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FINAL REPORT OF A MISSION
CARRIED OUT IN
BULGARIA
FROM 07 APRIL TO 11 APRIL 2008
IN ORDER TO
EVALUATE CONTROLS OF PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN

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.

Control system for pesticide residues

Relevant legislation is in place.

Vertical and horizontal communication between the competent (CAs) is generally working well. Audits of the inspection bodies responsible for pesticide residue controls have not yet been implemented. Relevant training for inspectors has been provided.

Annual control plans for pesticide residues in food of plant origin are established and implemented. No infringements of the Maximum Residue Level (MRL) legislation have been detected since the accession of Bulgaria. The CA has the legal power to follow up infringements.

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

Six laboratories under the Ministry of Health responsible for pesticide residue analysis in food of plant origin have only initiated accreditation. The methods which are being implemented cover only a limited range of analytes (42 active substances). This does not allow full application of the pesticide residue legislation to food of plant origin and especially to baby food.

The laboratories under the Ministry of Health in Pleven and Sofia, which were visited during the mission, have adequate facilities and all relevant instrumentation with the exception of LC-MS/MS instruments. The analytical methods used have not yet been validated. The technical training provided to the staff is not sufficient to enable the staff to use the GC-MS equipment effectively. The procedure for sample preparation is not fully in line with legislation.

One laboratory under the Ministry of Agriculture and Food Safety is accredited and uses methods, including single-residue methods, which cover a range of 75 analytes altogether. It is not currently used for analysis of pesticide residues in food of plant origin for enforcement of the MRL legislation.

Overall conclusion

A control system for pesticide residues in food of plant origin is in place. However, the effectiveness of the system is still limited because of the insufficient range of analytes covered by the methods implemented and the lack of validation and of accreditation.

This report makes a number of recommendations to the Bulgarian authorities to address the deficiencies detected.

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
BIP	Border Inspection Post
CA	Competent Authority
CCC	Council for Coordination of Controls
CLCTC	Central Laboratory for Chemical Testing and Control
CRL	Community Reference Laboratory
CSHI	Chief State Health Inspector (Главен държавен здравен инспектор, ГДЗИ)
ECD	Electron Capture Detector
EN	European Norm
EU	European Union
FVO	Food and Veterinary Office
GC	Gas Chromatography
GC-MS	Gas Chromatography Mass Spectrometry
ISO	International Organisation for Standardisation
LC	Liquid Chromatography
LOQ	Limit of Quantification
LTC	Laboratory Testing Complex
MAFS	Ministry of Agriculture and Food Supply
MH	Ministry of Health (Министество на здравеопазването, МЗ)
MRL	Maximum Residue Level
MS	Mass Spectrometry
NCFS	National Council for Food Safety (Национален съвет по безопасност на храните, НСБХ)
NPD	Nitrogen Phosphorus Detector
NRL	National Reference Laboratory
NSPP	National Service for Plant Protection

Abbreviation	Explanation
PHARE	Pre-accession instrument financed by the European Communities
PHD	Public Health Directorate of the Ministry of Health(Дирекция Обществено здраве, ДОЗ)
RASFF	Rapid Alert System for Food and Feed
RIPHPC	Regional Inspectorate for Public Health Protection and Control (Регионална инспекция за опазване и контрол на общественото здраве, РИОКОЗ)
RSPP	Regional Service for Plant Protection
SOP	Standard Operating Procedure

1 INTRODUCTION

The mission took place in Bulgaria from 7 to 11 April 2008. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one national expert.

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

The inspection team was accompanied during mission by a representative from the central competent authority (CA), i.e. the Ministry of Health (MH).

An opening meeting was held on 7 April 2008 with representatives from the CAs — the MH, the Ministry of Agriculture and Food Supply (MAFS), the Customs Authority, the National Service for Plant Protection (NSPP), the Sofia and Plevan Regional Inspectorates for Public Health Protection and Control (RIPHPC) and from the 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 European Union (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

Competent Authorities		
Central	2	MH, with the attendance of MAFS, NSPP, Customs Authorities, Sofia and Pleven RIPHPC
Regional	2	NSPP, with the attendance of the Ministry of the Environment and Water and the Regional Service for Plant Protection (RSPP) Sofia RIPHPC Sofia, with the attendance of the MH Pleven RIPHPC , with the attendance of MH, MAFS and RSPP Pleven
Laboratories		
Public	3	RIPHPC laboratories in Sofia and Pleven Central Laboratory for Chemical Testing and Controlin Sofia (CLCTC)
INSPECTION VISITS		
An importer in Sofia	1	Observation of a sampling of a consignment of tomatoes
A wholesaler	1	Observation of a sampling of a consignment of cucumbers

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 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 (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 CAs.

