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FINAL REPORT OF A MISSION  
CARRIED OUT IN  
ROMANIA  
FROM 10 MARCH TO 14 MARCH 2008  
IN ORDER TO  
EVALUATE CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN

*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 mission took place to evaluate the control of pesticide residues in and on food of plant origin that is imported and/or is on the domestic market.*

*Relevant legislation is in place. The division of responsibilities between the three concerned Competent Authorities (CAs) has been decided by an Inter-Ministerial Committee.*

*Vertical and horizontal communication between the CAs is generally working well. Audits of the inspection bodies responsible for pesticide residue controls have not yet been implemented. Relevant training has not been provided for the inspectors of one of the CAs involved in controls within the scope of the mission.*

*Annual control plans for pesticide residues in food of plant origin are established and implemented by three CAs. They currently do not fully follow the decision of the Inter-Ministerial Committee concerning the division of competencies, which leads to some overlap of the control activities of the different CAs. No infringements of the Maximum Residue Level (MRL) legislation were detected since the accession of Romania. All three CAs have the legal power to follow-up infringements.*

*National Reference Laboratories (NRLs) have been appointed for the 3 Community Reference Laboratories (CRLs) for pesticide residue analysis in food of plant origin. No efficient coordination between these laboratories takes place in the cases where 2 NRLs have been appointed for the same CRL.*

*Only seven of the 17 laboratories responsible for official controls of pesticide residues are accredited. Accreditation covers only the analysis for a limited range of active substances. Only two of the laboratories have taken part in international proficiency tests. The range of analysis (4 – 158 analytes) does not allow full application of the pesticide residue legislation for food of plant origin and especially for baby food. Not all regional CAs responsible for controls of baby food have access to appropriate laboratory capacity for the analysis of pesticide residues.*

*The laboratories of the National Sanitary Veterinary and Food Safety Authority (NVFSA) in Bucharest and Constanta, which were visited during the mission, have adequate facilities and relevant instrumentation with the exception of LC-MS/MS instruments. Relevant training has been provided only for staff of the Bucharest laboratory. In this laboratory the relevant analytical method is not yet fully validated. The laboratory in Constanta currently analyses pesticide residues in food of animal origin and feed. It is only starting to implement a method for pesticide residue analysis in fruit.*

### ***Overall conclusion***

*A control system for pesticide residues in food of plant origin is in place. However, its effectiveness is restricted due to the lack of coordination of control activities between different services, the insufficient range of pesticides covered by the analytical methods applied, the incomplete quality control procedures and lack of accreditation in many of the laboratories.*

*This report contains a number of recommendations to the Romanian authorities to address the deficiencies noted.*

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## ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
ASP	Authority of Public Health ( <i>Autoritatea de Sănătate Publică</i> )
BIP	Border Inspection Post
CA	Competent Authority
CLPR	Central Laboratory for Pesticide Residues ( <i>Laboratorul Central de Control al Reziduurilor de Pesticide</i> )
CPU	County Phytosanitary Unit ( <i>Unitate Județeană Fitosanitară</i> )
CRL	Community Reference Laboratory
DSVSA	Sanitary Veterinary and Food Safety County Division ( <i>Direcția Sanitară Veterinară și pentru Siguranța Alimentelor Județeană</i> )
EU	European Union
FVO	Food and Veterinary Office
GC	Gas Chromatography
GC-MS	Gas Chromatography Mass Spectrometry
IISPV	Institute of Hygiene and Public Health Bucharest ( <i>Institutul de Igienă și Sănătate Publică Veterinară</i> )
ISO	International Organisation for Standardisation
ITD	Ion Trap Detector
LC-MS	Liquid Chromatography with Mass Spectrometry
MARD	Ministry of Agriculture and Rural Development ( <i>Ministerul Agriculturii și Dezvoltării Rurale, MADR</i> )
MESD	Ministry of Environment and Sustainable Development ( <i>Ministerul Mediului și Dezvoltării Durabile MMDD</i> )
MPH	Ministry of Public Health ( <i>Ministerul Sănătății Publice, MSP</i> )
MRL	Maximum Residue Level
NACP	National Authority for Consumer Protection
NPA	National Phytosanitary Agency ( <i>Agenția Națională Fitosanitară</i> )
NPD	Nitrogen Phosphorous Detector
NRL	National Reference Laboratory

Abbreviation	Explanation
NSVFSA	National Sanitary Veterinary and Food Safety Authority ( <i>Autoritatea Sanitară Veterinară și pentru Siguranța Alimentelor, ANSVSA</i> )
PHARE	Pre-accession instrument financed by the European Communities
RASFF	Rapid Alert System for Food and Feed
RENAR	Romanian National Accreditation Body
TAIEX	Technical Assistance and Information Exchange
TOF	Time of Flight

## **1 INTRODUCTION**

The mission took place in Romania from 10 to 14 March 2008. 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 mission by representatives from the central competent authorities, the National Sanitary Veterinary and Food Safety Authority (NSVFSA) and the Ministry of Agriculture and Rural Development (MARD).

