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FINAL REPORT OF A MISSION
CARRIED OUT IN BRAZIL
FROM 16 TO 25 NOVEMBER 2005

IN ORDER TO EVALUATE CONTROL SYSTEMS FOR PESTICIDE RESIDUES IN
FOODSTUFFS OF PLANT ORIGIN, IN PARTICULAR IN APPLES AND PAPAYAS,
INTENDED FOR EXPORT INTO THE EUROPEAN UNION

*Please note that factual errors in the draft report have been corrected in the text.
Clarifications provided by the Brazilian 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

ANVISA	National Health Vigilance Agency
CGAL	General Co-ordination of Laboratory Support Division of MAPA
CIDASC	Integrated Company for Agricultural Development of Santa Catarina
CIPAC	Collaborative International Pesticides Analytical Council
DAD	Diode Array Detector
ECD	Electron Capture Detector
EUROSTAT	Directorate-General for European Statistics
FAPAS	Food Analysis Performance Assessment Scheme
FID	Flame Ionisation Detector
GAP	Good Agricultural Practice
GC	Gas Chromatograph
GC-MS	Gas Chromatograph-Mass Spectrometer
HPLC	High Performance Liquid Chromatography
IDAF	Institute for the Protection of Agriculture & Forestry in Espirito Santo
IBAMA	Institute for the Environment and Natural Resources
IBSP	Biological Institute of São Paulo
IPM	Integrated Pest Management
MAPA	Ministry of Agriculture, Livestock and Food Supply
MMA	Ministry for Environment
MRL	Maximum Residue Level
MRM	Multi-Residue Method
MS	Ministry of Health
NPD	Nitrogen Phosphorous Detector
PHI	Pre-harvest interval
PIF	Integrated Production System for Fruit
SDA	Secretariat of Animal and Plant Health and Inspection
SEAG	State Secretariat of Agriculture
UV-VIS	Ultra Violet-Visible Spectroscopy
WHO	World Health Organisation

EXECUTIVE SUMMARY

Exceedances of the Maximum Residue Levels for pesticide residues in plant produce from Brazil have been reported by Member States to the European Commission and an increase in trade in plant produce has been noted. Therefore, it was proposed to conduct a mission to evaluate the control system for pesticide residues in foodstuffs of plant origin, particularly apples and papayas, intended for export to the European Union. The control system for marketing and use of plant protection products was also evaluated.

Control of Marketing and Use of Plant Protection Products

Legislation in force is sufficient to adequately control the marketing and use of plant protection products. Retailers of plant protection products are inspected frequently, act as advisers to growers and must be certified by control and research authorities. All plant protection products being placed on the market must be registered at Federal and at State level. Sales outlets for plant protection products are frequently inspected but follow-up of infringements is deficient. Inspections of users of plant protection products are not conducted in all States and, where conducted, concentrate mainly on health and safety of the users and the possible presence of non-registered plant protection products.

Control system for pesticide residues in foodstuffs of plant origin

The competent authority for control of residues in produce of plant origin, intended for export, is the Ministry of Agriculture, Livestock and Food Supply. However, it does not officially control plant produce intended for export to the EU for the presence of pesticide residues. Many National MRLs differ from harmonised European Union (EU) MRLs. The competent authority has no legal basis to apply the EU MRLs.

The national programme for analysis of plant produce for the presence of pesticide residues is only partially implemented. Results show that a significant number (19%) of samples were non-compliant with national legislation. ‘Continuous monitoring’, which is part of the sub-programmes for plant produce intended for export and for the domestic market, is not being officially conducted by the competent authority. However, private industry is following the sub-programmes but is not reporting the results to the competent authority and the time delay, between sampling and reporting of the analytical result, means that the produce is frequently exported before the result is known. In addition, follow-up of infringements detected as part of official monitoring and of Rapid Alerts communicated from the European Commission was deficient or non-existent.

The competent authority has certified 8 laboratories for official analysis of plant produce intended for export for pesticide residues, but only 1 of the laboratories is accredited to international standards.

Additional voluntary control systems

Systems for quality control of plant produce intended for export are in place, but compliance with the conditions of the systems is not officially checked or monitored. The systems are voluntarily operated by the majority of exporters of plant produce to the EU in order to comply with conditions demanded by their European customers.

Overall, the limited official control systems provide little assurance that produce of plant origin, particularly apples and papayas, being exported to the EU will comply with EU legislation. This raises concerns about compliance with Article 11 of Regulation (EC) No. 178/2002.

