by Ordinance Nr 10 of the Chief Inspector for Plant Health and Seed dated on 16 May 2008. The sampling protocol form is attached as an Annex to the Ordinance. A written procedure on inspection performance has also been adopted by Ordinance Nr 7 of the Chief Inspector for Plant Health and Seed dated on 28 October 2005, and templates for inspection protocols are provided as Annexes. Written instructions are also in place for imposing sanctions and fines. They were developed by the MIPHSI and approved in April 2005.

Once the inspections have been completed, standard protocols are drafted by both SSI and SPHSIS inspectors. The original copy is always provided to FBOs and growers being inspected. The inspection protocols are detailed and contain information on the scope of the inspection and findings. In the cases when irregularities have been identified, recommendations and deadlines for corrective measures are also listed in the protocols, as well as the legal basis for sanctions and fines to be imposed.

Sampling protocols are completed on a standardised form. The original copy is handed to the owner of the sample, one copy is sent to the laboratory and another copy is left with the inspector.

There is an electronic system in place in SPHSIS where the inspectors register data on inspections and samplings performed and results. The inspectors use the data available in the system to prepare for the inspection.
5.3.5 Transparency and confidentiality

Legal Requirements

Article 7 of Regulation (EC) No 882/2004 requires that competent authorities carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Findings

Annual reports on official controls drafted by CSI are published on their website. National and EU legislation within the scope of the mission, information on MRLs, list of PPPs authorised for marketing and use, important information and measures for protection in the case of unsafe food are also published on the web-sites of the relevant CAs. In addition, the regional CAs have their own web-sites, where information useful for FBOs and growers is published, including application forms, contact details of companies providing trainings for growers, locations and further details about application equipment control units and other related information.

Requirements set in Article 76(2) of the Food Safety and Nutrition Act and Article 29 (a) of the SSI Act provide for FBO related information to be covered by professional secrecy. Information on non-compliant FBOs is only published in the case where it is necessary to recall a product from consumers.

Conclusions on Organisation and Implementation of Official Controls

Both SSI and SPHSIS perform regular and risk based controls as required by Article 3 of Regulation (EC) No 882/2004.

Reliability of auto-control systems at FBOs is not taken into account when the frequency of official controls is considered, that is not in line with Article 3 (1) (c) of Regulation (EC) No 882/2004.

In accordance with Article 10 of Regulation (EC) No 882/2004, appropriate methods and techniques are used by the inspectors for the purposes of the official controls. However, no clear evidence was provided by the SSI, that FBOs' own control systems in place for pesticide residues are examined, as required by Article 10 (2) (a).

In line with Article 8, documented procedures and written instructions on the official controls within the scope of the mission are in place. However, the written procedure on official controls followed by the SSI inspectors is a general procedure for all types of controls in the food safety area, and specific requirements for pesticide residue controls are not listed in this document.

Access of the CAs to an adequate laboratory capacity is ensured. All designated laboratories are accredited to ISO 17025, as required by Article 12 (2) (a) of Regulation (EC) No 882/2004. In line with Article 33 of Regulation (EC) No 882/2004, a NRL in the scope of the mission has been designated.

Both CAs draw up reports (inspection protocols), and their format is fully in compliance with the requirements of Article 9 (2) of Regulation (EC) No 882/2004. In line with Article 9 (3) of the same Regulation, a copy of the inspection protocol is always provided to FBOs and growers.

Information on the control activities of the CAs are publicly available and legal provisions are in place for FBO related information to be covered by professional secrecy, as required by Article 7 of Regulation (EC) No 882/2004.
5.4  **ENFORCEMENT MEASURES**

5.4.1  **Measures in the case of non-compliance**

**Legal Requirements**

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

**Findings**

When non-compliances have been identified fines and administrative sanctions are imposed by both CAs - SSI and SPHSIS. The Food Safety and Nutrition Act, the SSI Act and the Code of Administrative Proceedings are the legal basis for sanctions to be imposed for MRL exceedances found by the state sanitary inspectors. The administrative sanctions include as follows: restriction or prohibition for placing on the market, changing the intended use or further processing, withdrawal or recall of non-compliant products from the market, suspension of operation and closure of all or part of the business concerned. In addition, the existing national legislation provides for imposing fines, and when serious infringements of the legal provisions have been identified punitive sanctions can be imposed by public prosecutors.

In the case of imported produce found to be non-compliant, the consignment concerned is detained and destroyed, re-dispatched to the country of origin or subjected to special treatment. The FBO concerned is in charge for implementing these measures. In the case of destruction of non-compliant food, this process is performed under supervision by both – the relevant PSESs or VSESs and the Customs. In addition, documentary evidence is provided by the FBO to the CAs.

In the case of irregularities identified during the controls on use of PPPs, including misuse or illegal pesticides used, sanctions and fines to be imposed are defined in Article 107 of the PPA. Where an inspector identifies an infringement, or in the case of suspicion that PPPs have not been used in accordance with the legal requirements in place, intervention samples for pesticide residues could be taken. If laboratory results identify either MRLs in excess or illegal pesticide used, the inspector has to issue a penalty notice. Producers who were found to be non-compliant are subject to more frequent controls, including a new round of sampling for pesticide residues.

At the end of the inspections, staff of both PSESs and field units draft inspection protocols. The standard inspection protocol contains a specific chapter on recommendations. In the case of irregularities found corrective measures are listed and deadlines are fixed by the inspectors. Follow-up visits always take place.