An opening meeting was held on 10 March 2008 with representatives from the central competent authorities — the NSVFSA, the MARD, the Ministry of Public Health (MPH), the Ministry of Environment and Sustainable Development (MESD) and laboratories.

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 under Council Directives 86/362/EEC 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.

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:

### **Table 1: Mission visits and meetings**

<b>Competent Authorities</b>		
Central	1	NSVFSA, with the attendance of MPH, MARD and MESD Sanitary Veterinary and Food Safety County Division (DSVSA) Ilfov, with the attendance of NSVFSA, MARD, County Phytosanitary Unit (CPU) Ilfov, Authority of Public Health (ASP) Ilfov and the Border Inspection Post (BIP) Otopeni DSVSA Constanta, with the attendance of NSVFSA, MARD, CPU Constanta, ASP Constanta and BIP Constanta
Regional	2	
<b>Laboratories</b>		
Public	2	NSVFSA laboratories for pesticide residue analysis in Bucharest and Constanta
<b>INSPECTION VISITS</b>		
Warehouse of first destination of imported consignments in Ilfov Cash-and-carry premises in Constanta	1 1	Observation of a sampling of a consignment of garlic Observation of a sampling of a consignment of cabbage

### **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.

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.

## **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](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 (RASFF), 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.

In addition, the FVO has published country profiles for Member States, which describe in summary form the control systems for food and feed safety, animal health, animal welfare and plant health. The country profile for Romania (DG(SANCO)/7463/2007) can be found at:

[http://ec.europa.eu/food/fvo/country\\_profiles/CP\\_Romania.pdf](http://ec.europa.eu/food/fvo/country_profiles/CP_Romania.pdf)

This was the first mission undertaken to Romania for pesticide controls in food of plant origin since accession.

### **4.2 TRADE AND AGRICULTURAL STATISTICS**

According to statistics supplied by the competent authorities, the main commodities of plant origin produced domestically in Romania in 2007 were potatoes (3.7 million tonnes), wheat (2.9 million tonnes), grapes (0.9 million tonnes), tomatoes (0.7 million tonnes) and apples (0.4 million tonnes). The main imported commodities of plant origin in 2007 were beans (10 thousand tonnes), apples (9 thousand tonnes), oranges (4 thousand tonnes), garlic (0.8 thousand tonnes) and tomatoes (0.2 thousand tonnes).

## **5 MAIN FINDINGS**

### **5.1 LEGISLATION**

National legislation is in place specifying implementing measures for Regulations (EC) 178/2002 and 882/2004 such as competencies, procedures and penalties and sanctions for non-compliances.

Directive 2002/63/EC on sampling for the analysis of pesticide residues has been transposed by the Order No 147/2004 of the NSVSFA and Ministerial Order No

1256/2005 of the MARD.

Order No 145/2007 of the NSVFSA specifies procedures concerning the import of food of non-animal origin and the official control thereof.

## **5.2 COMPETENT AUTHORITIES**

### *5.2.1 Structures*

The structures and competencies of the Competent Authorities (CAs) responsible for controls of pesticide residues in food of plant origin have not changed since the country profile mission DG(SANCO)/7463/2007.

Under the Joint Order No 12/173/286/1/124 of the NSVFSA, MARD, MPH and the National Authority for Consumer Protection (NACP) from 2006 fixing maximum levels for pesticide residues in and on fruit, vegetables, cereals and other products of plant origin, the CAs for controls are the MARD and the NSVFSA in co-operation with the MPH.

The division of task between these CAs has been decided in a meeting of the Inter-Ministerial Committee for Surveillance and Official Control of Food and Feed. It was decided that controls of pesticide residues in food of plant origin at the domestic market are the competency of the MARD. Import controls for pesticide residues in food of plant origin are to be carried out by NSVFSA. Controls of baby food are the competency of the MPH.

In the NSVFSA, five specialists at central level and approximately 2 inspectors in each of the counties and 3 staff at each of the Border Inspection Posts (BIPs) are involved in controls for pesticide residues in food of plant origin. In the MARD, one staff member at central level is responsible for controls of pesticide residues in food of plant origin, while generally two inspectors take samples for pesticide residue analysis in each of the counties. In the MPH, two staff at central level, 20 staff at regional level and 111 staff at county level are responsible for controls of pesticide residues. Most of the staff spend only a small portion of their working time on controls of pesticide residues.

### *5.2.2 Structure of designated control bodies*

No private control bodies are used for official control.

### *5.2.3 Communication between competent authorities*

At the beginning of each year the NSVFSA organises a meeting of the heads of units at central level, representatives of the General Directorate and the heads of units of the DSVSAs to coordinate the annual programme. The NSVFSA informs the DSVSAs through service notes which are sent per Internet. The DSVSAs also report to the central level via Internet. In the event of emergencies they communicate through telephone. The BIPs are in contact with the NSVFSA by phone, fax and Internet and they send quarterly and yearly reports.

The MARD notifies the CPUs in written form concerning the control programme and procedures. The CPUs send their reports in written form. Additionally, they communicate by fax, electronic mail and telephone. There are frequent meetings with the inspectors for training and to discuss non-conformities.

The Inter-Ministerial Committee for Surveillance and Official Control of Food and Feed has been established to coordinate the control activities of the NSVFSA, the MARD and the MPH. It meets quarterly, and additionally when the need arises, to discuss and decide issues such as the MANCP, to coordinate the reports and to discuss the RASFF system. Joint training concerning legislation and the RASFF system has taken place (see also section 5.2.6).

Joint controls of the different CAs are sometimes organised at county level, but not in the field of controls of pesticide residues. No co-ordination takes place at county level on controls for pesticide residues.

#### *5.2.4 Communication between competent authorities and stakeholders*

The mission team was informed by the CAs that stakeholders are consulted during the process of drafting of legislation and procedures. The CA which initiates the normative act has the obligation to publish the draft proposal on the Internet, to consult with stakeholders and to organise meetings. After its approval the new legislation is published in the Official Journal.

#### *5.2.5 Supervision and auditing of controls by competent authorities*

Representatives of the NSVFSA informed the mission team that they had started to establish structures for internal audits as required by Article 4(6) of Regulation (EC) No 882/2004. At central level a unit for auditing with six staff will be established. Additionally, there will be one auditor in each of the DSVSAs and in the three reference institutes. However, most of the staff still has to be recruited. The strategic plans for audits for 2007 and 2008 were provided to the mission team. A representative of the NSVFSA stated that audits of the BIPs concerning controls of pesticide residues are planned for the future.

Under the MARD, only internal audits and annual audits by the accreditation body of the Central Laboratory for Pesticide Residues (CLPR) are in place. Representatives of the MARD stated that it was intended to introduce internal audits of the CPUs, but there were no concrete plans as yet.

No audits for their inspection bodies have yet been planned by the MPH.

#### *5.2.6 Training of staff*

Several training sessions which covered the relevant legislation, sampling for pesticide residue analysis, illegal pesticides, etc. have been provided for NSVFSA staff by the Authority and in the framework of TAIEX. Also specific training for BIP staff regarding the RASFF system, import legislation and procedures and taking samples for analysis of pesticide residues has already taken place.

The MARD has provided a one-day training session for its staff covering controls of marketing and use and controls of pesticide residues including sampling. Additionally, training on MRL legislation and sampling for pesticide residue analysis was provided in the framework of a PHARE project.

No training concerning controls of pesticide residues has been provided by the MPH for their inspectors.

### **5.3 IMPLEMENTATION OF CONTROLS FOR PESTICIDE RESIDUES IN DOMESTIC AND IMPORTED PRODUCE**

#### *5.3.1 General import procedures*

The general import procedures have not changed since the country profile mission DG(SANCO) 7463/2007 (see section 2.8 of the respective report).

Under the Order No 145/2007 of the NSVFSA President the importer has to notify the NSVFSA BIP office of the arrival of the consignment 24 hours in advance. Documentary and identity checks of 2-3% of consignments of food of plant origin are carried out at the BIP. The BIP inspector informs the DSVSA where the warehouse of first destination is located according to the information provided by the importer.

Under the same Order the DSVSAs also have to be informed by the importers of the arrival of consignments of food of plant origin produced in other Member States or of third-country produce imported via another Member State.

