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FINAL REPORT OF A MISSION
CARRIED OUT IN PORTUGAL
FROM 21 TO 25 May 2007
IN ORDER TO EVALUATE CONTROLS OF PESTICIDE RESIDUES
IN AND ON FOOD OF PLANT ORIGIN

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

ASAE	Food Safety and Economical Authority (<i>Autoridade de Segurança Alimentar e Económica</i>)
CA	Competent Authority
CCA	Central Competent Authority
DAD	Diode-Array Detector
DGADR	Directorate-General of Agriculture and Rural Development (<i>Direcção-Geral de Agricultura e Desenvolvimento Rural</i>)
DGAIEC	Directorate General of Customs Excises (<i>Direcção-Geral das Alfândegas e dos Impostos Especiais sobre o Consumo</i>)
DGS	Directorate-General for Health (<i>Direcção-Geral de Saúde</i>)
DGV	Directorate-General of Veterinary Issues (<i>Direcção-Geral de Veterinária</i>)
DRADR	Regional Directorate of Agriculture and Rural Development (<i>Direcção Regional de Agricultura e do Desenvolvimento Rural</i>)
DRAP	Regional Directorate of Agriculture and Fisheries (<i>Direcção Regional de Agricultura e Pescas</i>)
DSAP	Directorate of Services of Agriculture and Livestock Farming(<i>Direcção de Serviços de Sgriculturs e Pecuária</i>)
ECD	Electron Capture Detector
FPD	Flame Photometric Detector
FVO	Food and Veterinary Office
GC	Gas Chromatograph
GC-MS-ITD	Gas chromatograph-Ion Trap Detector-Mass Spectrometer
GC-MS -TOF	Gas Chromatograph-Time of Flight-Mass Spectrometer
GAP	Good Agricultural Practice
GPP	Planning and Policies Office (<i>Gabinete de Planeamento e Políticas</i>)
GTI	Office for Intra-Community Trade and Trade with Third Countries (<i>Gabinete das Trocas Intracomunitarias e com Países Terceiros</i>)
HPLC	High Performance Liquid Chromatograph
INSA	National Institute of Health (<i>Instituto Nacional de Saúde</i>)
IRAE	<i>Inspecção Regional das Actividades Económicas</i> (Regional Inspectorate for Economic Activities)
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-Mass Spectrometer/Mass Spectrometer
LQA	Laboratory of Agricultural Quality
MADRP	Ministry of Agriculture, Rural Development and Fisheries (<i>Ministério da Agricultura, do Desenvolvimento Rural e das Pescas</i>)
MEI	Ministry of Economy and Innovation (<i>Ministério da Economia e Inovação</i>)
MFAP	Ministry of Finances and Public Administration (<i>Ministério das Finanças e da Administração Pública</i>)
MRL	Maximum Residue Level
MS	Ministry of Health (<i>Ministério de Saúde</i>)
NPD	Nitrogen Phosphorous Detector
NRL	National Reference Laboratory
RASFF	Rapid Alert System for Food and Feed

EXECUTIVE SUMMARY

The aim of this mission was to evaluate the controls of pesticide residues in food of plant origin being imported and on the domestic market and to follow up the recommendations made in report DG/SANCO/9250/2003.

Control system for pesticide residues

Relevant legislation is in place, but is sometimes transposed with delay. Substantial re-organisation of the public administration is under way. Clarification of responsibilities, transfer of staff and revision of procedures are still required.

Annual sampling plans have been established and are being implemented but are limited to some 900 samples and only a few commodities. Samples are taken at market level, primarily at retailer and wholesale level, but not at the point of import. Sampling procedures substantially comply with Directive 2002/63/EC. Detected infringements are followed up.

Inspections for traceability and self-controls of businesses are implemented.

Only one of the five laboratories involved in official controls of pesticide residues is accredited. Not all the laboratories take part in proficiency tests. The range of analytes (from one to 148 analytes) does not allow full enforcement of the legislation on pesticide residues in food of plant origin and, especially, in baby food. No national reference laboratory has been officially designated for pesticide residue analysis in food of plant origin.

The laboratories in Oeiras and Porto were visited during the mission. Both have adequate facilities and the necessary instrumentation with the exception of GC-MS in the Porto laboratory and LC-MS(/MS) in both. Relevant training is provided at the Oeiras laboratory only. The progress made with implementing quality control procedures varies. Neither of the laboratories fully follows the SANCO guidelines on 'Quality Control Procedures for Pesticide Residue Analysis'.

Follow-up of previous mission

A total of 10 recommendations were made in report DG (SANCO) 9250/2003. One has been addressed fully and nine partly.

Overall conclusion

A control system for pesticide residues in food of plant origin is in place. However, due to ongoing re-organisations of the Portuguese administration, not all responsibilities are clearly defined. Staff still have to be transferred and procedures revised. The effectiveness of the control system is limited especially because of the insufficient range of pesticides covered by the methods of analysis applied and lack of accreditation at many of the laboratories.

This report makes a number of recommendations to the Portuguese authorities to address the deficiencies noted.

1. INTRODUCTION

The mission took place in Portugal from 21 to 25 May 2007. The mission team comprised two inspectors from the Food and Veterinary Office (FVO).

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

The inspection team was accompanied during the whole mission by representatives from the central competent authority (CCA), the Ministry of Agriculture, Rural Development and Fisheries (MADRP).

An opening meeting was held on 21 May 2007 with representatives from the CCAs, MADRP, the Ministry of Economy and Innovation (MEI), the Ministry of Health (MS) and the Ministry of Finances and Public Administration (MFAP) and the competent authorities (CAs) from two regions and two autonomous regions.

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

2. OBJECTIVES OF THE MISSION

The main objective of the mission was to evaluate the control systems put in place for pesticide residues in foodstuffs of plant origin in the framework of Council Directives 86/362/EEC¹ and 90/642/EEC, Regulations (EC) No 396/2005, No 882/2004 and No 178/2002 of the European Parliament and of the Council and Commission Regulation (EC) No 645/2000. The follow-up of recommendations made by mission DG/SANCO/9250/2003 was a further objective of the present mission.

Findings during missions to Third Countries have shown deficiencies in the control system for pesticide residues in plant produce exported to the EU. As a result, the assessment of controls at the point of import from Third Countries is included in the current series of missions.

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

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

¹ 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 Annex 1.

Table 1: Mission visits and meetings

Visits/meetings		Comments
COMPETENT AUTHORITIES		
Central	1	opening meeting with representatives of MADRP, MEI, MS and MFAP and CAs of 2 regions and 2 autonomous regions
Regional	2	CAs of the region Norte and the region Lisboa e Vale do Tejo with presence of representatives of CCAs
LABORATORIES		
Public	2	Laboratories for pesticide residue analysis of the DGADR in Oeiras (Lisbon) and of DRAP Norte in Porto
INSPECTION VISITS		
Cash-and-carry premises	1	Observation of a sampling of a consignment of peppers
Importer	1	Observation of a sampling of a consignment of imported mangos

3. LEGAL BASIS FOR THE MISSION

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

- Article 45 of Regulation (EC) No 882/2004 of the Parliament and the Council;
- Article 5 of Commission Regulation (EC) No 645/2000.

4. BACKGROUND

4.1. Previous mission series

Prior to this mission series, the FVO carried out two series of missions to all Member States concerning pesticides in food of plant origin. The final reports of these missions can be found on the DG Health and Consumer Protection Internet site: http://ec.europa.eu/food/fvo/ir_search_en.cfm

During these missions, a number of deficiencies in control systems were identified such as deficiencies in the planning and conducting of inspections for control of the marketing and use of plant protection products, the technique of sampling, assessment of risk to consumers and operation of the EU Rapid Alert System for Food and Feed, the follow-up of infringements and the range of analysis in pesticide residue laboratories. Action Plans outlining how the recommendations would be addressed were submitted by the competent authorities.

This was the third mission undertaken to Portugal for pesticide controls in food of plant origin. Earlier missions with similar objective, (DG/SANCO/1104/1999 and DG/SANCO/9250/2003), had been carried out from 3 to 7 May 1999 and from 13 to 17 October 2003 respectively.

4.2. Trade and agricultural statistics

According to statistics (source: National Statistics Institute) supplied by the competent authorities approximately 4,045 thousand tons of fresh vegetables (data from 2005) and 741 thousand tonnes of horticultural products (data from 2002) are produced in Portugal each year. The main commodities are tomatoes for processing (1,085 thousand tonnes), sugar beet (586 thousand tonnes), potatoes (511 thousand tonnes), maize (509 thousand tonnes) and apples (248 thousand tonnes). In all, 2,496 thousand tonnes of food of plant origin were imported in 2005. The main commodities imported were soya (911 thousand tonnes), maize (544 thousand tonnes), wheat (177 thousand tonnes), bananas (126 thousand tonnes) and manioc (77 thousand tonnes).

5. MAIN FINDINGS

5.1. Transposition and implementation of legislation

All the legislation up to and including Commission Directive 2006/62/EC amending the Annexes to Council Directives 76/895/EEC, 86/362/EEC and 90/642/EEC has been transposed, some of the Directives with some delay. At the time of the mission the transposition of one Directive was delayed.

Recent national legislation (Decreto-Lei 237/2005 and Despacho 5864/2006) specifies the structure of the Food Safety and Economical Authority (ASAE). Further national legislation has been drafted to establish a centralised management system for official controls.

5.2. Competent Authority

5.2.1. Structure and resources at Central, Regional and Local levels

Table 2: Structure and responsibilities of CAs

Ministry	Levels	Organisation	Competencies
Ministry of Agriculture, Rural Development and Fishery (MADRP)	Central	Directorate-General of Agriculture and Rural Development (DGADR)	Pesticide residue legislation, setting MRLs and planning of controls for pesticide residues on the domestic market.
MADRP	Central	Planning and Policies Office (GPP)	Coordinating controls of pesticide residues at the point of import; in future also planning controls on the domestic market.
Ministry of Economy and Innovation (MEI)	Central	Food Safety and Economical Authority (ASAE)	Participation in planning controls for pesticide residues on the domestic market. Responsible for sampling for pesticide residue analysis and for follow-up of controls on the domestic market
MEI	Regional	5 Regional Services of ASAE	Carrying out inspections including checks on self-controls and traceability.

Ministry	Levels	Organisation	Competencies
Ministry of Health (MS)	Central	Directorate-General of Health (DGS)	Planning and follow-up of controls of baby food. The DGS asked the ASAE to cooperate with the collection of samples of products to be checked and with the development of the initial part of the preparation of proceedings.
Ministry of Finances and Public Administration (MFAP)	Central	Directorate General of Customs Excise (DGAIEC)	Customs control policy and coordination of customs procedures.
Ministry of Finances and Public Administration (MFAP)	Points of import	Customs services	Customs controls. Release of imported food onto the market.
MADRP	Regional	5 Regional Directorates of Agriculture and Fisheries (DRAPs)	Performance of controls of pesticide residues at import.
Autonomous Regions of Madeira and the Azores		Regional Directorate of Agriculture and Rural Development (DRADR) Madeira and Directorate of Services of Agriculture and Livestock Farming (DSAP) Azores	Planning and performing controls for pesticide residues on the markets of the Autonomous Regions of Madeira and the Azores respectively.
Autonomous Regions of Madeira and the Azores		Regional Inspectorate of Agriculture and Rural Development IRAE Madeira together with the laboratory and DSAP and IREA Azores	Follow-up in the markets of the Autonomous Regions of Madeira and the Azores respectively.

The Portuguese administration is undergoing substantial reorganisation. On 30 December 2005 the ASAE was established under the MEI and most of the control functions concerning food safety have been shifted from the MADRP to the ASAE to separate responsibility for controls and production². In addition, a reform of all ministries started in 2006 and is still in progress.

A revision of the organic laws of MADRP was completed in March 2007. It is now being followed by transfer of staff, in line with the new structures, and revision of procedures.