Several cases were followed where sanctions have been imposed in both regions visited. A uniform approach was followed by the inspectors.

Supporting documents were provided by the CAs for follow-up actions performed in the cases when MRL exceedances have been found or illegal pesticides have been used. All cases were notified by both CAs within the national RASFF system, as provided for in the Guidance document of the Chief Sanitary Inspector (last up-date in July 2010). In all cases demonstrated by the CAs, the follow-up measures were in accordance with the provisions in place. Effective communication was taking place even in the cases when different Voivodships and Poviats were involved in these follow-up activities. Non-compliant FBOs and growers were subject of follow-up inspections and higher frequency of controls.
FBOs are aware of their right to appeal. However, it was stated by the CAs that they did not have such cases so far. A second sample is only taken if required by the FBO. At the importer where sampling was demonstrated a second sample was taken on his request.

5.4.2 Sanctions

Legal Requirements

Article 55 of Regulation (EC) No 882/2004 states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community 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

At SSI, decisions on administrative and financial sanctions are taken by the sanitary inspectors at Poviats (ticketing), Voivodships (penalties) or the Poviat Courts (fines). Depending on the seriousness of risk arising from the non-compliance identified, the amount of fines could vary from 1000 to 5000 PLN (250 to 1250 EUR), or up to thirty times the average monthly salary, or five times the gross value of the non-compliant product concerned.

At SPHSIS, inspectors are responsible for taking the final decision on sanctions to be imposed based on the legal provisions in place and in accordance with the Instructions from April 2005 depending on the type of irregularity found. Fines to be imposed are within the range between 50 and 500 PLN (12.5 to 125 EUR). If the offender refuses to accept the penalty notice or fails to pay the fine within the prescribed period, the case shall be brought to Court.

Decisions on sanctions take account of all documentation in order to ensure that sanctions are effective, proportionate and dissuasive. Both the seriousness of infringement and previous history, if any are taken into account when a fine is to be imposed.

Conclusions on Enforcement Measures

In the case of non-compliances identified, a uniform approach was followed by the inspectors of both CAs. In line with Article 54 of Regulation (EC) No 882/2004, legal provisions are in place for enforcement measures.

The legal basis is in place for sanctions to be imposed in the case of non-compliances. Sanctions are effective, proportionate and dissuasive as required by Article 55 (1) of Regulation (EC) No 882/2004.

FBOs are aware of their right of appeal as provided for in Article 54 (3) (b) of Regulation (EC) No 882/2004.
5.5 **VERIFICATION AND REVIEW OF OFFICIAL CONTROLS AND PROCEDURES**

5.5.1 **Verification procedures**

**Legal Requirements**

Article 4 of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. 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**

There is a system in place within SSI for performing both comprehensive controls covering all aspects of activities at VSEs, and thematic controls including checks on the implementation of official controls in specific areas. These controls may also include visits to Poviats.

The VSES Lodz was subject of a thematic control performed by the CCA in 2008. The VSES in Lodz also performs controls at Poviats in accordance with an annual control programme. These controls could be also comprehensive or thematic. In 2009, 6 comprehensive and 7 thematic controls have been performed and in 2010, 4 comprehensive and 5 thematic controls were carried out until mid of November 2010. Further controls are planned to be performed till the end of the year.

A similar system is in place within the SPHSIS. The VPHSISs carry out either comprehensive or thematic controls at field units according to the annual control plans in place that are developed at regional level.

In addition, reporting and documentary checks are performed for the purposes of supervision, and appraisal procedure is exercised within both CAs. With effect from March 2009, all civil servants are subject to a 24-monthly review, and every member of staff is supervised by the upper level.

5.5.2 **Audit**

**Legal Requirements**

Under Article 4 of Regulation (EC) No 882/2004 competent authorities 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.

**Findings**

An audit system is in place within SSI. Internal audits are performed by the CCAs at Voivodships, and by VSES at the Poviats according to the audit programmes in place. The VSES in Lodz was subject of an internal audit in 2009. VSES in Lodz has implemented a multiannual audit programme covering a period of 5 years. The VSES audit team has performed 4 internal audits at PSES in 2009.

A system for internal audits is also in place at the SPHSIS. Internal audits are performed in accordance with the existing annual audit programme. A specialized Audit Unit was established at the MIPHSI in 2008 with two staff members. In 2009, 13 internal audits were performed by the
MIPHSI at the Voivodships, and the number of audits planned for 2010 is 12; two of them are still to take place till the end of the year.

In all cases audit reports were drawn up. They contain recommendations and deadlines for corrective measures needed. Auditees report back to the auditor teams on measures and activities undertaken within the deadlines fixed.

All official laboratories for pesticide residue analyses are subject to external audits by the Polish Centre for Accreditation (PCA).

Conclusions on Verification Procedures

In accordance with Article 8 (3) (a), procedures are in place for verification of the effectiveness of official controls performed by both CAs.

Audit systems have been established in both SSI and SPHSIS. Internal audits are performed in compliance with the provisions laid down in Article 6 of Regulation (EC) No 882/2004.

5.6 Multi Annual National Control Plan

Legal Requirements

Article 41 of Regulation (EC) No 882/2004 requires that each Member State prepares a single integrated multi-annual national control plan (MANCP). According to Article 42 it should be implemented for the first time no later than 1 January 2007 and be regularly updated in light of developments. Details on the type of general information on the structure and organisation of the systems of feed and food control and of animal health and welfare control in the Member State concerned are provided.