#### *5.3.2 Planning of controls*

The mission team was informed by the CAs that a National Multi-Annual Control Plan had been established, which included also controls for pesticide residues.

The NSVFSA, the MARD and the MPH draw up three independent annual plans for controls of pesticide residues in food of plant origin.

The NSVFSA annually plans the surveillance programme in the field of food safety, which also covers controls of pesticide residues in food of plant origin. The programme specifies samples of food of plant origin from Third Countries or Member States other than Romania to be taken at warehouses of first destination up to and including the first semester of 2008, and at BIPs from the second semester of 2008.

The programme is drawn up at central level at the end of each year. Concerning pesticide residue analysis, it is based on the EU monitoring recommendation, the number of warehouses of first destination in the counties and the capacity of the laboratories. The central plan specifies the number of samples to be taken from certain commodities and the active substances to be analysed. The central plan is broken down into quarterly county plans by the DSVSAs and approved at central level.

In 2008, 12 samples have to be taken each from 12 commodities, the 8 commodities specified in the 2008 EU monitoring programme (Commission Recommendation 2008/103/EC) and additionally tomatoes, apples, plums and garlic. However, they are analysed only for 15 active substances.

Since 2005, the MARD plan for monitoring of pesticide residues in fruit, vegetables and cereals is drawn up annually by the CLPR and approved by the MARD. The programme was established in cooperation with experts of another EU Member State under a PHARE project. It is based on several criteria such as population per county, consumption data, production area of the crop, import statistics, results of controls from previous years in Romania and the other Member States and the capability and capacity of the CLPR. It includes samples to be taken and analysed for the EU coordinated programme.

The central plan specifies the number of samples to be taken from certain commodities of imported or domestic produce in each of the counties. The central plan is broken down into regional plans, which specify the sampling dates for each sample. In 2008, overall 1 865 samples from 36 commodities from the domestic market and overall 636 samples from 25 commodities from Third Countries have to be sampled. They are analysed for 155 analytes.

Since 2007, the Public Health Programme planned by the MPH includes sampling cereal-based baby food for analysis of pesticide residues. Besides baby food the programme also covers food for general consumption, despite the fact that the MPH was stated to have only specific competency for the pesticide residue controls of baby food. In 2008, 15 samples for pesticide residue analysis should be taken in each of the counties. ([see Endnote](#))

### *5.3.3 Carrying-out of controls*

Samples for pesticide residue analysis under the annual surveillance program in the field of food safety are taken by inspectors of the concerned DSVSA. The DSVSAs are notified of the arrival of consignments from Third Countries imported directly into Romania or via another Member State and of consignments from Member States other than Romania at warehouses of first destination. They decide on the basis of the control plan, and of criteria such as the size of the consignment and the country of origin, which of the consignments they should sample.

The mission team observed an inspection of a warehouse of first destination carried out by inspectors of the Ilfov DSVSA. A representative of the warehouse provided copies of reports of sampling procedures which had taken place previously. It was noted by the mission team that one sample for pesticide residue analysis had been taken also by inspectors of the CPU. It was stated by a senior staff member of the MARD that this overlap of activities is regarded to be necessary until the NSVFSAs laboratories can provide a sufficient scope of analysis.

The DSVSA inspectors demonstrated a sampling procedure of a consignment of five tonnes of garlic from a Third Country. They followed Order No 147/2004 of the NSVFSAs when sampling for pesticide residue analysis. The inspector took two or three garlic bulbs or bags containing several garlic bulbs from 10 boxes chosen randomly throughout the consignment. The primary samples were mixed and split into three samples (1 kg): one sample for the business operator and one sample and one counter-sample were sent to the NSVFSAs laboratory in Bucharest. The samples were put into bags which were weighed, labelled and sealed. The inspector completed the

sampling report and the laboratory request for analysis.

The samples taken in the different counties are analysed by the seven NSVFSA laboratories. A service note specifies for each of the laboratories the counties from which the samples have to be analysed and the group of analytes. For further information concerning the laboratories under the NSVFSA see section 5.5.1.

The inspectors of the DSVSAs also carry out inspections including checks for traceability and the business operators' self-controls concerning pesticide residues of the business operators. During the visit to the warehouse the inspectors demonstrated a check on traceability. They asked the quality manager to demonstrate traceability on the basis of the documentation.

Samples for pesticide residue analysis under the MARD's plan for monitoring of pesticide residues in fruit, vegetables and cereals are taken by staff of the CPUs. Samples are taken from the domestic market, at warehouses of producers, supermarkets and local markets. The inspectors follow Ministerial Order No 1256/2005 when sampling for pesticide residue analysis.