The regional structure of some CAs has also changed. The MADRP now has Regional Directorates in five regions (previously seven): Norte, Centro, Lisboa e Vale do Tejo, Alentejo and Algarve. This territorial division corresponds to the five Regional Directorates of the ASAE.

Overall, approximately 60 staff are involved in the planning and carrying out controls and analyses of pesticide residues in food of plant origin: 4 in the

² *In their response to the draft report the Portuguese authorities stated that "The ASAE has brought together most of the MADRP inspection services, to ensure greater effectiveness in matters of food safety."*

Directorate-General of Veterinary Issues (DGV) in the MADRP who will be transferred to the GPP, 2 to 4 in each of the 5 DRAPs under the MADRP, 16 in the ASAE, 9 in the DGADR laboratory, 1 in the National Institute of Health (INSA) laboratory, 5 in the DRAP Norte, 1 in the DRAP Algarve laboratory, 6 on Madeira and 8 on the Azores.

5.2.2. Structure and resources of designated control bodies

No private control bodies are used for official control.

5.2.3. Communication within and between competent authorities

Meetings are held at central level, with the participation of all CAs concerned, to prepare the national monitoring programme, discuss new legislation and co-ordinate follow-up in the event of infringements.

The mission team was informed by representatives of the MADRP that procedures for communication and co-ordination within the MADRP between the central level and the DRAPs will have to be revised once the re-organisations are finalised. Currently communication primarily concerns the ongoing reforms.

The ASAE organises meetings with their regional services every 14 days to distribute tasks, discuss any difficulties emerging and harmonise procedures.

Regarding import controls, meetings are held between the central services of the MADRP and the MFAP to establish procedures. The MADRP has provided training for the customs services on controls on food safety. The customs services receive the information relevant to their work from central level via circular letters and the intranet. In the event of problems concerning food consignments the customs services contact the DRAPs by phone, fax or e-mail. If food consignments are rejected, the DRAP issues a rejection certificate, which acts as an administrative notification for the customs services and the RASFF.

See also section 5.3 for details of communication between the MADRP, the ASAE and the laboratories on controls and follow-up.

5.2.4. Communication between competent authorities and stakeholders

Stakeholders are informed about new legislation by the DGADR via the DRAPs, the internet and circular letters. The ASAE organises meetings with associations or contacts stakeholders directly to provide them with relevant information. In Madeira stakeholders are informed by the DRADR via circular letters.

5.2.5. Supervision and auditing of controls by competent authorities

The ASAE is preparing audits of its bodies responsible for pesticide residue controls, but they have not been implemented yet. The MADRP has not yet started to establish internal audits for its bodies for pesticide residue controls.

5.2.6. Training of staff

In previous years the MADRP provided training for its inspectors and also for customs officers, but this has been affected by the ongoing re-organisation. Representatives of the DRAP Norte informed the mission team that there are no training plans at the moment.

ASAE experts provide training for inspectors and technicians on controls on food safety. Copies of certificates conforming 4 to 5 hours' training on sampling and on the national monitoring programme for pesticide residues have been provided to the mission team. A long-term programme for training newcomers is under way, which includes a module on sampling.

5.3. Implementation of controls for pesticide residues in domestic and imported produce

5.3.1. General import procedures

The import procedures for food of plant origin were evaluated by the FVO in 2003 (mission DG(SANCO)/9132/2003). A senior member of staff from the MADRP informed the mission team that since then changes had been necessary because of change in the legislation. Additionally, procedures have to be revised because of the organisational changes.

5.3.2. Planning of controls:

As the responsibilities of the institutions involved in the official controls on food are not yet clearly defined, it has not yet been possible to establish a Multi-Annual National Control Plan.

A sectoral programme for controls for pesticide residues has been planned for 2007 by the DGADR together with the ASEA, the DGS, the DRADR Madeira, the DRDA Azores and the laboratories responsible for pesticide residue analysis. Coordination of the programme for 2008 will be the responsibility of the GPP.

For 2007, a total of 889 samples are planned, including 25 samples of baby food. The mission team was informed that the main factor limiting the programme is the capacity of the laboratories.

The national programme is based primarily on the 2007 EU coordinated monitoring programme. It is planned to sample only a few commodities in addition to the eight listed in the Recommendation. Spinach has been added because of more frequent maximum residue level (MRL) infringements. Rice has been included in the national programme as a result of some infringements in 2005, especially involving deltamethrin.³ Other commodities such as bananas and custard apples (Madeira) and passion fruit and pineapples (Azores) were selected because of their importance to agriculture in the Autonomous Regions.

The annex of the annual monitoring programme includes the distribution of tasks for sampling and analysis. It also specifies the methods of analysis to be used by the laboratories and the reporting limits.

On the basis of the annual monitoring programme, the ASAE establishes monthly plans taking into account the availability of the laboratories. For further details see section 5.3.3.

³ *In their response to the draft report the Portuguese authorities have clarified that "The records for rice infringements are not comparable with those for spinach, since only spinach usually has a substantial number of infringements."*

Under the Portuguese procedures for sampling at the point of import, sampling for pesticide residue analysis at the point of import is possible, but is not a priority. The mission team was informed by a representative of the GPP that a decision not to sample for pesticide residue analysis at the point of import was taken on the basis of a preliminary risk assessment.

Therefore, imported produce is sampled only at market level. Under the national monitoring programme, sampling should be carried out in proportion to the availability of products at the market, which is assumed to reflect the shares of imported produce. Samples are taken at retailer and wholesale level rather than at importers. If RASFF notifications concerning pesticide residues in produce from Third Countries are received, the ASAE is responsible for sampling the concerned commodities at market level.

5.3.3. *Carrying out of controls:*

The ASAE has five centrally based teams of two technicians each for taking food samples for analysis. One of these teams routinely carries out sampling for pesticide residue analysis as it has a car equipped with the necessary cooling and freezing facilities. According to the monthly sampling programmes, the team visits the five regions in a rolling programme. It stays in one region for five days, during which it takes 15 samples. Regions with higher populations and/or higher production are visited more frequently.

Samples are taken primarily at retail and wholesale level. A written procedure for sampling is in place.

A sampling procedure of peppers observed at a cash-and-carry premises was carried out by the team of ASAE technicians responsible for sampling for pesticide residues. They checked the lot number to make sure that they were sampling from a single lot. They chose three crates at random and the representative of the business chose two more. They took two peppers from each crate and put them in a bag which was immediately sealed and identified. The label was signed by two members of staff from the business and by the ASAE officials sent there for this sampling.

The ASAE technicians filled in the sample collection report, read it out loud and, after its conformity was verified, it was signed by all participants. A duly completed sample collection statement was given to the representatives of the company and a copy of this document was kept by the ASAE technicians. The mission team was informed that the lot number is used to establish which wholesaler supplied the consignment. The legal representative of the business where the sample was taken may nominate an expert to observe the analysis of the sample in the laboratory. The legal representative of the supplier (producer or packer) may also exercise this prerogative. If both experts are interested, the business with higher responsibility within the food chain is given priority.

The mission team was informed that durable products like rice or cereals are sampled in triplicate. In the case of fresh fruit or vegetables, inspectors take no

reference samples, nor do they offer to the representative of the owner the taking of a reference sample.⁴

Samples taken by the ASAE are brought to the DGADR laboratory in Oeiras, the DRAP Norte or the DRAP Algarve laboratory once a week.

In Madeira DRADR staff take samples at wholesale level and the IRAE at retail level. The samples are analysed at the Laboratory of Agricultural Quality (LQA) in Madeira. On the Azores samples are taken by staff from the DSAP. The samples are sent to the Oeiras laboratory by courier.

The DGS has requested the ASAE to take samples of baby food. In 2005 and 2006, baby food samples were analysed by the INSA analyst during her training at the DGDAR laboratory in Oeiras. From 2007 onwards baby food is analysed at the INSA laboratory.

Although sampling for pesticide residue analysis is not carried out routinely (see also section 5.3.2) a sampling procedure of mangoes imported at the port of Leixões was demonstrated by two inspectors of DRAP Norte. Sampling was carried out in parallel to a plant health inspection.

As inspections are not possible at the port the consignment was transported to the importer under customs detention. The inspectors took 10 mangoes from 10 different pallets throughout the whole consignment. They took only note of the number of the consignment, but paid no attention to the different lot numbers on the individual crates on these pallets. The sample was put in a bag which was sealed and labelled.

Inspectors from the regional services of the ASAE carry out inspections on food businesses, such as HACCP, sampling and label checks. Checks on traceability and on self-controls by businesses, such as reports on pesticide residue analyses carried out on the initiative of the business, are the most relevant to this mission.

The ASAE inspectors receive their instructions to carry out these inspections in the form of "operation orders", which also include the legal basis and contact addresses. A manual of procedures for carrying out inspections is being prepared.

During the visit to the importer, inspectors from the ASAE Norte carried out an inspection for traceability. They asked a representative of the business to demonstrate the traceability one step forward and one step back by providing the relevant documentation and explaining the codes used. Self-controls by the importer visited are carried out primarily prior to export by staff based in the Third Countries. Documents were therefore not available on the premises in Portugal.

However, evidence of checks on analytical reports was submitted to the mission team as part of the documentation on the follow-up to an infringement case (see also section 5.3.5).

⁴ *In their response to the draft report the Portuguese authorities stated that " In the case of fresh fruit or vegetables, inspectors take no reference samples, nor do they offer to the representative of the owner the taking of a reference sample, since they are perishable products"*

5.3.4. Reporting of controls:

The laboratories send the results of the analyses to ASAE. Decisions concerning MRL exceedances are the responsibility of the laboratories. The laboratory in Oeiras takes into account a generic measurement uncertainty of 40%, but uncertainty is not taken into account by the laboratory in Porto.

The laboratory in Oeiras collates the reports of results of analyses for official controls of pesticide residues received from the other laboratories and sends the consolidated report to the European Commission annually.

In 2005 Portugal reported the analysis of pesticide residues of 776 samples of fruits and vegetables (75.8% domestic produce) with MRL exceedances found for 2.7% of the samples. 71 samples of cereals (74.6% from the domestic market) were analysed for pesticide residues. 7% of the samples, all of which were rice samples, showed exceedances of MRLs. All 37 samples of processed food other than baby food (91.9% from the domestic market) and 20 samples of baby food (91.9% from the domestic market) were compliant. Overall, only three of the non-compliant samples were taken from imported produce.

5.3.5. Follow-up of controls:

In cases where the MRLs are exceeded the MADRP and the ASAE are informed of the analytical results and the DGADR carries out a risk assessment. If a risk to the consumer is identified the national RASFF contact point - the Office for Intra-Community Trade and Trade with Third Countries (GTI) of the DGV - is notified.

Written procedures for operation of the RASFF system have not yet been changed to reflect the organisational changes. Nor do they include instructions for carrying out a risk assessment and criteria for notification of pesticide residue findings, as specified in the "Draft guidance document on notification criteria for pesticide residue findings to the Rapid Alert System for Food and Feed" (SANCO/3346/2001, rev. 7).

The regional services of the ASAE are responsible for investigating cases where the MRLs have been exceeded. The inspectors inspect the businesses where the non-compliant products have been sampled. They check if the business carries out auto-controls and take a second sample from the same consignment if it is still available or if not, from a subsequent consignment.

On the basis of the results of the investigations and of the risk assessment a decision is taken on which CA is responsible for the prosecution. In the case of minor infringements, e.g. MRL exceedances where no risk to the consumer is identified, the MEI is responsible for the prosecution. MRL exceedances where a health risk is identified are referred to the competent Public Ministry of that region. If pesticide residues are found in commodities for which no formulation containing the respective active substance is registered in Portugal, the case is referred to the DRAP responsible and followed up as illegal use.

In addition to fines, a variety of precautionary measures exist, such as withdrawal of the produce from the market or seizure and destruction of the produce. Documentation on the follow-up to infringements concerning pesticide residues was provided to the mission team. Fresh fruit and vegetables are usually eaten by the

time the analytical results are available. In the case of a non-compliant rice consignment follow-up included investigation in several regions of the country including checks of self-controls of the producer, followed by recall, seizure and incineration of the produce.

5.4. Control of the marketing and use of illegal pesticides and of the illegal use of pesticides

Illegal use of pesticides is occasionally detected as a result of analysis of pesticide residues or during controls of users. Unauthorised products have been detected during controls of the marketing of plant protection products.

Following RASFF notifications concerning isofenphos-methyl in peppers, analysis for this substance was started in the Oeiras laboratory and one positive sample was detected. However, the range of analysis at the pesticide residue laboratories is too limited for systematic control of the use of illegal pesticides.

5.5. Laboratories for pesticide residue analysis

5.5.1. Organisation

Pesticide residue analysis for the national monitoring programme, including the EU coordinated programme, is carried out in three laboratories under the MADRP, the DGADR laboratory in Oeiras/Lisbon and the laboratories of the DRAP Norte and DRAP Algarve plus the LQA in Madeira.

The coverage of analysis ranges from only one analyte (maneb group in the DRAP Algarve laboratory) to 148 substances. In 2005 the laboratories analysed from 55 to 477 samples and in 2006 from 13 (at the DRAP Algarve laboratory) to 351 samples for official controls for pesticide residues.

Currently only the DGADR laboratory in Oeiras is accredited under ISO 17025. The DRAP Algarve laboratory was audited for accreditation of the dithiocarbamate method in 2006. The two other laboratories have not yet initiated the accreditation procedure. The quality control systems for the analyses could be evaluated only at the laboratories which were visited during the mission (see section 5.5.2). Not all the laboratories have taken part in the EU or other relevant proficiency tests.

A fifth laboratory is being established - the INSA laboratory under the MS. It will be responsible for the analysis of baby food from 2007 onwards. It does not have the analytical capability to enforce the directives on baby food fully due to lack of range (only 36 active substances are covered) and lack of sensitivity.

The DGADR laboratory in Oeiras is in contact with the three Community reference laboratories for analysis of pesticide residues in food of plant origin and distributes the information it receives to the other Portuguese laboratories. It has provided several months' training for a member of INSA staff, training for technicians from various laboratories in a third country and has also trained staff from other Portuguese laboratories, but not lately. It provides additional information when requested by the other laboratories. However, because of the ongoing re-organisations it has not yet been officially designated as the national reference laboratory (NRL).

5.5.2. Laboratories visited during the mission

The mission team visited two laboratories, the DGADR laboratory in Oeiras and the DRAP Norte laboratory in Porto.

5.5.2.1. Resources and training

The facilities of the Oeiras laboratory have been refurbished to modern standards. It is equipped with modern instruments, such as HPLC with fluorescence detector, HPLC-DAD, GC instruments with ECD, FPD or NPD, GC-MS-IDT and GC-MS-TOF and two UV-Vis spectrometers. No LC-MS/MS instrument is available yet.

Five senior analysts (including the head of the laboratory), all with university or higher degrees, and four assistants with technical-professional training, are involved in pesticide residue analysis. Regular training is provided.

The facilities of the Porto laboratory have been also refurbished recently. It is equipped with modern instruments such as one GC with NPD and one GC with ECD and an UV-Vis spectrometer. An HPLC instrument with fluorescence detector and DAD has been purchased but is not yet operational. Neither GC nor LC instruments with MS are available. Analysis is frequently hindered by lack of funds or of support from suppliers for repairs in the event of break-downs of equipment.

Four senior staff (including the head of the laboratory) and one assistant are responsible for pesticide residue analysis. No relevant training has been provided since 2002. Staff recently had the opportunity to attend an LC-MS workshop.

The laboratory analysed 210 samples in 2005 and 145 samples in 2006 for official controls of pesticide residues.

5.5.2.2. Analysis

The Oeiras laboratory has implemented GC-NPD/FPD and GC/ECD multi-residue methods, an HPLC method for the determining N-methylcarbamates, an HPLC-DAD method of analysis of benzimidazolecarbamates, a method of the analysis for organophosphorus precursors of sulfoxides and sulfones, including an oxidation step, and a spectrophotometric method of analysis for the maneb group. All the methods include GPC clean-up after extraction and filtration. The GC-MS-ITD and GC-MS-TOF methods are not yet fully implemented. The available instruments do not allow confirmation analysis of all analytes, particularly of some N-methyl carbamates.

The laboratory can analyse for 148 substances (pesticides and their metabolites), of which 90 are currently covered by accreditation. The laboratory has applied for extension of its accreditation to another 16 substances.⁵ All active substances in the EU coordinated programme for 2006, with the exception of chlormequat, are covered.⁶

⁵ *In their response to the draft report the Portuguese authorities stated that "The laboratory can analyse for 148 substances, including the majority of metabolites covered by the definition of residue, with accreditation for 90."*

⁶ *In their response to the draft report the Portuguese authorities stated that "Accreditation has been extended (new certificate attached)."*

The laboratory analysed 477 samples in 2005 and 351 samples in 2006 for official controls of pesticide residues. The head of the laboratory informed the mission team that the reports on the analyses are finalised approximately one month after receipt of the samples.

The Porto laboratory has implemented GC-NPD and GC-ECD multi-residue methods and a photometric method of analysis for the maneb-group, following the methods used at the Oeiras laboratory. For confirmation of positive findings in an analysis by GC, the different column approach is used.

The laboratory can analyse for 36 analytes in the multi-residue method and the maneb group. Only 23 of the 54 substances in the EU coordinated programme for 2006 are covered. The mission team was informed by staff from the laboratory that analyses of dithiocarbamates are finalised within 24 hours and GC analyses within approximately one week except in the case of failure of the equipment (see section 5.5.2.1).

5.5.2.3. Quality assurance system

The Oeiras laboratory has been accredited since 2005. Generally good quality procedures are in place. At the time of the mission no quality manager was appointed because of the ongoing re-organisations.⁷

Validation includes parameters such as linearity of the calibration curve, recovery, repeatability and selectivity. The methods are validated for all analytes and for at least four matrices, but only for a minimum of one fortification level at any concentration within the calibrated range.

For all GC methods bracketing matrix-matched calibration for all analytes is used. Standards are included in three standard mixtures, for each of the instrumental techniques. Recovery samples for one of the standard mixtures are analysed only once per month and method.

The laboratory has participated in EU and FAPAS proficiency tests with good results.

An SOP describing different procedures for the estimation of the measurement uncertainty is in place, but the calculation has not yet been carried out for all analytes. The laboratory applies a generic uncertainty of 40% for estimating MRL infringements.

The Porto laboratory is not accredited. It has started to establish a quality management handbook, including the necessary SOPs, and has started with validation of the methods. No procedures are yet in place for the management of analytical standards and standard solutions.

⁷ *In their response to the draft report the Portuguese authorities stated that "The information provided to the mission team that, at the time of the mission, there was no quality manager at the Oeiras Laboratory may raise some doubts that need to be cleared up. This information was given because, as part of the restructuring under way, the official carrying out the duties of quality manager had been incorporated into the new DGADR, whereas the rest of the staff of this laboratory are still waiting to move to the new National Biological Resources Institute. However, under an informal agreement, the said official continued to carry out the duties of quality manager until he was replaced in August 2007."*

For routine analysis bracketing calibration with all analytes is used. A procedure for carrying out recovery checks has been established, but is not yet implemented.

The laboratory has not participated in proficiency tests in recent years. Participation in EU PT 9 was hindered by break-down of equipment.

The laboratory has not carried out calculation of measurement uncertainty. Measurement uncertainty is not taken into account for estimating MRL infringements.

5.6. Follow-up on previous missions

The report on the previous mission identified a number of shortcomings. The table set out below lists the recommendations made and indicates how they have been addressed by the CAs. The action plan submitted by the CAs following the previous mission has been only partially fulfilled.

Recommendations of DG/SANCO 9250/2003	Follow-up in SANCO 2007/7222
(1) The competent authority should establish adequate controls of the uses of plant protection products, in accordance with Article 17 of Council Directive 91/414/EEC.	Partly addressed. Controls of users carried out in the framework of the Rural Development have increased during the last years. They cover controls of pesticide stores, whether products are authorised and, since 2006, whether products are used in accordance with Good Agricultural Practice (GAP). However, it is not yet obligatory for farmers in Portugal to keep spraying records. A revised recommendation is made to the CAs in Chapter 8.
(2) The competent authority should commence, without delay, adequate inspection and enforcement procedures for the marketing of plant protection products, in accordance with Article 17 of Council Directive 91/414/EEC.	Partly addressed. The Portuguese CAs reported inspections of 187 pesticide shops in their 2004 report to the Commission under Article 17 of Directive 91/414/EEC and of 98 outlets in their 2005 report. In their action plan submitted following mission DG/SANCO/9250/2003, they had planned to carry out around 600 inspections per year in 2005 and subsequent years. A revised recommendation is made to the CAs in Chapter 8.
(3) The competent authority should provide the necessary resources to ensure the efficient operation, including quality control, of the Formulation Laboratory and to recommence chemical analysis of plant protection product formulations.	Partly addressed. The formulation laboratory of DGADR has been refurbished. Modern instruments for analysis of the active substances and a broad range of physical/chemical parameters are being installed and validated. Routine analysis is expected to start in 2008. A revised recommendation is made to the CAs in Chapter 8.
(4) The competent authority should establish an adequate control system for pesticide residues in baby foods.	Partly addressed. Analysis of baby food is included in the monitoring programme for 2007. However, full

Recommendations of DG/SANCO 9250/2003	Follow-up in SANCO 2007/7222
	<p>enforcement of the directives on baby food is not possible, as the range of analytes is not broad enough and the limits of quantification for a number of pesticides are not sufficiently low in the laboratory responsible for carrying out the analysis.</p> <p>A revised recommendation is made to the CAs in Chapter 8.</p>
<p>(5) The competent authorities should provide the necessary resources to increase the scope of the sampling plan for analysis of food of plant origin for pesticide residues.</p>	<p>Partly addressed.</p> <p>Some laboratory equipment has been purchased but the number of staff has not been increased.</p> <p>In the action plan following the previous mission the CAs planned to increase the numbers of samples to be taken per year from 600 in 2003 to 1200 in 2008. The national monitoring programme for 2007 provides for only some 900 samples.</p> <p>The number of analytes covered by the methods of analysis has not been increased substantially.</p> <p>A revised recommendation is made to the CAs in Chapter 8.</p>
<p>(6) The competent authorities should continue to seek accreditation for all laboratories involved in official pesticide residue controls.</p>	<p>Partly addressed.</p> <p>Although some progress has been made in the accreditation process, still only one of the laboratories involved in the official control of pesticide residues in food of plant origin has achieved accreditation.</p> <p>A revised recommendation is made to the CAs in Chapter 8.</p>
<p>(7) The competent authorities should take into account the supporting quality control data for estimation of analytical uncertainty when comparing analytical results with the MRL.</p>	<p>Partly addressed.</p> <p>See section 5.5.2.3 for details on estimation of measurement uncertainty in the two laboratories visited. The situation at the other laboratories was not evaluated.</p> <p>A revised recommendation is made to the CAs in Chapter 8.</p>
<p>(8) In cases of MRL infringements, the competent authorities should carry out systematic consumer risk assessments taking into account the draft “Proposal on how to notify pesticide residues in foodstuffs in the Rapid Alert System for Foodstuffs” (SANCO/3346/2001).</p>	<p>Addressed.</p>
<p>(9) The competent authorities should establish written procedures for the functioning of the Rapid Alert System in Portugal.</p>	<p>Partly addressed.</p> <p>See section 5.3.5 for details on written procedures for operation of the Rapid Alert System.</p> <p>A revised recommendation is made to the CAs in Chapter 8.</p>
<p>(10) The competent authorities should take all necessary steps to reduce the time-lapse between sampling and analysis for pesticide residues and</p>	<p>Partly addressed.</p> <p>See section 5.5.2.2 for details on the time-lapse</p>

Recommendations of DG/SANCO 9250/2003	Follow-up in SANCO 2007/7222
ensure that enforcement and follow-up actions are taken without delay	<p>between sampling and analysis for pesticide residues in the two laboratories visited. In the action plan following the previous mission it was planned to reduce the time-lapse to one week by 2006 at the Oeiras laboratory. The situation at the other laboratories was not evaluated.</p> <p>A revised recommendation is made to the CAs in Chapter 8.</p>

6. CONCLUSIONS

6.1. Transposition and implementation of legislation

- (1) The relevant legislation is in place. However, some of the MRL Directives are transposed with some delay.