Findings

There is an integrated MANCP in place for the period 2010 – 2014. SSI and SPHSIS are listed in the MANCP as the CAs responsible for controls of pesticide residues and on the use of PPPs respectively. In the MANCP, information is provided about the structure and main tasks of the CAs, control systems applied and co-ordination between CAs, training, and references are made to documented procedures and written instructions in place. However, in the SSI chapter general information is provided on controls in the food safety area and no references are made to pesticide residue controls particularly. Improvement of analytical capabilities of the official laboratories for pesticide residues is listed as one of the strategic objectives.

Conclusions on Multi-Annual National Control Plan

The MANCP in place does not fully comply with the requirements of Article 42 (2) of Regulation (EC) No 882/2004, in particular no information on official controls for pesticide residues is provided.
6 Sector Specific findings and conclusions

6.1 Legislation

Legal Requirements

The EC legislation within the scope of this mission is listed in the Annex.

Findings

According to information provided by the CAs, Regulations (EC) No 178/2002, 882/2004, 852/2004, 396/2005 and 669/2009 are applied and Commission Directive 2002/63/EC has been transposed into the national legislation by Regulation of the Minister of Health dated on 17 October 2007 (OJ 207). In addition, requirements on sanctions to be imposed in cases of non – compliance are laid down in the Polish legislation.


Transposition into the national legislation of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, and Directive 2009/128/EC of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides is in progress. Representatives of the MARD explained that a new Plant Protection Product Act should be adopted providing the legal basis for PPP related issues. In addition, the PPA should be amended so as to cover the area of phytosanitary control. These two pieces of legislation have already been drafted, and they will be ready for public consultations at the end of November. Entering into force is expected to be not later than 14 June 2011.

Conclusions

According to the information provided by the CAs, EU legislation within the scope of the mission has been transposed into the national legislation and implemented.

6.2 Controls for pesticide residues

6.2.1 National control programme

Legal Requirements

Article 26 of Regulation (EC) No 396/2005 requires Member States to carry out official controls on pesticide residues in order to enforce compliance with the Regulation. Article 27 requires Member States to take a sufficient number and range of samples to ensure that the results are representative of the market. Article 30 requires Member States to establish multi-annual control programmes for pesticide residues. It specifies the requirements of the control programme and requires Member States to participate in the Community control programme.
Findings

An annual control programme for pesticide residues is in place. This programme is an integrated part of a comprehensive annual control programme in the area of food safety. It is developed at central level. From 2010 it is a responsibility of both the CSI and the official laboratory at the VSES in Warsaw. The NIPH - NIH, who were previously responsible for that task, will be involved as consultants.

The programme is very detailed and specifies the products to be sampled, number of samples to be taken, pesticides to be analysed, a break-down per voivodship and country of origin (domestic produce, originating from MSs and from TCs). Additional instructions are also provided on sampling, analytical methods, actions to be undertaken in the case of MRL exceedance and frequency of control on imported produce in the scope of Regulation (EC) No 669/2009. The EU control programme is also taken into account. Processed food of plant origin (mainly juices), baby food and food of animal origin are also covered in the annual control programme. A specific requirement is listed providing for samples from organic produce to be taken keeping into account their share on the market and outlining that at least one sample per commodity should be taken. Although the existing national control programme is very detailed and comprehensive, it is not multi annual as required by Article 30 of Regulation (EC) No 396 / 2005.

Written guidelines are provided by the CCA. Both the annual control programme and the guidelines are sent to all VSEs. The VSEs are responsible to transmit them to all PSEs.

Based on the annual national control programme the VSEs develop more detailed plans containing a break – down of number of samples to be taken per commodity per district within both the national and EU control programmes.

At district level, PSEs prepare monthly sampling plans listing the number of samples, commodities to be sampled and timing of sampling. Regular updates of the plans are prepared when needed. Additional instructions to the sampling inspectors are also included. Decisions on businesses to be controlled, samples to be taken and distribution of tasks are taken by the inspectors at district level, after internal discussions and consultations with their superiors.

In addition, the laboratories at the VSEs prepare laboratory sampling plans taking account of their capacity, so as to avoid work overload and to be able to perform analyses within the agreed deadlines of 15 days after the sample reception. These laboratory plans are then provided to the PSEs inspectors.

The CA stated that the national control programme in place identifies the minimum number of samples to be taken. In addition, samples could be taken in the case of suspicion or complaint, as well as intervention samples when non-compliances have been found.

In 2008, 1455 samples were planned to be taken. The number of samples analysed was 1584, and the majority (1154 samples or 72, 5 % of the total number of samples) were fresh fruit and vegetables. In 2009, the total number of samples planned and analysed was respectively 1650 and 1816. Fresh fruit and vegetables represented 67, 5%, or 1226 samples. Other food groups that were sampled and analysed for pesticide residues in the same period include cereals, products of animal origin and processed food, including baby food.

The annual national control programme for 2011 was submitted to the Commission and the European Food Safety Authority (EFSA).
Conclusions

A comprehensive annual national control programme for pesticide residues is in place, containing the information provided for in Article 30 (1) of Regulation (EC) No 396/2005. However, it is not multiannual as laid down in the same Article.

In both regions visited, comprehensive annual and monthly sampling programmes for pesticide residues exist at regional and district level respectively.

The programme for 2011 was submitted to the Commission and EFSA as required by Article 30 (2) of the Regulation.

6.2.2 Sampling

Legal Requirements

Commission Directive 2002/63/EC lays down methods of sampling for the official control of pesticide residues. Article 11(7) of Regulation (EC) No 882/2004 requires that samples must be handled and labelled in such a way as to guarantee their legal and analytical validity.

Findings

Sampling for pesticide residues was observed by the mission team at an importer in the Region of Warsaw, where lemons from Turkey were sampled, and in a supermarket in the region of Lodz, where cucumbers from Spain were sampled. In both cases the sampling was performed by a team of two sanitary inspectors, and a uniform approach was followed. Both inspections were structured in four stages: checks of all accompanying documents; checks of the storage conditions (including temperature and humidity); sampling and completing the sampling protocol. The sampling inspectors had copies of the national legislation, sampling plans and protocols from the last inspection at the FBO concerned. In principal, the requirements for random sampling were followed by the sampling officers. The lot numbers were correctly identified, and the requirements on the minimum weight and number of units required by EU legislation were complied with. However, in both cases the weight of samples and number of units were doubled, according to the requirements set out by the official laboratories. These requirements are neither set out in the Regulation of the Minister of Health nor in further written instructions. Both sampling teams explained that the sample is divided into two sub-samples after the reception in the laboratories. One of the sub-samples is analysed, and the second is kept. The samples were correctly sealed and labelled. Standard sampling protocols were completed and numbered. It was confirmed by both the inspectors and the laboratory staff that samples are delivered to the laboratories on the same day.

Conclusions

The sampling requirements set out in Commission Directive 2002/63/EC were generally followed. However, the specific requirements on double weight of the sample and number of units, followed by the sampling inspectors, are neither set out in the national legislation nor in written instructions, so that to ensure a uniform approach across the country.

Requirements on handling and labelling of samples, laid down in Article 11(7) of Regulation (EC) No 882/2004, were complied with.
6.2.3 Reporting

Legal Requirements

Article 30(3) of Regulation (EC) No 396/2005 requires Member States to publish on the Internet, on an annual basis, all results of national residue monitoring. Article 31 of the Regulation requires Member States to submit the results of official controls on pesticide residues to the Commission, the European Food Safety Authority, and the other Member States.

Findings

PSESs submit reports on control activities performed to the VSESs on a monthly basis. BSESs report to the CSI twice a year. The CSI is responsible for summarising data and drafting annual reports. These reports are published on the CSI web-site: www.gis.gov.pl

Annual reports on as well as all results of national residue monitoring are published on the CSI web-site. The CSI also communicates the results of the national control programme to the European Commission, EFSA and the other MSs on an annual basis.

Conclusions

In accordance with the requirements of Article 30(3) and 31 of Regulation (EC) No 396/2005, annual reports as well as all results of national residue monitoring are published on the Internet, and results of the national control programme are communicated to the Commission, EFSA and the other MSs.

6.2.4 Controls of pesticide residues in imported produce

Legal Requirements

Article 11 of Regulation (EC) No 178/2002 requires that food and feed imported into the Community shall comply with the relevant requirements of food law.

Article 15 of Regulation (EC) No 882/2004 establishes that the CA shall carry out regular official controls on food and feed of non-animal origin imported into the EU. Under Article 8(1) of Regulation (EC) No 669/2009, an increased level of official controls at designated points of entry is required for specific commodities, countries of origin and hazards in accordance with Annex I to the Regulation. Article 16(3) of the Regulation requires Member States to ensure that the equipment and methodology are adequate for measuring the limit values laid down under Community or national legislation. Article 24 of the Regulation requires that the CA and the customs services shall cooperate closely on the organisation of the official controls.

Findings

Import controls for pesticide residues in food of plant origin are performed at the local market, or at importers’ warehouses, or at the points of entry.
Regarding controls at the points of entry, their frequency is in accordance with the requirements of Regulation (EC) No 669/2009. In addition, written instructions on frequency of controls, commodity / country of origin combinations and pesticides to be analysed are provided in the annual control programme for pesticide residues for 2010. These instructions are identical to the information provided in Annex I of Regulation (EC) No 669 /2009. Further criteria about obligatory border sanitary controls are laid down in the Regulation of the Minister of Health dated on 24 January 2007. However, these national requirements cover a limited number of plant products without specifying the related risk and requiring sampling for pesticide residues. There is no strategy in place to perform physical checks, including sampling for pesticide residues, at points of entry taking account of risks associated with different types of food and previous history regarding products concerned, countries of origin and FBOs (importers and exporters), as required by Article 16 (2) (a) and (b) of Regulation (EC) No 882/2004. Controls at the point of entry may be also performed in the case of suspicion.

Requirements on controls of non-domestic produce, expressed as percentage of the total number of samples per commodity for both originating from MSs and TCs, are listed in the annual national control programme for pesticide residues. According to data provided by SSI the number of samples taken at points of entry is limited. The majority of samples for the purposes of the import controls are taken on the local market.

It was confirmed by both the border sanitary inspectors and laboratory staff that in the case where sampling for pesticide residues has been performed at the point of entry, these samples are considered as priority and analytical results are provided within 2 to 4 days. The consignment is kept under customs supervision and cannot be released before the analytical report has been submitted.

According to information provided by SSI, border sanitary inspectors work in close co-operation with customs officers.

**Conclusions**

The number of samples to be taken from non – domestic produce is specified in the national annual control programme for pesticide residues as required by Article 30 (1) of Regulation (EC) No 396/2005.

Requirements on increased level of controls, as provided for in Article 8 (1) of Regulation (EC) No 669/2009, are incorporated into the annual national control programme for pesticide residues.

Although legal provisions on obligatory border sanitary controls are in place, they cover only a limited number of plant products without specifying the related risk, and physical checks performed at points of entry do not take account the requirements, laid down in Article 16 (2) (a) and (b) of Regulation (EC) No 882/2004.

SSI and customs services work in close co – operation as required by Article 24 of Regulation (EC) No 882/2004

**6.3 CONTROLS ON THE USE OF PLANT PROTECTION PRODUCTS**

**6.3.1 Planning and performance of controls**

**Legal Requirements**

Article 17 of Directive 91/414/EEC requires Member States to make the necessary arrangements for
plant protection products which have been placed on the market and for their use to be officially 
checked in order to see whether they comply with the requirements of the Directive. Particular 
attention shall be paid to the requirements of the authorization and information appearing on the 
label.

Findings

Controls on the use of PPPs at growers are planned taking account of various criteria, including the 
risk profile of the farm. These inspections at farmers and holdings are performed in accordance with 
the annual control programmes in place at regional and district level.

In 2009, 19,533 inspections at user level were performed. The main irregularities found include lack 
of application equipment testing certificate (1802 cases), lack of training certificates (1327 cases) 
and lack of records for PPP applications (1001 cases). The situation was similar in 2008, when the 
total number of inspections performed was 20.080

Two inspections at farmers were demonstrated during the mission. In the region of Lodz the 
cultivation area of the farm was 46 hectares (ha), and it is specialised in growing fruit and berries. 
The farm in the region of Warsaw is specialized in growing wheat, onions and potatoes and the total 
cultivation area is 32 ha. During both inspections observed the inspection teams followed a uniform 
approach. Inspections were structured into four parts, as follows: documentary checks (including 
certificates available and log books), checks of the application equipment, checks of the premises 
where PPPs are stored and completion of the inspection protocol. The inspectors explained that 
when the inspection is performed during the growing season an observation of the spraying process 
may also take place. The original copy of the inspection protocol is always provided to the grower.

In addition to inspections at growers, controls on the use of PPPs are performed by the means of 
pre-harvest monitoring. For this purpose, samples are taken for pesticide residue analyses. Sampling 
plans are developed at central level by the MIPHSI, listing the commodities, the number of samples 
and the laboratories where the analyses are to be performed. The sampling plan and additional 
instructions on its implementation are provided to all VSPHSIS. The samples taken are sent for 
analyses to one of the laboratories nominated for this task, including the Central Laboratory at the 
SPHSIS in Torun, the Institute for Horticulture and Floriculture in Skirniewice and the Institute for 
Plant Protection in Poznan (including all five laboratories for pesticide residues established at this 
Institute).

At regional and district level, the VSPHSISs and the field units develop more detailed plans, 
containing additional information on number of samples per commodity per field unit and the 
timing.

Sampling is performed before or after harvesting, on the field or at growers’ stores and warehouses. 
In 2008 and 2009, the number of samples analysed was respectively 2482 and 2452.

Another type of inspections related to PPPs are the checks of the application equipment. These 
checks are performed by the inspection units listed under point 5.1.1. Controls at those inspection 
units are performed by the Institute for Industrial Agricultural Machinery in Poznan. The results of 
the checks performed by the Institute are approved after an internal discussion within a Committee 
established at the MIPHSI. The MIPHSI decides on the number of controls to be performed every 
year and provides the annual control plan. In addition, intervention checks should be performed 
when considered as necessary (in the case of irregularities found in the past or complaints). In 2010, 
the number of inspection units checked was 40, as requested by the Chief Inspector for Plant Health 
and Seed, including 38 checks planned and 2 intervention checks.
Conclusions

Official controls on the use of PPPs are performed in compliance with the provisions laid down in Article 17 of Council Directive 91/414/EEC.

6.3.2 Reporting

Legal Requirements

Article 17 of Directive 91/414/EEC requires Member States to report on an annual basis to the other member States and the Commission on the results of the inspection measures taken.

Findings

Inspection protocols are completed following a standard form. After the inspection, information on the findings and results is entered in the electronic system. The electronic system is also used for generating reports depending on the criteria entered.

Annual reports under Article 17 of Directive 91/414 are prepared by the central CAs and provided to the EU.

Conclusions

The annual report on inspections performed on the use of PPPs is communicated to the other MSs and the European Commission, as required by Article 17 of Council Directive 91/414/EEC.

6.3.3 Controls on illegal pesticides

Legal Requirements

Article 17 of Directive 91/414/EEC requires Member States to officially check the use of plant protection products to see whether they comply with the requirements of the Directive.

Findings

According to the provisions laid down in the Guidelines on RASFF notification, all illegal uses of PPPs or illegal pesticides used should be notified to the national contact point. In all cases when a use of illegal pesticide has been identified, a follow-up inspection is performed at the non-compliant grower, recommendations are provided and sanctions and/or fines are imposed. These growers are subject to additional control in the following growing season. Four cases were demonstrated during the visit in the VPHISIs in Lodz and Warsaw. In all cases adequate measures have been taken and sanctions were imposed. When the non-compliances are notified by sanitary inspectors at Poviats, a joint inspection is performed.

According to data provided by the CAs, the number of cases when illegal pesticides have been used was 38 in 2008 and 36 in 2009.
Conclusions

All cases of illegal uses of PPPs or illegal pesticides used are notified to the national contact point for RASFF, as required by the written Guidelines in place.