The mission team observed sampling of a 280 kg consignment of cabbage at a cash-and-carry premises carried out by two inspectors of the Constanta CPU. They took 5 cabbages each from 5 randomly chosen bags. Then they chose one cabbage from each of the primary samples and combined them into one laboratory sample. They stated that counter-samples are not taken for perishable products such as cabbage. The cabbages were put into a bag which was sealed and labelled. The sampling report is completed in triplicate, one copy each for the business operator, the inspection body and the laboratory.

Samples taken by CPU staff are sent to the CLPR in Bucharest for pesticide residue analysis, usually by service car. Cooling facilities are available if required.

Samples under the Public Health Programme of the MPH are taken by staff of the ASPs. In both visited counties the mission team was informed by MPH staff that no samples were taken for pesticide residue analysis as no laboratory was at their disposal which could provide the analysis. For further information concerning the laboratories under the MPH see section 5.5.1. ([see Endnote](#))

#### *5.3.4 Reporting of controls*

The NSVFSA laboratories send the analytical results to the DSVSA of the county where the sample have been taken. In the event of non-compliance the inspectors are informed by telephone. The NSVFSA laboratory in Bucharest collects the results of the pesticide residue analysis carried out by the NSVFSA laboratories and reports them quarterly to the NSVFSA.

In 2006, 537 samples taken from imported produce and 326 samples of Romanian produce were analysed for pesticide residues by NSVFSA laboratories. In 2007, 504 samples of third-country produce and produce from Member States other than Romania were analysed. No MRL exceedances were detected.

The CLPR informs the CPUs of the counties where samples have been taken only in the event of non-compliance. It reports the results of its pesticide residue analyses to the

MARD monthly.

In 2006, 241 samples of imported produce and 1817 samples of domestic produce were sampled for pesticide residue analysis by CPUs. Overall, 10 exceedances of MRLs were detected. No MRL infringements were detected in 197 samples from Member States other than Romania, 277 samples from Third Countries and 1 567 samples from Romania sampled in 2007.

The mission team was informed that a meeting has taken place to prepare and coordinate the report of the NSVFSA and the MARD to the European Commission. The ASPs report the results of the samples taken in their counties to the Public Health Institute of Iasi which is responsible for elaboration of national synthesis. A representative of the MPH stated that they have received only the results for 2007 from 11 counties so far. The reported results of pesticide residue analysis of 110 samples of baby food, 120 vegetable samples and 50 samples of total diets were all compliant. ([see Endnote](#))

#### *5.3.5 Follow-up of controls*

Documentation of cases from 2006 where MRL infringements were detected was provided to the mission team. The CLPR had asked the CPU inspectors in writing to contact the business where the samples had been taken and to inform them that the produce cannot be sold and to give advice, e.g. to use a different plant protection product. The MARD did not have the legal power for the follow-up infringement cases at the time.

The mission team was informed by the CAs that staff of all services carrying out controls of pesticide residues now have the legal power to act in the event of non-compliance. The non-compliant produce can be seized and disposed of and fines can be imposed. No MRL infringements have been detected since accession.

Order No 772/68/442 identifies the NSVFSA as the national contact point and coordinator for the RASFF system. The Order also outlines the procedures and communication rules and establishes measures to be taken by each CA in the event of an alert. The mission team was informed that the NSVFSA is prepared to carry out the necessary risk assessment. However, it was not necessary to apply it so far.

### **5.4 CONTROL OF THE MARKETING AND USE OF ILLEGAL PESTICIDES**

To prevent trade in illegal pesticides, importers and exporters of plant protection products are required to obtain import/export certificates from the MESD, which have to be presented to the customs officers. The mission team was informed by the CA that these certificates are issued only for the plant protection products controlled under PIC procedure established by Rotterdam Convention.

The mission team was informed by representatives of the MARD that some cases of sale or use of pesticides not registered in Romania or of fake pesticides had been detected occasionally during inspections of marketing and use carried out by inspectors of the CPUs or during controls for dangerous substances carried out by the police. The mission team was informed by the Ministry of Environment and Sustainable Development that during the PHARE project, developed in 2006, some 2528 tones of obsolete pesticides

were collected in Romania and destroyed in Germany.

The current analytical scope of the pesticide residue laboratories is not sufficient to detect residues of illegal pesticides.