6.2. Competent authorities

- (2) The Portuguese administration in general and the CAs responsible for food safety in particular are being reorganised. Clarification of responsibilities, transfer of staff and revision of procedures are still required in many areas.
- (3) Horizontal and vertical communication between the CAs responsible for controls of pesticide residues are generally working well. However, the current re-organisations require updating of some of the communication procedures.
- (4) No internal audits have yet been implemented by the MADRP or the ASAE for their control bodies, although this is required by Article 4(6) of Regulation (EC) No 882/2004.
- (5) The ASAE provides comprehensive training on food safety controls for its inspectors including training on sampling and the national monitoring programme for pesticide residues in plant protection. Training activities by the MADRP are disrupted by the current re-organisations.

6.3. Implementation of controls

6.3.1. Control activities for pesticide residues

- (6) A national plan for the control of pesticide residues is established annually.
- (7) No routine controls of pesticide residues are planned and carried out at the point of import or at importers, whereas Article 15 of Regulation (EC) No 882/2004 requires CAs to carry out controls of imported produce at an appropriate place.
- (8) Written procedures for carrying out controls of pesticide residues and sampling for analysis of pesticide residues are in place or in preparation.
- (9) The sampling procedures observed were substantially in line with Directive 2002/63/EC. However, during a sampling procedure at the point of import

the inspector did not try to identify the lots, but sampled throughout the whole consignment.

- (10) Inspections for traceability and self-controls by businesses are in place.
- (11) All results of analyses for pesticide residues are systematically reported to the European Commission.
- (12) The follow-up of non-compliant consignments is effective and appropriate.
- (13) Written procedures for operation of the RASFF system are in place but they have not been up-dated to bring them into line with the organisational changes and do not include instructions for carrying out a risk assessment and criteria for the notification of pesticide residue findings, as specified by the "Draft guidance document on notification criteria for pesticide residue findings to the Rapid Alert System for Food and Feed" (SANCO/3346/2001, rev. 7).

6.3.2. Controls of the marketing and use of illegal pesticides and the illegal use of pesticides

- (14) Controls in place for marketing and use of pesticides and for pesticide residues in food of plant origin allow occasionally the detection of the marketing or use of illegal pesticides and illegal use of pesticides. However, the range of analysis at the pesticide residue laboratories is too limited for systematic control of the use of illegal pesticides.

6.4. Laboratories for pesticide residue analysis

- (15) Only one of the five laboratories involved in official controls of pesticide residues is accredited. Three of the non-accredited laboratories do not fall under the derogation from accreditation provided for by Article 18 of Commission Regulation (EC) No 2076/2005, as they have not yet initiated the accreditation process for the analysis of pesticide residues. The fifth laboratory fulfils the criteria in Article 18(a) of the Regulation. However, as the quality control schemes were not evaluated during the mission, it is not possible to conclude to what extent the laboratory complies with Article 18(b).
- (16) In all laboratories the range of pesticides sought during analysis is too limited to fully enforce compliance with Directive 86/362/EEC and Directive 90/642/EEC. Despite these limitations, all three laboratories under the MADRP and the Madeira laboratory have contributed results to the Portuguese monitoring report.
- (17) In the laboratory responsible for the analysis of baby food, the limits of quantification for a number of pesticides are not sufficiently low and the range of pesticides is too narrow to permit implementation of Directive 2006/125/EC and Directive 91/321/EC regarding foodstuffs for infants and young children.
- (18) No national reference laboratory (NRL) has yet been officially designated for the three Community Reference Laboratories for analysis of pesticide residues in food of plant origin.

- (19) The laboratory in Oeiras has modern facilities and is equipped with modern analytical instruments. However, lack of an LC-MS/MS instrument limits the analysis of many polar substances, attainment of the necessary LOQs in many cases and confirmation analysis of some substances such as dithio-carbamates. The time-lapse between receipt of samples and finalisation of the analysis is too long for effective follow-up.
- (20) In Oeiras, the staff are well trained and the laboratory regularly and successfully takes part in EU and other proficiency tests. Although generally good quality procedures are in place, the SANCO Guidelines for Quality Control Procedures are not fully followed.
- (21) The laboratory in Porto has modern facilities and equipment. Lack of GC-MS and LC-MS/(MS) instruments limits analysis of many polar substances, the attainment of the necessary LOQs in many cases and confirmation analysis. The time-lapse between receipt of the samples and finalisation of the analysis is usually acceptable. However, analysis is frequently delayed for several weeks because of equipment failure.
- (22) The Porto laboratory has not taken part in proficiency test in recent years and no relevant training for the staff has been provided.

6.5. Follow-up of previous mission

- (23) In total, ten recommendations were made: one has been fully addressed and nine have been partly addressed.

6.6. Overall conclusion

A control system for pesticide residues in food of plant origin is in place. However, due to ongoing re-organisations of the Portuguese administration, not all competencies are clearly defined. Staff still have to be transferred and procedures revised. The effectiveness of the control system is limited especially because of the insufficient range of pesticides covered by the analytical methods applied and lack of accreditation in many of the laboratories.

