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Directorate F - Food and Veterinary Office

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FINAL REPORT OF A MISSION CARRIED OUT IN ARGENTINA FROM 11 JUNE TO 19 JUNE 2008 IN ORDER TO EVALUATE CONTROLS OF PESTICIDES IN FOOD OF PLANT ORIGIN INTENDED FOR EXPORT TO THE EUROPEAN UNION

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Competent Authority are included in endnotes.

Executive Summary

The objective of the mission was to evaluate the control system in Argentina for pesticide residues in food of plant origin intended for export to the European Union (EU). It was decided to carry out a mission to Argentina in view of the volume of Argentina's fruit and vegetable exports to the EU. There have also been eight notifications of unacceptable levels of pesticide residues in food of plant origin from Argentina within the EU Rapid Alert System for Food and Feed (RASFF) for the period 01 January 2000 - 31 May 2008.

Legislation is in place for authorisation and control of the marketing and use of PPPs providing an adequate legal base for controls of pesticides on the market and for approval of pesticide points of sale. National MRLs are set according to the provisions laid down in the national legislation, but the CA has no legal basis to apply the EC MRLs. Legislation for registration of exporters of plant produce is in force, but there are no legal requirements for traceability or for keeping records of PPP applications.

There are clear requirements, procedures and staff for the authorisation of PPPs. Pesticide wholesalers and distributors must be approved by the municipal or provincial governments. Official controls of the marketing of PPPs are performed by the National Agrifood Health and Quality Service (SENASA), but the number of inspections performed in the period 2005 – 2007 was low. There are no systematic official controls carried out at users of PPPs.

Neither special provisions nor control plans exist for food of plant origin being exported to the EU. However, private controls for pesticide residues are operated by the farmers and by the well organised exporters. Pesticide residue laboratories and exporters provide information on EC MRLs. Traceability systems are in place on farms and in pack houses.

Before they can operate as exporters, pack houses and cool stores are authorised and registered by SENASA. Prior authorisation by the municipal or provincial authorities is required. Growers of apples, pears and citrus fruits must also be registered with SENASA.

A draft procedure for the follow – up of RASFF notifications has recently been developed and implemented. There was evidence of follow-up of a recent EU RASFF notification on pesticide residues in table grapes.

*A laboratory network is built up consisting of 10 laboratories, including SENASA Central Laboratory. Nine of them, including both of the laboratories visited by the mission team are accredited to ISO 17025. They analyse mainly private samples, but the scope of analyses is small and does not cover all of the pesticides used by growers. Both of the laboratories visited have adequate facilities and staff are sufficiently qualified. Nevertheless, for analysis of monitoring samples with a broad multi-residue screen these laboratories would need an LC-MS-MS to be also able to detect new pesticides.**(see Endnote)*

Overall conclusion

Legislation for controls on pesticide residues is in place, but an official control system has not been established yet either for the domestic market or for export of plant

produce. Most of the laboratories in the SENASA laboratory network are accredited to ISO 17025, but the scope of analyses is limited. In order to analyse monitoring samples with a broad multi residue screen both of the laboratories visited would need an LC-MS-MS to be also able to detect new pesticides. Export – oriented pack houses and producers operate private controls for pesticide residues. Most of the export companies and growers are certified by European private standards of trade and retail organizations. The legal basis for official controls on the marketing and use of PPPs is in place, but the controls are at a very early stage of development.

The report contains recommendations to Argentina to address the shortcomings identified.

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
CA	Competent Authority
CASAFE	Plant Health and Fertiliser Chamber
CO	Central Office
DAPFyV	Agrochemicals, Pharmacological and Veterinary Products Directorate
DILAB	Official Laboratories and Technical Control Directorate at SENASA
DNFA	National Agrifood Inspection Directorate at SENASA
ECD	Electron Capture Detector
EEA	Agroindustrial Experimental Station
EU	European Union
EUROSTAT	Statistical Office of the European Communities
FID	Flame Ionisation Detector
FTIR	Fourier Transform Infrared Spectroscopy
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GC	Gas Chromatograph
GLP	Good Laboratory Practice
HPLC	High Performance Liquid Chromatography
INTA	National Institute for Agricultural Technologies
INTI	National Institute for Industrial Technology
IPM	Integrated Pest Management
ISO	International Organisation for Standardisation
ME	Ministry of Economy
MFA	Ministry of Foreign Affairs
MRL	Maximum Residue Level

Abbreviation	Explanation
MSD	Mass Selective Detector
NPD	Nitrogen Phosphorous Detector
OAA	Argentinean Accreditation Body
PPP	Plant Protection Product
RASFF	Rapid Alert System for Food and Feed
RO	Regional Office
SAGPyA	Secretariat of Agriculture, Livestock, Fisheries and Food
SENASA	National Agrifood Health and Quality Service
SICOFHOR	Fresh Fruit and Vegetable Products Control System
SIFFAB	Federal Control System for Agrochemicals and Biological Products
UV	Ultraviolet

1 INTRODUCTION

The mission took place in Argentina from 11 to 19 June 2008. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one Member State expert.

The mission was undertaken as a part of the FVO's planned mission programme and was the first mission to Argentina dealing with pesticide residues in produce of plant origin.

The inspection team was accompanied during the whole mission by representatives from the central CA (SENASA) and the Embassy of Argentina to the EU.

An opening meeting was held on 11 June 2008 with SENASA, the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA), the Ministry of Foreign Affairs (MFA) and the Embassy of Argentina to the EU. At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team.