## **5.5 LABORATORIES FOR PESTICIDE RESIDUE ANALYSIS**

### *5.5.1 General overview*

Under the NSVFSA seven laboratories (in Bucharest, Timis, Calarasi, Iasi, Galati, Dolj and Suceava) carry out pesticide residue analysis of food of plant origin. Since 2007 the laboratory in Bucharest has been responsible for coordination of the laboratory network under the NSVFSA concerning analysis of food of non-animal origin. It established a database including the stage of accreditation of the laboratories and the development plans. It is also responsible for providing training for colleagues of the other laboratories.

According to the information received by the mission team, only three of the laboratories are accredited and only one of the laboratories has taken part in an international proficiency test for the analysis of pesticide residues in food of plant origin. Regarding the laboratories not visited during the mission, it was not possible to evaluate their quality control schemes and the initialisation of accreditation to establish if they fall under the derogation from accreditation provided for by Article 18 of Commission Regulation (EC) No 2076/2005. The methods of analysis cover between 10 and 34 analytes, mostly organochlorine and organophosphorous pesticides. For one of the laboratories no information has been received by the mission team concerning the range of analytes covered.

Under the MARD one laboratory carries out analysis of pesticide residues in food of plant origin, i.e. the CLPR. The laboratory was visited during missions before Romania's accession. It has been accredited since 2006 for a GC-MS multi-residue method for pesticide residue analysis. The laboratory took part in recent EU proficiency tests with satisfactory to good results.

A senior staff member of the CLPR informed the mission team about recent developments. She stated that the range of analytes had been substantially increased in recent years. Under the 2008 monitoring programme it analyses for 155 active substances. In 2007, the laboratory purchased additional analytical instruments such as GC-MS-ITD, GC-MS-TOF, LC-MS/MS (triple quadrupole). Staff received training from specialists from other Member States.

Under the MPH nine laboratories (for regional laboratories in Bucharest, Iasi, Cluj-Napoca and Targu-Mures and five county laboratories in Prahova, Suceava, Buzau, Sibiu and Brasov) carry out analysis of pesticide residues in food of plant origin. According to information received by the mission team, only three of the laboratories are currently accredited and none of the laboratories has participated in international proficiency tests. Seven of the laboratories only carry out analysis of organochlorine pesticides covering 4 to 21 analytes. The laboratory in Targu-Mures analyses residues of organochlorine and organophosphorous pesticides covering 35 analytes. No information concerning the scope of analysis was received for the laboratory in Bucharest.

The CLRP has been appointed as the NRL for pesticide residue analysis in cereal food

samples, the Institute for Hygiene and Veterinary Public Health (IISPV) under the NSVFSA as the NRL for cereal feed samples. The CLPR and the NSVFSA laboratory in Bucharest have been appointed as NRLs for analysis of pesticide residues in fruit and vegetables. However, no evidence was provided of coordination of their NRL activities as required under Article 33(5) of Regulation (EC) No 882/2004. The IISPV has been appointed as the NRL for single residue methods.

#### *5.5.2 Laboratories visited during the mission*

The mission team visited two laboratories, the NSVFSA laboratories in Bucharest and Constanta.

##### *5.5.2.1 Resources and training*

The NSVFSA laboratory in Bucharest carries out pesticide residue analysis of samples of food of plant origin and also of a few samples of food of animal origin. In addition to analysis for official controls, the laboratory analyses 20-25% private samples.

The laboratory has good facilities and modern GC equipment with all the necessary detectors, including an MS detector. It was stated by senior staff that LC-MS/MS equipment would be purchased in the near future. Five staff with university degrees and two assistants are involved in pesticide residue analysis. Internal and external training for the staff is provided.

The NSVFSA laboratory in Constanta carries out pesticide residue analysis in food of animal origin and in feed, but is currently not responsible for analysis for official controls of pesticide residues in food of plant origin. A senior staff member of the laboratory stated that they received new equipment, but that they currently did not have sufficient staff and the necessary expertise for carrying out also pesticide residue analysis in food of plant origin. A senior staff member of the NSVFSA informed the mission team that the necessary training would be provided by the NSVFSA laboratory in Bucharest and that a decision to broaden the responsibilities would only be taken once the laboratory had the capability to fulfil the task.

The laboratory in Constanta has adequate facilities and modern GC equipment with ECD and NPD detectors. A GC-MS instrument was purchased only recently. Two staff with university degree and one assistant are responsible for pesticide residue analysis. They have received training for pesticide residue analysis, but not for food of plant origin.