7. CLOSING MEETING

A closing meeting was held on 26 May 2007 with representatives of the MADRP, the MEI, the MS, the Ministry MFAP and the CAs from two regions and two autonomous regions. At this meeting, the initial findings and conclusions of the mission were presented by the inspection team. The representatives of the CAs provided some clarifications and comments on the initial findings and conclusions presented.

8. RECOMMENDATIONS TO THE COMPETENT AUTHORITIES OF PORTUGAL

Recommendations (1), (2), (7), and (9), (10) and (12) also relate to deficiencies found by the 2003 mission. The recommendations made by that mission have been revised to take account of the progress made since the last mission and the new legislation introduced.

- (1) The CAs should continue to establish adequate controls of the marketing and use of plant protection products in accordance with Article 17 of Council Directive 91/414/EEC.
- (2) The CAs should continue to establish analysis of plant protection products in the formulation laboratory in order to be able to test whether they comply with the requirements of the Directive 91/414/EEC and in particular with the requirements of the authorization and information appearing on the label, as required under Article 17 of the Directive.
- (3) The CAs should transpose the amendments to Directives 76/895/EEC, 86/362/EEC and 90/642/EEC on pesticide MRLs within the required timelines.
- (4) The CAs should finalise without delay the current re-organisations. They should clarify responsibilities, allocate staff, revise procedures and continue to provide training for their staff where this has been interrupted.
- (5) The CAs should implement audit systems as required by Article 4(6) of Regulation (EC) No 882/2004.
- (6) The CAs should provide guarantees that Third Country imports of foodstuffs within the scope of this mission are subject to official controls at an appropriate place in accordance with Articles 15 and 16 of Regulation (EC) No 882/2004.
- (7) The CAs should consider including instructions for carrying out a risk assessment and criteria for the notification of pesticide residue findings as specified by the "Draft guidance document on notification criteria for pesticide residue findings to the Rapid Alert System for Food and Feed " (SANCO/3346/2001, rev. 7) into the written procedures for the operation of the RASFF system.
- (8) The CAs should arrange for designation of one or more national reference laboratories for the three Community reference laboratories for pesticide residues in food of plant origin in accordance with Article 33(1) of Regulation (EC) No 882/2004.
- (9) The CAs should consider providing the necessary resources, particularly the necessary equipment, to increase the scope of the sampling plan for analysis of food of plant origin and to reduce the time-lapse between sampling and analysis in the Oeiras laboratory.
- (10) The CAs should ensure that all designated laboratories comply with Article 12 of Regulation (EC) No 882/2004, or fall under the derogation provided for in Article 18 of Commission Regulation (EC) No 2076/2005. The laboratories could implement the SANCO guidelines for 'Quality Control Procedures for Pesticide Residue Analysis' (Document No SANCO/10232/2006). The CAs should consider taking account of measurement uncertainty for the assessment whether or not a sample contains a violative residue in accordance with the guideline.
- (11) The CAs should ensure that participation in the coordinated Community programme is restricted to laboratories which participate in relevant

Community proficiency tests in accordance with Article 4 of Regulation (EC) No 645/2000.

- (12) The CAs should consider substantially increasing the range of analytes including metabolites covered by their analytical methods for pesticide residues in food of plant origin, in order better to reflect the substances marketed and used and to ensure effective implementation of Article 7 of Directive 86/362/EEC, Article 4 of Directive 90/642/EEC and Article 7 of Directive 2006/125/EC. They should ensure that analytical methods used comply with Article 11 and Annex III of Regulation (EC) No 882/2004 and, for analysis of baby food with Article 7(2) of Directive 2006/125/EC.

The CA of Portugal is invited to send to the Commission, within 25 working days of receipt of the report, an action plan in response to the recommendations. This action plan should clearly set out the manner and deadline by which the competent authorities will address each recommendation.

9. COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS

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

http://ec.europa.eu/comm/food/fvo/ap/ap_portugal_7222_2007.pdf, as soon as this report is published.

ANNEX 1 - LEGISLATION

European Legislation	Official Journal	Title
Directive 76/895/EEC	OJ L 340, 09/12/1976, p. 0026 – 0031	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, 07/08/1986, p. 0037 – 0042	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. 0071 – 0079	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 91/321/EEC	OJ L 175, 04/07/1991, p. 0035 – 0049	Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae.
Directive 91/414/EEC	OJ L 230, 19/08/1991, p. 0001 - 0032	Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.
Regulation (EC) No 645/2000	OJ L 78, 29/03/2000, p. 0007 - 0009	Commission Regulation (EC) No 645/2000 of 28 March 2000 setting out detailed implementing rules necessary for the proper functioning of certain provisions of Article 7 of Council Directive 86/362/EEC and of Article 4 of Council Directive 90/642/EEC concerning the arrangements for monitoring the maximum levels of pesticide residues in and on cereals and products of plant origin, including fruit and vegetables, respectively.
Regulation (EC) No 178/2002	OJ L 31, 01/02/2002, p.0001 - 0024	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.
Directive 2002/63/EC	OJ L 187, 16/07/2002, p. 0030 - 0043	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC.
Regulation (EC) No 882/2004	OJ L 165, 30/04/2004. Corrected and re-published in OJ L 191, 28/05/2004 p. 0001 - 0052	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, 16/03/2005. p. 0001 - 0016	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 maximum residue levels of pesticide in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.
Commission Regulation (EC) No 2076/2005	OJ L 338, 22/12/2005, p. 0083 - 0088	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.
Commission Recommendation 2006/26/EC	OJ L 19, 24/01/2006, p. 0023 - 0029	Commission Recommendation 2006/26/EC of 18 January 2006 concerning a coordinated Community monitoring programme for 2006 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain other products of plant origin and national monitoring programmes for 2007.
Directive 2006/62/EC	OJ L 206, 12/07/2006, p. 0027 - 0035	Commission Directive 2006/62/EC of 12 July 2006 amending the Annexes to Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC as regards maximum residue levels for desmedipham, phenmedipham and chlorfenvinphos
Directive 2006/125/EC	OJ L 339. 05/12/2006, p. 0016 - 35	Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children