The report contains recommendations to the competent authority of Brazil to address identified shortcomings.

1. INTRODUCTION

The mission took place in Brazil from 16 to 25 November 2005. The mission team comprised of 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 and was the first mission to Brazil dealing with pesticide residues in produce of plant origin.

The inspection team was accompanied during the whole mission by a representative from the central competent authority Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA).

An opening meeting was held on 16 November 2005 with the central competent authority, MAPA. At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team, and additional information required for the satisfactory completion of the mission was requested. However, the mission programme could not be finalised at this meeting and was changed several times during the mission. This hindered the efficient progress and the meeting of the objectives of the mission.

2. OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the control systems for pesticide residues in foodstuffs of plant origin, in particular apples and papayas, intended for export into the European Union. The implementation and the effectiveness of any existing pesticide residue monitoring plan for pesticides was evaluated.

The facilities and measures in place for the determination of such residues in foodstuffs of plant origin were also assessed to ensure that the produce is within specified limits set down in European Union legislation. As residue controls are related to the placing on the market and use of plant protection products, the control system for the latter functions was also evaluated. The mission formed part of a wider series of missions to Third Countries evaluating control systems and operational standards in this sector.

The mission was carried out in the framework of:

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹, as amended;
- Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables², as amended;

¹ OJ L 31, 01/02/2002, p. 1-24

² OJ L 340, 09/12/1976, p. 26-31

- Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain produce of plant origin, including fruit and vegetables³, as amended;
- Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC⁴
- Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals⁵, as amended.

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

COMPETENT AUTHORITIES VISITED	Comments
Ministry of Agriculture, Livestock and Food Supply (MAPA).	Central competent authority for the control of marketing and use of plant protection products and for control of pesticide residues in plant produce.
State Superintendencies of Agriculture at the Federal Offices of MAPA in Santa Catarina and Espírito Santo.	State competent authority responsible for State registration of plant protection products and control of pesticide residues in plant produce.
State Agencies of the State Secretariats of Agriculture (SFA) - CIDASC and IDAF.	Agencies for the control of marketing and use of plant protection products.
LABORATORY VISITED	Comments
Laboratory for Pesticide Residues in Biological Institute of São Paulo.	Conducts analysis for pesticide residues in plant produce and other matrices.
INSPECTION VISITS	Comments
Meetings with organisations involved in growing/packing/exporting of apples and papayas to the EU.	Voluntary organisations involved in the production and export of apples and papayas.
Inspection visits to growers and pack-houses of apples in Fraiburgo, Santa Catarina and of papayas in Linhares, Espírito Santo.	Producers and packers of apples and papayas for the export and domestic market.
Inspection visits to retailers of plant protection products in Santa Catarina and Espírito Santo.	Retailers of plant protection products to growers of fruit & vegetables.
Meeting with representatives of a wholesale distribution market for São Paulo	Establishment handling fruit & vegetables for the domestic market of Brazil.

3. BASIS FOR THE MISSION

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

³ OJ L 350, 14/12/1990, p. 71-79

⁴ OJ L 70, 16/3/2005, p. 1-16

⁵ OJ L 221, 07/08/1986, p. 37-42

4. BACKGROUND

4.1. Background to present mission

Exceedances of the Maximum Residue Levels for pesticide residues in plant produce from Brazil have been reported by Member States to the European Commission. However, some of the exceedances reported are of a technical nature resulting from the EU MRL being established at the Limit of Detection, because the use is not authorised in the EU or because no data to support an MRL was provided by industry. In addition, imports of apples from Brazil into the EU have increased in recent years. It is also noted that produce of plant origin from Brazil has been notified on 4 occasions - grapes (1999), mango (2001), dried pepper (2004) and dried chilli (2005) - through the EU Rapid Alert system (RASFF) for the presence of unacceptable levels of pesticide residues.

4.2. Production and trade information

According to EUROSTAT, 57,487 tonnes and 69,010 tonnes of apples from Brazil were imported to the EU in 2002 and 2003, respectively. In 2004, the volume of imported apples almost doubled to 122,489 tonnes. Apples are mainly grown in the States of Santa Catarina (Fraiburgo), Rio Grande do Sul (Vacaria) and Paraná. The mission team was informed that the total apple growing area is around 32,000 ha, of which 14,000 ha are produced under an Integrated Production System for Fruit (PIF), which is part of the Fruit Production Development Programme prioritised by MAPA. The average production in Fraiburgo is 30 tonnes/ha. In Santa Catarina, there are about 900 apple producers. It was stated that almost 95% of the apples exported to the EU are produced under PIF or under a voluntary system developed by a private European-based trade organisation, whose members consists of growers, product marketing organisations, growers' co-operatives, food manufacturers and retailers.

The EU imported 20,378 tonnes of Brazilian papayas in 2002 and some 29,000 tonnes in both 2003 and 2004. Papayas are mainly grown in Espírito Santo (Linhares) and Bahia e Pernambuco (Petrolina). In 2004, Brazil exported 35,930 tonnes of papaya in total. Around 70% of the exported papayas are produced in Espírito Santo.

These figures indicate that trade in apples and papayas from Brazil has increased substantially over recent years. Moreover, Brazil is now ranked as the 4th most important exporter of apples to the EU (behind New Zealand, Chile and South Africa).

According to the data provided by MAPA, there were 214,725 tonnes of plant protection products marketed in 2004, of which 124,060 tonnes were herbicides, 33,291 tonnes were insecticides and 25,631 tonnes were fungicides. Over 57% of the total plant protection products sold in 2004 were used on soya and maize crops. The figures indicate a significant increase in sales of plant protection products when compared with the 1999 figures of 127,585 tonnes.

5. MAIN FINDINGS

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

5.1.1. Legislation

Legislation for registration and control of the marketing and use of pesticides has been introduced at Federal level by Law No. 7.802 of 11 July 1989 and Decree No. 4.074 of 4 January 2002. Regulations for implementation of the controls are developed at Federal and at State level.

Additional Federal legislation, Law No. 9.974 of 6 June 2000 requires that empty plant protection product packaging must be returned after use to specified collection points for re-cycling or safe disposal.

5.1.2. Competent authority

The competence for registration of plant protection products is shared between the MAPA, the Ministry of Health (MS) and the Ministry for Environment (MMA).

The competence for planning and implementing controls in the marketing and use of plant protection products is with agencies of the State Secretariats of Agriculture (SEAG) in each of the 26 States and the Federal District of Brasilia.

5.1.3. Registration of plant protection products

Prior registration at Federal and State level is required before plant protection products may be marketed in Brazil. At the time of the mission, there were 1,123 plant protection products containing one or more of 351 different active substances registered for placing on the market. A list of registered products is accessible at http://extranet.agricultura.gov.br/agrofit_cons/principal_agrofit_cons.

The certificate of registration is issued by the Department of Control of Agricultural Inputs which is one of 6 Departments in the Secretariat of Animal and Plant Health and Inspection (SDA) of MAPA. The certificate is issued on the basis of a hazard assessment and following agreement by Brazilian National Health Vigilance Agency (ANVISA) of the MS and the Brazilian Institute for the Environment and Natural Resources (IBAMA) of the MMA. Further registration, based on the registration granted by the Federal authorities, must be obtained from the inspection agencies of the SFA where marketing of the plant protection products is intended. Registrations granted for marketing plant protection products contain recommendations for the proper use of the product. A plant protection product may only be sold on the basis of a prescription issued by a certified technical expert.

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

Control activities are organised at State level by affiliated agencies of the SEAG. The level of planning and the scope of the inspections vary from State to State, but normally involve inspection of pesticide retail outlets once or twice per year. Users of plant protection products are not inspected in some States.

5.1.4.2. Performance of inspections

The mission team observed inspections of 2 retailers of plant protection products. Retailers must have certified technical experts, trained by Federal Agencies, available to act as advisers to growers. During the inspection, checks were made that the certificates were valid, prescriptions and invoices were in order, inventory of stocks was correct and that the plant protection products were registered and properly stored. It was noted, during the inspections observed that, due to the lack of appropriate documentation, the inspectors could not verify whether the plant protection products are packaged and labelled in accordance with the registration granted. During one of the inspections, the store for used containers was inspected. It was stated that, nationally, almost 15,000 tonnes of used packaging for plant protection products has been returned in 2005, representing almost 65% of all packaging used.

5.1.4.3. Controls on Use

A ‘prescription system’ was introduced by MAPA to facilitate the safe and proper use of the plant protection products by issuing specific instructions on use. Checking of compliance of the users with the instructions issued in the prescription system is only officially done in Espírito Santo if the grower is participating in the PIF⁶.

The mission team observed an official inspection of a user of plant protection products in Espírito Santo. The pesticide store was inspected, mainly from a health and safety viewpoint, but also for the presence of non-registered plant protection products. The prescriptions or invoices were not checked in detail and there is no legal requirement for the grower to retain records of pesticide applications. No documentation regarding previous visits was available to the inspector during the inspection.

5.1.4.4. Follow-up of infringements

It was stated by the competent authority that infringements in the marketing and use of plant protection products are followed up administratively, but no evidence was provided. It was noted by the mission team that, in 2 of the 3 inspections observed, the inspectors did not have the reports of the previous inspections available during inspection of the retailers or users, thus making effective, on-the-spot follow-up difficult⁷.

⁶ *In their response to the draft report, the competent authority of Brazil noted that “In the producer and exporter states, the structure of the SEAGs is sufficient for carrying out the required controls. Moreover, Brazilian legislation allows states that are not in a position to carry out these inspections to ask the Federal Government to do so. There are legal mechanisms available to the Federal Government to provide these states with technical assistance to enable them to carry out the necessary controls.”*

⁷ *In their response to the draft report, the competent authority of Brazil noted that “systematic mechanisms relating to this sub-item will be introduced to address these shortcomings.”*

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

5.2.1. Legislation

Pesticide residues in produce of plant origin are governed by Law No. 7.802 of 11 July 1989 and Decree No. 4.074 of 4 January 2002 which is also the legislation for registration and control of the marketing and use of pesticides. Additional legislation, Law No. 9.712 of 20 November 1998, establishing a system for the inspection of plant produce, and Law No. 9.782 of 26 January 1999, establishing the competence of ANVISA have been introduced at Federal level. Further technical Regulations for implementation of the controls may be introduced at State level, but none of the legislation relates specifically to pesticide residues in produce of plant origin intended for export to the EU.

National MRLs were stated by MAPA to exist for all substances registered for use on plant produce. National MRLs established in Brazil differ in many cases from the MRLs established in the European Union, but this is not unexpected since many crops, not grown in Europe, are grown in Brazil⁸. MAPA provided documents after the mission showing that a national review of 10 of these substances has taken place, resulting in a revision of the MRLs and a further 9 substances are currently being reviewed. The legislation, establishing specific MRLs for substances not yet reviewed, was not provided. No MRLs are established for substances which are not on the Brazilian market, for substances manufactured for export or for non-registered uses.

5.2.2. Competent authorities

ANVISA is the competent authority for establishment of MRLs. It was stated by the competent authority that many MRLs were set on the basis of old data, some dating back to the 1970's, but in some cases CODEX MRLs are adopted.

Control of residues of pesticides in produce of plant origin on the domestic market at retail level is the responsibility of ANVISA. ANVISA has no function in the control of pesticide residues in produce intended for export.

MAPA, through the Federal Superintendencies at State level, is the competent authority for control of residues in plant produce during production and distribution, including for export. Also inspection agencies of the State Secretariats of Agriculture may sample plant produce at farm and pack-house level, although exported produce is not specifically targeted.

5.2.3. Control activities regarding pesticide residues

5.2.3.1. Planning, scope and results

A national programme for analysis of plant produce for pesticide residues was first drafted by MAPA in 2003 and contains 4 sub-programmes, as follows: i) sub-

⁸ *In their response to the draft report, the competent authority of Brazil noted that “We adopt the MRLs set by Brazilian legislation and, for reference, those set by the JMPR (FAO/WHO) for some active substances in agricultural pesticides registered for use in Brazil. We are familiar with the MRLs set by the European Union and our exported plant products comply with the provisions of the specific legislation of the importing country.”*

programme for development of the basic structures for the programme; ii) sub-programme for monitoring of residues in agricultural produce intended for export, to be implemented in 2 phases – ‘exploratory monitoring’ and ‘continuous monitoring’; iii) sub-programme for monitoring of residues in agricultural produce intended for the domestic market, to be implemented in 3 phases – ‘exploratory monitoring’, ‘continuous monitoring’ and ‘control monitoring’; iv) sub-programme for monitoring of residues in imported agricultural produce.

‘Exploratory monitoring’ involves random sampling of produce for analysis for the presence of pesticide residues. The results would then be used as a basis for deciding which commodities should be subjected to ‘continuous monitoring’. ‘Control monitoring’ would be used as an enforcement tool where there are persistent breaches of the legislation, detected under ‘exploratory’ and ‘continuous’ monitoring.

Results of ‘exploratory monitoring’ of plant produce intended for export and for the domestic market, conducted as part of official controls, were presented during the mission by the central authorities. The results showed that 224 samples of plant produce were analysed for the presence of 104 substances during a period from August 2003 to September 2004, with only 5 samples being non-compliant. It was subsequently determined at State level that the summary results provided to the mission team were incorrect and that, of 12 results provided for 2004 by the State authorities of Espírito Santo, 5 non-compliant results were reported as compliant. A corrected summary of results, provided after the mission, show that 53 of the 224 samples were non-compliant, with some 43 non-compliant samples relating to produce of Brazilian origin.

It was further explained to the mission team by the competent authorities that the sub-programmes relating to ‘continuous monitoring’ were only being operated by the suppliers and distributors, including exporters, and that the results were not communicated to the competent authorities. The laboratory visited by the mission team confirmed that analytical results are sent only to the client who requested and paid for the analysis.

A similar, non-specific programme is being drafted for 2006 by MAPA at Federal level. No details regarding number of samples, location of sampling, scope of analysis, timing of sampling, commodities or analysing laboratories are given.

The mission team was informed by a representative of one of the 3 Public Health laboratories involved in the programme, that a programme for the analysis of pesticide residues in domestic produce was started in 2001 by ANVISA. Up to 40 samples from 9 commodities are taken at retail level each week and sent to one of the 3 laboratories for analysis. No results were made available to the mission team but it was stated that a problem was identified with dithiocarbamates in strawberries and papayas. It was also learned that the State Health Authorities had powers of enforcement where non-compliances were identified, but there was no requirement to communicate with MAPA.

5.2.3.2. Inspection and Sampling

No samples of produce of plant origin have been taken for official controls for pesticides residues in Santa Catarina, and therefore, the official sampling techniques could not be observed.

In Espírito Santo, an inspection of a grower of papayas and a sampling of produce, by the Institute for the Protection of Agriculture & Forestry (IDAF), an Agency of the State Secretariat of Agriculture, was observed. A reference document on sampling work, which is not binding, was issued by MAPA in 1998. The sample size specified in the document for fresh fruit and vegetables is broadly in line with that specified in Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on produce of plant and animal origin and repealing Directive 79/700/EEC⁹. Sampling was conducted in the field during harvesting and consisted of a single sample of 10 randomly selected fruits (the guidance specified a minimum of 5 fruits or 2 kg), which were placed in a plastic bag, sealed, labelled on-the-spot and placed in a cool-box. The procedures require that the sample be transported to the headquarters of the State agency, where it would be frozen to -8°C and stored for 6-8 days while further samples were gathered. A smaller number of the gathered samples would then be randomly selected for transfer to the laboratory for analysis. A sampling protocol was completed in triplicate and signed by the sampling officer, 2 witnesses and the owner of the produce. It was explained that if the sample is shown to be non-compliant, a further 3 samples are taken as soon as the result is known but, because no non-compliances have been detected in Espírito Santo, this procedure has not yet been required. Records of pesticide applications are requested but, with the exception of prescriptions and invoices, there is no legal requirement for the grower to retain such records and were available only because the grower was participating in a voluntary quality control system.

It was explained that the Federal Superintendencies at State level may also take samples but that exporters of produce to the EU are not normally controlled by inspections or sampling.

5.2.3.3. Follow up of infringements

In Espírito Santo, it was stated that when an official sample is shown on analysis to be non-compliant, further samples are taken to confirm the result. There are legal provisions for enforcement, including, if necessary, destruction of the crop, if the result is confirmed. No example of such measures was provided. In the cases of 5 non-compliant samples identified in 2004 in Espírito Santo, it was confirmed by the State authorities that no follow-up was conducted in the case of non-compliant coffee or apricot samples because the produce had already been exported.

5.2.4. *Rapid Alert System*

A rapid alert system for Brazil is not operational but is planned. A mandatory system for traceability of produce of plant origin is also planned.

Four Rapid Alerts within the EU system has involved pesticide residues in plant produce from Brazil. Evidence of follow-up to an 'information notification' issued in 2004, involving the presence of aflatoxins and a pesticide in ground red pepper, was provided after the mission. The documentation shows that the follow-up was concentrated on the aflatoxin issue, with no action taken on the pesticide findings.

⁹ OJ L 187, 16/07/2002, p. 30-43

In addition, no evidence of follow-up to the ‘information notification’ issued in May 2005, involving triazaphos in dried chilli, was provided.

5.2.5. Laboratories for pesticide residue analysis

5.2.5.1. Organisation

The mission team was informed by the competent authority that plans are currently being discussed to change the laboratory structures. It is planned to engage 15 laboratories for pesticide residue analysis, 3 owned by chemical companies, 5 private laboratories and 7 State-owned laboratories. Information received prior to the mission indicated that 6 laboratories were involved in the analysis for pesticide residues of plant produce intended for export to the EU. During the mission it was clarified that the information was inaccurate. Corrected information, received after the mission, shows that only the 7 publicly owned laboratories are engaged in the official analyses for pesticide residues of plant produce on the domestic market or intended for export, though not exclusively for export to the EU. All laboratories are certified by the ‘General Co-ordination of Laboratory Support’ Division (CGAL) of MAPA, but CGAL is not yet accredited as a certification body¹⁰. Only one of the laboratories conducting official pesticide residue analyses is reported to be accredited to ISO 17025.

It had been planned that the mission team would visit both a public and a private laboratory but, due to information received during the mission, the plan was changed. Consequently, the visit to a private laboratory was cancelled and a visit to an alternative public laboratory, the Biological Institute of São Paulo, (IBSP) was arranged at short notice. The Laboratory for Pesticide Residues, in the IBSP, was the first laboratory certified by CGAL/MAPA, in 1997. The IBSP was founded in the 1970’s with FAO support and in the 1990’s benefited from considerable support in training and equipment from a German Technical Institute. The laboratory is not involved in analysing samples of plant produce intended for export.

5.2.5.2. Resources and training

The laboratory has 12 employees, 6 of whom have a university diploma or higher degree (master or doctorate), 5 technician analysts and 1 assistant without specific background. Four staff are permanent employees with the remainder being on temporary contracts.

¹⁰ *In their response to the draft report, the competent authority of Brazil noted that “It should be emphasised that, although CGAL is not yet internationally recognised as an accreditation body, its accreditation methods are applied according to the requirements of the relevant international standards (ISO/IEC 17025, OECD Principles of Good Laboratory Practice and ISO 19011).*

A joint project is under way between MAPA and the National Health Vigilance Agency (ANVISA) to ensure that MAPA’s CGAL and ANVISA’s Unit for the General Management of Public Health Laboratories (Gerência Geral de Laboratórios de Saúde Pública) (GGLAS) are recognised internationally as accredited bodies.

In this connection, in December 2006, the II Office for Joint MAPA-ANVISA Work was created. It has more than 30 technicians from these two bodies working to adapt the operational procedures for laboratory accreditation by the CGAL and GGLAS to the requirements of ISO 17011. In the first half of 2006, a consultant from the American National Standards Institute (ANSI) will carry out a technical consultation of CGAL and GGLAS. In addition to assessing to what extent the two bodies currently meet the requirements of ISO 17011, ANSI will train the technical staff involved.”

5.2.5.3. Analytical spectrum and methods

The existing analytical instrumentation includes 5x GC with various detectors, 2x HPLC-FD, one of which is equipped with post-column derivatisation module for the analysis of N-methylcarbamates, 1x spectrophotometer with UV-visible detector for the analysis of dithiocarbamates. Furthermore, 2x GC with dual ECD and 1x HPLC MS/MS have recently being purchased, and are expected to be operating soon. The instrumentation is also used for pesticide residue studies and monitoring in other types of matrices, such as eggs and milk.

The multi-residue method used is the German DFG S19 method (Specht, 1992). The scope of analysis covers 106 active substances, but not all metabolites are included. The number of analytes has increased considerably in the past 5 years and it was explained that further extension of the scope of the analytes is often hampered by difficulties in obtaining analytical reference standards.

5.2.5.4. Quality assurance systems

IBSP is in the early stages of preparing for accreditation, but a consultancy has just been contracted with a view to speeding up the process. According to Brazilian requirements for accreditation, method validation must be carried out for each active substance/commodity combination, even for Multi-Residue Methods. Validation work is on-going, and the acceptance criteria followed by IBSP are generally in agreement with EU harmonized requirements. Matrix matched standards are not used, and no differences in GC response due to matrix effect are acknowledged, even for highly polar compounds. Routine quality control procedures are not yet implemented.