##### *5.5.2.2 Analysis*

The NSVFSA laboratory in Bucharest applies currently a GC-ECD/NPD multi-residue methods for 15 analytes. GC-MS can be used to confirm positive results. A method using a new method of sample preparation and with an increased scope of analytes is being implemented and validated. The limits of determination range between 0.025 mg/kg and 0.1 mg/kg for the different analytes.

The NSVFSA laboratory in Constanta currently uses a GC-ECD/FPD multi-residue method for cereals covering 26 analytes. They started with the preparation for the implementation of a new method for fruit (grapes) only a few days before the mission.

### 5.5.2.3 *Quality assurance system*

The laboratory in Bucharest has been accredited under ISO 17025 by the Romanian National Accreditation Body (RENAR) for the analysis of pesticides since 2007. General quality control procedures are in place. The laboratory has participated in one international proficiency test and in ring tests organised by the IISPV. Validation data for the currently implemented method are limited.

The NSVFSA laboratory in Constanta has been accredited under ISO 17025 by RENAR since 2004, but only the analysis of cereals for a few organochlorine and organophosphorous pesticides in cereals are covered by the accreditation. General quality control procedures are in place. The laboratory has not participated in national or international proficiency tests for pesticide residue analysis in food of plant origin.

## 6 CONCLUSIONS

### 6.1 LEGISLATION

The relevant legislation is in place.

### 6.2 COMPETENT AUTHORITIES

The competencies of CAs are generally clearly defined. The Romanian legislation does not provide a clear allocation of competencies concerning controls of pesticide residues in food of plant origin. The division of responsibilities between the concerned CAs was decided by an Inter-Ministerial Committee.

Horizontal and vertical communication between the CAs responsible for controls of pesticide residues are generally working well. Some deficiencies have been noted concerning coordination of the controls of pesticide residues at county level, which is not in compliance with Article 4(3) of Regulation (EC) No 882/2004.

Audits of the inspection bodies responsible for pesticide residue controls as required by Article 4(6) of Regulation (EC) No 882/2004 have not yet been implemented.

Comprehensive training concerning controls of pesticide residues has been provided to staff of the NVSFSA and the MARD as required by Article 6 of Regulation (EC) No 882/2004. MPH staff have not received respective training. ([see Endnote](#))

### 6.3 IMPLEMENTATION OF CONTROLS

#### 6.3.1 *Control of pesticide residues*

The NSVFSA, the MARD and the MPH plan three independent annual sampling programmes. Planning and implementation of controls of pesticide residues is not yet carried out fully in accordance with the decision of the Inter-Ministerial Committee concerning the division of responsibilities of the three CAs. This leads to some overlap of

their control activities.

Samples are taken at appropriate points of the food chain in accordance with Article 15 of Regulation (EC) No 882/2004.

The sampling procedures observed were in line with Directive 2002/63/EC. Inspections for traceability and self-controls by businesses are in place as required by Article 10 of Regulation (EC) No 882/2004.

All services carrying out controls of pesticide residues have the legal power to follow up MRL infringements as required by Art. 4(2.e) of Regulation (EC) No 882/2004. No MRL infringements have been detected since accession.

### *6.3.2 Control of the marketing and use of illegal pesticides*

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. However, the range of analysis at the pesticide residue laboratories is too limited for systematic control of the use of illegal pesticides.

## **6.4 LABORATORY SERVICES FOR PESTICIDE ANALYSIS**

NRLs have been appointed for the 3 CRLs for pesticide residue analysis in food of plant origin as required by Article 33(1) of Regulation (EC) No 882/2004. For two of the CRLs, two NRLs have been appointed. However, no evidence was provided regarding efficient coordination between these laboratories, which is not compliant with the requirements of Article 33(5) of Regulation (EC) No 882/2004.

According to information received from the CAs, seven of the 17 laboratories involved in official controls of pesticide residues are accredited with a limited scope of accreditation. For the non-accredited laboratories, it was not possible to establish if they fall under the derogation from accreditation provided for by Article 18 of Commission Regulation (EC) No 2076/2005.

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.

The analytical capability of the laboratories responsible for analysis of baby food does not permit implementation of Directive 2006/125/EC and Directive 2006/141/EC. Not all county authorities responsible for pesticide residue analysis in baby food have access to laboratories which can provide the necessary analysis.

The NVFSA laboratories in Bucharest and Constanta have good facilities and are equipped with some modern analytical instruments. However, current lack of an LC-MS/MS instrument limits the analysis of many polar substances and the attainment of the necessary limits of quantification.

Both laboratories are accredited, but only for a very limited scope of analytes and in Constanta only for cereals. Quality control procedures are in place. Only the laboratory in Bucharest has participated in proficiency tests relevant within the scope of the mission.

As validation and implementation of the relevant analytical method are at an early stage in the Bucharest and are only being started in Constanta, it is not possible to conclude to what extent they follow the Method validation and quality control procedures for pesticide residue analysis in food and feed Document No SANCO 2007/3131.

## 6.5 OVERALL CONCLUSION

A control system for pesticide residues in food of plant origin is in place. However, its effectiveness is restricted due to the lack of coordination of control activities between different services, the insufficient range of pesticides covered by the analytical methods applied, the incomplete quality control procedures and lack of accreditation in many of the laboratories.

## 7 CLOSING MEETING

A closing meeting was held on 14 March 2008 with representatives of the NSVFSA, the MPH, the MARD, the MEWM and laboratories. At this meeting, the initial findings and conclusions of the mission were represented by the inspection team. The representatives of the CAs provided some clarifications and comments on the initial findings and conclusions presented.

## 8 RECOMMENDATIONS

The central competent authority of Romania 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.

No.	Recommendation
1	The CAs should implement audit systems as required by Article 4(6) of Regulation (EC) No 882/2004.
2	The CAs should ensure that there is efficient and effective coordination between all competent authorities carrying out official controls in accordance with Article 4(3) of Regulation (EC) No 882/2004. Especially, they should avoid an overlap of their control activities.
3	The MPH should provide appropriate training for the inspectors concerning controls of pesticide residues in food of plant origin as required by Article 6 of Regulation (EC) No 882/2004.
4	The MPH should ensure that the ASPs of all counties have access to appropriate laboratory capacity for analysis of pesticide residues in baby food.
5	The CAs should ensure that the NRLs work closely together, so as to ensure efficient coordination between them, with other national laboratories and the CRLs in accordance with 33(5) of Regulation (EC) No 882/2004.

No.	Recommendation
6	The CAs should ensure that all laboratories responsible for pesticide residue analysis in food of plant origin have appropriate and properly maintained equipment to ensure that staff can perform official controls effectively and efficiently as required by Article 4 (1)(d) of Regulation (EC) No 882/2004.
7	The CAs should ensure that (i) all laboratories involved in the official control of pesticide residues are designated in accordance with Article 12 of Regulation (EC) No 882/2004, and (ii) all designated laboratories comply with Article 12 of Regulation (EC) No 882/2004, or are availing of the derogation foreseen in Article 18 of Commission Regulation (EC) No 2076/2005. The quality control system in the laboratories availing of Article 18 should be based on the Method validation and quality control procedures for pesticide residue analysis in food and feed Document No SANCO 2007/3131.
8	The CAs should consider substantially increasing the range of analytes 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, Article 7 of Directive 2006/125/EC and Article 10 of Directive 2006/141/EC.
9	The CAs should ensure that the 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 and Article 10 of Directive 2006/141/EC.

## 9 ENDNOTES

Concerning	Detail
Section 5.3.2	In their response to the draft report, the Romanian Authorities informed that "In 2008 samples will not be analyzed anymore food for general consumption by the MPH".
Section 5.3.3	In their response to the draft report, the Romanian Authorities informed that "The ASPs of all counties can analyze their taken samples to all the labs from the MPH's network (if there are no lab within an ASP, the taken samples can be analyzed in any other lab from the MPH's network). This issue will be specified in the working methodology for 2008".
Section 5.3.4	In their response to the draft report, the Romanian Authorities informed that "In 2007 some 315 samples had been taken by ASPs (all of them

Concerning	Detail
	comply with legal provisions)".
Section 6.2	In their response to the draft report, the Romanian Authorities informed that " MPH will organize a training for the inspectors concerning pesticide residues in food of plant origin during 2008".

## 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
Regulation (EC) No 645/2000	OJ L 78, 29.3.2000, p. 7–9	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, 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
Directive 2002/63/EC	OJ L 187, 16.7.2002, p. 30–43	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, 30.4.2004, 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

Reference	OJ Ref.	Detail
		food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Regulation (EC) No 2076/2005	OJ L 338, 22.12.2005, p. 83–88	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
Directive 2006/125/EC	OJ L 339, 6.12.2006, p. 16–35	Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version)
Directive 2006/141/EC	OJ L 401, 30.12.2006, p. 1–33	Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC