EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG (SANCO)/7333/2004 – MR Final

# FINAL REPORT OF A MISSION

# CARRIED OUT IN GREECE

# FROM 15 TO 19 NOVEMBER 2004

# CONCERNING CONTROLS OF PESTICIDES IN FOOD OF PLANT ORIGIN

# AND

# FOLLOW UP ON THE RECOMMENDATIONS MADE IN THE REPORT DG (SANCO) 8711/2002

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

| | |
|---|---|
| BPI | Benaki Phytopathological Institute |
| CIPAC | Collaborative International Pesticides Analytical Council |
| DAD | Diode Array Detector |
| ECD | Electron Capture Detector |
| EFET | Hellenic Food Safety Authority |
| EU | European Union |
| EUROSTAT | Statistical Office of the European Communities |
| FVO | Food and Veterinary Office |
| GC | Gas Chromatograph |
| GC-MS | Gas Chromatograph-Mass Spectrometer |
| GCSL | General Chemical State Laboratory |
| HPLC | High Performance Liquid Chromatograph |
| LC | Liquid Chromatograph |
| LOD | Limit of Determination |
| MRDF | Ministry of Rural Development & Food |
| MRL | Maximum Residue Limit |
| MS | Mass Spectrometer |
| NPD | Nitrogen Phosphorous Detector |
| RASFF | Rapid Alert System for Food and Feed |
| RCPPQC | Regional Centre for Plant Protection and Quality Control |

## EXECUTIVE SUMMARY

The mission took place to assess the Greek control of pesticides residues in food of plant origin and to follow up the recommendations made in report DG (SANCO) 8711/2002.

*Marketing and use of plant protection products:*
All legislation relating to marketing and use of plant protection products has been transposed, and the competent authorities have been clearly identified.

A number of shortcomings were identified in the application of the legislation. In particular, inspections of retailers and users of plant protection products is very limited in scope or in number; the provisions of Directive 1999/45/EC of the European Parliament and of the Council regarding the classification, packaging and labelling of dangerous preparations are being incorrectly applied regarding the timelines for compliance of labels of plant protection products with the Directive; no research is being conducted for alternatives for the 10 'essential uses' granted in accordance with Commission Regulation (EC) No. 2076/2002, as amended.

*Pesticide residues:*
All EU legislation relating to Maximum Residue Limits (MRLs) for pesticide residues in produce of plant origin, up to Commission Directive 118/2003/EC, has been fully transposed and the competent authorities have been identified.

However, a number of shortcomings were identified, such as, only 1 of the 8 laboratories involved in the analysis of primary products of plant origin is accredited, the absence of MRLs for many substances already on the market when Council Directive 91/414/EEC came into force in July 1993, the range of analytes being sought is low, produce treated post-harvest is not being systematically checked for pesticide residues and, finally, legislation regarding pesticide residues in babyfood, while transposed, is not being implemented.

### Follow-up of Mission SANCO/8711/2002

The recommendation, regarding the EU co-ordinated programme being representative for the whole country, has been satisfactorily addressed. Four of the remaining 5 recommendations have been partially fulfilled. These relate to enforcement of MRL legislation; submission, to the Commission, of an annual report on inspections on marketing and use of plant protection products; the definition of tasks of the control services and the achievement of accreditation for all laboratories performing pesticide residues analysis. Further work is required to fully address these recommendations.

Finally, the recommendation relating to establishment of Maximum Residue Limits for all active substances on the Greek market has not been addressed.

### Overall Conclusion

EU legislation has been fully transposed but, while some improvement since the previous mission can be reported, deficiencies in the implementation of controls have been detected, particularly regarding controls on the marketing and use of plant protection products, the continued failure of the majority of laboratories to achieve accreditation and regarding co-ordination between the authorities involved in the monitoring programmes.

This report contains a number of recommendations to the Greek authorities to address the identified shortcomings.

## 1. INTRODUCTION

The mission took place in Greece from 15 to 19 November 2004. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one Member State expert.

The mission was undertaken as part of the FVO's planned mission programme.

The inspection team was accompanied during the whole mission by a representative from the Ministry of Rural Development and Food (MRDF).

An opening meeting was held on 15 November 2004. Representatives from the central competent authority (MRDF), the Hellenic Food Safety Authority (EFET), the Benaki Phytopathological Institute (BPI), the General Chemical State Laboratory (GCSL) and the Regional Centres for Plant Protection and Quality Control (RCPPQC) of Kavala and of Piraeus attended the meeting.

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

## 2. OBJECTIVES OF THE MISSION

The main objective of the mission was to evaluate the control systems put in place for pesticide residues in foodstuffs of plant origin in the framework of Council Directives 86/362/EEC[1] on the fixing of maximum levels for pesticide residues in and on cereals and 90/642/EEC[2] on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables. As residue monitoring is related to the placing on the market and use of plant protection products, the control system for the latter functions, in the framework of Council Directive 91/414/EEC[3] concerning the placing of plant protection products on the market, was also evaluated.

This was the second mission undertaken to Greece for this purpose. An earlier mission with this objective (SANCO/8711/2002) had been carried out in Greece from 4 to 8 November 2002.

Further objectives were to follow up findings of this previous mission, and to assess the implementation of Art. 50 (Rapid Alert System) of Regulation (EC) No. 178/2002[4] of the European Parliament and of the Council 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, with regard to pesticide residues.

The mission formed part of a wider series of missions to Member States to evaluate control systems and operational standards in this sector, and to follow up findings of the first round of missions.

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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
4 OJ L31, 1/02/2002, p. 0001 - 0024

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

**Placing on the market and use of plant protection products:**

| COMPETENT AUTHORITIES VISITED | Comments |
|---|---|
| Ministry of Rural Development & Food (MRDF). | Central competent authority for transposition of legislation relating to marketing and use of plant protection products. |
| Regional Centre of Plant Protection and Quality Control (RCPPQC), Kavala. | Regional competent authority for control inspections on marketing and use of plant protection products. |
| **LABORATORY VISIT** | **Comments** |
| Visit to Laboratory of Physical and Chemical Analysis of Pesticides, Benaki Phytopathological Institute. | Laboratory for analysis of pesticide formulations. |
| **INSPECTION VISITS** | **Comments** |
| Inspection visit to a retailer of plant protection products and observation of the sampling of a plant protection product by the Regional Plant Protection Service in Xanthi. | Inspections conducted and sample taken in the context of control on marketing of plant protection products. |
| Observation of an inspection visit to a grower of vegetable crops by the Regional Plant Protection Service in Xanthi. | Inspections conducted in the context of control on the use of plant protection products. |

**Pesticide residues in foodstuffs of plant origin**

| COMPETENT AUTHORITIES VISITED | Comments |
|---|---|
| Ministry of Rural Development & Food) (MRDF). | Central competent authority for transposition of legislation relating to pesticide residues in food of plant origin and for the controls of pesticide residues in primary food of plant origin. |
| Hellenic Food Safety Authority (EFET) | Central competent authority for control of pesticide residues in processed products of plant origin. |
| RCPPQC, Kavala. | Regional competent authority for controls on pesticide residues in food of plant origin. |
| **LABORATORY VISITS** | **Comments** |
| Visits to Laboratories of the RCPPQC in Kavala and in Kifisia. | Laboratories performing pesticide residue analysis. |
| **INSPECTION VISITS** | **Comments** |
| Observation of a sampling procedure at a packing premises by the Regional Plant Protection Service in Kavala. | Sampling of consignment of grapes. |

## 3. LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of the Treaty of the European Community (in particular Articles 10, 152, 153 and 211), other general provisions of Community legislation, and in agreement with the Competent Authorities.

In particular, the mission was carried out under Article 5 of Commission Regulation (EC) No. 645/2000 of 28 March 2000[5] setting out detailed implementing 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, respectively.

## 4. BACKGROUND

### 4.1. Mission background

A previous mission to Greece on control systems for pesticides residues was undertaken from 4 to 8 November 2002, and recommendations were addressed to the Greek competent authorities. The report on this mission is available under DG (SANCO) 8711/2002 – MR – Final on the Health and Consumer Protection DG's Internet site at http://europa.eu.int/comm/food/fvo/index_en.htm .

The report of this previous mission identified some shortcomings and a number of recommendations were made to the competent authorities in Greece, (see Chapter 6.3).

### 4.2. General description of Greece's agriculture

Statistics from EUROSTAT indicate that the total utilised agricultural area in 2000 was some 3,583,190 hectares, with arable land accounting for some 1,965,470 ha. Cereals account for 1,127,980 ha, industrial plants for 476,360 ha, forage plants for 137,110 ha and fresh vegetables, melons and strawberries for 60,580 ha. Out of a total of 817,060 holdings, over 76.7% are less than 5 ha in area, 13.3% are between 5 and 10 ha and only 1.7 % are above 30 ha. The total value of plant protection products used in Greece in 2002 was estimated at €208.71 million.

MRDF provided statistics of the estimated volume of pesticides used by farmers in Greece, as follows:

| | |
|---|---|
| Insecticides | 2,500 tonnes |
| Fungicides | 4,000 tonnes |
| Herbicides | 2,500 tonnes |
| Others | 1,000 tonnes |
| **Total** | **10,000 tonnes** |

5 OJ L 78, 29.03.2000, p. 0007 - 0009

# 5. MAIN FINDINGS

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

### *5.1.1. Legislation*

#### 5.1.1.1. Transposition of EC legislation

Council Directive 91/414/EEC concerning the placing of plant protection products on the market was transposed by Presidential Decree 115/1997, as amended by Presidential Decree 290/1998. A series of Ministerial Decisions have transposed amendments to the Annexes to the Directive, the most recent being a Joint Ministerial Decision 1368/2004.

Council Directive 79/117/EEC[6] prohibiting the placing on the market and use of plant protection products containing certain active substances has been transposed by a Ministerial Decree 103999/2001.

Legislation relating to Directive 1999/45/EC of the European Parliament and of the Council[7], concerning the classification, packaging and labelling of dangerous preparations was transposed by Ministerial Decree 265/1002. Implementation procedures regarding labelling of plant protection products were laid down in Ministerial Decree 108114/2003. The Decision states that only consignments of products entering the market after 1 August 2004 must be labelled in compliance with the Directive, while products already on the market may continue to be sold and used.

#### 5.1.1.2. National legislation

Law 220/1973, as amended, requiring persons or companies engaged in selling plant protection products to be licensed, to be subject to renewal every 5 years, and to employ an agronomist, has not changed since the previous mission. Additional legislation, Ministerial Decree 103995/2003, was introduced to facilitate 'off-label' authorisations for minor uses.

### *5.1.2. Competent authorities*

The Department of Pesticides, Directorate of Plant Produce Protection of the MRDF is the competent authority with responsibility for transposition of legislation relating to Council Directive 91/414/EEC. It also holds responsibility for authorisation of plant protection products, for controls on the marketing and use of plant protection products and for reporting an annual summary of the controls conducted by the authorities of the regions in accordance with Article 17 of the Directive.

In relation to Directive 1999/45/EC of the European Parliament and of the Council, regarding classification, packaging and labelling of dangerous preparations, including plant protection products, the competent authority is the Department of Pesticides of the MRDF.

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[6] OJ L 33, 08.02.1979, p. 0036 – 0040

[7] OJ L 200, 30.07.1999, p. 0001 - 0068

The competence for conducting the controls on marketing and use of plant protection products is with the Regional Plant Protection Services of the Prefectures.

### *5.1.3. Authorisation of Plant Protection Products*

The authorisation procedure under Council Directive 91/414/EEC has not changed since the previous mission. It involves evaluation of a dossier submitted by the applicant. The BPI, the National Research Institute and the MRDF have responsibility for evaluation of different sections of the dossier. The scientific evaluations are submitted to the MRDF who table a proposal to the Supreme Council for Pesticides. The Supreme Council, consisting of representatives from Universities, MRDF, Ministry of Health and the Union of Professional Agronomists, Foresters and Geologists, makes a recommendation to the Minister for Rural Development & Food who authorises the product through a Ministerial Decision.

#### 5.1.3.1. Essential uses

The EU review of active substances, already existing on the market when Council Directive 91/414/EEC came into force, has resulted in the removal of a substantial number of plant protection products from the market. Article 2 of Commission Regulation (EC) No. 2076/2002[8] requires the withdrawal of authorisations of plant protection products containing those active substances, which have been excluded from Annex I to Council Directive 91/414/EEC, by 25 July 2003 and to be sold and used before 31 December 2003. Article 2.3 of the Regulation allows Member States to retain specified 'essential uses', up to 31 July 2007, subject to certain conditions.

Greece has retained 'essential uses' for 10 active substances. Under Article 2.3 (d), it is a condition for granting 'essential uses' that research into alternatives is undertaken but it was confirmed by the central competent authority that no research is being conducted. An interim report on the application of Article 2.3 was due at the end of 2004.

However, it was confirmed that research is being conducted in the case of products containing fenthion. Fenthion was the subject of a derogation in Commission Decision 2003/199/EC with conditions identical to those of Article 2.3 of the above Regulation.

#### 5.1.3.2. Parallel imports

An accelerated procedure for approval of parallel imports was introduced before the previous mission and is based on the EU guidance on the subject. No applications have been received by the Greek competent authorities under this procedure.

#### 5.1.3.3. Minor uses

Authorisations for minor uses are facilitated by legal provisions introduced in 2003. It involves authorising the use of certain products on the basis of draft EU guidelines on extrapolation. Many such authorisations have been granted since the introduction of the legislation.

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8 OJ L 319, 23.11.2002, p. 3 - 11

In September 2004, a total of 1,625 plant protection products, containing some 348 active substances, were authorised for marketing and use in Greece.

### *5.1.4. Control activities regarding the placing on the market and the use of plant protection products*

#### 5.1.4.1. Planning, priorities and scope

MRDF, in consultation with the BPI, drafts annual plans for control of the marketing of plant protection products. One plan sets down the plant protection products, containing specific active substances, which may be sampled for analysis of content and identity of active substance and certain physical/chemical properties. Neither the number of samples nor the region in which the sampling is to be conducted is specified, leading to a number of samples of the same products being submitted for analysis by the regional authorities. Sampling should be done at retail level only. The plan also specifies that products containing any of the substances retained for 'essential use' should be sampled for label control, to ensure that only uses specified are recommended.

A separate plan for control of marketing of plant protection products, also drafted by the MRDF, proposes the inspection of at least 10 retail premises by the Prefectural authorities every year. The central competent authority has no precise information on the total number of pesticide points of sale and can only estimate the number at 800. The plan for the inspections contains a 15-point checklist which is based on the draft guidance document for reporting to the EU Commission in the context of Article 17 of Council Directive 91/414/EEC. It is the responsibility of the authorities of the Prefectures to determine when, and by whom, the inspections are conducted, but no detailed Prefectural plans were presented.

The plan for control on the users of plant protection products was first drafted by the MRDF in 2003 and proposes the inspection of 10 farmers in each of the 52 Prefectures. It also contains a checklist for conducting the inspection and deals mainly with the health and safety of the user. It was noted that the central competent authority may request, but not require, the authorities of the Prefectures to carry out inspections or to report the results of those inspections.

Results issued to the EU Commission, in the context of Article 17 of Council Directive 91/414/EEC, indicate that not all results have been received by the central authorities. It is also apparent that the plans for controls on marketing and use of plant protection products were only partly achieved by those Prefectures who reported to the central competent authority.

#### 5.1.4.2. Performance of inspections

Generally, marketing and use of plant protection products is controlled in the Prefectures by Plant Health Inspectors of the Department of Agriculture, whose principal duties relate to plant health and to giving advice to growers and farmers. The total amount of time devoted to marketing and use controls by the inspectors depended on other duties assigned and varied from 5% up to 30% in the Prefecture visited. The inspection reports show that most of the inspections took place since the mission was announced. Only one of the inspectors met during the mission received specific training in market and use controls and no manual of procedures was available to the inspectors.

The mission team observed an inspection of a retailer of plant protection products in Xanthi. The retailer was one of the five largest retailers of plant protection products in Xanthi. Inspections are not announced. The inspector checked the license for the premises and completed an inspection form (checklist). The inspection emphasised issues relating to health and safety, such as ventilation, first aid, fire fighting equipment, segregation of products (especially toxic products) and the presence of products whose authorisation had expired. The inspector had a copy of the register of authorised plant protection products but no additional supporting documentation to verify that the information on the label was accurate and in accordance with the authorisation. No record of the findings of the inspection was left with the owner of the point of sale, but it was noted that documents relevant to issues on plant protection products were provided to the retailer.

It was noted by the mission team that none of plant protection products, seen during the inspection, were classified or labelled in compliance with Directive 1999/45/EC of the European Parliament and of the Council, especially with regard to environmental classification and labelling. It was later explained to the mission team that Ministerial Decree 108114/2003 introduced an administrative procedure whereby the onus was placed on the registration holders to propose the appropriate classification for the products and to amend the labels accordingly. The competent authority was not sufficiently resourced to verify the accuracy of the proposed classification. The Laboratory for Chemical Analysis of Pesticides in the BPI conducts the only official checks on labels of plant protection products on the Greek market.

The mission team also observed the sampling of a plant protection product. This was the first sample taken in the Xanthi in 2004. Eight samples were taken in 2003. The sampling procedure was identical to that described in the previous report and ensured the integrity of the sample. A completed and signed copy of the sampling form was given to the owner of the retail outlet.

Inspections of users had only very recently begun in Xanthi and only 2 inspections had taken place in there up to the time of the mission. The mission team observed an inspection of a user of plant protection products which relied primarily on an interview. A checklist was used as a basis for interviewing the user/grower and focussed mainly on issues of health and safety for the user/operator of the application equipment. Plant protection products in stock were inspected but no attempt was made to verify that the plant protection products in stock were authorised for use on the crops grown and no documentation was available to the inspector to carry out such verification.

#### 5.1.4.3. Follow-up of infringements

It was noted that the legislative basis for follow-up is in place. This is confirmed by follow-up which took place in incidents involving unauthorised uses of plant protection products, highlighted through the Rapid Alert System for Food and Feed (RASFF), and resulted in substantial fines being levied on the producers (See Chapter 5.2.4).

Evidence was also provided to confirm that follow-up of a non-compliance detected during the analyses of a plant protection product took place through the removal of the non-compliant batch from the market.

5.1.4.4. Obsolete pesticides

There is no official definition of the term 'obsolete pesticides' in Greece. However, it was explained that plant protection products which can no longer be used for their intended purpose or any other purpose and require disposal, are considered to be 'obsolete'. This definition includes prohibited or severely restricted products and products where the contents, packaging or labels have deteriorated and can no longer be used. No statistics are available at central or regional level on the possible stocks of obsolete pesticides but, as a result of a collection scheme in the recent past, it is probable that only small quantities are in storage.

*5.1.5. Laboratory for formulation analysis*

As described in the previous report, the Laboratory for Chemical Analysis of Pesticides in the BPI is the only laboratory in Greece with official responsibility for formulation analysis. The structure, activities, procedures and staffing are at the same level as at the previous mission. Since the last visit an HPLC-DAD system has been procured, and is being used for routine analysis and for method development. Since the last mission, the laboratory has taken part in 2 CIPAC collaborative trials with good results. Procedures for accreditation under ISO 17025 are ongoing.

In the framework of Article 17 of Council Directive 91/414/EEC, the laboratory analysed 107 samples from 45 products for 7 active substances, in 2002, and detected 3 non-compliances for content of active substance. In 2003, 64 samples from 22 products were analysed for 6 active substances and 0 non-compliances were detected. In addition, up to 20 samples are analysed annually at the request of private individuals.

The laboratory of the BPI continues to hold responsibility for checking, using a checklist, that the labels of the samples submitted for formulation analyses conform to the authorisations granted. In 2003, in addition to the label controls conducted on the 22 products sampled in the context of Article 17 of Council Directive 91/414/EEC, some 15 label controls were conducted on 37 samples in the context 'essential uses' granted in accordance with Article 2 of Commission Regulation (EC) No. 2076/2002. Overall, 5 non-compliances were detected.

## 5.2. Control system for pesticide residues in foodstuffs of plant origin

*5.2.1. Legislation*

5.2.1.1. Transposition of EC legislation

Council Directives 76/895/EEC[9] relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables, 86/362/EEC and 90/642/EEC, as amended, have been transposed. Ministerial Decrees 119576 (OJ 1344/B/ 18.8.2004) and 119118 (OJ 1183/B/3.8.2004) have transposed Commission Directives 113/2003/EC and 118/2003/EC. Later Directives have yet to be transposed.

9 OJ L 340, 09.12.1976, p. 0026 - 0031

Commission Directive 2002/63/EC[10] on sampling for pesticide residue analysis has been transposed through Ministerial Decree 91972, OJ 123/B/27.01.2003, which established the sampling methods for the control of pesticide residues in products of plant and animal origin.

Commission Directive 91/321/EEC[11], as amended by Commission Directive 1999/50/EC[12] and 2003/13/EC[13], concerning infant formulae and follow-on formulae has been transposed by Ministerial Decrees 1510/93, 3203/2000 and 75195/2004 respectively. Commission Directive 96/5/EC[14], as amended by Commission Directive 1999/39/EC[15] and 2003/14/EC[16], concerning processed cereal-based foods and baby foods for infants and young children, has been transposed by Ministerial Decrees 4243/97, 3204/2000 and 75201/2004 respectively.

5.2.1.2. National legislation

No changes in national legislation have taken place since the previous mission. Where no harmonised EU Maximum Residue Limits (MRLs) exist, CODEX MRLs are applied, where available, as national MRLs under Article 14 of Law 721/77. Provisional MRLs may also be established under Article 4 of Presidential Decree 115 of 1997. MRLs for unauthorised uses are set at the Limit of Determination.

Infringements and sanctions relating to the residues legislation are regulated by Law 721/77, as amended by Law 2538/97.

*5.2.2. Competent authorities*

Department of Pesticides, Directorate of Plant Produce Protection of the MRDF is the Competent Authority for transposition of the EU legislation relating to pesticide MRLs in foodstuffs of plant origin and for establishment of National and provisional MRLs in such products. The Department is also responsible for enforcement of the residues controls on primary products of plant origin, for co-ordination of the implementation of the controls and for the operation of the EU co-ordinated monitoring programme. The implementation of the controls, such as sampling and analysis, is the responsibility of the authorities of the Prefectures.

EFET is the Competent Authority for the control of pesticide residues in all processed products of plant origin.

The National Organisation for Medicines of the Ministry of Health is the Competent Authority for control of pesticide residues in baby food.

The MRDF has responsibility for operation of the Rapid Alert system for products of plant origin and for risk assessment for non-compliant samples.

10 OJ L 187, 16.07.2002, p. 0030 - 0043
11 OJ L 175, 04/07/1991, p. 0035 - 0049
12 OJ L 139, 02/06/1999, p. 0029 - 0031
13 OJ L 041, 14/02/2003, p. 0033 - 0036
14 OJ L 049, 28/02/1996, p. 0017 - 0028
15 OJ L 124, 18/05/1999, p. 0008 - 0010
16 OJ L 041, 14/02/2003, p. 0037 - 0040

### *5.2.3. Control activities regarding pesticide residues*

#### 5.2.3.1. Planning, priorities and scope

An annual pesticide monitoring plan, incorporating the EU co-ordinated monitoring programme and the national monitoring programme, is prepared annually by the MRDF in consultation with the BPI and the regional services. A copy of the finalised plan is communicated to EFET for information. The plan relates mainly to primary products of plant origin. Priorities are based on the same parameters as identified in the previous mission, e.g. importance of the crop production, rate of import, daily dietary intake, analytical capacity of each laboratory, results from previous years. Responsibility for analysis of specific commodities is divided between the BPI and the 7 laboratories of the RCPPQC.

In addition, a monitoring programme for pesticide residues in processed foods of plant origin, such as breakfast cereals, tea, biscuits, fruit juice, tinned fruit, etc., has been conducted by EFET in 2003 and 2004. However, the programme is only operating in 5 of the 13 regions of Greece and resulted in 49 samples being analysed in 2003 and 59 in 2004. The small number of samples taken were analysed by the General Chemical State Laboratory, which is accredited but is not one of the laboratories used for the MRDF monitoring programme. Since May 2004, EFET has been assigned the powers to co-ordinate the controls of all foods, after primary production, at Prefectural level. No co-ordinated plan has been drafted between EFET and MRDF for pesticide residues and apparent overlaps exist in the control of fruit juices, insofar as the EU co-ordinated programme is concerned, and olive oil.

It was confirmed that the monitoring of babyfood for pesticide residues has not been conducted and no plans to initiate such monitoring were presented.

#### 5.2.3.2. Sampling

Sampling for pesticide residues is conducted at Prefecture level by officers of the Prefectural Directorates of Agriculture. It is conducted at points of import, points of delivery to packhouses and at wholesale and retail level.

The mission team observed sampling of a consignment of domestically produced table grapes at a packhouse in Kavala. While the sampling of produce forms a small part of the overall duties of the inspector of the Directorate of Agriculture, the sampling procedure was carried out efficiently by the inspector. Sampling was conducted in general compliance with Commission Directive 2002/63/EC. Since individual containers were not labelled, the inspector relied on the owner of the packhouse to confirm the identity of the producer. Although the sample was split between 2 bags, it was considered to be 1 sample. A counter sample was not taken. A sampling report form was completed in triplicate, with a copy being provided to the owner of the produce, a copy retained by the inspector and the original form accompanying the sample to the laboratory.

Sampling is done prior to grading and final packing and, therefore, prior to any post-harvest treatment which may occur (unless post-harvest treatment had already taken place prior to delivery). Since different laboratories have been assigned responsibility for analysis of specific commodities, samples are delivered, by courier, to the appropriate laboratory, usually within 24 hours of sampling.

Sampling of produce in the context of the EFET monitoring programme is effected by personnel of the regional services of EFET.

5.2.3.3. Follow up of infringements

The central administration authorities of the MRDF are responsible for infringement procedures. Enforcement action is taken when the analytical result shows an exceedance of the MRL, with no correction for analytical uncertainty, but risk to the consumer is taken into account. Acute dietary risk assessments, based on the UK model for adults and toddlers, are conducted on samples which exceeded the MRL.

Evidence was presented of administrative follow-up, whereby the RCPPQC contacted the grower by letter and sent the resulting response together with the analytical result to the central competent authority. The central competent authority informed the RCPPQC of the fine to be imposed and the grower was duly informed by the RCPPQC. Legislation states that appeals against fines can only be made to the courts following payment, but, in this case, the grower has appealed without payment and a legal argument is ongoing. Further evidence of follow-up was shown in some cases where Rapid Alerts were issued by other Member States involving Greek produce of plant origin.

Although evidence of administrative follow-up was presented, no evidence of systematic targeted follow-up sampling of the suppliers/producers of samples which were non-compliant with MRL legislation was presented. In fact, in a particular incident investigated by the mission team, where sampling was to take place as part of the follow-up procedure, sampling had not taken place over 1 year after the infringement was detected. It is noted, however, that follow-up samples were taken in 4 other instances and reported to the Commission for 2003.

MRDF reported that for 2003, 2,082 samples of products of plant origin, including 1,620 samples of fruit and vegetables, 427 samples of olive oil and 35 samples of cereals were analysed, with 37 (2.3%) samples of fruit and vegetables exceeding EU MRLs. No samples exceeded the national MRLs. None of the 49 samples in the EFET programme for 2003 exceeded the MRL.

*5.2.4. Rapid Alert System.*

The GCSL is the national contact point for operation of the EU Rapid Alert System for Food and Feed (RASFF). When a Rapid Alert is received through the RASFF relating to pesticide residues, the GCSL informs the Department of Pesticides of the MRDF, the RCPPQCs, EFET and, for babyfood, the National Organisation for Medicines.

When a Greek laboratory detects an exceedance of a pesticide MRL, the MRDF is informed. The Department of Pesticides conducts a dietary risk assessment, and, when a notification is appropriate, informs the GCSL, RCPPQCs and EFET. However, there is no manual of procedures for operation of the RASFF in Greece.

According to the 2003 monitoring report, there was a total of 37 samples which were non-compliant with MRL legislation and 1 Rapid Alert notification was issued. It is noted that no notifications within the RASFF have been issued by Greece for produce of Greek origin, while 11 notifications relating to produce of Greek origin have been issued by other Member States.

No specific plan exists for the sampling of produce being imported from third countries, and sampling normally takes place as a result of information received through the RASFF. All 12 notifications issued by Greece since 1999 relate to produce from third countries.

### *5.2.5. Laboratories for pesticide residue analysis*

#### 5.2.5.1. Organisation

In Greece, a total of 8 laboratories - the BPI and 7 laboratories under the competence of the RCPPQCs - perform residue control analysis in the framework of Council Directive 90/642/EEC. In addition, the GCSL, which is accredited by UKAS, conducts pesticide residue analyses on processed foods of plant origin, on behalf of EFET. The number of laboratories accredited under ISO 17025 has not changed since the previous mission. It was noted that a plan for the remaining 7 laboratories to achieve accreditation under ISO 17025 has been drafted and that they are at various stages in the process of achieving accreditation, but progress is slow.

Laboratories for pesticide residues under the competence of the RCPPQCs of Kavala, which started residue analysis only two years ago, and Piraeus were visited during this mission. In 2003, the laboratory in Kavala analysed about 45 samples and accounted for 3% of the samples taken for the EU co-ordinated programme. The laboratory in Piraeus analysed 276 samples and accounted for 13% of the samples taken for the EU co-ordinated programme.

#### 5.2.5.2. Resources and training

The staff resources available, in the laboratories visited, varied from 3 agronomists in Kavala to 5 staff in Piraeus, including 2 agronomists, 1 chemist and 2 laboratory technicians, 3 of which are on annual contracts.

The range of equipment available in the laboratories visited also differed widely. The laboratory in Kavala has excellent facilities but is equipped with only one GC with one ECD and NPD detector and an HPLC-system. The HPLC-system will begin operation in early 2005.

The laboratory in Piraeus is much better equipped but space is limited. The mission team was informed that the laboratory will move to a new location closer to the Port of Piraeus in 2005.

Some training on quality control procedures, accreditation requirements and analytical equipment and methods has been conducted in both laboratories, but further training is required.

#### 5.2.5.3. Analytical spectrum and methods

The laboratory in Kavala uses a multi-residue analytical method for gas chromatography which is capable of detecting up to 25 analytes. The Piraeus laboratory analyses for some 73 analytes using 3 in-house multi-residue analytical methods. In addition, 2 single residue analytical methods for carbendazim and dithiocarbamates are used. None of the methods have been validated.

The Piraeus laboratory uses a system of two-column confirmation which is suitable for specified cases. It is noted, however, that the guidance on EU Quality Control

Procedures advises confirmation by MS but available GC-MS equipment has not been used for some time due to the un-availability of trained staff.

It was noted that many substances, and also many metabolites incorporated in the harmonised EU residue definition of some compounds, are not in the residue screens and are not available as standard materials in the laboratories.

Both laboratories report the results of the analyses conducted and do not provide any interpretations, assessments or conclusions. Neither laboratory estimates analytical uncertainty and, consequently, reports uncorrected results.

5.2.5.4. Quality assurance systems

Neither of the laboratories visited holds accreditation under ISO 17025. Drafting of Standard Operating Procedures is at an early stage. During the mission it was noted that the implementation of, or compliance with, all parts of the EU guidance on Quality Control Procedures for Pesticide Residue Analysis (SANCO 10476/2003 which supersedes SANCO 3103/2000) was considerably less than that stated in the national pesticide residue monitoring report submitted to the EU Commission.

The absence of some frequently occurring pesticides in the screen of the analytical methods resulted in neither laboratories reporting sufficient pesticides in EU Proficiency Test 6 to be recognised as having a sufficient scope. In general the quantitative results were acceptable.

# 6. CONCLUSIONS

## 6.1. Control system for the placing on the market and use of plant protection products

### *6.1.1. Legislation*

Council Directives 91/414/EEC, 79/117/EEC and Directive 1999/45/EC of the European Parliament and of the Council have been transposed in a timely manner, although the deadline for implementation of Directive 1999/45/EC regarding labelling of plant protection products has been incorrectly interpreted.

Additional national legislation has been put in place, since the previous mission, to facilitate authorisation for minor uses.

### *6.1.2. Central competent authority*

The competent authorities for transposition of EU legislation, for authorisation of plant protection, for implementation of the controls on marketing and use of plant protection products and for classification, packaging and labelling of plant protection products are clearly defined.

### *6.1.3. Authorisation of Plant Protection Products*

The procedure for authorisation has not changed since the previous mission except for legislation introduced in 2003 to facilitate ‘off-label’ authorisation for minor uses of plant protection products which has resulted in many such authorisations. It is considered to be in compliance with Council Directive 91/414/EEC.

Research for alternatives for the 10 active substances retained as 'essential' under Regulation (EC) No. 2076/2002 is not taking place and is not in compliance with Article 2.3 (d). An interim report on the application of Article 2.3 was due by the end of 2004.

### *6.1.4. Control activities*

Marketing control plans are drafted, annually, by the central authorities in consultation with the Benaki Phytopathological Institute (BPI), but implementation of the plans by the regional authorities is not obligatory and is largely not fulfilled.

Training of inspectors, for controls on marketing or use, is not being systematically conducted or planned, and the resources allocated to control activities are secondary to work assigned in other areas.

Although checklists for inspection of sellers and users of plant protection products have been developed by the central authorities, no manual of procedures for inspections has been drafted. Furthermore, the un-availability, during inspections, of appropriate documentation restricts the effectiveness and efficiency of the controls on marketing and use, particularly with regard to labelling and authorised use.

Control of the quality of plant protection products is taking place through sampling and analysis of products containing a limited range of substances on the market.

Detailed label controls are only conducted on those products which are sampled and submitted to the BPI. This constitutes checks on less than 2.5% of the plant protection products on the market each year.

As a result of the incorrect transposition of the deadlines specified in Directive 1999/45/EC of the European Parliament and of the Council, the labels of plant protection products on the market, observed by the mission team, did not comply with Directive, particularly in respect of environmental classification and labelling.

Controls on the user and on the use of plant protection products have recently been introduced but are limited to issues of health and safety of the user. They are not sufficient, in scope or in number, to ensure that such products are used in accordance with the conditions attached to their authorisation.

The legislative basis is in place for the appropriate follow-up of infringements in the marketing and use of plant protection products.

Responsibilities under Article 17 of Council Directive 91/414/EEC are not being fulfilled, due mainly to reports on inspections and controls not being submitted to the central authorities by the authorities of the majority of Prefectures. Consequently, the annual report to the Commission, in the context of Article 17 of Council Directive 91/414/EEC, is incomplete.

There is no official definition of the term 'obsolete pesticides' in Greece and no statistics on such products are recorded at central or regional level. A recent collection scheme was believed by the competent authority to have reduced stocks in storage at all levels of the supply chain.

### *6.1.5. Laboratory for formulation analysis*

Apart from procurement of additional analytical equipment, no further changes can be recorded since the last mission.

## 6.2. Control system for pesticide residues in foodstuffs of plant origin.

### *6.2.1. Legislation*

Transposition of EU directives with respect to Maximum Residue Limits (MRLs), concerning pesticides in foodstuffs of plant origin, including babyfoods, and the sampling of such products has taken place within the specified deadlines.

National MRLs have still not been established for all existing active substances on the Greek market.

### *6.2.2. Competent authorities*

The competent authorities for transposition of EU legislation regarding pesticide residues in food of plant origin and babyfood and for implementation of the legislation are clearly defined.

### *6.2.3. Control activities*

An official monitoring plan for primary products of plant origin, which incorporates the EU co-ordinated programme including fruit juice but not other processed products of plant origin, is prepared annually by the Ministry of Rural Development & Food.

A limited monitoring programme for processed food of plant origin is drafted and conducted by the Hellenic Food Safety Authority (EFET).

There is a need for further co-ordination and planning between the MRDF, EFET and the National Organisation for Medicines regarding monitoring of all food of plant origin for pesticide residues.

The Directives relating to the monitoring of babyfood for pesticide residues are not implemented.

Sampling is carried out in broad compliance with Commission Directive 2002/63/EC and no counter sample is taken.

While post-harvest treatment can be detected in samples taken at retail level, controls for pesticide residues following post-harvest treatment at packhouse level are not systematically conducted.

The central authorities are responsible for infringement procedures following liaison with the regional authorities, and fines have been imposed.

An acute consumer risk assessment and enforcement action is taken when the analytical result from the laboratory shows an exceedance of the MRL, without correction for the analytical uncertainty.

Follow-up of Rapid Alerts involving Greek produce and notified by other Member States is taking place.

*6.2.4. Rapid Alert System*

The national contact point for the Rapid Alert System for Food and Feed is identified but no manual of procedures for the operation of the Rapid Alert System in Greece, have been drafted.

Greece has issued a number of 'Information' notifications regarding pesticide residues in the context of import controls of foodstuffs of plant origin coming from third countries only, but none for domestic produce or produce from other EU Member States, despite MRL exceedances being detected in such produce.

*6.2.5. Laboratories for pesticide residue analysis*

Seven of the 8 laboratories involved in the official monitoring programme have not achieved accreditation under ISO 17025 and progress towards accreditation is slow.

The report on the national monitoring programme to the EU Commission does not accurately identify the considerable deficiencies in the implementation of EU Quality Control guidelines for pesticide residue analysis (SANCO Guideline Documents 3103/2000, as revised by document 10476/2003, and 825/2000, rev. 7).

While laboratory facilities are generally acceptable, additional resources and training is required to ensure effective monitoring.

The laboratories visited varied greatly in analytical capacity regarding number of samples being analysed and the range of analytes being sought and the methods have not been validated.

Many substances, and many metabolites included in the harmonised EU residue definition, are not in the residue screens of the laboratories visited. This is not in compliance with EU MRL Directives.

The laboratories provide no assessments, interpretations or conclusions of the results reported and analytical uncertainty is not calculated.

The time-lapse between the taking of samples and reporting the analysis results of those samples is sufficiently short to permit follow-up.

## 6.3. Follow-up of recommendations of the previous report.

The report of the previous mission identified some shortcomings. The following Table lists the recommendations which were addressed to the competent authorities of Greece and how they have been assessed during the current mission.

| Recommendations of SANCO 8711/2002 | Assessment during mission SANCO 7333/2004 |
|---|---|
| (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 | The recommendation has not been fulfilled as many active substances already on the market when Council Directive 91/414/EEC came into |

| Recommendations of SANCO 8711/2002 | Assessment during mission SANCO 7333/2004 |
|---|---|
| protection. | force have no established MRL. |
| (2) The competent authorities of Greece should ensure that in case of MRL exceedances legislation is enforced efficiently and consistently in all Prefectures and RCPPQC's and that there are clear and systematic dietary risk assessment and communication procedures where there are risks for consumer health. | The recommendation has been partially fulfilled by evidence of enforcement action. However there is a lack of clarity in the procedures and no manuals of procedures have been drafted to ensure consistent enforcement, risk assessment or communication of consumer risk. |
| (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. | The recommendation has been partially fulfilled. Reports are being sent to the Commission but are substantially incomplete due to the lack of reporting by the regional authorities. Also, the level of inspection is unacceptably low. |
| (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. | The recommendation has been substantially fulfilled through the definition of tasks between MRDF and EFET, but further co-ordination between these authorities is required. |
| (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. | The recommendation has been satisfactorily addressed. |
| (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. | This recommendation has not been satisfactorily addressed.<br>While a plan for accreditation is being implemented, progress towards accreditation is slow, implementation of the quality control procedures is inconsistent and the number of analytes sought is not appropriate to evaluate consumer risk. |

### 6.4. Overall conclusion.

Some progress has been achieved since the last mission, with the relevant EU legislation being transposed. Deficiencies in the implementation of controls have been detected, particularly regarding controls on the marketing and use of plant protection products, the continued failure of the majority of laboratories to achieve accreditation and regarding co-ordination between the authorities involved in the monitoring programmes.

## 7. CLOSING MEETING

A closing meeting was held on 19 November 2004 with the central and regional competent authorities. At this meeting, the main findings of the mission were presented by the inspection team. The representatives of the competent authorities provisionally accepted the majority of the findings.

## 8. RECOMMENDATIONS

### 8.1. To the competent authorities of Greece

(1) The competent authorities should continue to establish a co-ordinated and comprehensive control plan and associated procedures for the marketing and use of plant protection products and assign sufficient trained staff to implement the controls, including follow-up, in accordance with Article 17 of Council Directive 91/414/EEC. The competent authority should provide the equipment and documentation necessary to carry out the controls.

(2) The competent authorities should ensure that all plant protection products on the Greek market are classified and labelled fully in accordance with Directive 1999/45/EC of the European Parliament and of the Council.

(3) The competent authorities should ensure that the annual report to the Commission, in the framework of Article 17 of Council Directive 91/414/EEC, includes results from all regions.

(4) The competent authorities of Greece should ensure that MRL's are established for all the active substances authorised.

(5) The competent authorities should ensure that a co-ordinated plan is operated so that all food of plant origin, including babyfood, is monitored for pesticide residues at market level and that, in cases of non-compliance, appropriate enforcement measures are taken.

(6) The competent authorities should ensure that all laboratories involved in the official control of pesticide residues in food of plant origin achieve accreditation without delay. They should also ensure that participation in the co-ordinated Community monitoring programme is restricted to laboratories which are accredited and which have participated in a previous round, or which will participate in the next round, of the European Proficiency testing.

(7) The competent authorities should ensure effective monitoring for pesticide residues by providing additional resources and training and by substantially

increasing the range of pesticide substances, and their metabolites, being sought, so as to better reflect those substances being marketed and used.

(8) Decisions on non-compliant samples should take account of the analytical uncertainty, in accordance with Commission Directive 2002/63/EC, Annex I, point 5. In addition, the full implementation of the EU guidelines 3103/2000 (as revised by document 10476/2003) and 825/00, rev. 7 concerning quality control procedures for pesticide residue analysis is encouraged.

(9) In cases of MRL infringements, the competent authorities should put in place systematic follow-up procedures to ensure that enforcement and follow-up actions are taken efficiently and effectively.

(10) The competent authorities should draft written procedures for the functioning of the Rapid Alert System for Food and Feed in Greece, and consider taking into account the draft "Proposal on notification criteria for pesticide residues findings to the Rapid Alert System for Food and Feed (RASFF)" (SANCO/3346/2001, as amended).

An action plan, in response to the recommendations, should be forwarded to the Commission within 2 months of dispatch of the final translated report. This action plan should clearly set out the manner and deadline by which the competent authorities will address each recommendation.

## 9. ADDENDUM

In their response to the draft report, the Greek authorities provided no comments on the findings or conclusions and provided preliminary information on each of the 10 recommendations in the format of an 'action plan'.

In relation to Recommendations (2), (4) (5) and (10), the Greek authorities provided information on proposed measures to be taken regarding compliance with Directive 1999/45/EC of the European Parliament and of the Council, establishment of MRLs for all active substances on the Greek market, the monitoring of all foods of plant origin, including babyfoods, for pesticide residues and the drafting of written procedures for operation of the Rapid Alert System for Food and Feed.

In relation to Recommendations (1), (3) (6), (7) (8) and (9), some information was provided on measures taken, or proposed, for implementation of controls in the context of Article 17 of Council Directive 91/414/EEC, the reporting of such controls to the Commission, accreditation of laboratories involved in pesticide residue analyses, improving the effectiveness of the pesticide residue monitoring, compliance with EU guidance for analytical laboratories and procedures for efficient and effective follow-up of non-compliances.