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 Bulgaria (DG(SANCO)/7465/2007) can be found at:

http://ec.europa.eu/food/fvo/country_profiles/CP_Bulgaria.pdf

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

4.2 TRADE AND AGRICULTURAL STATISTICS

According to statistics provided by the competent authorities, the main commodities of food of plant origin produced domestically in Bulgaria in 2006 were potatoes (386 thousand tonnes), tomatoes (213 thousand tonnes), peppers (157 thousand tonnes), watermelons (136 thousand tonnes), cabbage (73 thousand tonnes) and apples (26 thousand tonnes). The main imported commodities of food of plant origin in 2007 were tomatoes (37 thousand tonnes), wheat (30 thousand tonnes), apples (29 thousand tonnes), bananas (28 thousand tonnes) and potatoes (15 thousand tonnes).

5 MAIN FINDINGS

5.1 LEGISLATION

The Bulgarian Food Law (Law on Foodstuffs from 1999 as amended) lays down the procedures, competencies of inspectors and penalties for infringements, as required to implement Regulations (EC) No 178/2002 and 882/2004.

Directive 2002/63/EC on sampling for the analysis of pesticide residues has been transposed by Ordinance No 31 on maximum levels of pesticide residues.

5.2 COMPETENT AUTHORITIES

5.2.1 Structures

The structures and competencies of the CAs responsible for controls of pesticide residues in food of plant origin have not changed since the country profile mission DG(SANCO) 7465/2007.

Drafting legislation on pesticide residues, along with planning, implementing and following up controls on pesticide residues in food of plant origin on the domestic market and at import, are the responsibility of the MH and the 28 RIPHPCs.

In the MH, five staff are responsible for controls of pesticide residues in food of plant origin. In the 28 RIPHPCs, a total of 520 health inspectors, 110 with Masters degrees and 410 with Bachelors degrees, are authorised to carry out controls and sampling for food safety including pesticide residues. However, not all of them routinely carry out controls for pesticide residues. Five of the 20 staff in the Sofia RIPHPC and in the RIPHPC Pleven, 17 of 21 staff take samples for pesticide residue analysis.

5.2.2 Structure of designated control bodies

No private control bodies are used for official controls.

5.2.3 Communication between competent authorities

The MH organises a national annual meeting with the Health Directorates and the Laboratory Analysis Directorates of the RIPHPCs to discuss issues such as new legislation, results from the previous year and procedures. Further meetings of working groups of directors or inspectors are organised whenever the need arises. Instructions and guidelines developed by the MH are sent to the RIPHPCs in the form of circular letters. Informal communication between central and regional level takes place regularly by telephone or e-mail. For details of communication with the laboratories and reporting see section 5.3.

Two bodies have been established for horizontal communication and cooperation

between the CAs responsible for controls of food safety. The National Council for Food Safety (NCFS) is responsible for policymaking, whereas the Council for Coordination of Controls (CCC) coordinates implementation of controls. For further information on the structure and tasks of these bodies, see section 1 of the country profile of Bulgaria DG(SANCO)/7465/2007.

Joint training has been organised for staff from the MH, the MAFS and the NSPP and their regional services under a PHARE project. Information, for example on monitoring results, is exchanged between the services. Before establishments producing food are registered, joint inspections by the RIPHPCs and the RSPPs are carried out.

The MH, the MAFS and their regional services are in regular contact with the customs services. For further information see section 5.3.1.

5.2.4 Communication between competent authorities and stakeholders

The NCFS includes one representative each of the Bulgarian Association of Food Processing and Beverage Industry and of the Consumer Protection Associations. The MH informs stakeholders about new legislation and answers their inquiries by e-mail, at seminars and on its official website. Experts from the MH participate in meetings of stakeholders and contribute articles to their publications.

5.2.5 Supervision and auditing of controls by competent authorities

In 2006 and 2007, the RIPHPCs carried out assessments of inspection procedures conducted by their staff on request of the MH. The mission team was informed that these assessments were not carried out in line with Decision 2006/677/EC. For further information, see report DG(SANCO)/7197/2007 on controls for food hygiene, section 5.2.2.