2 OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the control systems for pesticide residues in foodstuffs of plant origin intended for export to the European Union (EU). The facilities and measures in place for the determination of such residues in foodstuffs of plant origin intended for export to the EU were assessed to ensure that the produce is within specified limits laid down in EU 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 to evaluate control systems and operational standards in this sector.

The mission was carried out within the framework of:

- Regulation (EC) No 178/2002;
- Regulation (EC) No 882/2004;
- Regulation (EC) No 852/2004;
- Council Directive 76/895/EEC;
- Council Directive 90/642/EEC;
- Council Directive 86/362/EEC;
- Regulation (EC) No 396/2005.

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

Table 1: Mission visits and meetings

Meetings/Visits		Comments
Competent Authorities		
Central	1	SENASA
Regional	2	SENASA – Rio Negro and SENASA – Tucuman
Provincial Governments	2	Provincial Governments in Rio Negro and Tucuman
Laboratories		
SENASA Plant Laboratory	1	Conducts analysis for formulation and pesticide residue controls
Private Laboratory for Pesticide Residues analysis	1	Conducts analysis for pesticide residues in foodstuffs of plant origin
Inspection or site visits		
Packing houses/Exporters	2	Visit to an exporter of apples and pears in Rio Negro province; visit to another exporter of lemons in Tucuman province
Growers	2	Visit to a farmer growing apples and pears in Rio Negro province (around 25 ha of land); visit to another farmer in Tucuman province (170 ha of land)
Retailer of PPPs	1	Visit to a retailer in Rio Negro province (annual turnover : 4 million US $)
Distributor of PPPs	1	Visit to a distributor of PPPs in Tucuman province
Experimental stations	2	Visit to INTA Alto Valle in Rio Negro province and EEA Obispo Colombres in Tucuman province

3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation, in particular under Article 46 of Regulation (EC) No 882/2004, and in agreement with the competent authorities in Argentina.

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

4 BACKGROUND

According to data from EUROSTAT for the year 2007, Argentina was the second largest exporter of fresh fruits to the EU, accounting for approximately 719,000 tonnes or 10.5 % of the total imports to the EU. Argentina is also a significant exporter of fresh and chilled vegetables (approximately 191,000 tonnes or 3.8 % of vegetables exported to the EU).

According to information received from the CA, apples production in 2007 was 1,001,982 tonnes (including 286,432 tonnes for export). Pears production in 2007 was 735,665 tonnes (including 457,374 tonnes for export). Approximately 39 % of total exports of apples and 35 % of pears were shipped to countries within the EU. Apples and pears are mainly grown in Rio Negro province. The total number of farmers registered with SENASA in Rio Negro province is 3,466 and smallholders (1 to 25 hectares) account for 82 % of the production . Their produce is intended for export, for the internal market or for the processing industry. 64 % of pears and 24 % of apples produced in the province are exported.

According to data provided by the CA, lemons production in the same year was 1,516,972 tonnes. In Tucuman province lemons are grown on 35 000 hectares, which produced 1,328,000 tonnes in 2007 or 88 % of the country's total production. 61 % of total exports of lemons in 2007 were shipped to the EU and 30 % – to Eastern Europe (in particular Russia). Most lemon farms are medium – sized (100 – 200 hectares). The farmer visited in Tucuman province owned a farm of 170 hectares (four plantations in four different locations).

The CA provided data on the quantities of PPPs marketed in the country. Argentina imported 76,000 tonnes of pesticides in 2006/2007 and 72,600 tonnes in 2005/2006. Most of the pesticides used in the country are manufactured or formulated by local companies (approximately 70 %). The total quantity (imported and manufactured in the country) of PPPs marketed in 2006/2007 was 176,400 tonnes, compared to 169,400 tonnes in 2005/2006. The statistical data provided for the period 1999 – 2007 show that the local market for pesticides has increased significantly since 2003. The increase in grain production over that same period due to higher international prices was given as the main reason by the authorities.

According to data provided by the central CA the total number of national producers of PPPs is 136; 76 of them are formulators and the other 60 are manufacturers (11 dealing with the synthesis of active substances and 49 dealing with the synthesis of active substances and formulation of PPPs).

5 MAIN FINDINGS

5.1 LEGISLATION

Legislation for authorisation is laid down in Decree Law 3489/58, which establishes the general framework for the registration of PPPs. A Manual of Procedures, criteria and scope for authorisation of PPPs was adopted by way of SAGPyA Regulation 350/99 of 30 August 1998. This Manual implements in practice the FAO Manual on the Development and Use of FAO specifications for PPPs. The rules for authorisation of active substances, formulations, extension of use and equivalence checks are also laid down in the Manual. The requirements adopted are similar to those laid down in Council Directive 91/414/EEC.

Legislation on control of the marketing and use of PPPs is laid down in SENASA Regulation 500/03 establishing the Federal Control System for Agrochemicals and Biological Products (SIFFAB). The control system was amended by DNFA Decision 119/07, which clearly defines the scope, the general objectives, the specific objectives and the coordination of the system.

National MRLs are established by SENASA Regulations 256/03 and 619/05. Regulation 256/03 also sets clear rules that agricultural products or by-products being imported or produced in the country must comply with national MRLs or CODEX MRLs. Nevertheless, there are no legal provisions for official controls in case of export of plant produce and for compliance with national MRLs in the countries of destination, including EC MRLs. The Fresh Fruit and Vegetable Products Control System (SICOFHOR) was established by SENASA Regulation 493/2001. The Monitoring and Surveillance Plan was approved by SENASA Decision 42/2008. In the Annex to this Decision, the scope and the specific objectives of the plan are defined and the general actions and procedures are set, including sampling, laboratory analysis and follow-up activities in case of non-compliance.

5.2 COMPETENT AUTHORITIES

The competent authority for the authorisation of plant protection products and controls of marketing and use is the National Agrifood Health and Quality Service (SENASA) within the Ministry of Economy (ME). SENASA is also responsible for the registration of farmers and companies dealing with PPPs (importers, formulators and manufacturers), controls of pesticide residues in products of plant origin and follow – up of EU Rapid Alert notifications. Thirteen regional offices (RO), including 360 local offices of SENASA, cover all 23 provinces plus the autonomous city of Buenos Aires.

The recent re – structuring of SENASA and the regionalisation process that - started in mid – 2006 - empowers the staff at regional and local level to undertake control activities under SIFFAB and SICOFHOR.

The Municipal and Provincial Governments are also involved in some control activities, mainly relating to environmental issues. In the provinces visited of Rio Negro and Tucuman, they are responsible for the approval of pesticide retailers and distributors. They also approve pack houses and cool stores.

5.3 CONTROLS OF THE MARKETING AND USE OF PLANT PROTECTION PRODUCTS

5.3.1 Authorisation of plant protection products

All PPPs require authorisation prior to placing on the market and use. Procedures and requirements set in the Manual adopted by SAGPyA Regulation 350/99 must be followed in the process of authorisation of PPPs.

The Agrochemicals, Pharmacological and Veterinary Products Directorate (DAPFyV) at SENASA Central Office (CO) in Buenos Aires is the authority responsible for the authorisation of PPPs and fertilisers. Thirty SENASA inspectors and two technicians from the SENASA Plant Laboratory are involved in the authorisation of PPPs and fertilisers. External consultants with specific expertise in toxicology can be involved as evaluators if needed. For a PPP to be authorised for placing on the market and use, applicants are required to submit data on efficacy, physical – chemical properties and toxicology, including acute and chronic toxicity for the active substance and for the formulation. Setting national MRLs is part of the authorisation process. Applicants must submit data gathered from residue trials performed in three regions of the country, for two growing seasons. Additional toxicological studies are also required. These are accepted by the Argentinean authorities if the analyses are performed in laboratories approved by SENASA. For the purposes of the authorisation a detailed evaluation of the data submitted is carried out. The conditions for authorisation are based on risk assessment. Authorisation of labels is also part of the authorisation procedure. Two different types of certificates are available, one for authorisation of active substances and one for authorisation of formulations.

Authorisation of active substances is valid for five years. For formulations, the period of validity is one year. Renewal of authorisations is an administrative procedure, with payment of a fee by applicants. The CA stated that risk assessment and risk management are part of post – registration activities. If a risk is identified the authorisation can be changed or withdrawn.

There are 2746 products authorised in Argentina, containing 398 active substances. For some of these substances, a decision has been taken on non-inclusion in the EU positive list, Annex I to Council Directive 91/414/EEC and they can not be placed on the market and used in the EU. If some of these pesticides are applied on produce for the export market, they can lead to exceedance of EC MRLs(see Endnote).

An official register of authorised PPPs is kept. The CA stated that the register is up-dated every two weeks. The register is not published on the internet, but it is available if requested. A list of PPPs authorised for placing on the market and use is published on the

SENASA web-site and is regularly up – dated. Additionally, a Manual on authorised active substances is published by a private body, the Plant Health and Fertiliser Chamber (CASAFE), which contains specific information on trade names of formulations, authorised uses, application rates, timing of applications, pre-harvest intervals and re-entry periods. It is published every two years; an annual up-date is provided on CD and further updates are provided on a regular basis via the internet.

5.3.2 Controls of the marketing of plant protection products

Inspections on the marketing of PPPs under SIFFAB are planned and carried out at retailers or wholesalers. Two staff from the CO office and inspectors from four Regional offices (ROs) – Santa Fe, Cordoba, Entre Rios and Cuyo – are responsible for performance of official controls. In addition, inspectors from the remaining ROs can be instructed to perform controls. The total number of controls performed in the period 2005–2007 is 220. The CA submitted information about the number of pesticide sale points approved in both of the provinces visited. Having in mind the number of provinces in the country and comparing the figures provided in Rio Negro and Tucuman provinces with the number of inspections targeted the total number of the controls performed is low. The data provided by the CA demonstrate that approximately 80 – 90 % of inspections are performed by the central CA and 10 – 20 % at regional level.

A Manual of Procedures has been drafted and is expected to be approved in 2009. At the time of the mission, there had been no control plans drawn up at either national or regional level. The CA stated that once the Manual is approved, and the staff at regional level are trained, control plans will be developed.

Currently inspections under SIFFAB are planned on the basis of seasonality, because different regions have different geographical locations, agro-climatic conditions and crops. Inspections are usually performed during the high season when the marketing and use of PPPs is more intensive.

An inspection of a distributor was observed by the mission team in Tucuman province. The inspection was performed by an inspector from the CO and a representative from the RO of SENASA. All products in stock were checked for registration number, lot number, labels, expiry date and toxicological classification (category). An IT tool was used to confirm the authorisation details. A list of prohibited products is also part of the database. The database is up-dated on a regular basis. It was stated by the inspector in charge that, after the physical check on the store premises, a random check of the company records is performed to control traceability by batch number, in accordance with the requirements of SAGPyA Regulation 1230/04. A report is drawn up in triplicates and signed by the inspector and by a representative of the company. Where infringements are found the non–compliant product can be retained and it can not be marketed.

Samples of PPPs are taken randomly for inspections. The CA stated that decisions on sampling are based on information on the PPPs that are widely used in the respective region and main crops in the region. Sampling is also performed in suspect cases or if users submit information to the CA on insufficient efficacy of a product.

A national Registry of companies dealing with PPPs is kept by SENASA. Manufacturers, formulators and importers only are listed in the Registry. The registration of companies is

an administrative procedure based on documentary checks of the papers submitted by the applicants, who also pay a fee. In order to be registered, the companies must have a legal advisor and a technical advisor. The technical advisor must be an agro–engineer by profession.

Regulation 21/75 of Rio Negro province requires warehouses of PPPs to be approved by the Provincial Government. An inspection by the responsible body is performed prior to the approval in order to prove, that the premises comply with the conditions set in the Regulation. Retailers of PPPs must have at least one member of staff qualified as an agro–engineer. Further inspection visits take place in the period after approval has been granted. The retailer visited stated that the last inspection performed by the provincial CA was two years ago. Inspection reports are not drawn up after the inspection unless non – compliances are detected.

A sample of PPPs was taken in 2005 on the premises of the retailer visited in Rio Negro province. The decision on sampling had been taken based on a complaint from a user regarding the efficacy of a product, a grower having contacted the CO of SENASA in Buenos Aires. The inspector in charge contacted the RO in Rio Negro to notify that sampling was required and provided instructions to the regional officer. The test report sent back by the SENASA formulation laboratory, showed non – compliance. The laboratory result was faxed to the retailer. There was no further follow – up from SENASA, but a follow – up action was performed by the retailer himself, who changed supplier.

Provincial Law 62/91 on Agrochemicals is in place in Tucuman province. Points of sale of PPPs must be approved by the provincial CA, in accordance with the requirements set out in the Law. In order to be listed in the Registry, points of sale must have an advisor qualified as an agro – engineer if the stocks available contain PPPs classified by SENASA as category A or B. The advisor should receive regular training. Registration is granted after an inspection and renewed annually. Provincial authorities perform unannounced inspections once a year and produce written reports. A copy of the report is provided to the companies whose premises were visited.

Two further registers are kept by the Tucuman provincial authorities – a Registry of technical advisors and a Registry of users of class A and class B PPPs. Provincial authorities can restrict or ban the use of authorised products where problems at local level are identified.

5.3.3 Controls of users of plant protection products

In order to export their produce growers of apples, pears and citrus fruits must be registered with SENASA. There are no systematic official controls for pesticide residues at growers. Official controls at growers take place as follow-up to usage of banned products or non-authorised uses, announced by laboratories in the SENASA laboratory network. CA are also informed about MRL exceedances detected by private residue monitoring (look at point 5.4), but it is not a legal requirement.

Official controls of the users of PPPs performed by the CA in Rio Negro province aim at sampling for quality check (maturity) of the fruits in order to determine the starting date for harvesting. The CA stated that the date of last treatment and the pre– harvest intervals

are also checked.

Detailed private controls are operated by the farmers themselves or by the exporters. The technical advisers on the farms visited check the field books kept by the farmers or take samples for pesticide residues prior to marketing. Pack-houses, exporters and European customers provide farmers with lists of PPPs authorised for use on apples, pears and lemons, which also contain information on MRLs and pre – harvest intervals.

The pack houses and farms visited in both of the provinces were certified by European private standards of the retail sector.

5.3.4 Formulation laboratory

The formulation laboratory of SENASA is one of 24 laboratories engaged in analysing PPP' formulations in Argentina. FTIR, HPLC-UV and GC-FID equipment is available. Products are analysed for identity by FTIR and for content of active substance by HPLC-UV or GC-FID. Additionally, physical – chemical properties are checked. Samples analysed in the formulation laboratory are taken under SIFFAB. Sampling is mandatory for imports and exports of PPPs. Analyses are also performed for the purposes of the PPPs authorisation. Laboratory staff stated that the average number of samples analysed per month is 80. The method of analysis must be provided by the applicants or authorisation holders. There are methods available for 330 active substances in the formulation laboratory.

5.4 CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN ON THE DOMESTIC MARKET

There are no regular sampling plans for official pesticide residue analysis. However, sampling is carried out under SICOFHOR. Samples are usually taken on the local markets, in the area of Buenos Aires. The main commodities for sampling are fresh vegetables (tomatoes, lettuce and chard). According to data provided by the CA the total number of inspections in 2007 was 118; 78 of them for monitoring purposes and 40 in the frames of surveillance.

Sampling for pesticide residues is also performed by representatives of the Central Market in Buenos Aires. The authorities explained that a significant part of the fresh plant produce intended for the internal market is sold there. The Central Market has its own laboratory for pesticide residues. It is part of the SENASA laboratory network and performs high number of analyses. If national MRLs are found to be exceeded, the laboratory staff submit information to the CO of SENASA. The SENASA inspector in charge then informs RO, which territory the plant produce is from in order to trace it back. In such cases, the regional inspectors follow the requirements of Regulation 1/2003, which lays down the instructions to be followed by SENASA staff for the preventive seizure of fresh fruits, fruit products and by – products due to suspected health risk.

According to data on surveillance provided by the central CA, there were 13 cases of infringements in 2007. Eleven samples taken from the lots in question were found to be non – compliant and the plant produce was destroyed. In the other 2 cases, samples were

considered to be compliant and the consignments were released. There were further 5 cases where inspection had shown samples not to be compliant, but corrective measures could not be undertaken because the plant produce had been distributed via the marketing chain. Under the provisions laid down in the national legislation (Regulation 1/2003) SENASA officials may adopt other preventive surveillance actions in such cases, these including taking samples of other products found in the establishment that, in their opinion may involve a health risk. Such products will be seized without right to use and marketing will not be permitted until the relevant analyses have been carried out by the SENASA official laboratory. DNFA may require the procedures laid down in SENASA Regulation 488/02 to be applied. Regulation 488/02 sets out the procedures to be followed by the inspectors and provides for reporting in cases of interdiction, preventive closure, seizure and confiscation.

The regional CA in Northern Patagonia told of a case of excess MRLs in a private sample and destruction of the contaminated produce; supporting documents were provided. The Instructions set out in Regulation 1/2003 were shown to have been followed.

5.5 CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN TO BE EXPORTED

5.5.1 Organisation of controls

An official control system for pesticide residues has not been established yet either for the domestic market or for export of plant produce. There are no legal requirements for compliance with national MRLs in the countries of destination, including EC MRLs. However, the export – oriented pack houses and producers operate self – control systems for pesticide residues.

5.5.2 Communication of EC MRLs

MRLs for produce exported to the EU are communicated by the Argentinean CA on request. Laboratories and exporters provide information on EU MRLs.

Farmers in Rio Negro and Tucuman provinces are provided by the export companies with a list of PPPs authorised for use on apples, pears and lemons being subject to the phytosanitary control programmes in place.

A list of MRLs for the main countries of destination (EU, USA, Russia, China, Brazil) was also provided by the pack house visited in Rio Negro province. The management of the pack house stated that in advising their clients they apply the rule of the lowest MRL. EU retailers also provide lists of non – acceptable pesticides.

5.5.3 Approval and control of exporters

In both provinces visited by the mission team pack houses and cool stores must be authorised by the municipal or provincial authorities prior to the authorisation by SENASA. An inspection is performed by SENASA staff after the submission of

documents. During the control visit a check list is filled in, which is based on the requirements of Regulation 48/98.

Regulation 48/98 sets out the general provisions for the registration of pack houses and cool stores, including requirements for compliance with GMP. The CA stated that in 2003 this registration became obligatory first for premises where apples and pears are stored and packed. In 2005 it became obligatory for premises dealing with fresh citrus fruits. Pack houses and cool stores dealing with other types of fresh plant produce are approved in accordance with general requirements, which differ from the provisions of Regulation 48/98 and do not include GMP.

Where inspections find cases of non – compliance written recommendations are made and a deadline for corrective actions is set. Registration is granted by SENASA after a follow – up visit to the premises. Registration must be renewed on an annual basis. Where pack houses are not registered with SENASA they are not allowed to operate as exporters. The CA stated that the register of exporters is up – dated at central level on a weekly basis and is circulated to the ROs of SENASA and other governmental and non – governmental interested parties.

5.5.4 Traceability and record-keeping

There are no legal requirements for traceability and record – keeping of pesticide applications, except for phytosanitary certification for certain commodities or countries of destination. The farmers visited in both provinces keep field books containing detailed information of every single application of PPP, including data on active substances, trade name of the formulations, timing, dose and rate of applications. SENASA staff performs 1 to 3 inspections per year and check the field books in order to establish whether the applications performed are in compliance with the phytosanitary programmes for control of specific pests, but they are not related to MRLs.

A well organized traceability system was demonstrated in the pack houses visited in Rio Negro and Tucuman provinces. The system in place allows tracing back to the farmer and even to the plot if necessary.

5.5.5 Sampling programme for pesticide residues

Monitoring and Surveillance Plan are approved by Regulation 42/2008, which entered into force at the end of March this year. There are no sampling plans for official analysis of pesticide residue to date, but draft guidelines for implementation of Monitoring and Control Programmes are available. The guidelines specify, *inter alia*, that 60 samples per selected species have to be taken. The CA stated that tomatoes, lettuce and chard have been targeted for sampling. The CA declared its intentions to extend the list to include other fresh fruits and vegetables. This decision will be taken by a Technical Committee once it has been established.

Sampling for the purposes of monitoring for pesticide residues is mainly performed at farm level and points of distribution. The sampling procedure is explained in details in the Annex to Regulation 42/2008. However, the procedure described in Regulation 42/2008 differs from the CODEX procedure, in that the minimum weight of the sample is

listed, but not the number of units. The CA stated that, depending on the commodity to be sampled, further procedures are available.

Official sampling for pesticide residues at pack houses in Rio Negro province is not performed except where follow – up activities are required. Instructions to be followed by the SENASA staff for the preventive seizure of fresh fruits, fruit products and by – products due to suspected health risk are approved by Regulation 1/2003. The procedure to be followed in case of excess MRLs is described in details in the Annex to this Regulation.

In both provinces, pack houses perform routine sampling for pesticide residues within auto-control systems.

5.5.6 Certification of exports

Certification of plant produce for pesticide residues intended for export to the EU is not required. Neither special provisions nor control plans exist for food of plant origin exported to the EU.

5.5.7 Follow-up of notifications in the EU RASFF

Since 2006, there have been three rapid alert notifications for pesticide residues in apples, lemons and table grapes. SENASA provided information on the follow-up to a rapid alert notification for table grapes dated 28 March 2008. The notification was received by the central CA on 31 March 2008. An e-mail was sent to the ROs of SENASA in Tucuman and San Juan, because the export company has premises in both regions. The e-mail was dated 20 April 2008. RO of SENASA in San Juan sent a letter to the exporter dated 19 May 2008, and the exporter replied on 20 May 2008. In addition, the CO of SENASA in Buenos Aires required the analysis' result generated in an EU laboratory. The test report was received on 29 May 2008.

The CA explained the ways they receive information on the rapid alerts. The contact point in Argentina is the DNFA at the CO of SENASA. RASFF notifications also have to be forwarded to one of the five officials whose responsibilities are stipulated according to the commodity, which is the subject of the RASFF notification for food of plant origin. A draft procedure was recently developed on the follow – up of rapid alerts.

5.5.8 Laboratory for pesticide residue analysis

5.5.8.1 Organisation

The SENASA Plant Laboratory is part of the Directorate of Laboratories and Technical Control (DILAB) established at SENASA. The Plant Laboratory has 4 units; Pesticide Residue Laboratory is part of the Chemical Residues and Diagnostic Methods Unit.

Nine further laboratories are included in the SENASA laboratory network. To become a member of the network, laboratories must be either authorised or recognised. Authorized laboratories must be accredited to ISO 17025 by the Argentinean Accreditation Body (OAA) or other international accreditation bodies. Recognised laboratories must be

approved by the SENASA Central laboratory, which is the national reference laboratory for pesticide residues. Recognised laboratories must comply with GLP requirements. Once recognised by the national reference laboratory, these laboratories are inspected by SENASA technical staff regularly. SENASA staff involved in the inspections follow a check-list based on ISO 17025. There are no specific requirements on the number of active substance to be analysed in order to become an authorized or recognised laboratory. Nevertheless, there is a list of minimum criteria to be covered by the laboratory - applicant, including minimum number of active substances. This list is developed by the SENASA Central Laboratory.

According to the requirements laid down in Regulation 736/2006 all the laboratories being part of the SENASA network must be accredited to ISO 17025 before July 2009(see Endnote).

According to the information provided by the central CA, 9 of the SENASA network laboratories for pesticide residues are accredited to ISO 17025, including the national reference laboratory. Two of the SENASA network laboratories cover a high number of residue analyses while other 6 have limited scope of analyses restricted to certain matrices of plant origin. The Central Market Pesticide Residue Laboratory in Buenos Aires is the only laboratory in the SENASA network that has not yet been accredited. The number of samples analysed in this laboratory is high; fresh fruits and vegetables are analysed and the scope of analyses covers pyrethroids, carbamates, organochlorine and organophosphorus pesticides.

The laboratory visited by the mission team in Rio Negro province is a joint venture of the Provincial Governments of Neuquen and Rio Negro, INTA and private companies. It is a private laboratory within the SENASA network. Food of plant origin is analysed in the laboratory for pesticide residues, microbiological and other chemical contaminants.

5.5.8.2 Resources and training

The SENASA central laboratory for pesticide residues has adequate facilities. Five professionals and one assistant work in the laboratory. The total staff of 6 are qualified and trained. Training for staff is provided by way of an annual training programme.

The private laboratory for pesticide residues visited by the mission team has adequate facilities. Fourteen professionals with university degree in food chemistry, chemistry or biochemistry are appointed as a permanent staff. Two further temporary posts are occupied by assistants with secondary education who are doing their university degree now. The total staff of 16 have been regularly trained and are sufficiently qualified to operate the current instruments.

5.5.8.3 Analytical spectrum and methods

The SENASA central laboratory for pesticide residues is equipped with GC-ECD, GC-NPD and GC-FPD. In addition, GC-MSD, HPLC-UV and HPLC-FLD with post column derivatisation equipment are available. The GC-MS was not operational at the time of the mission, and according to data provided by the CA the HPLC-UV and HPLC-FLD have not been used for routine pesticide residue analysis for the last two

years. The methods are validated for 1 organochlorine pesticide in vegetables, 4 pyrethroids in grain and 2 in vegetables and seven organophosphorus pesticides (see Endnote). Representatives of the laboratory stated that some other organochlorine pesticides detectable by GC-ECD and some other organophosphorus pesticides detectable by GC-NPD and GC-FPD are covered by the method and if present, identified by retention time according to a retention time list (see Endnote). The scope of analysis is small and does not cover many of the pesticides used by growers. The number of samples analysed in 2007 was 1815, mainly for controls on grain. Fruit and vegetables are analysed for certification in cases of export to neighbouring countries and under SICOFHOR. It was estimated by laboratory staff that 70 % of the analysed samples are official controls. The period between sampling and production of the test report is about a week.

The private laboratory for pesticide residues has adequate facilities and is equipped with GC-ECD, GC-NPD, GS-FPD, GC-MSD, HPLC-UV and HPLC-FLD. The scope of analysis is focused mainly on pesticides usually used in apples and pears mainly grown in the region and on citrus fruits, but does not cover some of the pesticides used by growers. A multi-residue method using GC-ECD, GC-NPD and GC-FPD using columns of different polarity is validated and accredited for 31 pesticides (5 organochlorine pesticides, 12 organophosphorus pesticides, 6 pyrethroids 4 azole and 2 imidazol fungicides, 1 carbamate and 1 other pesticide). In a standard laboratory report of an apple sample based on the multiresidue method a scope of 25 of these 31 pesticides is listed with overall low detection limits. GC-MSD is used to confirm positive findings. The multi-residue method does not cover some pesticides being used by growers. The laboratory has developed, validated and accredited 4 single residue methods based on GC-ECD, GC-NPD, GC-FPD and a single residue method for analysis of benzimidazol-fungicides based on HPLC-FLD which were performed on request of the customer. Additionally some single residue methods were developed for pesticides newly introduced in the agricultural practice (like strobilurine fungicides, neonicotinoid insecticides and a macrocyclic insecticide). According to the information provided, the number of analyses performed in 2007 was 3608. Most of them are private samples and around 10 samples are part of the official controls performed by SENASA. The period between sampling and reporting of the analytical results varies from 4 to 11 days. Test reports containing the results are sent to clients.

5.5.8.4 Quality assurance systems

The SENASA laboratory for pesticide residues has been accredited to ISO 17025 by OAA on 24 December 2004 and re-accredited on 24 October 2006. The accreditation for pesticide residues is based on the determination of pyrethroids on wheat, corn, soybeans, seeds and seed products of sunflower. A method for determination of organochlorine and organophosphorus pesticides in wheat and a method for analysis of organochlorine and pyrethroid pesticides are listed in the annex of the accreditation, but no specific pesticides are mentioned. This accreditation expired on 27 December 2007, but an application for extension of the scope of accreditation was submitted in December 2007. The laboratory is now in process of re – accreditation (see Endnote). Quality control procedures are implemented with some limitations in the case of routine analyses: no bracketing and no

matrix – matched calibration; internal standards are not used. The calibration curve is based on validation data and is checked by one calibration point. No second analysis is performed in case of exceeding MRL. The laboratory participates in proficiency tests (FAPAS) with limited scope, but mostly good and acceptable results. SENASA central laboratory organises inter – laboratory tests. The SENASA laboratory also took part in other inter – laboratory tests organised by GTZ / WHO and inter - laboratory rounds organised by the National Institute of Industrial Technology (INTI).

The private laboratory for pesticide residues was accredited to ISO 17025 by the National Accreditation Body of Spain (ENAC) on 23 April 1999. The last audit was performed by the accreditation body in April 2008. There were no negative findings. The accreditation certificate is expected to be renewed. Quality control procedures are implemented. The scope of accreditation of the multi – residue method covers 31 active substances and the single – residue method covers 7 further substances. Methods for other substances have been developed in response to customer request. The accredited methods are validated. The laboratory participates in proficiency tests (FAPAS and SENASA) with good or acceptable results.

5.5.9 Additional information

All growers and exporters met by the mission team in both provinces had established systems for food safety and traceability. The exporters had contracts with their suppliers, and established audit systems to cover suppliers. The growers had established systems for keeping records of PPP applications, and the mission team verified the information on the spot. The growers and exporters visited were certified to private standards of trade and retail organisations. These private standards also cover controls for the use of PPPs and pesticide residue analysis.

All the fruit and vegetable exporters visited had established lists of authorised PPPs for their suppliers. These lists have been agreed with pesticide distributors and customers in the EU. Spraying programmes are based on the requirements of certification programmes for citrus fruits and phytosanotary protocols with different countries of destination for pome fruits. These spraying programmes must be applied by growers, and inspections are performed during the growing season by the technical advisors of the export companies.

GAP manuals are available for fruits, vegetables and aromatics. It was stated by INTA representatives that the GAP manual for fruits has been used to produce three specific manuals – for pome fruits, citrus fruits and other fruits.

Two experimental stations were visited by the mission team in both provinces.

The INTA Alto Valle experimental station in Rio Negro province specialises in research and technology transfer for apples and pears, since these are the main crops grown in the region of Northern Patagonia. The experimental station has 7 external agencies in the region. Research activities focus on the development of chemical and non – chemical methods for control of the main pests on apples and pears, including new application techniques and guidelines on IPM. Another important activity is biological testing for efficacy and residue trials for the purposes of PPP authorisation, including national MRL' setting based on data gathered using the traditional methods of application. INTA staff

also provide trainings for farmers, professionals, export companies and SENASA inspectors, covering different topics, including food safety and food hygiene. The annual training program was available. They also advise farmers and provide services and technical support.

The EEA Obispo Colombres experimental station in North Western Region has similar activities – research, technology transfer, advising farmers and providing trainings. Their focus includes citrus fruits and sugar cane, which are among the main crops in the region.

6 CONCLUSIONS

6.1 LEGISLATION

(1) Legislation is in place for authorisation and control of the marketing and use of PPPs providing the legal base for controls of pesticides on the market and for approval of pesticide points of sale, including pesticide retailers, wholesalers and distributors. National MRLs are set according to the provisions laid down in the national legislation, but the CA has no legal basis to apply the EC MRLs in cases of plant produce being exported to EU. Legislation for registration of exporters of plant produce is in force, but there are no legal requirements for traceability or for keeping records of PPP applications as required by EU legislation.

6.2 COMPETENT AUTHORITIES

(2) The competent authorities are clearly defined.

6.3 CONTROLS OF THE MARKETING AND USE OF PLANT PROTECTION PRODUCTS

(3) There are clear requirements, procedures and staff for the authorisation of PPPs. The authorised PPPs include some pesticides, for which a decision on non-inclusion in Annex I to Council Directive 91/414/EEC has been taken. If applied on produce for the export market, they can lead to EC MRLs being exceeded.

(4) An official register of authorised PPPs is kept. It contains detailed information on active substances, formulations, uses and doses authorized, including also data on registration number, lot number, labels approved, expiry dates and toxicological classification. This database is accessible for inspectors on the spot at the time of the inspection.

(5) Pesticide retailers and distributors must be approved. Inspections at retailer level are performed by SENASA under SIFFAB. The number of controls is low, but the inspections are detailed and all products in stock are checked. Reporting is required by the CA.

(6) There are no systematic official control checks for pesticide residues carried out at the users of PPPs.

(7) Growers of apples, pears and citrus fruits must be registered with SENASA. In line with Article 10 of Regulation (EC) No 852/2004 in connection with Article 4 (1) and Annex I, Part A.III, of that Regulation, the producers met by the mission team kept records of uses of PPPs.

6.4 CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN ON THE DOMESTIC MARKET

(8) Sampling plans for official pesticide residue analysis are not available. However, sampling is carried out under SICOFHOR, mainly for fresh vegetables (tomatoes, lettuce and chard). Follow – up activities where national MRLs are exceeded are performed in accordance with the requirements of national legislation.

6.5 CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN TO BE EXPORTED

(9) Neither special provisions nor control plans exist for food of plant origin intended for export to the EU. However, private controls for pesticide residues are operated by well organised exporters and producers. Traceability systems on farms and in pack houses are in place.

(10) Pack houses and cool stores exporting fresh fruit and vegetables must be authorised by the municipal or provincial authorities and by SENASA. This is in line with Article 10 of Regulation (EC) No 852/2004, in connection with Article 6 of that Regulation.

(11) A draft procedure to follow – up on RASFF notifications has recently been developed and implemented. There was evidence of satisfactory follow-up of a recent EU RASFF notification on pesticide residues in table grapes.

(12) A laboratory network is built up consisting of 10 laboratories. Nine of them, including both of the laboratories visited by the mission team are accredited to ISO 17025. They analyse mainly private samples, but the scope of analyses is small and does not cover all of the pesticides used by growers. The Central Market Pesticide Residue Laboratory in Buenos Aires analyses a high number of samples and it is the only one in the SENASA network that has not been accredited yet.

6.6 OVERALL CONCLUSION

Legislation for controls on pesticide residues is in place, but an official control system has not been established yet either for the domestic market or for export of plant produce. Most of the laboratories in the SENASA laboratory network are accredited to ISO 17025, but the scope of analyses is limited. In order to analyse monitoring samples with a broad multi residue screen both of the laboratories visited would need an LC-MS/MS to be also able to detect new pesticides. Export – oriented pack houses and producers operate private controls for pesticide residues. Most of the export companies and growers are certified by European private standards of trade and retail organizations. The legal basis for official controls on the marketing and use of PPPs is in place, but the controls are at a very early stage of development.

7 CLOSING MEETING

A closing meeting was held on 19 June 2008 with the competent authorities. At this meeting, the main findings and conclusions of the mission were presented by the inspection team. The representatives of the competent authorities offered some initial comments and provisionally accepted the preliminary findings.

8 RECOMMENDATIONS

In relation to pesticide residues in food of plant origin intended for export to the European Union, Argentina should improve official controls, in order to guarantee that the produce complies with, or is equivalent to, European Union standards in accordance with Article 11 of Regulation (EC) No 178/2002. In particular,

No.	Recommendation
1	Argentina should continue the accreditation process to ISO 17025 of official control laboratories to ensure the equivalence with Article 18 of Commission Regulation (EC) No 2076/2005 and to ensure that these laboratories provide reliable analytical results. Equivalence with Art 12 (2) of Regulation (EC) No 882/2004 should be demonstrated by 1 January 2010.
2	Argentina should consider broadening the scope of the analytes sought to improve the effectiveness of controls for pesticide residues.
3	Argentina should continue implementation of the requirements on controls of the marketing and use of PPPs in accordance with the provisions laid down in the national legislation. The CA should develop a national control plan and consider increasing the number of inspections under SIFFAB.
4	Argentina should improve the official controls under SICOFHOR and implement the Monitoring and Surveillance Plan.

The competent authorities of Argentina are invited to send the Commission an action plan in response to these recommendations within 25 working days of dispatch of this report. This action plan should clearly set out the manner and deadline by which the competent authorities intend to address each recommendation.

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

http://ec.europa.eu/food/fvo/ap/ap_argentina_7845_2008.pdf

9 ENDNOTES

Concerning	Detail
Section Executive Summary	In their response to the draft report the Competent Authority noted that in order to broaden the scope of the analytes sought when analysing monitoring samples of plant produce, they have applied for a LC-MS/MS equipment to be delivered under the EU-MERCOSUR Agreement. The new equipment is expected to be available in the period 2009-2010.
Section 5.3.1	In their response to the draft report the Competent Authority noted that according to the requirements laid down in SENASA Regulation No 816/06 the labels of PPPs authorized for placing on the market should contain the warning that in case of plants or plant products intended for export the MRLs and pre-harvest intervals in the countries of destination should be complied with.
Section 5.5.8.1	In their response to the draft report the Competent Authority noted that a draft Regulation ammending Regulation No 736/2006 was submitted for approval by the Secretary of Agriculture, Livestock, Fisheries and Food. According to the provisions of this draft Regulation, the laboratories of SENASA network must be accredited to ISO 17025 by December 2009.
Section 5.5.8.3	In their response to the draft report the Competent Authority noted that methods are validated for active substances listed in the laboratory reports, and these active substances are within the scope of accreditation. For pesticides, which are not within the scope of accreditation, at least tests of recovery and detection limits are performed.
Section 5.5.8.3	In their responce to the draft report the Competent Authority noted that FPD and NPD detectors are used for identification and quantification of organophosphorus pesticides by injecting patterns of known concentration; retention time lists are available for different pesticides in order to facilitate the analysis.
Section 5.5.8.4	In their response to the draft report the Competent Authority noted that the SENASA Plant laboratory has passed re-accreditation process successfully and re-accreditation certificate should be granted soon.

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Directive 76/895/EEC	OJ L 340, 9.12.1976, p. 26–31	Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables
Directive 86/362/EEC	OJ L 221, 7.8.1986, p. 37–42	Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals
Directive 90/642/EEC	OJ L 350, 14.12.1990, p. 71–79	Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables
Directive 91/414/EEC	OJ L 230, 19.8.1991, p. 1–32	Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market
Regulation (EC) No 178/2002	OJ L 31, 1.2.2002, p. 1–24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) No 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Regulation (EC) No 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Regulation (EC) No 396/2005	OJ L 70, 16.3.2005, p. 1–16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Regulation (EC) No	OJ L 338, 22.12.2005, p.	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional

Reference	OJ Ref.	Detail
2076/2005	83–88	arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

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