In accordance with Article 17 of Council Directive 91/414/EEC, results on official controls, including information on illegal uses of PPPs or illegal pesticides used, are reported to the European Commission on an annual basis.

6.4 Laboratories for pesticide residues

Legal Requirements

Article 12 of Regulation (EC) No 882/2004 requires that competent authorities designate only those laboratories that operate and are assessed and accredited in accordance with the standards EN ISO/IEC 17025 and EN ISO/IEC 17011. Article 33 of the Regulation requires Member States to designate National Reference Laboratories (NRL) for each Community reference laboratory, and specifies tasks for the NRL. Regulation (EC) No 2076/2005 allows competent authorities to designate a non accredited laboratory until the end of 2009, provided it has initiated and is pursuing the accreditation procedure and provides satisfactory guarantees that quality control schemes are in place for the analyses it conducts for the purpose of official controls.

Article 28 of Regulation (EC) No 396/2005 requires that the methods of analysis of pesticide residues shall comply with the criteria set out in the relevant provisions of Community law relating to official controls for food and feed, and that all laboratories analysing samples for the official controls on pesticide residues should participate in the Community proficiency tests for pesticide residues organised by the Commission.

Findings

General overview

The NRL at the NPHI-NIH and the official laboratories at the VSESs in Lodz and Warsaw were visited by the mission team. The pesticide residue laboratory at the Institute of Horticulture and Floriculture in Skierniewice where analyses for the pre – harvest monitoring was also visited during the mission.

At SSI, there is a network of 16 laboratories designated for analysis of pesticide residues. Since the last mission, successful efforts have been made with a view to accreditation of the official regional laboratories. Currently, all laboratories within the network are accredited to ISO 17025. A decision has been taken to limit the number of the regional official laboratories for pesticide residues in food to five.

The pesticide residue laboratory at VSES Warsaw was accredited on 19 October 2004 by the Polish Centre for Accreditation (PCA). The accreditation certificate was renewed in 2008.

The first accreditation certificate was granted to the official laboratory for pesticide residues at VSES Lodz in January 2006 by PCA.

The current NRL does not have appropriate facilities, equipments and funds to fully comply with the requirements laid down in Article 33 of Regulation (EC) No 882/2004. The CCA declared that
the official laboratory at VSES in Warsaw will be designated as NRL. The process has been initiated 18 months ago.

CAs stated that amendments of the existing legislation are needed and additional financial arrangements should be made for both limiting the number of the official laboratories and designation of a new NRL. These legislative changes are in an advanced stage, and the expectations are to have them in place in the beginning of 2011.

**Resources**

A food safety laboratory is established at VSES Warsaw dealing with different types of analysis in food. The official laboratory for pesticide residues is one of those sections. The laboratory for pesticide residue analysis has very good facilities. It was modernized in 2008. There are 12 members of staff in total, as follows: one Head of Section and 8 technical staff with a university degree and 3 technicians. The Head of Section and four of the technical staff have further postgraduate experience. The laboratory is equipped with one UV-spectrophotometer, one GC/ECD/NPD, one GC/MS and one LC/MS/MS.

In the VSES laboratory in Lodz there are 7 departments of which two dealing with pesticide residues. The pesticide residue department has a manager and staff of 6 who are responsible for sample receipt, extraction and cleanup. Three of these have a university degree level, and the other three are with secondary education. In the second unit (the instrument laboratory for determination of pesticide residues), there are 3 staff members who have a university degree and who have undertaken further post-graduate qualifications. This laboratory is equipped with one UV-VIS spectrophotometer, one GC/ECD/NPD, one GC/MS, one HPLC/UV-VIS and one LC/MS.

The laboratory in Skierniewice was built in 2007 and has modern facilities. Nineteen staff are employed of which 3 have a PhD, 5 have a university degree, and the rest are with secondary education. The laboratory is equipped with two HPLC/PDA, two GC/MS, two GC/FPDs and one LC/MS/MS. Laboratory staff receive training related to pesticide residue analysis. Staff working with instruments also receive specialised training.

**Analysis**

The pesticide residue laboratory at VSES Warsaw is accredited for 4 methods: EN 12393 multi-residue analysis in fruit and vegetables using GC/ECD/NPD and GC/MS, PBP-07 (QuEChERS) multi-residues analysis using LC/MS/MS. Single residue methods are used for dithiocarbamates (EN 12396-3) and Amitraz (PBP-06). The flexible scope of accreditation is for 156 pesticides (including metabolites). Sample preparation is well documented and starts immediately when the sample is received. Samples are not cryogenically processed. Four sub samples are taken; 3 for analysis and 1 as the archive. All samples are stored frozen under controlled conditions. The turnaround time for routine samples is 10 working days except in the case of dithiocarbamates which are analysed within 24-48 hours of receipt. In 2009 the laboratory analysed 152 samples.

The VSES laboratory in Lodz is accredited for 3 methods; EN 12393 (1-3) multi-residue for fruit and vegetables using GC/ECD/NPD and GC/MS; EN 14333-3, benomyl group and thiabendazole using HPLC/PDA and EN 12396-1, single residue method for dithiocarbamates using UV-spectrophotometry. The laboratory is presently validating EN 15662 (QuEChERS) and hopes to add this to their list of accredited methods. The fixed scope of accreditation is for 59 pesticides.¹ There is a need to increase the scope (number of pesticides sought) in the VSES laboratory in Lodz so that the pesticides set out in Annex I to Commission Regulation (EC) No 901/2009 are covered. Samples are not cryogenically processed and 10 sub samples are taken, 1 of which is the archive.

¹ According to the comments on the draft report provided by the CAs, in January 2011 the VSES laboratory in Lodz managed to extend the scope of accreditation. Currently, the methods EN 12396-3 and EN-15662 are included in the accreditation scope and the number of analytes sought is 145.
All samples are stored frozen under controlled conditions. The turn-around time for routine samples is 10 working days. In 2009 the laboratory analysed 90 for both national and EU monitoring.

The food safety laboratory in Skierniewice is accredited for 3 methods; EN 12393 (1-3), multi-residue using GC/MS; PB-01 multi-residue using HPLC/PDA and LC/MS/MS, and EN 12396-2, analysis of dithiocarbamates using GC/FPD and GC/MS. A total of 192 pesticides are included in a flexible scope accreditation. Samples are cryogenically processed and stored in freezers. Four sub samples are taken; 3 for analysis and 1 as the archive. Results for single samples can be produced within 24 hours. However batches of samples are usually reported within 2-3 weeks. In 2009 the laboratory analysed 500 samples for the purposes of the pre-harvest monitoring.

Quality control procedures

All 3 laboratories have Quality Managers and quality control procedures were traceable and comply with SANCO guidelines "Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed" (SANCO/10684/2009). The laboratories visited participate in the EU proficiency tests for pesticide residues.

All methods are fully validated and include data for accuracy, precision, linearity, sensitivity and measurement uncertainty. Instrumentation presently in use is capable of meeting all required limits of quantification (LOQ’s).

Routine recovery checks are carried out with each batch of samples and all pesticides are included. Each batch of samples also includes a chemical/matrix blank. All laboratories use matrix/matched standards that are bracketed within the sample sequence. Internal standards are also used. Reference standards are fully traceable with associated purity certificates available.

The VSES laboratory in Warsaw uses single point calibration for screening followed by 3 point calibration for confirmation where as the VSES laboratory in Lodz uses 3 point calibration for both screening and confirmation. The Skierniewice laboratory uses single point calibration for both screening and confirmations.

All laboratories analyse a second test portion if the MRL has been exceeded or if there is any doubt with the result.

The official laboratory in Warsaw participates in EU proficiency tests (PTs) for both multi and single residue methods and very good scores have been achieved. In the 2009 EUPT11 the laboratory identified 20 of the 21 pesticides, all with satisfactory z-scores and was classed as category A. The regional laboratory in Lodz takes part in the EU multi-residue PT’s however their EUPT11 performance indicates that although results are accurate, the scope is not sufficient with only 9 of the 21 pesticides identified. The laboratory in Skierniewice participates in both multi- and single residue methods with good results produced. For the EUPT11 exercise 17 of the 21 pesticides were identified.

Conclusions

The official laboratories are accredited to ISO 17025 as required by Article 12 of Regulation (EC) No 882/2004. They have generally implemented the SANCO Guidelines "Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed” (SANCO/10684/2009).

The laboratories visited participate in the EU proficiency tests for pesticide residues as required by Article 28 of Regulation (EC) No 396/2005.
The staff in all of the laboratories visited are suitably qualified and receives regular training.

There is still a need to increase the analytical scope (number of pesticides sought) in most of the official laboratories, so that the PPPs authorized for placing on the market and use in Poland and the pesticides listed in Annex I to Commission Regulation (EC) No 901/2009 are covered.

The low LOQs ensure the determination of pesticide residues at the default MRL of 0.01 mg/kg laid down in Regulation (EC) No 396/2005, Commission Directive 2006/125/EC and Commission Directive 2006/141/EC.

The current NRL does not have proper facilities, equipment and funds to fully comply with the requirements laid down in Article 33 of Regulation (EC) No 882/2004;

6.5 Rapid Alert System for Food and Feed

Legal Requirements

Article 50 of Regulation (EC) No 178/2002 requires Member States to immediately notify to the Commission, under the rapid alert system, any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed. Article 35 of Regulation (EC) No 396/2005 lays down that Articles 53 and 54 of Regulation (EC) No 178/2002 on emergency measures shall apply in cases where pesticide residues or MRLs covered by this Regulation may endanger human or animal health, requiring immediate action.

Findings

Written Guidelines on RASFF notification approved by the Chief Sanitary Inspector and last updated in July 2010 is in place. According to these guidelines the inspectors of both – SSI and SPHSIS are obliged to notify all MRL exceedances and all cases when an illegal use of PPPs has been identified to the national contact point. The NRL at the NPHI-NIH is responsible for performing a risk assessment within 24 hours. However, in the case of non-compliant domestic produce considered to be a risk for the consumers, notifications are submitted to the EU RASFF only in the case when the product in question has been distributed to other MSs.

A uniform approach is also followed in the case when non-compliant produce originating from Poland is notified via the EU RASFF. According to the Guidelines in place, the national contact point is responsible for transmitting the information provided to all VSESs. The VSES and the relevant PSES on whose territory the producer is located are responsible to trace back the non-compliant lot and to report back to the national contact point within 48 hours. The national contact point’s responsibility is then to provide information to the EU RASFF and the notifying MS.

In the period January 2009 – October 2010 6 notifications were submitted to the EU RASFF (including 5 border rejections) for non-compliant food imported from TCs, based only on analytical results from the country of origin. No additional checks and analyses were performed by the CAs of Poland.

Conclusions

Written Guidelines are in place and the responsibilities of CAs for operation of RASFF. However,
in the case of non-compliant domestic produce considered to be a risk for the consumers, notifications are submitted to the EU RASFF only in the case when the product in question has been distributed to other MSs, that is not fully in line with Article 50 of Regulation (EC) No 178/2002.

6.6 FOLLOW-UP ON PREVIOUS MISSIONS

Legal Requirements

Article 45(5)(a) of Regulation (EC) No 882/2004 requires Member States to take appropriate follow-up action in the light of the recommendations resulting from Community controls.

Findings

The country profile of Poland contains one recommendation from the previous mission DG(SANCO)/7665/2005, where action by the CAs has not been completed yet.

<table>
<thead>
<tr>
<th>Recommendation of DG(SANCO)/7665/2005</th>
<th>Findings</th>
</tr>
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<tbody>
<tr>
<td>1. The CAs should identify the exact quantities of obsolete pesticides in &quot;tombs&quot;, warehouses, farms and at manufacturers, and co-ordinate activities for their supervision and safe destruction, in order to avoid possible contamination of food, feed and the environment.</td>
<td>In progress</td>
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</table>

According to the information provided by the Ministry of Environmental Protection, 30 tombs still exist. Seven of them are located in the Voivodship of Lodz. The final deadline for their destruction is re-scheduled for June 2011.

Conclusions

Action is still required for the remaining recommendation from mission DG(SANCO)/7665/2005 listed in the table above.

7 OVERALL CONCLUSION

Competent Authorities (CAs) are designated and their responsibilities at all levels are clearly defined. Efficient and effective co-ordination between and within the CAs takes place. Regular and risk-based controls are performed in accordance with annual control programmes. However, shortcomings were identified, relating to the content of the MANCP, contingency plans and the evaluation of auto-control systems.

Comprehensive systems are in place for the control of the use of PPPs and for the control of pesticide residues in domestic and imported produce. Deficiencies were identified regarding the control programme for pesticide residues, sampling and risk-based import controls.

The designated laboratories are accredited and the quality control systems generally follow the SANCO Guidelines. However, the analytical scope (number of pesticides sought) in most of the official laboratories is not sufficiently broad for an effective control of all PPPs authorised and the pesticide residues included in the EU control programme.
Illegal uses of PPPs are notified to the national contact point of the Rapid Alert System for Food and Feed (RASFF), but MRL infringements in domestic products are only notified to the EU if the product was distributed to other MSs.

Recommendations made in the report of the previous mission have been addressed, but the destruction of obsolete pesticides is not finalised yet.

8 Closing Meeting

A closing meeting was held on 23 November 2010 with MoH and MRDF. At this meeting, the main findings and preliminary conclusions of the mission were presented by the mission team. The representatives of the CAs provisionally accepted these findings and offered some clarifications and initial comments.

9 Recommendations

The CAs of Poland are invited to send to the Commission, within 25 working days of the receipt of the report, an action plan in response to the recommendations. This action plan should clearly set out the manner and deadline by which the CAs will address each recommendation. The CAs are recommended to:

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<tr>
<th>No.</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>1.</td>
<td>Ensure the implementation of a contingency plan as required by Article 4 (2) (f) and 13 of Regulation (EC) No 882/2004.</td>
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<td>2.</td>
<td>Ensure that auto-control systems in place at FBOs are evaluated for the purposes of the official controls as stipulated in Article 10 (2) (a) of Regulation (EC) No 882/2004.</td>
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<td>3.</td>
<td>Ensure that the MANCP contains all the information required in Article 42 (2) of Regulation (EC) No 882/2004 for the different sectors in the food safety area.</td>
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<td>4.</td>
<td>Ensure that the national control programme for pesticide residues is multi-annual as required by Article 30 (1) of Regulation (EC) No 396/2005.</td>
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<tr>
<td>5.</td>
<td>Ensure that all the necessary details are provided in the written instructions on sampling for pesticide residues in order to ensure that a uniform approach is followed by all the inspectors.</td>
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<td>6.</td>
<td>Ensure that decisions are taken on the frequency of physical checks, including sampling for pesticide residues at the points of entry, based on the criteria listed under Article 16 (2) (a) and (b) of Regulation (EC) No 882/2004.</td>
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<tr>
<td>Nº.</td>
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<td>7.</td>
<td>Increase the analytical scope (number of pesticides sought) in most of the official laboratories, so that the PPPs authorized for placing on the market and use in Poland and the pesticides listed in Annex I to Commission Regulation (EC) No 901/2009 are covered.</td>
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<tr>
<td>8.</td>
<td>Ensure that any information relating to MRLs or pesticide residues in and on FNAO considered as a serious direct or indirect risk to human health is immediately notified to the Commission under the RASFF as required by Article 50(2) of Regulation (EC) No 178/2002.</td>
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<td>9.</td>
<td>Ensure that in the case of suspicion of non-compliance of FNAO imported from TCs official controls are performed in order to confirm or to eliminate any suspicion or doubt concerning the compliance, as laid down in Article 18 of Regulation (EC) No 882/2004.</td>
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<tr>
<td>10.</td>
<td>Ensure that obsolete pesticides in “tombs” are kept under supervision and safely disposed of in order to avoid possible contamination of food, feed and the environment.</td>
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</table>

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

### ANNEX 1 - LEGAL REFERENCES

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
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<td></td>
<td>p. 11-21</td>
<td>882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC</td>
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</table>