A draft programme of the MH for 2008 for audits of the RIPHPCs was submitted to the mission team. It had not yet been approved at the time of the mission. The plan is to carry out audits according to Decision 2006/677/EC of all control activities of three RIPHPCs, and audits of two RIPHPCs each for three specific areas: controls of pesticide residues, controls of genetically modified organisms and controls of imports of food respectively. The mission team was informed by a senior staff member of the MH that they intended to contract external auditors as far as resources were available and to additionally appoint staff of the MH as auditors.

5.2.6 Training of staff

Since 2004 training has been provided under several PHARE projects. In 2007, ten training sessions were organised under the PHARE project "National Programme for monitoring of pesticide residues and mycotoxins contamination of food, products and raw materials of plant origin". They also covered sampling techniques, risk assessment for pesticide residues in food and methods for pesticide residue analysis.

Training given by staff from the MH or veterinarians is organised by the Centre for Coordination and Support of Training for Control on Food Safety under the MH, which

was founded in 2006 under a PHARE project and is now financed from the budget of the MH.

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

5.3.1 General import procedures

The general import procedures for food of plant origin have not changed since the country profile mission DG(SANCO)/7465/2007.

The customs services carry out documentary checks of imported foodstuffs at border inspection posts (BIPs) and release consignments into free circulation. In the event of any of suspicions of violations of food safety requirements the RIPHPC is notified. Suspicious consignments can be released into free circulation only after approval by the RIPHPC.

Under a co-operation agreement with the customs services, the MH can require the customs services to notify the RIPHPCs of the arrival of all consignments of a certain product from a certain origin for a specified period of time. At the time of the mission, there was no such requirement related to pesticide residues.

5.3.2 Planning of controls

The mission team was informed that a Multi-Annual Control Plan for 2008–2010 has been drafted, but is still under discussion. It includes the monitoring programme for pesticide residues.

The annual monitoring programme for pesticide residues in food of plant origin is drawn up by the MH in consultation with the laboratories. The plan was based on statistics on imports and production, Bulgarian diet, RASFF notifications and results from the monitoring programme of the NSPP. The mission team was informed by a senior staff member of the MH that the small range of analytes covered by the analytical methods used in the laboratories and the capacity and budget of the laboratories were still limiting planning. Therefore, the 2008 programme could not take full account of all criteria.

Under the 2007 programme, 2820 samples had to be taken of eight commodities, each of which had to be analysed for only two analytes. Under the 2008 programme, 948 samples have to be taken of 26 commodities. Sampling of baby food and of all commodities included in the 2008 EU monitoring programme is covered. However, the plan is to analyse the samples for the 2008 programme for 42 analytes only.

The annual monitoring programme specifies the responsibilities of each of the six laboratories (see section 5.5.1) for carrying out analyses of samples taken in certain regions. It also provides a breakdown of the number of samples to be taken from each commodity in each region. On this basis the RIPHPCs draft detailed regional plans which specify the sampling dates in consultation with the laboratories.

5.3.3 *Carrying out of controls*

Under the monitoring programme for pesticide residues in food of plant origin, samples are taken by inspectors from the 28 RIPHPCs at warehouses, mills, wholesalers, producers, markets and supermarkets as specified in the programme.

Controls on pesticide residues are not currently carried out at BIPs. However, under the agreement with the customs services such controls can be implemented if required (see also section 5.3.1). The mission team was informed that in response to approaches by other Member States, the MH decided to give a non-binding instruction to the RIPHPCs to sample produce from Bulgaria, other EU Member States and Third Countries in the proportions 40:30:30. This approach would be fine-tuned in the year ahead, based on the experience gained.

A standard operating procedure (SOP) for pesticide residue controls in food of non-animal origin lays down procedures for taking samples, sample preparation, analysis, reporting, evaluation of compliance and follow-up. It specifies that controls on traceability and on self-controls by the businesses should be carried out. Furthermore, copies of an SOP for sampling at import and checklists for inspections concerning food safety for four categories of food businesses were provided to the mission team.

The mission team observed an inspection carried out by two inspectors of the RIPHPC Sofia on the premises of an importer of vegetables. The inspectors demonstrated relevant parts of a food safety inspection following the check-list. It included checks on traceability and on self-controls of the business.

The inspectors also carried out a sampling procedure on a 500 kg consignment of tomatoes. They took one tomato from each of ten randomly chosen boxes. The combined weight of the primary samples was slightly above 2 kg. The laboratory sample was put into a black plastic bag, which was sealed and labelled. The sampling report was completed in triplicate, one copy each for the business, the inspection body and the laboratory.

The inspectors and a senior staff member from the MH informed the mission team that usually only one laboratory sample was taken under the monitoring programme. Counter-samples were taken only in the case of suspicion or for follow-up when infringements had been identified. Under the procedure, the representative of the business can request that a counter-sample be taken.

The mission team also observed sampling by two inspectors from the Pleven RIPHPC of a 420 kg consignment of cucumbers on the premises of a fruit and vegetables wholesaler. The inspectors took one cucumber from each of five randomly chosen bags. As the combined weight of the primary sample was less than 2 kg, they took two additional cucumbers from different bags. Packaging and reporting were carried out as described above.

The samples are transported in cool boxes by service cars to the laboratory responsible for the analysis for the respective region (see also section 5.5.1).

5.3.4 Reporting of controls

The RIPHPC laboratories send the results of the analyses to the RIPHPC of the region where the samples were taken. The inspectors inform the business where the samples were taken of the result.

The RIPHPCs have to report the results under the monitoring programme for pesticides residues in food of plant origin to the MH at the end of each year. A preliminary summary of the results from 2007 was presented to the mission team. In 2006, a total of 3 524 samples were analysed and one MRL infringement was detected. In 2007, a total of 3 926 samples were analysed. No MRL infringement was detected.

5.3.5 Follow-up of controls

Documentation on the infringement case from 2006 was provided to the mission team. A warning was issued to the trader responsible of the consignment who was asked to require guarantees from the supplier that the produce complied with the legislation.

Under the Law on Foodstuffs, the RIPHPCs have the necessary power to follow up infringements, such as to issue warnings, recall, seize and destroy non-compliant consignments and impose fines.

The MAFS is the national contact point for the RASFF. A guidance document on operation of the RASFF system was established under a PHARE project. It was noted that it does not yet contain any reference to the Guidance Document on notification criteria for pesticide residue findings to the Rapid Alert System for Food and Feed since the Guidance Document was not translated into Bulgarian until the beginning of 2008.

Under the MH, a Council for Risk Assessment is being established. One of the expert groups of the Council will be responsible for risk assessment of pesticide residues, also in the context of RASFF notifications. The mission team was informed by a representative of the MH that staff of the MH were already prepared to carry out risk assessments when required, even though they had not yet been officially appointed as experts for the Council.

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

The mission team was informed by representatives of the MAFS that some cases of illegal use of pesticides had been detected by inspectors in 2007. No cases of sale and use of illegal pesticides have been detected so far.

The current range of analytes 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

The Chemical Contaminants and Food Additives Department of the National Centre for Public Health Protection under the MH has been nominated as the National Reference

Laboratory (NRL) for pesticide residue analysis in cereal samples. It was accredited to ISO 17025 in 2003 for the first time and applied for re-accreditation in 2007. The laboratory is not involved in monitoring pesticide residues, but carries out analyses for a second opinion.

The pesticide residue laboratory of the Pleven RIPHPC under the MH and the CLCTC under the MAFS have been appointed as NRLs for the analysis of pesticide residues in fruit and vegetables. Both laboratories were visited during the mission (see section 5.5.3.3). As they were only recently appointed, coordination of their NRL activities as required by Article 33(5) of Regulation (EC) No 882/2004 has not yet been implemented.

The CLCTC has also been appointed as the NRL for single-residue methods.

Six laboratories under the MH have been appointed to carry out analysis of pesticide residues in food of plant origin under the annual monitoring programme. As the six laboratories are not yet accredited, the Chief State Health Inspector (CSHI) asked them, prior to their appointment, to prove that they fulfil the requirements of Article 18 of Regulation (EC) No 2076/2005 concerning derogation from the requirement for accreditation for official laboratories. A MH commission had visited the laboratories. All six laboratories reported to the CSHI that they had initiated the accreditation procedure to show that they fulfilled Article 18(a) of Regulation (EC) No 2076/2005. However, according to the evaluation of the mission team, the two laboratories under the MH which were visited during the mission did not completely fulfil Article 18(b) of the Regulation (see section 5.5.2).

According to the information received, none of the laboratories under the MH has taken part in an international proficiency test. All the laboratories have GC-MS equipment, but no LC-MS/MS instruments are available. The current range of analysis of all the laboratories is very limited, covering only 14 to 44 analytes. The laboratories have to finalise the analysis within five working days after receipt of the sample.

The CLCTC (see also section 5.5.3) under the MAFS currently analyses only samples under the NSPP monitoring programme, which are taken from produce which is not yet placed on the market. The MH has sent them an inquiry if they could provide analysis by single residue methods for samples under the MH monitoring program. The mission team was informed that discussions concerning a cooperation of the laboratories under the MH and the MAFS would take place in the near future.

5.5.2 Laboratories visited during the mission

The mission team visited three laboratories, the RIPHPC laboratories in Sofia and Pleven and the CLCTC laboratory in Sofia.

5.5.2.1 Resources and training

The laboratory responsible for pesticide residue analysis in the Laboratory Testing Complex (LTC) within the RIPHPC laboratory in Pleven has six staff (two chemists with university degrees, three chemists with high-school degrees and one assistant). It also carries out analyses for other parameters, such as heavy metals, nitrate and mycotoxins. In 2006 and 2007, the laboratory analysed 124 and 468 samples respectively for pesticide residues for the official control. Since 2007 it has been responsible for analysing samples

from four regions in addition to Pleven. The laboratory analyses a small number (<5%) of private samples.

The pesticide residue laboratory in the LTC within the RIPHPC laboratory in Sofia has six staff (three with university degrees and three laboratory technicians). The laboratory carries out only pesticide residue analysis in food of plant origin. In 2006 and 2007, the laboratory analysed 719 and 519 samples respectively for pesticide residues for the official control. It is responsible for analysing samples taken in four regions.

The facilities of both laboratories are adequate and they have modern GC equipment with all the necessary detectors, including an MS detector. Internal and external training for the staff is regularly provided. It was noted however, that the technical training provided to some of the staff members was not sufficient to enable them to use the GC-MS equipment effectively.

The CLCTC (see also 5.5.1) has six staff with university degrees. In-house and external training for the staff is provided. It has GC and LC instruments with all the necessary detectors, including MS detectors. It was noted that the GC-MS instrument is operational, but not the most up to date. In particular, the computer used to operate the instrument is no longer adequate. The LC-MS/MS equipment is currently not used for lack of technical support from the manufacturer. The facilities of the laboratory need to be refurbished.

5.5.2.2 Analysis

The RIPHPC laboratories in Pleven and Sofia are in the process of introducing a GC-MS method to cover 42 compounds. Sample preparation is based on standard EN 12393. It was noted by the mission team that the SOP for sample preparation foresees that the samples are washed prior to homogenisation. This is not in accordance with Annex I of Commission Regulation (EC) No 178/2006 specifying the parts of products to which the MRLs apply. It foresees rinsing only for few commodities.

The CLCTC laboratory in Sofia currently uses a GC-ECD/NPD multi-residue method and GC-MS for confirmation. It also applies single-residue methods for the maneb group, the benomyl group and n-methylcarbamates. In all, the methods applied cover 75 analytes. The laboratory is in the process of introducing a GC-MS multi-residue method. It is investigating the possibility of replacing the Luke's method by the QuEChERS method for sample preparation.

5.5.2.3 Quality assurance system

The RIPHPC laboratories in Pleven and Sofia have applied to the Bulgarian Accreditation Board for accreditation to standard EN 17025. The laboratory in Pleven has been already notified that an audit will take place in May 2008. The method used for pesticide residue analysis has not yet been validated. Therefore, the laboratories do not completely fulfil the requirements of Article 18 of Regulation (EC) No 2076/2005. The laboratories have not participated in proficiency tests. The method validation and quality control procedures for pesticide residue analysis in food and feed (Document No SANCO 2007/3131) were translated into Bulgarian at the beginning of 2008 and have been made available to the laboratories.

The CLCTC laboratory in Sofia was accredited under ISO 17025 in 2003 for the first time. An audit for re-accreditation took place in October 2007. Only minor issues were found. The laboratory has participated in proficiency tests with generally good results.

6 CONCLUSIONS

6.1 LEGISLATION

Relevant legislation is in place.

6.2 COMPETENT AUTHORITIES

The responsibilities of the CAs are clearly defined.

Horizontal and vertical communication pathways are in place within the MH and with the other CAs in the context of controls of pesticide residues.

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

Comprehensive training has been provided to staff responsible for controls of pesticide residues in food of plant origin as required by Article 6 of Regulation (EC) No 882/2004.

6.3 IMPLEMENTATION OF CONTROLS

6.3.1 Control of pesticide residues

Annual monitoring programmes for pesticide residues are implemented. The scope of the 2008 monitoring programme has been substantially increased in terms of both the commodities sampled and the active substances analysed compared with the previous year. However, the current capability and capacity of the laboratories still restricts the programme significantly.

Controls are carried out in accordance with documented procedures as required by Article 8(1) of Regulation (EC) No 882/2004.

Samples are taken at appropriate points along the food chain in accordance with Article 15(2) of Regulation (EC) No 882/2004.

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

The CA draws up reports on the official controls that it has carried out as required by Article 9 of Regulation (EC) No 882/2004.

The CA responsible for controls of pesticide residues has the legal powers to follow up MRL infringements as required by Art. 4(2)(e) of Regulation (EC) No 882/2004.

A written procedure for operating the RASFF system is in place but does not describe the risk assessment to be carried out according to Draft guidance document SANCO/3346/2001 (current version: rev. 7).

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

Controls occasionally detect illegal use of pesticides. 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 three Community Reference Laboratories (CRLs) for pesticide residue analysis in food of plant origin as required by Article 33(1) of Regulation (EC) No 882/2004. However, efficient coordination between the two laboratories appointed as NRLs for multi-residue analysis in fruit and vegetable as required by Article 33(5) of Regulation (EC) No 882/2004 has not yet been implemented.

The six laboratories under the MH appointed for pesticide residue analysis in food of plant origin are not yet accredited. The two laboratories visited during the mission do not completely fulfil the requirements of Article 18 of Regulation (EC) No 2076/2005 concerning derogation from accreditation for laboratories appointed for analysis for official control as stipulated by Article 12 of Regulation (EC) No 882/2004. It was not possible to establish whether the laboratories not visited during the mission fall under the derogation from accreditation. The laboratories have not participated in international proficiency tests.

In all the laboratories the range of pesticides sought during analysis is too limited to fully enforce compliance with Directives 86/362/EEC and 90/642/EEC. The analytical capability of the laboratories does not permit implementation of Directives 2006/125/EC and 2006/141/EC regarding foodstuffs for infants and young children.

Sample preparation is not in accordance with Annex I of Commission Regulation (EC) No 178/2006.

The laboratories under the MH in Sofia and Pleven which were visited during the mission have adequate facilities and are equipped with modern analytical instruments. However, the technical training was not sufficient to enable the staff to use the GC-MS equipment effectively. The current lack of LC-MS/MS instruments limits the analysis of many polar substances and attainment of the necessary limits of quantification (LOQs).

One laboratory under the MAFS is accredited and has participated in proficiency tests. It uses multi-residue and some single-residue methods for the analysis of 75 analytes. However, its capacity is not currently used for the analysis of pesticide residues to enforce Directives 86/362/EEC and 90/642/EEC. This is not in accordance with Article 4(3) of Regulation (EC) No 882/2004, which requires CAs to ensure efficient and effective coordination between the CAs involved in official controls.

6.5 OVERALL CONCLUSION

A control system for pesticide residues in food of plant origin is in place. However, the effectiveness of the system is still limited because of the insufficient range of analytes covered by the methods implemented and the lack of validation and of accreditation.

7 CLOSING MEETING

A closing meeting was held on 11 April 2008 with representatives of the MH, the MAFS, the Customs Authority, the NSPP, the RIPHPCs in Sofia and Pleven and the laboratories. 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

No.	Recommendation
1	The CAs should continue implementing audit systems, as required by Article 4(6) of Regulation (EC) No 882/2004.
2	The CA should ensure that the written procedures for the operation of the RASFF system include a reference to the Draft guidance document SANCO/3346/2001 (version: rev. 7).
3	The CAs should ensure that the NRLs work closely together to ensure efficient coordination between them, with other national laboratories and with the CRLs, in accordance with Article 33(5) of Regulation (EC) No 882/2004.
4	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. In particular, they should cooperate to optimise use of the available analytical resources.
5	The CAs should consider providing the necessary resources, especially for equipment and training, to all laboratories responsible for pesticide residue analysis in food of plant origin.
6	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

No.	Recommendation
	2007/3131.
7	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. They 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.
8	The CAs should ensure that sample preparation for pesticide residue analysis is carried out in accordance with Annex I of Commission Regulation (EC) No 178/2006.

The competent authority's response to the recommendations can be found at:
http://ec.europa.eu/food/fvo/ap/ap_bulgaria_7837_2008.pdf

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
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 178/2002	OJ L 31, 1.2.2002, p. 1–24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) No 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
Regulation (EC) No 178/2006	OJ L 29, 2.2.2006, p. 3–25	Commission Regulation (EC) No 178/2006 of 1 February 2006 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply
Decision 2006/677/EC	OJ L 278, 10.10.2006, p. 15–23	2006/677/EC: Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules