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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

GREECE

FROM 07 TO 15 SEPTEMBER 2009

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

IN THE CONTEXT OF A GENERAL AUDIT

Executive Summary

The objective of the mission was to evaluate the control systems put in place for pesticide residues in foodstuffs of plant origin. The mission formed part of the FVO's planned mission programme and was carried out as a Specific Audit and as a component of a General Audit, in accordance with Article 45 of Regulation (EC) No 882/2004. This report focuses on the sector – specific issues identified during the audit.

National legislation has been adopted to transpose and implement the EC legislation within the scope of this mission.

A risk-based annual national control programme for pesticide residues is in place. However, it does not fully meet the requirements of Article 30(1) of Regulation (EC) No 396/2005 in terms of the information to be specified. The CAs report and publish the results of the national control programme in accordance with Regulation (EC) No 396/2005. In the case of non – processed food of plant origin, reliability of the own checks carried out by FBOs is not taken into account, as required by Article 3 (1) (c) of Regulation (EC) No 882/2004.

A breakdown of the numbers of samples taken for the different stages of the food chain cannot be provided. It remains unclear whether official controls are carried out at all appropriate stages of production, processing and distribution as laid down in Article 3 (3) of Regulation (EC) No 882/2004, and whether sampling is carried out as close to the point of supply as is reasonable, as required by Article 27 of Regulation (EC) No 396/2005.

Although the sampling requirements set out in Commission Directive 2002/63/EC were generally followed, no specific documented procedure is in place for sampling, as laid down in Article 8 (1) of Regulation (EC) No 882/2004.

Samples for pesticide residues in imported food of plant origin are mainly taken on the market and at the points of entry. Although there are legal requirements in place for the frequency of controls at the points of entry, there is no systematic, risk based approach for planning of these controls, so as to ensure they are performed in accordance with the requirements laid down in Article 15 and Article 16 (2) of Regulation (EC) No 882/2004. Efficient enforcement measures are in place in the case of targeted follow – up sampling.

The regional laboratories are accredited as required by Article 12 of Regulation (EC) No 882/2004. They have implemented the SANCO guidelines "Method Validation and Quality Control Procedures" (SANCO 2007/3131). Nevertheless, there is still a need to increase the number of analytes sought in most of the laboratories, so that effective control can be ensured.

Written instructions are in place and the responsibilities for notifying the EU RASFF when risks for consumers have been identified as required by Article 50 of Regulation (EC) No 178/2002 are well defined.

Overall conclusion

Responsibilities of CAs are clearly defined. There is a system in place for performing official controls within the scope of the mission and the existing annual national control programme is risk based. However, a multi-annual control programme as required by Article 30 of Regulation (EC) No 396 / 2005 is still not in place. In most of the official laboratories the range of analytes sought is not sufficient to ensure an effective control.

The report contains recommendations to Greece to address identified shortcomings.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BPI	Benaki Phytopathological Institute
CA	Competent Authority
CRL	Community Reference Laboratory
DG SANCO	Directorate-General for Health and Consumers of the European Commission
DPPP	Directorate of Plant Produce Protection
EC	European Commission
ECD	Electron Capture Detector
EFET	Hellenic Food Authority
ESYD	Hellenic Accreditation System S.A.
EU	European Union
FPD	Flame Photometric Detector
FVO	Food and Veterinary Office
GC	Gas Chromatograph
GC-MS/MS	Gas Chromatograph - Tandem Mass Spectrometry
GC-MSD	Gas Chromatograph - Mass Selective Detector
GCSL	General Chemical State Laboratory
HQ	Head Quarters
ISO	International Organisation for Standardisation

JMD	Joint Ministerial Decision
LC	Liquid Chromatograph
LC-MS/MS	Liquid Chromatograph – Tandem Mass Spectrometry
LC-TOF/MS	Liquid Chromatograph Time-Of-Flight – Mass Spectrometer
LOD	Limit of Detection
MRDF	Ministry of Rural Development and Food
MRL	Maximum Residue Level
MRM	Multi Residue Method
MS	Mass Spectrometry
NPD	Nitrogen Phosphorous Detector
NRL	National Reference Laboratory
PPP	Plant Protection Product
PRDD	Prefectural Rural Development Directorate
RASFF	Rapid Alert System for Food and Feed
RCPQC	Regional Centre for Plant Protection and Quality Control
RD	Regional Directorate
SRM	Single Residue Method
SWZ	Weighted Z - Score
UV	Ultra Violet

1 INTRODUCTION

The Specific Audit took place in Greece from 07 to 15 September 2009. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one MS expert.

The Specific Audit formed part of the FVO's planned mission programme and was carried out as part of a General Audit, in accordance with 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. This report focuses on the sector – specific issues identified during the audit. It does not necessarily include aspects relating to Regulation (EC) No 882/2004; these aspects will be addressed in the subsequent General Audit report.

The inspection team was accompanied throughout the mission by representatives from the central competent authorities, the Department for Plant Produce Protection (DPPP) at the Ministry of Rural Development and Food (MRDF).

An opening meeting was held on 07 September 2009 with representatives from the central competent authorities, namely – the MRDF and the Hellenic Food Authority (EFET).

At this meeting, the objectives and itinerary for the mission were confirmed by the inspection team.

2 OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the control systems put in place for pesticide residues in foodstuffs of plant origin under Regulations (EC) No 396/2005, No 882/2004, No 852/2004 and No 178/2002 of the European Parliament and of the Council. A further objective of the present mission was to follow – up the recommendations made by mission DG(SANCO)/ 2007/7218.

The mission formed part of a wider series of missions to Member States to evaluate control systems and operational standards in this sector.

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

Table 1: Mission visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	2	MRDF, Athens HQ of EFET, Athens
Regional	2	RCPQC, Patras RD of EFET, Patras
Local	1	PRDD of Zakinthos island

Laboratories		
NRLs	2	Benaki Phytopathological Institute (BPI) General Chemical State Laboratory (GCSL)
Official laboratories	2	Pesticide Residue Laboratory at the RCPPQC, Patras Pesticide Residue Laboratory at the RCPPQC, Piraeus
INSPECTION VISITS		
Green grocer	1	Sampling for pesticide residue analysis - PRDD of Egio
Supermarket	1	Sampling for pesticide residue analysis - PRDD of Zakynthos
Import point	1	Sampling at point of entry - Port of Piraeus

3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation, in particular:

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

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

4 BACKGROUND

Prior to this mission series, the FVO carried out two series of missions to all Member States 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, including deficiencies in the planning, conducting and reporting of inspections for control of the marketing and use of plant protection products (PPPs), the co – ordination and scope of the official controls for pesticide residues, assessment of risk to consumers and operation of the EU Rapid Alert System for Food and Feed (RASFF), the follow – up of infringements, the accreditation of the official laboratories for pesticide residue analyses and the range of analysis in pesticide residue laboratories. Action Plans outlining how the recommendations would be addressed were submitted by the competent authorities (CAs).

In addition, the FVO has published a country profile for Greece, which describes the control systems for food and feed safety, animal health, animal welfare and plant health in summary form.

The country profile for Greece (DG(SANCO)/7704/2008) can be found at:

http://ec.europa.eu/food/fvo/country_profiles/CP_greece.pdf

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

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION

Legal basis

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

Audit findings

National legislation to implement EC Regulations No 882/2004, 178/2002 and 854/2004 was adopted by Joint Ministerial Decision (JMD) 15523/2006. Regulation (EC) No 396/2005 was implemented into Greek legislation through JMD 122805, which was published and entered into force on 06 October 2008. All of the above national legislation can be accessed on the web – sites of both central competent authorities – MRDF and EFET.

Conclusions

According to the information and supporting documents provided by the CAs, national legislation has been adopted to transpose and implement the EC legislation within the scope of this mission.

5.2 CONTROLS FOR PESTICIDE RESIDUES

5.2.1 National control programmes

Legal basis

Article 26 of Regulation (EC) No 396/2005 requires Member States to carry out official controls on pesticide residues in order to enforce the 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.

Audit findings

A multi – annual national control programme for pesticide residues is still not in place. The CAs

stated that a process has been initiated for developing a multi – annual national control programme which is to be in place from 2010. Nevertheless, an annual national control programme for pesticide residues in food of plant origin is in place for 2009.

The national control programme is developed at national level. Both of the central CAs, MRDF and EFET – are taking part in drafting the programme, so that in principle both non – processed and processed plant produce are included in the programme. Nevertheless, based on data from previous years processed food was considered not to be a high risk, and it is not part of the annual national control programme for 2009.

When the control programme is drafted, preliminary discussions are being held at all levels; regional and local authorities also contribute by submitting official proposals to the central CAs. The programme in place specifies the number of samples to be taken, the products to be sampled, including baby food, and the laboratories where the analyses are to be performed. The programme is risk based and takes account of results from previous years, the EU control programme, daily dietary intake for the commodities listed, volumes of imports, PPPs authorized for marketing and use in the country, plots of crops cultivated and the capacity of the pesticide residue laboratories. Although the programme is risk based, it does not specify which pesticides are to be analysed, the number of samples to be taken for domestic and non-domestic produce and the pesticide / product combination to be selected as required by Article 30 of Regulation (EC) No 396/2005.

Additionally, annual control plans are being developed by the regional authorities of MRDF and EFET, providing more detailed information about the number of samples, commodities and timing of sampling for each prefecture. At the local level, prefectures can decide that additional samples for pesticide residues need to be taken. Samples are usually taken at green grocers, retailers, wholesalers, supermarkets and at points of entry. Controls for pesticide residues on imported products of plant origin are performed on the local market and at the points of entry. Nevertheless, neither the national nor the regional programmes list the locations and premises where the samples should be taken, and it is not possible to provide specific numbers of the samples taken at the different stages of the food chain. The decision on which businesses are to be inspected, the samples to be taken and the distribution of tasks, is taken informally by heads of services.

The programme was submitted to the European Commission (EC).

Official controls for pesticide residues are mainly performed by way of sampling and laboratory analysis. Checks on auto – control systems in place for pesticide residues and traceability are only performed for processed food of plant origin. CAs stated that in the case of non – processed food own controls carried out by FBOs are checked, if available. However, neither reports nor check lists are drawn up after the inspection as a documentary evidence and traceability checks are only performed when a non – compliance has been identified.

Conclusions

A risk – based multi – annual national control programme as required by Article 30(1) of Regulation (EC) No 396/2005 is still not in place.

Although, the existing annual national control programme is risk based, it does not fully meet the requirements of Article 30(1) in terms of the information to be specified.

The programme was submitted to the European Commission as stipulated in Article 30 (2).

Official controls for pesticide residues are mainly performed by way of sampling and laboratory analysis. No documented checks are performed on the auto – control systems in place for pesticide residues, and reliability of the own checks carried out by FBOs is not taken into account in

the case of non – processed food of plant origin, as required by Article 3 (1) (c) of Regulation (EC) No 882/2004.

A breakdown of samples taken at different stages of the food chain cannot be provided. It remains unclear whether official controls are carried out at all appropriate stages of production, processing and distribution as laid down in Article 3 (3) of Regulation (EC) No 882/2004, and whether sampling is carried out as close to the point of supply as is reasonable, to allow for any subsequent enforcement action to be taken as required by Article 27 of Regulation (EC) No 396/2005.

5.2.2 Sampling

Legal basis

Commission Directive 2002/63/EC establishes 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.

Audit findings

In Patras, the mission team observed sampling for pesticide residues in green peppers, originating from Ilia, which was supplied to a wholesaler in Patras and then to the green grocer whose premises were visited. The sampling team consisted of two members – one inspector and one assistant. Two samples were taken: – one for the purposes of the official control and one counter sample.

Sampling was also observed in a supermarket belonging to a large chain in Zakynthos. A team of two inspectors took a sample of table grapes originating from Corinthos. The total quantity of commodity delivered to the supermarket was 34 kg. No counter sample was taken in this case.

During the inspection both sampling teams had access to copies of the national legislation and to the control programme provided by the RCPQC Patras. The requirements laid down in the national legislation by JMD 91972/2003 transposing Directive 2002/63/EC were generally followed by the inspectors. In both cases the lot number could not be identified because the quantities delivered were too small; the main quantity had been delivered to a wholesaler and to the central store premises of the supermarket chain respectively. The accompanying documents provided by the green grocer in Patras did not allow the origin of the produce to be traced back to the farmer. The unique registration number of the producer was identified in the supermarket in Zakynthos, where the commodity was put in the original packages. In Patras, the sample was taken from the only two boxes available in the store which contained not more than 5 kg, but the inspectors did not consider the remainder of the lot in the cool-store. Thus, the lot was not correctly identified. The requirements concerning the number of units required by Commission Directive 2002/63/EC were complied with in Patras and Zakynthos. The samples were correctly sealed. Both of the inspectors in the Zakynthos prefecture had personal stamps available, while the inspectors in Patras used the stamp of the PRDD and signed all documents, including the sample labels. Standardized sampling protocols were completed in duplicate and numbered. The first original accompanies the sample; the inspector keeps the second original for the archive. Additional documents (delivery notes and invoices) are enclosed with the sampling protocol kept by the inspectors. The green grocer in Patras and the person in charge of the supermarket in Zakynthos were provided with photocopies of the sampling protocols. Cool boxes for the samples were available. The sample is normally delivered to the laboratory by the sampling officer on the same day or sent by courier and delivered to the laboratory on the following day.

At the port of Piraeus, a consignment of 25 920 kg of lemons was imported from Argentina. One sampling inspector was present and the requirements laid down in JMD 91972/2003 and in Commission Directive 2002/63/EC respectively were strictly followed. The lot number was identified; primary samples were correctly selected and the requirements in respect of the weight and number of units required by legislation were fully complied with. The sample was correctly sealed. Two copies of a standard sampling protocol were filled in; one for the inspector and one accompanying the sample to the laboratory. All details about the imported produce were listed, including lot number, unique registration number of the producer, contact details and registration number of the pack house in the country of origin. The inspector used a personal stamp when filling in all documents required, including the sample labels.

The observed sampling procedures generally complied with Commission Directive 2002/63/EC. As neither specific documented procedure nor detailed written instructions are in place, it was not possible to ensure a unified approach by all inspectors involved in sampling for pesticide residues.

Conclusions

The sampling requirements set out in Commission Directive 2002/63/EC were generally followed.

Neither specific documented procedure nor detailed written instructions are in place for sampling, as laid down in Article 8 (1) of Regulation (EC) No 882/2004, so as to ensure that a unified approach by the sampling inspectors is followed.

5.2.3 Reporting

Legal basis

Article 30(3) of Regulation (EC) No 396/2005 requires Member States to publish, on an annual basis, all results of national residue monitoring on the Internet. 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.

Audit findings

Specific formats for reports are in place in both – EFET and MRDF. The regional offices of EFET submit reports on control activities to the HQ in Athens on a monthly basis. Prefectural and regional authorities report to MRDF every three month. The central CAs summarise the data provided and draft an annual report containing all results.

In accordance with the requirements of Article 30(3) of Regulation (EC) No 396/2005, annual reports as well as all results of national residue monitoring are published on the MRDF web – site. MRDF also communicates the results of the national control programme annually to the EC as required by Article 31 of the above mentioned Regulation.

Conclusions

The CAs report and publish the results of the national control programme for pesticide residues in accordance with Regulation (EC) No 396/2005.

5.2.4 *Controls of pesticide residues in imported produce*

Legal basis

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. 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 for the organisation of the official controls.

Audit findings

Importers are obliged to notify customs about imports. The importers or their custom agents are advised by the customs officers to contact the relevant RCPPQC where they are required to submit a standardised application form prior to import. Applications are registered in a protocol book by the inspectors of RCPPQC. Efforts were made and a tender was launched for the development of an electronic system for registering applications for the import of plant produce. Imported produce of plant origin cannot be released by customs without written approval from the control bodies of MRDF.

CAs stated that the decision on sampling for pesticide residues at the point of entry is taken by the head of the relevant RCPPQC on a case - by - case basis, taking into account the previous history, RASFF notifications, and the capacity of the pesticide residue laboratories, as well as the requirement of 10 % random sampling on imports. The frequency of controls at the points of entry should comply with the provisions laid down in JMD 2144/02.08.2006 and Circular letter 4910/10.03.1995. The legal basis for the frequency of controls has not been changed since the previous mission in 2007. Sampling for pesticide residues at the points of entry is carried out under customs supervision.

When samples are taken at the points of entry, these controls are performed under customs supervision. Although a requirement for 10 % random sampling on imports is in place, the national annual control programme for pesticide residues does not specify a precise number of samples to be taken from non – domestic produce. CAs are unable to provide the exact number of samples taken at points of entry.

If non – compliance has been identified, the next consignment of the same produce, with the same country of origin, supplier and producer, if possible, is sampled and can only be released when the laboratory report has been submitted and no MRL exceedances have been identified. These samples are rated as having high priority and analytical results are submitted within 2 or 3 working days.

Where non-compliance is detected, the import is rejected and the consignment is destroyed or re – despatched to the country of origin.

Conclusions

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

Although there are legal requirements in place for the frequency of controls at points of entry, there is no systematic, risk - based approach for planning of these controls, so as to ensure they are performed in accordance with the requirements laid down in Article 15 and Article 16 (2) of Regulation (EC) No 882/2004.

The number of samples to be taken from non – domestic produce is not specified in the national annual control programme for pesticide residues as required by Article 30 (1) of Regulation (EC) No 396/2005.

Procedures for enforcement measures are in place, where imported plant produce is considered as non - compliant, as required by Article 19 and Article 21 of Regulation (EC) No 882/2004.

5.3 CONTROLS OF ILLEGAL PESTICIDES

Legal basis

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.

Audit findings

An annual national control programme for marketing and use of plant protection products (PPPs) is in place. Illegal uses of PPPs and the use of illegal pesticides are checked either by site visits or by laboratory analyses for pesticide residues. In all cases of infringement, fines and administrative sanctions are imposed in accordance with the provisions laid down in Law 721/77 as amended by Law 2538/97.

If laboratory analyses have identified an illegal use of PPP or a use of illegal pesticide, the laboratory staff send the analytical report to the DPPP at MRDF and to the PRDD where the sample has been taken. Inspectors from PRDDs are responsible for a follow - up visit and any further action. If the produce found to be non – compliant originates from another region, then all of the information is sent to the relevant PRDD to carry out the necessary follow – up activities. The final decision on the administrative sanctions and fines to be imposed is taken by the General Secretary of MRDF, on the basis of a written proposal prepared by experts of the DPPP.

In 2007, 44 cases of illegal use of PPPs were reported. The fines imposed amount to a total amount of 38.800 Euros. No cases of the use of illegal pesticides were identified during 2007. In 2008, 38 cases of illegal use and 28 cases of use of illegal pesticides respectively were reported. Fines amounting to a total of 30.800 Euros were imposed and paid in respect of both types of infringement. CAs stated that follow – up visits and laboratory analyses are conducted whenever there is an infringement. If a further infringement occurs, the amount of the fines imposed is doubled.

Reports on controls of marketing and use are sent to the EC annually. These annual reports contain data on illegal use of PPPs and use of illegal pesticides, as well as details of the fines imposed.

Conclusions

Legal provisions are in place setting out the procedures to be followed, and administrative sanctions and fines are imposed in cases of infringement.

The PRDDs check the illegal use and use of illegal pesticides. These official controls are co-ordinated by the DPPP at MRDF.

Results are reported to the EC annually as required by Article 17 of Council Directive 91/414/EEC.

5.4 LABORATORIES FOR PESTICIDE RESIDUE ANALYSIS

Legal basis

Article 12 of Regulation (EC) No 882/2004 requires that competent authorities only designate laboratories that operate and are assessed and accredited in accordance with the standards ISO/IEC 17025 and ISO/IEC 17011. Article 33 of the Regulation requires Member States to designate National Reference Laboratories (NRL) for each Community reference laboratory (CRL), 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 for the analyses it conducts for the purpose of official controls are in place.

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 participate in the Community proficiency tests for pesticide residues organised by the Commission.

Audit findings

General overview

There is a network of 10 laboratories designated for the analysis of pesticide residues – the BPI, the GCSL and 8 regional laboratories established at the RCPPQCs. The BPI and the GCSL were designated as NRLs by EFET in March 2007. Both laboratories are NRLs for pesticide residues in cereals, in food of animal origin and products with a high fat content, and for single residue methods (SRM). In addition, the BPI is also the NRL for pesticide residues in fruit and vegetables, and it is designated as a contact point with the CRLs.

Both NRLs agree on an annual basis to disseminate technical support to designated regional official laboratories. Both undertake communication with CRLs and assist with training for their staff members under MRDF approval; they are accredited to ISO 17025 with open scope.

The BPI has been accredited by the national accreditation body – the Hellenic Accreditation System S.A. (ESYD) since July 2002. The accreditation was renewed in 2006, and it is valid till July 2010. The BPI is responsible for conducting of all the analyses under the Community monitoring programme for 2009.

The GCSL has been accredited by the United Kingdom Accreditation Service (UKAS) since November 1999. The latest renewal of accreditation is dated February 2009.

Successful efforts have been made with a view to accreditation of the regional official laboratories. Temporary accreditation certificates are in place. Final payment is expected to be approved by MRDF management and to be made to the ESYD before granting the official accreditation certificates. All of the official regional laboratories for pesticide residues are accredited with fixed

scope.

Resources

Six scientific staff and one technician are available in the laboratory for pesticide residues which is established within the Pesticide Control Department at BPI. This laboratory is equipped with three GC-NPD/ECD/FPD, two LC-MS/MS, one GC-MS/MS, one GC-MS and one LC-TOF/MS used for the determination of unknown compounds.

There are four scientists and one technician in GCSL. The equipment available comprises one GC-NPD/FPD, one GC-MS, one GC-MS/MS, one LC-MS and one LC-MS/MS.

The official laboratory in Patras has excellent new premises. It has been an official laboratory since 2001. Staff of two scientists and two technicians are qualified and well trained. The equipment available consists of one UV visible spectrophotometer and three GC-NPD/FPD. New equipment, namely one LC-MS and one GC-MS/MS, has been purchased and is installed in the laboratory, although it is not yet in use.

The official laboratory in Piraeus has been in operation for 15 years. It has three permanent staff (1 chemist and 2 technicians) and 4 temporary staff. The temporary staff are hired during the high season for a period of 8 months. They all receive specific training in pesticide residues and quality control; however, the temporary staff have to leave once they have become efficient in the routine work. The laboratory is equipped with three GC-NPD/ECD.

Analysis

BPI has six accredited methods for different matrices: water, fruit and vegetables, olive oil, cereals, olive tree leaves and wine. Among these six methods, there are two methods to determine 37 pesticides in cereals and one more to determine 228 pesticides in fruit and vegetables using standard EN 12393-1/2 as the extraction method, determining them by GC-NPD/ECD and confirming by GC-MS or by LC-MS/MS. New methods have been developed and validated to extend the scope. Four of these methods for fruit and vegetables use QuEChERS method as the extraction method: one for multi residue methods (MRM) and the other three for SRM residue methods respectively. All four methods are used for analysing baby food samples. CAs stated that they will be accredited in the near future. New methods for eggs and butter are also validated. The BPI is responsible for conducting of all the analyses under the Community control programme for 2009.

GCSL has nine accredited methods for different matrices: fruit and vegetables, cereals and pulses, edible oils, honey, wine and water. The methods cover 172 compounds in total. In the case of fruit and vegetables (128 pesticides covered), two extraction methods are used: the modified Luke method and the Ethyl Acetate method. Ethyl Acetate extractions are determined by GC-NPD/FPD and confirmed by GC-MS/MS; Luke extractions are injected in LC-MS/MS. The analyses of baby food are carried out using the latter method. The GCSL is in charge of pesticide residue analyses in processed food of plant origin. In 2008, 254 samples were analysed in the laboratory. Although processed food has not been included in the annual national control programme for pesticide residues in 2009 and considered not to be a high risk, some 105 samples were taken based on request by the prefectures and analysed at the time of the mission.

The official laboratory in Patras reports only degradation of dithiocarbamates to CS₂ as their only accredited SRM performed under EN 12396.01. This laboratory performs the analyses within 48 hours of receiving the sample.

The official laboratory in Piraeus is accredited in one method for 21 organophosphorus pesticides in fruit and vegetables determined by GC-NPD. They have a validated method to be accredited for 28 further organochlorine pesticides determined by GC-ECD for fruit and vegetables, and two more methods for olives and olive oil for a further 26 pesticides. In both cases, EN 12393-1/2 is used as

the extraction method.

Both of the regional laboratories visited are responsible for analysing 125 samples under the annual national control programme.

In general, the observed turn-around time for analysis of routine samples varies from 1 to 3 months. Urgent samples are analysed in a few days without the need for a written specification.

Quality control procedures

In all of the laboratories visited, the quality control system is properly structured, organised and documented. It is based on the SANCO guidelines "Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed" (SANCO 2007/3131), although there are exceptions to some paragraphs, as paragraph 71, when the Piraeus regional official laboratory does not have the mass spectrometry available for confirmation.

The BPI laboratory has validated its methods for a number of representative matrices at two concentration levels (one the maximum residue level (MRL), or 0.003 mg/kg for baby food, and the other 10 times higher) with six replicates achieving appropriate recovery for all the analytes. Routine recovery checks are carried out once a day. The laboratory uses matrix-match calibration and single-point calibration. Confirmation of positive samples is based on library comparison in the case of GC-MSD analysis and on the ratio of two transitions in the case of LC-MS/MS analysis. A further test portion is analysed to ascertain whether the MRL has been exceeded. Individual stock solutions from pesticide standards are kept separately from the solid stock of standards for a maximum of 3 years. The main sample and the second sample are stored in separate freezers at -20°C.

In GCSL, working solutions are kept for 6 months, and the calibration solution is stored for 2 months. Matrix match calibration is used where there are positive findings; otherwise, solvent calibration is performed, using 5-point calibration curves. Nine-point curves are used for baby food analyses. Confirmation of positive findings is based on library comparison in the case of GC-MSD analyses and on the ratio of two transitions for LC-MS/MS analyses. Analyses of another test portion are performed in cases where the MRL has been exceeded.

BPI and GCSL reporting levels at 0.01 mg/kg and 0.003 mg/kg for baby food comply with the requirements laid down in the Community legislation on baby foods and infant formulae.

The official laboratory in Patras performs three different analyses of the same sample in the case of positive results. They use a 5-point calibration curve in the UV-visible spectrophotometer.

The official laboratory in Piraeus performs method validation using representative matrices. Three-point calibration curves are used. Routine recovery checks are conducted every 20 analyses. Different polarity columns are used for confirmation of positive findings.

All of the laboratories visited follow the SANCO quality control guidelines regarding measurement uncertainty. For the decision on non-compliance the default value of 50 % is applied as specified in the SANCO Guidelines. If MRL exceedances are identified, analytical reports are immediately sent to the DPPP at MRDF whose staff are responsible for risk assessment.

The BPI proficiency test results in fruit and vegetables and in cereals are good throughout the years. There is a lack of scope for submitting results of SRM tests.

The GCSL proficiency test results in fruit and vegetables, cereals and food of animal origin generally show acceptable accuracy, but a lack of scope. The opposite is also seen: i.e. the results demonstrate sufficient scope, but high weighted z-scores (SWZ) values. The scope is not sufficient to be able to submit results for SRM tests.

The performance of Patras laboratory in EU proficiency tests SRM3 was weak due to the lack of

scope, although the accuracy achieved was acceptable (SWZ of 1.5).

Piraeus laboratory participated in the last EU proficiency tests for fruit and vegetables. Their performance indicates that results are accurate, although the scope is not sufficient.

Conclusions

The laboratories are accredited as required by Article 12 of Regulation (EC) No 882/2004. They have implemented the SANCO guidelines "Method Validation and Quality Control Procedures" (SANCO 2007/3131). The laboratories visited have participated in the Community proficiency tests for pesticide residues as required by Article 28 of Regulation (EC) No 396/2005.

There is still a need to increase the number of analytes sought in most of the laboratories so that the pesticides set out in Annex I to Commission Regulation (EC) No 1213/2008 are covered. Owing to the lack of staff in both of the regional laboratories visited, it is not possible to extend the scope of the analyses. An additional constraint for the laboratory in Piraeus is the lack of equipment. Thus, the effectiveness and appropriateness of official controls as required by Article 4 (2) (c) and 4 (2) (d) of Regulation (EC) No 882/2004 could not be ensured.

The staff in all of the laboratories visited are suitably qualified and receive regular training.

The low limits of detection (LODs) generally 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.

NRLs have been designated as required by Article 33 of Regulation (EC) No 882/2004.

5.5 RAPID ALERT SYSTEM FOR FOOD AND FEED

Legal basis

Article 50 of Regulation (EC) No 178/2002 requires Member States to immediately notify any information relating to the existence of a serious direct or indirect risk to human health deriving from food, to the Commission under the rapid alert system. 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 where pesticide residues or MRLs covered by this Regulation may endanger human or animal health requiring immediate action.

Audit findings

EFET is the contact point for RASFF. Instructions for carrying out a risk assessment and criteria for the notification of pesticide residue findings to RASFF are set out by EFET Circular letter Ref. Nr. 18704 dated 28 November 2008. The Draft Guidance Document (SANCO/3346/2001) on criteria for the notification of pesticide residue findings to the Rapid Alert System for Food and Feed (RASFF), is followed in the main.

When non-compliant samples are found within the national control programme, the pesticide residue laboratories immediately inform the MRDF. The DPPP at MRDF is in charge of performing the risk assessment. Two members of staff are involved; the EFSA Primo model is used to conduct the risk assessment. When a possible risk to the consumer is identified, the MRDF staff complete

the RASFF notification and send it to EFET; all supporting documents are also enclosed. EFET is responsible for informing the EU RASFF.

No notifications related to pesticide residues were sent to the European Commission in 2009. Two information notifications were sent to EU RASFF in the period from 01 January 2007 to 31 December 2008. In both cases the risk assessment did not consider that the MRL being exceeded constituted a direct or indirect risk to the health of the consumers. Nevertheless, in both cases, the pesticides used were not authorised. According to data provided by the CAs, the numbers of cases of MRL exceedances identified in 2007 and 2008 were 13 and 20 respectively. The risk assessment that was performed found no risk to consumers.

Conclusions

Written instructions are in place and the responsibilities for notifying the EU RASFF when risks for consumers have been identified as required by Article 50 of Regulation (EC) No 178/2002 are well defined. The Draft Guidance Document SANCO/3346/2001 is followed for risk assessment purposes.

5.6 FOLLOW UP ON PREVIOUS MISSIONS

Legal basis

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.

Audit findings

The country profile of Greece contains six recommendations from the previous mission DG(SANCO)/2007/7218, where action by the CAs has not been completed yet.

Recommendations of DG(SANCO)/2007/7218	Follow-up in DG(SANCO)/2009-8162
1. The CAs should establish a co-ordinated and comprehensive control plan for marketing and use of plant protection products and assign sufficient staff to implement the controls, including follow-up in accordance with Article 17 of Council Directive 91/414/EEC.	Action taken An annual national control programme for marketing and use of PPPs is in place. Training sessions were organised in the period 2008 – 2009 and additional staff of 144 was reported to have been incorporated for performing these controls. Follow – up visits and laboratory analyses are conducted whenever there is an infringement.
2. The CAs should ensure that the annual report to the Commission, under Article 17 of Council Directive	Action taken

91/414/EEC, is complete.	CAs submitted documents demonstrating that the annual report under Article 17 of Council Directive 91/414/EEC to be sent to the EC is complete and provides data from all prefectures in the country.
3. The CAs should implement audit systems as required by Article 4 (6) of Regulation (EC) No 882/2004.	Action still required Audit systems have not been implemented yet. Decision about audits has not been taken. Deadlines are fixed neither for development nor for implementation of audit systems.
4. The CAs should ensure that they take account of the reliability of food business operators' own checks when carrying out official controls as stipulated in Article 3 (1) (c) of Regulation (EC) No 882/2004.	Action still required Inspections for pesticide residues are mainly performed by way of sampling. Auto – control systems in place at the premises are only checked by the inspectors from RDs of EFET in the cases of processed food of plant origin. In the case of non – processed food of plant origin auto – control systems in place were reported to be checked; nevertheless, neither check lists nor other types of documents were used to report the results of the inspection.
5. The CAs should ensure that all designated laboratories comply with Article 12 of Regulation (EC) No 882/2004, or come under the derogation provided for in Article 18 of Commission Regulation (EC) No 2076/2005. The laboratories could put in place the SANCO guidelines for Quality Control procedures for Pesticide Residue Analysis (Document No SANCO/10232/2006) which foresees regular participation in relevant proficiency tests.	Action taken Both of the NRLs are accredited to ISO 17025. Successful efforts have been made with a view to accreditation of the regional official laboratories. Temporary accreditation certificates are in place. Final payment is expected to be approved by MRDF management and to be made to the ESYD before granting the official accreditation certificates. All of the laboratories have implemented the SANCO Method Validation and Quality Control Procedures (SANCO 2007/3131). The laboratories visited have participated in the Community proficiency tests for pesticide residues as required by Article 28 of Regulation (EC) No

	396/2005.
6. The CAs should consider substantially increasing the range of analytes including metabolites covered by their analytical methods for pesticide residues in food of plant origin, so as to better reflect the substances that are marketed and used and to ensure effective implementation of Article 7 of Directive 86/362/EEC, Article 4 of Directive 90/642/EEC and Article 7 of Directive 2006/125/EC. They should ensure that analytical methods used comply with Article 11 of Regulation (EC) No 882/2004 and for the analysis of baby food with Article 7 (2) of Directive 2006/125/EC.	<p>In progress</p> <p>CAs reported that taking into account data from the last two years, there is an annual increase of 20 % in the number of analytes sought ; nevertheless, increasing the scope of analytes is still needed in most of the laboratories in order efficient control to be ensured and the substances, that are marketed and used, to be better reflected.</p> <p>The low limits of detection (LODs) generally 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.</p> <p>Analytical methods used in the laboratories visited are validated and comply with relevant Community rules.</p>

Conclusions

Action is still required for two of the remaining recommendations from mission DG(SANCO)/2007/7218. Significant steps were made to address three other recommendations, and implementation is still in progress for one of the recommendations.

6 OVERALL CONCLUSIONS

Responsibilities of CAs are clearly defined. There is a system in place for performing official controls within the scope of the mission and the existing annual national control programme is risk based. However, a multiannual control programme as required by Article 30 of Regulation (EC) No 396 / 2005 is still not in place. In most of the official laboratories the range of analytes sought is not sufficient to ensure an effective control.

7 CLOSING MEETING

A closing meeting was held on 15 September 2009 with MRDF and EFET. At this meeting, the main and conclusions of the mission were presented by the inspection team. The representatives of the CAs offered some initial comments and provisionally accepted the preliminary findings.

8 RECOMMENDATIONS

The CAs of Greece 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:

N°.	Recommendation
1.	Ensure that a multi-annual national control programme for pesticide residues is established as required by Article 30 (1) of Regulation (EC) No 396/2005.
2.	Ensure that the national control programme for pesticide residues in place contains at least the information listed in Article 30 (1) (a), (b), (c) and (d).
3.	Ensure that official controls are carried out at all appropriate stages of production, processing and distribution, as required by Article 3 (3) of Regulation (EC) 882/2004 and consider that samples within the national control programme for pesticide residues are taken as close to the point of supply as is reasonable to allow for any subsequent enforcement action to be taken, as set out in Article 27(1) of Regulation (EC) No 396/2005.
4.	Ensure that a documented procedure is in place in the case of sampling for pesticide residues as laid down in Article 8 (1) of Regulation (EC) No 882/2004.
5.	Take account of the reliability of food business operators' own checks, especially when carrying out official controls on non – processed food of plant origin, as stipulated in Article 3 (1) (c) of Regulation (EC) No 882/2004.
6.	Ensure that official controls on imported food of plant origin, including controls at points of entry, are risk – based and frequency of controls is considered in accordance with the requirements laid down in Article 15 and Article 16 (2) of Regulation (EC) No 882/2004.
7.	Substantially increase the number of analytes including metabolites covered by their analytical methods for pesticide residues in food of plant origin; guarantee the effectiveness and appropriateness of official controls as required by Article 4 (2) (c) and 4 (2) (d) of Regulation (EC) No 882/2004, ensure implementation of Regulation (EC) No 396/2005 and take account of the provisions laid down in Commission Regulation (EC) No 1213/2008.

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

http://ec.europa.eu/food/fvo/ap/ap_gr_2009-8162.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 91/414/EEC	OJ L 230, 19.8.1991, p. 1-32	Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Reg. 2076/2005	OJ L 338, 22.12.2005, p. 83-88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

Legal Reference	Official Journal	Title
Dir. 2006/125/EC	OJ L 339, 6.12.2006, p. 16-35	Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version)
Dir. 2006/141/EC	OJ L 401, 30.12.2006, p. 1-33	Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC
Reg. 1213/2008	OJ L 328, 6.12.2008, p. 9-17	Commission Regulation (EC) No 1213/2008 of 5 December 2008 concerning a coordinated multiannual Community control programme for 2009, 2010 and 2011 to ensure compliance with maximum levels of and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin