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FINAL REPORT OF A MISSION

CARRIED OUT IN GREECE

FROM 4 TO 8 NOVEMBER 2002

IN THE FIELD OF CONTROL SYSTEMS FOR THE PLACING ON THE MARKET
AND USES OF PLANT PROTECTION PRODUCTS AND FOR RESIDUES IN
FOODSTUFFS OF PLANT ORIGIN

Please note that factual errors in the draft report have been corrected in bold, italic, type. Clarifications provided by the Greek authorities are given as footnotes, in bold, italic, type, to the relevant part of the report.



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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

BPI	Benaki Phytopathological Institute
CIPAC	Collaborative International Pesticides Analytical Council
EFET	Central Food Control Agency
GSCL	General State Chemical Laboratory
GC	Gaschromatograph
GC-MS	Gaschromatograph with Mass Spectrometric detector
HPLC	High Performance Liquid Chromatography
MRL	Maximum Residue Level
PAD	Prefecture Agriculture Directorate
QCG	Quality Control Guidelines
RASFF	Rapid Alert System for Food and Feed
RPPQCC	Regional Plant Protection and Quality Control Centre
SOP	Standard Operating Procedure

1. INTRODUCTION

The mission took place in Greece from 4 November to 8 November 2002. The mission team comprised 3 inspectors from the Food and Veterinary Office and 1 Member State expert.

The mission was undertaken as part of the FVO's planned mission programme and in agreement with the Ministry of Agriculture.

The FVO inspection team was accompanied during the mission by representatives from the central competent authority, the Ministry of Agriculture.

An opening meeting was held on 4 November 2002 with the central competent authority, the Ministry of Agriculture in Athens. At this meeting the objectives of and itinerary for the mission were finalised and confirmed by the FVO inspection team.

2. OBJECTIVES OF THE MISSION

The objective of the mission was the assessment of the control systems for residues in foodstuffs of plant origin, in the framework of Directives 86/362/EEC of 24 July 1986¹ on the fixing of maximum levels for pesticide residues in and on cereals and 90/642/EEC of 27 November 1990² on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables. As the residue monitoring is related to the placing on the market and uses of plant protection products, the control system for these issues, in the framework of Directive 91/414/EEC of 15 July 1991³ concerning the placing of plant protection products on the market, was also evaluated. This was the first mission undertaken in Greece for this purpose. It forms part of a wider series of missions to all Member States evaluating control systems and operational standards in this sector.

In pursuit of this objective, the following sites were visited:

A) marketing and uses:

COMPETENT AUTHORITY VISITS FOR MARKETING AND USES		DEFINITION
Competent authority	Central	Ministry of Agriculture – General Directorate of Plant Protection – Department of Pesticides, Athens
	Local	Prefecture Agriculture Directorate of <i>Iraklion</i> - Ministry of Interior, Iraklion
	Local	Meeting with Prefecture Agriculture Directorate of Eastern Attika – Ministry of Interior, Athens

¹ OJ L 221, 07/08/1986, p. 0037 - 0042

² OJ L350, 14/12/1990, p. 0071 - 0079

³ OJ L230, 19/08/1991, p. 0001 - 0032

LABORATORY VISITS FOR MARKETING AND USES	DEFINITION
CENTRAL	Laboratory of Physical Chemical Analysis of Benaki Phytopathological Institute – Ministry of Agriculture, Athens

OTHER VISITS	DEFINITION
Participation in an inspection visit at Prefecture Agriculture Directorate of <i>Iraklion</i>	Sampling for formulation analysis at a retailer of plant protection products

B) residues:

COMPETENT VISITS FOR MONITORING OF RESIDUES	AUTHORITY	DEFINITION
Competent authority	Central	Ministry of Agriculture – General Directorate of Plant Protection – Department of Pesticides
	Regional	Regional Plant Protection and Quality Control Centre of Crete
	Regional	Regional Plant Protection and Quality Control Centre of Piraeus
	Local	Prefecture Agriculture Directorate of <i>Iraklion</i>
	Local	Meeting with Prefecture Agriculture Directorate of Eastern Attika

LABORATORY VISITS FOR MONITORING OF RESIDUES	DEFINITION
Central	Laboratory for pesticide residues of Benaki Phytopathological Institute
Regional	Iraklion laboratory of Regional Plant Protection and Quality Control Centre of Crete

OTHER VISITS	DEFINITION
Participation in sampling procedure for residue analysis with inspectors of RPPQCC's	Sampling at a greengrocery in Iraklion and at a fruit and vegetables import wholesaler in Athens

3. LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation, and in agreement with the Ministry of Agriculture.

In particular, the mission was carried out under Article 5 of Commission Regulation (EC) No 645/2000 of 28 March 2000⁴ setting out detailed implementation rules necessary for the proper functioning of certain provisions of Article 7 of Council Directive 86/362/EEC and of Article 4 of Council Directive 90/642/EEC concerning the arrangements for monitoring the maximum levels of pesticide residues in and on cereals and products of plant origin, including fruit and vegetables.

4. MAIN FINDINGS

4.1. Control system for marketing and uses of plant protection products

4.1.1. Legislation

Council Directive 91/414/EEC on the placing on the market and uses of plant protection products has been implemented by Presidential Decree 115/97 as last amended by Presidential Decree 290/98.

Classification of plant protection products is performed according to Ministerial Decisions 378/94 and 587/86 which adopt Directive 78/631/EEC of 26 June 1978⁵ on the classification, packaging and labelling of dangerous preparations (pesticides), as amended by Directives 81/187/EEC⁶ and 84/291/EEC⁷. Directive 1999/45/EC⁸ has been recently transposed by Ministerial Decision 265/2002.

Council Directive 79/117/EEC⁹ as amended concerning prohibition of plant protection products containing certain active substances is implemented by a consolidated Ministerial Decree 103999/2001.

The main act regulating pesticide matters is Law 721/77, as amended by Law 2538/97; it defines the frame of responsibilities for the whole sector including enforcement measures to be applied.

4.1.2 Competent authorities

The Ministry of Agriculture, General Directorate of Plant Protection, Department of Pesticides is in charge of the transposition and implementation of legislation concerning marketing and use of plant protection products. The Department is structured in 4 units:

- Evaluation group (7 staff of whom 3 under temporary contract)
- Approval of new authorisations (4)

⁴ OJ L 78, 29.03.2000, p. 0007 - 0009

⁵ OJ L 206, 29/07/78, p. 0013 - 0025

⁶ OJ L 88 02/04/81, p. 0029 - 0030

⁷ OJ L 144 30/05/84, p. 0001 - 0009

⁸ OJ L 200 30/07/99, p. 0001- 0016

⁹ OJ L33 08/02/79, p. 0036 - 0040

- Pesticide Residues (3)
- Use and Marketing (4 of whom 1 temporary)

As laid down in National Law 721/77, the Prefectures are the authorities in charge of control of use and marketing of plant protection products. There are 54 Prefectures in Greece reporting to the Ministry of the Interior.

In the two Prefectures visited, *Iraklion* and Eastern Attika, the Prefecture Agriculture Directorates (PAD's) are in charge of the control on marketing and use of plant protection products but in other Prefectures the Trade Directorates can also be involved in control.

4.1.2.1. Authorisation of plant protection products

The authorisation procedure for placing on the market of plant protection products implies that after the evaluation of the dossier submitted by an applicant, a proposal from the Ministry of Agriculture is presented to the Supreme Council for pesticides (composed of representatives of Ministry of Agriculture, Ministry of Health, University) for an opinion. The Ministry of Agriculture signs the final decision for the authorisation of the plant protection product.

With respect to the transposed EU legislation, dossiers are evaluated with the assistance of the Benaki Phytopathological Institute (BPI). The BPI is a research institute under the Ministry of Agriculture and it consists of 4 main departments. The Physical and Chemical Analysis Laboratory under the Control of Agricultural Pharmaceuticals Department performs the control of formulations. In BPI different working groups are in charge of toxicological studies, ecotoxicological studies, fate and behaviour in the environment, residues, physical chemical analysis and efficacy properties of the pesticide. In the framework of a National Programme, 22 technicians have been employed for 6 years under temporary contract to support the BPI on these issues.

Currently 1674 plant protection products, containing 430 active substances, are authorised in Greece.

Information on new authorisations, withdrawals or any modification of issued authorisations is notified to all the companies involved in the production, importation and sale of plant protection products, to the Prefecture administrations and to the BPI.

4.1.2.2. Parallel import

A Ministerial Decision 96504/2000 sets up an accelerated procedure for granting authorisation for parallel imports of plant protection products.

4.1.2.3. Extension of uses

No legal provisions are in place for extension of use on “minor crops”. All uses must follow the normal procedure to be authorised.

The issue of minor uses was considered a problematic matter by the authorities because of the great variety of crops which characterises Greek agriculture. A simplified procedure to deal with this issue is at present under consideration.

4.1.3. Control activities

4.1.3.1. Planning

A plan for control activities is set up on an annual basis by the Department of Pesticides under the Ministry of Agriculture in collaboration with the BPI, in particular the Physical Chemical Analysis Laboratory. There is no formal consultation procedure with the regional and local authorities to set up the plan.

The plan focuses on the control of the marketing of specific active substances and is approved by Ministerial Decision. The plan lists the range of authorised formulations containing the selected active substances being studied, to be sampled by the local authorities. The choice of the active substances is based on their rate of use as well as on their toxicological characteristics and environmental impact.

During the last three years the plan has been drawn up with delays of up to 8 months in 2002. There were also notable delays in the transmission of the results to the Commission in recent years.

The officials of the PAD's were well aware of the plan even though the plan for 2002 did not arrive until August 2002.

4.1.3.2. Control on marketing

The PAD's are in charge of issuing licences for the sale of plant protection products which according to the national Law 220/73 can be issued only to retailers having a high technical qualification.

Prior to issuing the licence the PAD's officials perform an inspection of the premises to verify the requirements foreseen by the Law, mainly safety requirements of the premises. The licence is valid for 5 years after which it has to be renewed. A further inspection takes place only if any change has occurred.

In addition some inspections of the retailers are carried out focusing on storage conditions and sale. The licence holder is expected to be on the premises full time.

There are no particular requirements for the purchase of plant protection products.

The mission team took part in an inspection visit of an outlet for the retail sale of plant protection products together with representatives of the PAD of **Iraklion**.

One agronomist of the PAD of **Iraklion** deals full time with plant protection products control issues.

The inspector carried out the inspection accompanied by the person in charge of the premises. The inspection did not cover safety, hygiene and environmental aspects of the premises, because this was examined already in the first inspection carried out during the licensing procedure.

The check of the labels was limited to verification of expiry date and presence of batch number. The inspector did not verify the legal status of the products concerned or whether the labels complied with the authorisations granted, e.g. with respect to authorised uses. She did not carry any documentation that could help her to verify these aspects.

During the inspection, it was noticed by the inspection team that highly toxic products were kept with lower toxicological classified products, under glass but not locked.

The inspector did not have a checklist during the inspection. The inspection was focused on the sampling of formulations according to the requirements of the national plan and according to a procedure laid down in Ministerial Decision 155501/1983. The choice of the commercial formulation in the visited Prefecture was done according the official published list and the availability in the retail outlet visited as suggested by the trader.

Sampling for analysis can be carried out by the PAD's inspectors not only under the national plan but also if any complaint is received.

Three samples of the same plant protection product with the same batch number were taken and 4 copies of a report of sampling were completed using a standard form for all Prefectures, and signed by both retailer and inspector. The samples were wrapped in paper and sealed. One of the samples was retained by the person in charge of the premises for a possible independent analysis, the other two were transferred to the BPI Laboratory for Physical Chemical Analysis together with the sampling reports. The first sample was to be analysed in the first instance, the second to be retained in case of infringement for a confirmatory analysis.

The BPI Laboratory analyses samples for their content of active substance, their physical chemical properties and to control its label and packaging.

4.1.3.3. Control on use

In the two Prefectures visited no control is performed at user level. The officials have an advisory role towards the farmers on mainly integrated pest management issues only.

With regard to possible misuse of plant protection products, a recent RASFF notification 2002/AYA (5 August 2002) relating to the MRL being exceeded for use of methamidophos on peppers in the Region of Crete had been transmitted (4 September 2002) by the Ministry of Agriculture to all the regional offices of Ministry of Agriculture and to the PAD of Lasithio in which the problem had arisen. Despite the request for further investigation made by the Ministry of Agriculture, only a letter of communication (18 September 2002) of the problem was sent by the PAD of Lasithio to the traders of plant protection products and to agricultural organisations, but no follow up measures have been proposed by the Lasithio PAD so far.

4.1.3.4. Reporting

The Ministry of Agriculture keeps a data base relating to authorised retailers of plant protection products. No information on routine controls carried out at sale or use level was transmitted by the PAD's. Data on infringement cases concerning formulations are forwarded to the Ministry of Agriculture from the BPI.

The situation is reflected in the reports transmitted by the Ministry of Agriculture to the European Commission in which data relate only to the results of the analysis of formulations and of the control on their labels and packaging performed by the BPI Physical Chemical Laboratory.

4.1.3.5. Infringement procedure

The competent authority in charge of follow up of infringements in the area of marketing and uses of plant protection products can be a Prefecture who is in charge of penal sanctions and the General Secretariat of the Ministry of Agriculture who is in charge of administrative sanctions. Penalties can be applied according to Law 721/77 Art.31 and 32 as amended by Law 2538/97.

A few examples were provided by the PAD's, all of them linked to licence issuing and renewal. One example was examined where the case had been handed over to the Public Prosecutor for further action. No evidence was given for any action relating to other infringements.

Art. 37 of Law 2538/97 establishes that the Services carrying out the controls must notify the infringement to the offender. The offender is then required to submit any objections within 15 days. After this deadline, irrespective of the answer received, the control authority must send all the data related to the infringement to the Directorate of Plant Protection for administrative sanctions, which can only be decided by the General Secretariat of the Ministry of Agriculture.

In the event of a plant protection product non complying with the terms of its authorisation, the BPI Laboratory transmits the results of the analysis to the Ministry of Agriculture. The Ministry of Agriculture should proceed directly against the manufacturer who has the right of appeal and can require a second analysis to be carried out in the presence of a privately nominated expert. In case of infringement the cost of analysis is charged to the offender. A deadline is usually given to the manufacturer to recall the plant protection products. If this deadline is not respected the Ministry of Agriculture can decide to withdraw authorisation.

4.1.4. Formulations Laboratory

The Laboratory of Physical Chemical Analysis of the BPI undertakes formulation analysis in the framework of the national annual plan.

The laboratory is staffed with 3 chemists, 1 technician and 1 agronomist. The staff are well qualified and appropriate for the operation of the laboratory. Two of them are employed under temporary contract.

The analytical equipment used in the laboratory consists of 3 GC fitted with specific detectors and an HPLC fitted with UV/visible detector. This equipment, while appropriate for the analyses performed, is generally old.

The laboratory uses both CIPAC and specific company analytical methods when analysing samples of plant protection products.

The laboratory is not accredited at present but is assessing the possibility of becoming accredited. The performance of the laboratory is evaluated by its participation in CIPAC collaborative studies. These studies relate to the determination of both the content of active substance present and the determination of specific physical/chemical properties of the selected plant protection product being studied.

Samples of plant protection products taken as part of the official control programme can be stored for in excess of 8 weeks prior to being analysed, it is common practice to await the consignment of all the samples containing a specific active substance prior to the samples being analysed.

The analyses performed determine the content of active substance and the physical chemical properties of the plant protection products.

In case of infringement a confirmatory analysis can be carried out at the request of the interested party.

A comprehensive control of the label and packaging of the analysed formulations is performed as well.

In 2001 the laboratory analysed 85 samples with 10 label infringements arising from lack of batch number, date of production or expiry date. No infringements relating to the composition of the product were detected.

Results of the analyses are transmitted to the Ministry of Agriculture and to the Prefecture for possible enforcement measures.

4.2. Control system for residues of plant protection products in foodstuffs

4.2.1 Legislation

The main EU legislation with regard to pesticide residues has been transposed.

The MRLs¹⁰ for pesticide residues as laid down in the Annexes to Directives 86/362/EEC, 86/363/EEC¹¹ and 90/642/EEC as amended have been transposed into Greek law by Ministerial Decrees 352654/95, 290341/88 and by Presidential Decree 497/89.

Where no Community MRL exists, the CODEX MRL's are applicable and can be regularly enforced. However, there are 25 active substances authorised for use in

¹⁰ Maximum Residue Levels

¹¹ OJ L 221 07/08/86, p. 0043 - 0047

Greece for which no associated MRL have been set, consequently enforcement is limited to cases where misuse can be proved.

Ministerial Decree 236429/83 implements Directive 79/700/EEC of 24 July 1979¹² establishing Community methods of sampling for the official control of pesticide residues in and on fruit and vegetables.

Transposition of Directive 2002/63,¹³ which will repeal Directive 79/700/EEC from 1/01/03, is under preparation.

The Supreme Chemical Council under the Ministry of Economy transposed Directive 89/397/EEC on the official control of food with Decision AAXS 11/1992.

Council Directives 85/591/EEC and 93/99/EEC were transposed by two Joint Ministerial Decrees 352654/95 and 34258/2002.

4.2.2. Competent authorities

The Ministry of Agriculture, Directorate of Plant Protection Department of Pesticides is in charge of the transposition and implementation of legislation relating to pesticide residues in foodstuffs of plant origin.

Beside the Ministry of Agriculture, two other competent authorities are involved in the control of pesticide residues:

- the General State Chemical Laboratory (GSCL) under the Ministry of Economy
- the Central Food Control Agency (EFET) under the Ministry of Development

The GSCL has responsibilities for official control of foodstuffs, the chemical analysis performed by GSCL can include pesticide residues but mainly in processed food. The GSCL is the official contact point for the RASFF.

The EFET has responsibilities for official control of foodstuffs as well. The agency has recently been established by Act 2741/99 and is not yet fully operational.

The EFET has 4 regional offices in 4 of the 13 regions of Greece: Attika, Central Macedonia, Crete and Western Greece and is planned to be extended to the other regions.

EFET is one of the authorities who has been assigned some role in the National Monitoring Plan for pesticide residues by law, however, it currently has not contributed to its implementation. On the other hand, EFET has a main role in other targeted control programmes on pesticide residues (organic farming in collaboration with BPI Laboratory, olive oil control in collaboration with GSCL).

¹² OJ L 207 15/08/79, p. 0026 - 0028

¹³ OJ L 187 16/07/02, p. 0030 - 0043

As established by national law 721/77, the competence for the sampling for pesticides residues lies at local level with the following authorities:

- the 8 Regional Plant Protection and Quality Control Centres (RPPQCC) of the Ministry of Agriculture (each one includes a laboratory for residues analysis) in Thessaloniki, Patras, Crete, Volos, Nafplion, Ioannina, Kavala, Piraeus
- Benaki Phytopathological Institute mainly with the Pesticides Residues Laboratory
- the Prefectures, mainly the PAD's
- the EFET and its 4 regional offices.

Two regions were visited, Crete and Attika, in both of them the authorities carrying out the sampling for pesticides residues were the RPPQCC's.

In Crete staff from the residues laboratory of RPPQCC were in charge of sampling.

In Attika inspectors from the RPPQCC were in charge of sampling and sometimes also staff from the laboratory had to carry out the sampling to achieve the total number of samples to be analysed according to the annual plan.

The staff is suitably qualified, however, no structured training programme was in place in the regions visited. In Crete only 2 of the 5 technicians involved in the Monitoring Plan could attend training courses in the previous years.

4.2.3. Control activities

4.2.3.1. Planning

A National Monitoring Plan for the control of pesticide residues in foodstuffs of plant origin is set up on an annual basis, by the Department of Pesticides, which is also responsible for reporting the results to the European Commission.

The plan is defined on basis of the following criteria:

- importance of the crop production, rate of import, daily dietary intake
- specific analytical capacity of each laboratory
- results of previous years.

The National plan prescribes the number of samples for specific commodity to be delivered to each of the laboratories involved. The plan for 2002 includes 7 laboratories, the BPI Pesticide Residues laboratory and 6 of the 8 RPPQCC laboratories. It is communicated to all the authorities concerned, but there is no formalised procedure for consultation when drawing up this plan.

However, all of the officials met were well aware of the plan, having been notified by the Ministry of Agriculture in April 2002¹⁴.

In the plan there is no clear indication as to how many samples are to be taken by each of the authorities involved.

Furthermore, if in the laboratories visited at the end of the year the planned number of samples to be analysed has not been taken, the laboratory itself contacts the inspectors either of the RPPQCC or of the PAD's and requires further samples. It was also stated that sometimes on an annual basis the number of samples taken exceed the analytical capacity of the laboratory in which case the excess samples are destroyed.

The EU co-ordinated programme is incorporated into the annual plan. In previous years the laboratories of Iraklion and Patras had performed part of the analysis required by the EU co-ordinated programme, under the supervision of Likovrisi Laboratory, and the same collaboration was foreseen in the plan for 2002. However, during the mission, it was said that only the Likovrisi Laboratory performed all the required analysis for 2002 and that all the samples came from the Piraeus region¹⁵.

4.2.3.2. Sampling

The FVO inspection team attended a sampling procedure in both regions visited.

In both regions sampling took place according to a procedure combining Directive 79/700/EEC with some elements of the CODEX sampling procedure. The inspectors had a copy of it on the spot.

Usually 2 samples are taken, which are destined for the first and second analysis by the laboratory; the second is for confirmatory analysis in case of non-compliance.

In Crete, an agronomist and a technician from the RPPQCC Laboratory in the presence of the person in charge of the premises carried out the sampling at a greengrocery. When taking the samples the inspectors considered the general requirements of the National Plan. However, no monthly or weekly plan for the commodities to be sampled was available.

The samples are taken at wholesalers, packaging plants, supermarkets, greengroceries, open markets. In Crete the samples are *mostly* from domestic production chosen on a seasonal basis.

¹⁴ *In their comments the Greek authorities stated that the national plan was drawn up and finalised following written and oral consultations between the Pesticides Department of the Plant Production/Protection Directorate, the RPPQCCs and the BPI.*

¹⁵ *In their comments the Greek authorities stated that that the samples coming from the Piraeus region would constitute a representative sample for Greece's territory because 80% of domestic and almost all of imported agricultural products went to Piraeus Central Vegetable Market.*

Two samples of tomatoes were taken at random from a lot of 25 boxes originating from the same producer. The uniformity of the lot was established according to a copy of the delivery bill. From 10 of the 25 boxes, 2 units were chosen for the sample and the counter sample of 10 units each, which were then labelled and sealed. The plastic bag was closed with a sticky label. The equipment for the transportation was a polystyrene box containing some ice packs.

A sampling report was filled out in two copies and the labelled samples were transferred to the laboratory. The transport to the laboratory took place immediately after sampling and was carried out by the inspectors.

In Attika two inspectors from the RPPQCC of Piraeus carried out the sampling at a wholesale importer . Two samples of apples were taken from two different lots. The lots were identified by the batch number present on the box.

From 10 boxes of each lot, 2 units were chosen, mixed, divided into sample and counter-sample, labelled and sealed. The samples were sealed with a metal seal and on the label a unique number obtained from the office was provided to codify the sample. The standard sampling report was compiled in 3 copies and signed by both the inspector and the wholesaler. The samples were placed in a collar box while being transported to the laboratory. One of the inspectors reported that occasionally the consignment to the laboratory would be carried out directly by the party from whom the sample was taken (e.g. the importer).

4.2.3.3. Reporting

According to the internal procedure, the results of analysis should be transmitted to the inspector who carried out the sampling and to the Department of Pesticides who has the responsibility of performing a risk assessment where the MRL is exceeded and is in charge of deciding on enforcement actions to be taken.

The necessity of evaluating risk to the consumers due to dietary intake is determined on a case by case basis. The risk assessment is not performed systematically by the central authority, examples were discussed where no risk assessment was carried out despite the fact an acute toxic substance was repeatedly exceeding the MRL (e.g. metamidophos in strawberries).

However, it was reported by the central authority that not all the regions transmit the results in due time. This was confirmed in the Crete region where the data of analysis were forwarded to the central authority only in the framework of the annual report of the Monitoring Plan. No enforcement measures had been taken nor a written notification sent to those responsible for the infringements detected.

4.2.3.4. Enforcement procedures

While there is a procedure for administrative sanctions, no administrative sanction for exceeding the MRL has ever been imposed, although Greece reported that 6% of residues samples exceeded the MRL in 2000 (Tab.1). It was explained that administrative sanctions could not be imposed since only results from accredited laboratories (of which there is only one) could be used for enforcement measures.

However, some examples of enforcement actions relating to imported products were provided at central level: in these cases the product was rejected and an analysis of conformity was required prior to further import of the product being allowed.

Few examples of enforcement measures were provided for misuse of plant protection products on domestic crops. In these cases the transmission of analytical results to the PAD, in charge of control on use, was carried out in time together with a request for further investigation. In one case second analysis provided confirmation of levels exceeding the MRL and the product was destroyed.

Tab.1 Overview of the results from the National Monitoring Programme 2000

	Total number of samples	Number samples of domestic products	Number samples of imported products	% on total number of samples with residues exceeding MRL
Fresh food	1472	1023	449	6
Processed products (mainly olive oil)	161	151	10	2.5

4.2.4. Pesticide Residues Laboratories

In Greece there are eight pesticide residues laboratories that perform analysis for the Ministry of Agriculture, one is part of BPI, the others belong to the RPPCQC's.

Only the Pesticide Residues Laboratory of BPI has recently been accredited according to ISO 17025 in July 2002. The remaining residue laboratories are not accredited.

Analytical results deriving from seven of these laboratories will be included in the national monitoring programme for 2002. No results from the Kavala and Ioannina laboratories were included in the 2001 residues monitoring report, as these laboratories were still in a preparatory stage. In 2002, Ioannina laboratory was involved in the Monitoring Plan.

Two residue laboratories were visited: the BPI Pesticide Residues Laboratory and the Residues Laboratory of RPPQCC in Iraklion.

4.2.4.1. BPI Pesticide Residues Laboratory

The BPI Pesticide Residues Laboratory performs routine pesticide residues analysis.

In 2001 the Laboratory analysed approximately 8% of the samples taken in the framework of the Monitoring Plan, for 2002 it is planned that it will analyse around 15%.

The laboratory is accredited by the Hellenic Accreditation Council to the ISO 17025 standard for a specified number of plant matrices.

The laboratory is staffed with 3 chemists, 2 technicians and one agronomist. The staff are suitably qualified.

There was no structured training programme in place. However, the BPI has a major role in organising training for the laboratories and plant protection sector.

The laboratory is well equipped with 5 GC's having specific detectors as well as having the confirmatory capacity of GC-MS. There is one HPLC in the laboratory that is not in frequent use. The equipment is capable of analysing the range of pesticides included in the laboratory scope. Technical support for the maintenance of the analytical equipment is satisfactory.

The range of analytes includes 61 active substances, among them organochlorines, organophosphorous and pyrethroids compounds.

The analytical methods used in the laboratory are appropriate for the range of pesticides being analysed. When an MRL is exceeded 3 recovery studies are performed, the results of which are used to determine the uncertainty of the method. Furthermore, when an MRL is exceeded two samples are analysed and the result is considered acceptable if they do not differ by more than 30%. A Standard Operating Procedure (SOP) to deal with the uncertainty of analytical results is in place.

A SOP indicates that all samples must be analysed within two months of receipt.

The laboratory participates in European and Aquacheck proficiency studies and has organised an internal Greek proficiency study for the official laboratories participating in the national monitoring programme.

EU quality control guidelines (QCG) are followed as closely as possible.

4.2.4.2. Iraklion Pesticide Residues Laboratory

The Iraklion Residues Laboratory carries out routine residues analysis.

The annual plan for the laboratory in 2002 comprises residues analysis on 150 samples of olive oil in the framework of a Consumer Project of Surveillance and on 310 samples in the framework of the National Monitoring Plan (approximately 16% of the total number of samples). Of these 310, 200 are analysed for the maneb group and 310 for benomyl group and organophosphorous pesticides.

The laboratory staff is directly involved in the sampling for the national monitoring plan and the sampling procedures followed are consistent with the EU residue sampling Directive 79/700/EEC.

The laboratory is staffed with 2 agronomists, 1 chemist under temporary contract and two technicians 1 of them under temporary contract. The staff is suitably qualified. Only two of them had the opportunity to participate in training courses last year.

The analytical equipment available to the laboratory is limited to two GC's with specific detectors and one UV/Vis spectrophotometer. The equipment is capable of determining the range of pesticides being analysed but poor technical support for its maintenance has a very negative impact on the analytical capacity of the laboratory. It was reported that the equipment was not functioning for extended periods of time last year.

The range of active substances being analysed includes the benomyl group, the maneb group and 14 organophosphorous compounds. No organochlorines can be analysed.

The analytical methods used in the laboratory are appropriate for the range of pesticides being analysed. Sample extracts, which are analysed for organophosphorous pesticide residues, are stored for extended periods of time prior to final analysis due to unavailability of GC's. No validation data were available to confirm the stability of pesticide residues present in these stored extracts.

There was not an appropriate procedure for the purchase, preparation and handling of pesticide calibration standard solutions.

No validations of the analytical methods used were available.

The laboratory is not accredited and is unlikely to become accredited before 2004.

The laboratory has participated successfully in an internal Greek proficiency study for organophosphorous residues in grape matrix.

The EU QCG are partly implemented.

5. CONCLUSIONS

5.1. Control system for the placing on the market and uses of plant protection products

5.1.1. Legislation

EU legislation concerning the placing on the market and use of plant protection products has been transposed.

5.1.2. Competent authorities

The General Directorate of Plant Protection Department of Pesticides under the Ministry of Agriculture is in charge of the transposition and implementation of legislation concerning marketing and use of plant protection products.

A considerable number of temporary staff are employed in the Ministry of Agriculture for pesticide control systems, this might lead to a loss of expertise in the future.

Prefectures under the Ministry of the Interior are in charge of controls on marketing and use, according to national Law 721/77.

5.1.3. Control activities

With regard to the inspection measures to be taken according to Art.17 of Directive 91/414/EEC, a national annual plan of control is set up by the Ministry of Agriculture. This plan is limited to specifying a group of active substances that have to be sampled on local level for analysis by the BPI Physical Chemical Laboratory.

During the last three years the plan has been drawn up with considerable delay and the transmission of the results to the Commission was also delayed.

In the two regions visited, apart from the inspections for approval of premises and the sampling activities, no more comprehensive routine controls at market level were carried out.

The authorisation status of plant protection products is not checked on the spot. The inspectors were not provided with checklists or other documents to assist them to verify the validity of authorisations at sale level, e.g. copy of approved labels to check, withdrawn products list.

There are no controls at user level. The inspectors of the visited PAD's have mainly an advisory role towards the farmers. This constitutes a failure to comply with the requirements of art.17 of Dir. 91/414/EEC.

5.1.4. Formulations laboratory

There is one laboratory, which performs analysis of formulations at the Benaki Phytopathological Institute. It is working towards accreditation for formulation analysis.

The aim of the formulation analysis in the framework of the annual plan is the analysis of plant protection products to verify that the content of active substance present and its physical-chemical properties comply with the product specification. Furthermore, the laboratory carries out a comprehensive check on the label and packaging of the plant protection products sampled.

Considerable delays in the analysis of formulations have been noticed.

The laboratory has a high level of expertise to conduct the analysis, but at present some of the equipment is old.

5.2. Control system for residues of plant protection products in foodstuffs

5.2.1. Legislation

The Community legislation with regard to pesticide residues has been transposed into national law.

Where no Community MRL exists the Codex MRL is applicable and can be legally enforced.

25 active substances have been authorised without associated MRL, which may place consumer health at risk.

5.2.2. Competent authorities

The competent authority regarding pesticide residues is the General Directorate of Plant Protection Department of Pesticide under the Ministry of Agriculture. Besides the Ministry of Agriculture, two other competent authorities are involved in the control of pesticide residues in food:

- the General State Chemical Laboratory (GSCL) under the Ministry of Economy mainly for analysis of processed food
- the Central Food Control Agency (EFET) under the Ministry of Development

Official contact point for the RASFF is the GSCL.

A number of competent authorities are responsible for sampling in the framework of the national pesticide residue monitoring plan in food of plant origin:

- the 8 Regional Plant Protection and Quality Control Centres (RPPQCC) of the Ministry of Agriculture,
- the BPI
- the PAD's of the Prefectures
- the EFET.

5.2.3. Control activities

A national monitoring plan is drawn up annually. There is no formalised procedure for consultation between the Department of Pesticide and the authorities involved.

The requirements for the monitoring are communicated to the different authorities in broad terms and there is a lack of co-ordination of sampling activities, which may lead to a certain overlap.

The EU Co-ordinated Programme is incorporated in the National Plan but all samples in 2002 were taken from the Piraeus region only. This is not considered representative for Greece.

Dietary risk assessment where the MRL is exceeded is under the competence of the Department of Pesticide, but it is not performed systematically.

The national monitoring plan is mostly aimed at surveillance. The efficacy of enforcement measures is rather limited and dependent on the local authority concerned. Results of the analysis are not always transmitted in due time to the central authority responsible for dietary risk assessment.

The sampling procedure complies with the requirements of the Community legislation.

5.2.4. Pesticide Residues Laboratories

To date seven laboratories are participating in the monitoring for pesticide residues in Greece. Only 1 is accredited and analyses a limited percentage of samples. This is not in compliance with Directive 90/642/EEC with reference to Directive 93/99/EEC which requires accreditation for all laboratories participating in the monitoring programme.

In the two laboratories visited staff is suitably qualified and there is a good standard of analytical equipment in use.

In one region visited limited validation data for the analytical methods used were available and there was a serious lack of technical instrumental support available to the laboratory resulting in considerable delays in the analysis.

The EUQCG were partly implemented in the laboratories visited.

The range of analytes determined varies widely among the laboratories, being in some cases rather limited.

No structured training programme was in place.

5.3. General Overview

The control plan for marketing and uses of plant protection products does not comply with the requirements of Council Directive 91/414/EEC, which states that Member States shall make the necessary arrangements for plant protection products which have been placed on the market and for their use to be officially checked to see whether they comply with the requirements of the Directive and in particular with those concerning authorisation and information appearing on the label.

The control of pesticide residues is based on an annual monitoring programme, which rarely and inconsistently leads to enforcement measures. Dietary risk assessment is not systematically carried out. Furthermore, only one of the seven laboratories involved in the monitoring programme has been recently accredited. Lack of co-ordination between the different authorities involved puts at risk the effectiveness of the planned activities.

6. CLOSING MEETING

A closing meeting was held on 8 November 2002 with the central competent authority, at the Ministry of Agriculture in Athens. Representatives of the Ministry of Agriculture, of the Regional Centres of Ministry of Agriculture, of the General State Chemical Laboratory and of the EFET were also present. At this meeting, the main findings and initial conclusions of the mission were presented by the FVO inspection team. The representatives of the Competent Authority accepted the specific observations and initial conclusions presented during that meeting without major objections.

7. RECOMMENDATIONS

7.1. To the competent authorities of Greece

- (1) The competent authorities of Greece should ensure that associated MRL's are established for all the active substances authorised in order to guarantee consumer protection.
- (2) The competent authorities of Greece should ensure that in case of MRL exceedances legislation is enforced efficiently and consistently in all Prefectures and RPPQCC's and that there are clear and systematic dietary risk assessment and communication procedures where there are risks for consumer health.
- (3) Inspections should be carried out according to Art.17 of Directive 91/414/EEC including controls at user level and on the authorisation status of the plant protection products. Reports should be complete and sent to the Commission within the deadline set in the legislation.
- (4) The competent authorities of Greece should clearly define tasks and communication procedures for the authorities involved in planning and implementing the residues monitoring activities to avoid overlaps and to ensure that the samples taken are representative for the country.
- (5) The competent authority should ensure that the control activities in the context of the EU Co-ordinated programme are representative for the whole country.
- (6) The Greek authorities should make every effort to accelerate accreditation of laboratories performing pesticide residues analysis. They should ensure that participation in the co-ordinated EU monitoring programme is restricted to laboratories which are accredited and which have participated or will participate in European proficiency tests. Implementation of the EU quality

control procedures should be encouraged in all the laboratories involved. The competent authority should ensure that the number of analytes sought is appropriate to evaluate consumer exposure to pesticide residues.

8. ADDENDUM

The Greek authorities sent in the comments to the draft report together with an action plan which addressed the recommendations made.

In this action plan the Greek authorities stated that the MRLs for the authorised substances for which no MRL has yet been fixed was planned to be fixed by December 2003. They also stated that in the event of infringements the procedure for imposing administrative sanctions laid down by law would now be strictly followed.

Regarding the inspections according to Art. 17 of Directive 91/414/EEC several measures were proposed, including an annual meeting of all involved parties in the planning phase, a new procedure for checks at user level, training measures for the inspectors involved and a standardised reporting format for results and infringements.

The Greek authorities stated that recommendations 4 and 5 referring to the pesticide residues monitoring had been taken into account when the Greek 2003 monitoring plan was drawn up.

They indicated that samples for the coordinated programme would be tested in laboratories that have successfully participated in the European proficiency test and are deemed to fulfill the accreditation requirements. Some indication of a time schedule for accreditation was given.