The laboratory has participated in a number of proficiency tests organised at national and European level, such as National Institute for Control of the Quality of Health and FAPAS proficiency tests, but only two reports were provided to the mission team: the 1997 proficiency test promoted by German Technical Cooperation (GTZ) and the 1999 test promoted by Global Environmental Monitoring Systems/GTZ. In both cases the performance of the laboratory was good. More recent proficiency test results were not provided.

At present, estimation of uncertainty is not done. However, it was stated that estimation of uncertainties associated with the reported analytical results is envisaged, but no timelines were given.

5.3. Additional voluntary control systems

Many exporters of plant produce to the EU have introduced measures to meet the demands of their customers, including sampling for private analyses, introduction of quality control procedures and moving towards traceability of produce from growers. The analytical results are compared with EU MRLs which have been forwarded by their European customers.

Integrated Production System for Fruit (PIF) is a voluntary system involving over 1,000 growers who control 35,000 ha and produce almost 1 million tonnes of fruit. PIF operates in 13 States, is planned for 4 additional States and incorporates 17 fruit species, including apples and papayas. It was stated that the majority of the growers of produce of plant origin intended for export to the European Union are members

of one, or both, of two voluntary systems - PIF or under a voluntary system developed by a private European-based trade organisation, whose members consists of growers, product marketing organisations, growers' co-operatives, food manufacturers and retailers.

Growers participating in the PIF System for apples are obliged to take samples from about 10% of the production area, but compliance with this requirement is not officially checked. The mission team observed sampling of a consignment of apples in a pack-house in Santa Catarina as a part of auto-controls operated by the private company. Sampling was done prior to the post-harvest treatment and final packing of the product. Ten crates were randomly selected from the entire production from 1 area of the farm and 10 apples were selected from each crate. The apples were mixed and sub-sampled to provide 3 control samples of 10 apples (1kg) each, placed in a plastic bag and labelled. One sample was sent to a private laboratory and the remaining 2 samples were retained by the owner. While the contract with the laboratory requires receipt of the results within 10 working days, it is possible that the consignment is already exported before the laboratory results are available.

Two of the 6 main exporters of papayas to the EU are participating in the PIF, while 5 of the 6 exporters are participating in the alternative system outlined above. Under the alternative system, growers are required to take 1 sample at 6 monthly intervals and whenever requested by their clients. Samples of papayas from the growers met during the mission are analysed by a private laboratory accredited to international standards.

During a visit to a grower of apples intended for export to the EU, it was noted by the mission team that 22 to 25 applications of pesticides had taken place in a season. It was explained by a representative of the growers that most apple growers use a pest and disease control system which may involve up to 30 applications of plant protection products during the growing season. In the case of papayas intended for export, it was stated by a grower that pesticides may be applied at intervals of 7 to 42 days, depending on weather conditions and on the outcome of monitoring for pests and diseases. It was explained that harvesting of papayas takes place weekly and therefore requires the use of products with short pre-harvest intervals (PHI), but a number of registered fungicides have PHIs of 14 days. It was further confirmed that each papaya fruit takes 18-20 weeks to mature, and could result in more than 10 pesticide applications of pesticide on each fruit.

In Santa Catarina, there is also a voluntary requirement for the biennial certification of certain pesticide application equipment.

It was noted that, despite information to the contrary received during the Opening meeting, there is no requirement in Brazilian law for exporters of plant produce to the EU to be registered by MAPA nor is there a legal requirement for provision of a laboratory analytical report, for examination by the export control authorities. Furthermore, laboratory results relating to a consignment are provided only when requested by the customer/importer. Due to the time-delay between sampling and reporting of the analytical result, the produce is frequently already exported before the result is known.

6. CONCLUSIONS

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

- (1) Legislation for the effective control of the marketing and use of plant protection products is in place.
- (2) The competent authorities for marketing and use are clearly defined.
- (3) All plant protection products being placed on the market require prior registration at Federal and at State level.
- (4) A 'prescription', signed by a certified agronomist, is required before any plant protection product may be sold to the user.
- (5) Sales outlets for plant protection products are frequently inspected but follow-up of infringements is not systematically done.
- (6) Inspections of users of plant protection products are not conducted in all States and, where conducted, concentrate mainly on health and safety of the user and on the possible presence of non-registered plant protection products.

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

- (7) The legal status of established Maximum Residue Levels (MRLs), for substances not yet re-assessed, is not clear. Many National MRLs differ from harmonised European Union (EU) MRLs. The competent authority has no legal basis to apply the EU MRLs.
- (8) The competent authority for control of residues in produce of plant origin, intended for export, is the Ministry of Agriculture, Livestock and Food Supply. However, it does not officially control plant produce intended for export to the EU for the presence of pesticide residues¹¹.
- (9) The national programme for analysis of plant produce for the presence of pesticide residues is only partially implemented. Results show that a significant number (19%) of samples were non-compliant with national legislation.
- (10) 'Continuous monitoring', which is part of the sub-programmes for plant produce intended for export and for the domestic market, is not being officially done by the competent authorities. However, private industry is following the sub-programmes but is not reporting the results to the competent authority and

¹¹ *In their response to the draft report, the competent authority of Brazil noted that "We agree with the mission team. When it inspected the control systems for residues in plant products, it noted that the PNCRV was implemented through various mechanisms. Moreover, the PNCRV systematic action plan will be presented within the time-period stipulated in the report, as recommended by the mission team."*

the time delay, between sampling and reporting of the analytical result, means that the produce is frequently exported before the result is known.

- (11) The sample sizes for fresh fruit and vegetables are broadly in line with EU legislation.
- (12) The freezing of samples for dithiocarbamate analysis is not in accordance with the conventional practice¹².
- (13) Follow-up of infringements detected as part of official monitoring and of Rapid Alerts communicated from the EU Commission is deficient or non-existent.
- (14) The competent authority has certified 7 laboratories for official analysis of plant produce for pesticide residues, including plant produce intended for export, but only 1 of the laboratories is accredited to ISO 17025.

6.3. Additional voluntary control systems

- (15) Systems for quality control of plant produce intended for export, which observe European standards, are in place, but compliance with the conditions of the systems is not officially checked or monitored.
- (16) The systems are voluntarily operated by the majority of exporters of plant produce to the EU.

6.4. Overall conclusion

Overall, the limited official control systems provide little assurance that produce of plant origin, particularly apples and papayas, being exported to the EU will comply with EU legislation. This raises concerns about compliance with Article 11 of Regulation (EC) No. 178/2002.

However, voluntary controls on pesticide residues are performed by exporters of plant produce to the EU, in order to comply with conditions demanded by their European customers.

7. CLOSING MEETING

A closing meeting was held on 25 November 2005 with the central competent authority, MAPA. At this meeting, the main findings and conclusions of the mission were presented by the inspection team. The representatives of MAPA accepted these findings and conclusions and reserved the right to make detailed comment on the draft report.

¹² *In the response to the draft report, the competent authority of Brazil noted that “This does not reflect general practice as far as the system of freezing samples for dithiocarbamate analysis is concerned. The mistake identified in this case was an isolated error and such infringements will be corrected.”*

8. RECOMMENDATIONS THE COMPETENT AUTHORITIES OF BRAZIL

In relation to pesticide residues in produce of plant origin intended for export to the European Union,

- (1) The competent authority should provide guarantees that official controls comply with, or are equivalent to, European Union standards, in order to ensure that Article 11 of Regulation (EC) No 178/2002 of the European Parliament and of the Council is fulfilled¹³.
- (2) The competent authority shall ensure that laboratories initiate and actively pursue accreditation¹³.
- (3) The competent authority should consider following-up the notifications, involving plant produce from Brazil, issued within the European Union Rapid Alert System for Food and Feed.

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

9. ADDENDUM

In their response to the recommendations in the draft report, the Brazilian authorities stated,

- in relation to Recommendation 1 that they “would like to reiterate that MAPA is establishing systematic controls for the inspection and monitoring of raw materials, production processes and the quality and safety of products of plant origin in a preventive, proactive and rigorous way, both for products intended for the domestic market and those intended for export. It will also submit the required Action Plan within the stipulated time period.”
- in relation to Recommendation 3, that they “are establishing a follow-up system and a framework of legal instruments and regulatory packages to control and monitor infringements identified and communicated officially to the Brazilian Government.”

¹³ From 01/01/2006, food imported into the Community for placing on the market within the Community shall also comply with the relevant requirements established in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (*OJ L 139*, 30/04/2004 p. 1-54; *Corrected and re-published in OJ L 226*, 25/06/2004, p. 3-21) and Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*OJ L 165*, 30/04/2004 p. 1-14; *Corrected and re-published in OJ L 191*, 28/05/2004 p. 1-52), or conditions recognised by the Community to be at least equivalent thereto.