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Directorate F - Food and Veterinary Office

DG(SANCO)/ 2009-8138 - MR - FINAL

FINAL REPORT OF A MISSION CARRIED OUT IN ROMANIA FROM 02 MARCH TO 06 MARCH 2009 IN ORDER TO EVALUATE OFFICIAL CONTROL SYSTEMS FOR FOOD AND FEED CONSISTING OF OR PRODUCED FROM GENETICALLY MODIFIED ORGANISMS (GMOS)

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected;any clarification appears in the form of an endnote.

Executive Summary

The mission was carried out as a follow-up to a previous mission to evaluate official control systems on food, feed and seed consisting of or produced from genetically modified organisms (GMOs), which took place in April 2007. The mission team met with the Central Competent Authorities and two regional authorities. Visits were also made to 2 control laboratories, 1 border inspection post (BIP) and one visit each to a food and feed business.

All Community legislation within the scope of this mission has been transposed. The existence of national legislation setting labelling thresholds for adventitious presence of genetically modified (GM) material in non-GM seeds contravenes the provisions set out in Article 21.2 of Directive 2001/18/EC. In addition, until a EU labelling threshold for the adventitious presence of GM seed in conventional seed is set, under Article 30.2 of Directive 2001/18/EC, the limit of detection should be used.

The CAs with responsibilities in the control of GMO food, feed and seed are well defined and have not changed since the last mission in 2007.

The inspections for traceability and labelling observed were well conducted and structured. However, the inspection in one of the establishments visited did not check the unique identifier assigned to the GMO.

The import of rice products originating from the United States of America (USA) is in compliance with Commission Decision 2006/601/EC, as amended. The import of rice products originating in or consigned from China neither includes appropriate documentary checks nor sampling. So, it is not in compliance with Commission Decision 2008/289/EC.

Both laboratories visited are well structured, equipped and staffed. However, laboratories performing official controls do not participate regularly in proficiency tests. In addition, eight regional molecular biology laboratories performing official controls are not accredited under EN ISO/IEC 17025 and 31 December 2009 is the deadline for accreditation. There is no access to laboratory capacity for testing "Bt 63" and "LL RICE 601".

Overall, there is an operational control system in place for GMO food, feed and seed in Romania. Four of the six recommendations from previous GMO mission 2007/7186 have been satisfactorily implemented. However, there are no official controls on imports of rice products from China, the national thresholds of adventitious presence of GM in non GM seed contravene Directive 2001/18/EC, and there are shortcomings regarding laboratory capacity for GM rice testing.

At the closing meeting, the representatives of the CAs expressed their willingness to proceed to a swift correction of the shortcomings identified. The report makes a number of recommendations to the competent authorities of Romania.

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
BIP	Border Inspection Post
CA	Competent Authority
CCA	Central Competent Authority
CSVFSD	County Sanitary Veterinary and Food Safety Directorate
DG(SANCO)	Health and Consumers Directorate General
DNA	Deoxyribonucleic acid
ELISA	Enzyme-Linked ImmunoSorbent Assay
ENGL	European Network of GMO Laboratories
EU	European Union
FVO	Food and Veterinary Office
GD	Governmental Decision
GM	Genetically Modified
GMO	Genetically Modified Organism
IBA	Institute of Food Bioresources
IDAH	Institute for Diagnosis and Animal Health
IRMM	Institute for Reference Materials and Mesurements
ISO	International Organisation for Standardisation
MAFRD	Ministry of Agriculture, Forestry and Rural Development
ME	Ministry of Environment
NACP	National Authority for Consumer Protection
NCA	National Customs Authority
NEG	National Environmental Guard
NRL	National Reference Laboratory
NSVFSA	National Sanitary Veterinary and Food Safety Authority
PCR	Polymerase Chain Reaction
RASFF	Rapid Alert System for Food and Feed

Abbreviation	Explanation
RENAR	Romanian Accreditation Association
TARIC	Integrated Tariff of the European Communities
USA	United States of America

1 INTRODUCTION

The mission took place in Romania from 2 to 6 March 2009. The mission team comprised 3 inspectors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State.

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 authorities.

An opening meeting was held on 2 March 2009. At this meeting, the inspection team confirmed the objectives and the itinerary of the mission. Representatives of the following competent authorities (CAs) were present at the initial meeting:

- The National Sanitary Veterinary and Food Safety Authority (NSVFSA),
- The Ministry of Agriculture, Forestry and Rural Development (MAFRD),
- National Authority for Consumer Protection (NACP),
- The National Environmental Guard (NEG),
- The National Customs Authority (NCA).

2 OBJECTIVES OF THE MISSION

The overall objective of the mission was to evaluate the progress made since the mission DG(SANCO) 2007-7186, which took place in April 2007, on the official control systems for food, feed and seed containing, consisting of or produced from genetically modified organisms (GMO). Within this context the mission team evaluated the following:

- the supervision performed by the CA to ensure that the placing on the market of genetically modified (GM) food and feed complies with Regulation (EC) No 1829/2003 of the European Parliament and the Council, with the exception of the authorisation procedure;
- the application of Regulation (EC) No 1830/2003 of the European Parliament and the Council concerning the traceability and labelling of genetically modified organisms (including GM seeds, or the presence of GM seeds in conventional seeds) and the traceability of food and feed products produced from genetically modified organisms;
- the implementation of Council Directive 2002/53/EC in so far as it relates to the placing on the market of varieties of GM agricultural plant species contained in the common catalogue, and Commission Decision 2004/842/EC in so far as it relates to national authorisations for placing on the market of GM varieties not yet entered in this common catalogue;
- action taken by the competent authorities in order to comply with the requirements of Commission Decision 2006/601/EC, as amended, and Commission Decision 2008/289/EC.

- the follow up of recommendations in mission report DG (SANCO) 2007-7186 in order to confirm that planned actions have been implemented.

In pursuit of this objective, the sites visited and meetings held are outlined in the following table:

Table 1 Mission visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	7	-The National Sanitary Veterinary and Food Safety Authority (NSVFSA) -The Ministry of Agriculture, Forestry and Rural Development (MAFRD) -National Authority for Consumer Protection (NACP) -Ministry of Environment (ME) -The National Environmental Guard (NEG) -The National Environmental Protection Agency (NEPA) -The National Customs Authority (NCA) -County Sanitary Veterinary and Food Safety Directorates (CSVFSD) in Ialomita and Constanta -Border Inspection Post in Constanta
Regional	3	
Laboratories		
	2	-Institute of Food Bioresources (IBA) -Institute of Diagnosis and Animal Health (IDAH)
Food and feed establishments		
	3	-Feed mill -2 Soybean oil factories

3 LEGAL BASIS FOR THE MISSION

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

- Art. 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

A full list of the legal instruments referred to in this report is provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

There have been 15 missions to Member States in recent years with similar objectives. Finalised reports of these missions are available at the Directorate General's website:

http://ec.europa.eu/food/fvo/index_en.htm

A number of key documents served as background for the preparation of the mission and were used as basis for the drafting of this report. These included:

- Report of the mission DG(SANCO) 2007-7186 carried out in Romania in April 2007 in order to evaluate the official control systems for food, feed and seed containing, consisting of or produced from genetically modified organisms (GMO);
- Response to the premission questionnaire.

This is the second mission on the subject of GMO food, feed and seed since the accession of Romania to the EU.

4.1 IMPORT DATA FOR ROMANIA

Table 1 Relevant imports in tonnes (source: Eurostat)

Commodity imports	2007	January-September 2008
Soya beans - 12010010 (for sowing)	3,503	1,155
- 12010090 (other, soya grains)	56,853	48,872
- 1208 10 00 (Flours and meals of soya beans)	653	338
Maize (corn) - 1005 10 00 (seed)	564	3,016
- 1005 90 00 (other, mainly corn grain and corn flour)	262,728	4,379
Rape seeds - 12059000 (other)	2,067	991
Corn gluten feed - 23099020	15	
Oilcake/pellets from soya bean oil - 2304 00 00	208,382	222,962

Regarding rice products from China, subject to Commission Decision 2008/289, 3,557 tonnes of husked/brown rice (TARIC 100620) and 4,063 tonnes of peptones (TARIC 35040000) were imported into Romania in 2008. No significant amounts of rice from USA were imported into Romania in either 2007 or 2008.

5 MAIN FINDINGS

5.1 STATISTICS

Regarding authorised GM crops, a surface of 7,146 hectares was planted with maize MON 810 for commercial cultivation in 2008. The MAFRD approved the import of 307 tonnes of seeds of GM maize varieties with the MON 810 event, contained in the common catalogue, in 2008. In addition, national authorisations for tests or field trials, under Commission Decision 2004/842/EC, were granted for several varieties in 2008.

Regarding GM food and feed, 1,318,204 tonnes of GM feed, including compound feed, and 44,816 tonnes of GM food were produced in 2008. Imports for GM food and feed amounted to 54,187 tonnes in 2007 and 66,009 tonnes in 2008, according to NSVFSA.

5.2 LEGISLATION

Governmental Decisions (GD) 256/2006 and 173/2006, which implemented Regulations (EC) Nos 1829 and 1830/2003 before accession, are still in the process of being repealed. GD 173/2006 sets also the penalties for infringements of Regulations (EC) Nos 1829/2003 and 1830/2003.

The Emergency Governmental Ordinance 43/2007 has transposed Directive 2001/18/EC of the European Parliament and of the Council on deliberate release into the environment of GMOs.

Law No 265/2006 approving Emergency Government Ordinance No 195/2005 has banned the cultivation of GM soya since January 2007. In addition, MAFRD Order No 730 provides for the deletion of GM varieties of soya from the Romanian national catalogue of varieties. Moreover, MAFRD order No 631 of 2006 on control and certification of seed quality provides for the testing of non GM varieties which can be contaminated with GM.

MAFRD Order No 150 sets a labelling threshold of 0.9% GM in non GM soya bean seeds. In addition, limits of 0.9% GM in non GM seed are provided for in MARD Orders 147/2007 for sugar beet, 148/2007 for fodder species and 149/2007 for cereals and maize. No threshold for GMO in seed has yet been set at EU level for authorised GMO under Article 21 of Directive 2001/18/EC. This area is covered by harmonised Community rules and such thresholds may only be set by means of Community action. Therefore, Member States are prevented from introducing national provisions to regulate such thresholds.

The MAFRD informed the mission team that a new Ministerial Order on coexistence in seed production, which will include also the level of adventitious presence of GMO in non GM seeds, is being drafted. This new legislation will take into account Commission Recommendation 2003/556/EC, the opinion of the Scientific Committee on Plants, the results of a research project on co-existance of GM, conventional and organic crops and the views of the stakeholders.

GD 106/2002 on food labelling transposes Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. GDs 511/2004, 1719/2004, 1870/2005, 1529/2007 and 751/2008 have transposed the different amendments to Directive 2000/13/EC.

5.3 COMPETENT AUTHORITIES

There are four main CAs (NSVFSA, MAFRD, NEG-ME and NACP) responsible for official control of GMO in all stages of the food, feed and seed chain. Their functions and structure have not changed since the last mission DG(SANCO)/2007-7186 in April 2007.

5.4 CONTROLS ON GMO IN FOOD AND FEED

The planning and organisation of official controls of GMO in food and feed have not changed since the last mission DG(SANCO)/2007-7186. NSVFSA is responsible for traceability and labelling requirements of food and feed at the processing establishments. Local inspectors verify documentation at processors for incoming raw materials and the labelling of products in these production facilities. Traceability and labelling controls on GM food and feed are restricted to operators using soya and maize. No official controls were performed for rapeseed or rice, under Commission Decisions 2006/578/EC, as amended, and 2008/289/EC. The results of the official controls are reported by the County Sanitary Veterinary and Food Safety Directorates (CSVFSD) to NSVFSA on a monthly basis.

In 2007, 2,416 inspections were carried out -1,949 in food businesses and 467 in feed establishments- and 20 penalties were imposed. In 2008, 2,615 inspections were performed -2,135 in food premises and 480 for feed- and 4 penalties were imposed. In 2009, around 2,600 inspections are planned, 500 of them will be for feed.

The NSVFSA has an annual sampling plan in operation that indicates which counties should send samples, containing soya and maize, and to which laboratory. In 2007, 445 food and 79 feed samples were analysed and 15 and 67 were positive for GMOs. In 2008, 792 food and 178 feed samples were analysed and 17 and 54 were positive for GMOs.

The NACP is responsible for official control of labelling of foodstuffs at retail level. NACP took 17 samples of soya products at retail level for GMO analysis in 2007 and 11 samples in 2008, of which none was non compliant.

5.4.1 Performance of inspections and sampling

The mission team observed the inspections for traceability and labelling of a feed mill and an oil plant. The inspections were well conducted and structured. However, the inspection of one of the establishments visited did not check the unique identifier assigned to the GMO, required by Article 4 of Regulation (EC) No. 1830/2003.

The mission team obtained evidence of official controls conducted and sanctions imposed in the two counties visited.

5.4.2 Labelling of GM soya oil

Mission DG(SANCO) 2007-7186 found evidence that GM soya oil was not labelled appropriately, as required by Article 12 and 13 of Regulation (EC) No 1829/2003. To implement the recommendation in this mission report, in 2008, official controls took place of the 8 oil producers that had been using soya as raw material. Only 5 of the 8 were still using soya, at the time of the inspection, and only 3 of these 5 were producing food or feed. Among those 3 operators, 2 were mentioning in the labelling and accompanying documents that the oil was obtained from GM soya bean. The soya in store of the third operator was found positive for Roundup Ready soya. According to this operator, around 900 tonnes of oil to be used as part of compound feed were released into the market without correct labelling.

The operator who did not label correctly the oil produced from GM soya was fined and the oil still in stock, around 350 Kg., was correctly relabelled as GM. Moreover, the CSVFSD of the counties where the suppliers of the soya beans where located were

informed. In addition, oil producers were informed of the GM labelling requirements.

5.5 CONTROLS ON GMO IN PROPAGATING MATERIALS

The planning and organisation of official controls of GMO in seeds have not changed since the last mission DG(SANCO)/2007-7186.

The MAFRD is responsible for the implementation of the legislation on seed, the official control and certification of seed, the testing and registering of varieties in the national and common catalogue, the issuing of import licenses for seed from third countries and the approval of intracommunity movement of GM seed. In 2008, 170 GM tests of soya bean seed from the 2007 harvest were performed and 11 were not compliant. In 2009, 105 analysis are planned.

The MAFRD has put in place a system for registration, authorisation and inspection of all growers who cultivate GM maize MON 810. In addition, MAFRD monitors the field trials for GM crops and destroys their outputs. A total of 164 official controls for GM maize MON 810 and 58 official controls for field trials took place in 2008. Regarding soya bean crops, the MAFRD performed 861 lateral flow strip tests of the plants in the fields for GM detection in 2008. The soya bean plants of 59 hectares were contaminated with Roundup Ready soya and were destroyed. All infringements were reported to the NEG and the CSVFSDs. In 2009, 105 GM tests of conventional soya bean seed for sowing, from the 2008 harvest, are planned.

Within the ME, the NEG carries out controls to ensure that GM maize is not cultivated in protected areas, such as national parks. They performed 520 controls during 2006 and 39 sanctions were applied.

5.6 GENERAL IMPORT CONTROL PROCEDURES

All importers of food and feed of non animal origin have to declare the nature of their imported products to the BIP (Order 145/2007). BIPs notify the County Sanitary Veterinary and Food Safety Directorate (CSVFSD) of the destination county of the import and the inspectors from the CSVFSD take samples from selected imports of soya and maize not declared as GM, according to the "Program for Surveillance and Control in the field of Food Safety". In case the product is declared as GM to the BIP, the inspectors from the CSVFSD follow the goods through the entire chain to control the traceability requirements. The draft "Program for Surveillance and Control in the field of Food Safety for 2009" provides that samples of soya and maize to be used as food and feed not declared as GM will be taken at the first import of each specific product from a specific country of origin.

The import of GMO seeds registered in the European Common Catalogue requires an import license issued by the MAFRD, as provided by MAFDR Orders No 257/2002 and 461/2006. Border phytosanitary inspectors carry out documentary checks on seed lots at entry. The accompanying documents, including labelling, have to be in conformity with the import license issued by MAFDR, to assure the seeds' traceability under OECD and EC rules.

NSVFSA has forwarded Commission Decision 2006/601/EC, as amended, and

Commission Decision 2008/289/EC, to all BIPs and requested that information on controls implemented is reported on a monthly basis. In addition, operational procedures for the implementation of both Decisions have been prepared and disseminated through the NSVFSA intranet. The operational procedures for the implementation of Commission Decision 2008/289/EC do not list the Chinese laboratories nominated to undertake the analysis and do not include the sanitary certificate model endorsing the analytical report.

At the import point visited, the mission team obtained evidence that the import of one consignment of US rice fulfilled the requirements of Commission Decision 2006/601/EC, as amended. On the other hand, the import of two consignments of rice products from China was not in compliance with Commission Decision 2008/289/EC. One consignment file included neither the analytical report nor the sanitary certificate. The other consignment file was missing the analytical report. In both cases neither sampling nor laboratory analyses were performed before import.

5.7 LABORATORIES

Official control analyses of GM food and feed are performed by the Institute for Diagnosis and Animal Health (IDAH) and by a network of ten regional molecular biology laboratories coordinated by IDAH. In 2008, only six of the ten regional molecular biology laboratories conducted GM analyses of food and feed. According to the pre-mission questionnaire only two of the ten regional molecular biology laboratories are accredited to EN ISO/IEC 17025.

The Institute of Food Bioresources (IBA), under MAFRD, is responsible for official control analysis of GMOs in seeds.

The mission team visited the IDAH and the IBA laboratories.

5.7.1 IDAH-Institute for Diagnosis and Animal Health

IDAH, which is a public laboratory under the NSVFSA, is the National Reference Laboratory (NRL) for GMO in food and feed and a member of the European Network of GMO Laboratories (ENGL). Within its NRL duties, IDAH coordinates the work in the molecular biology network of NSVFSA-IDAH.

IDAH is accredited under EN ISO/IEC 17025 by the Romanian accreditation body RENAR. The scope of accreditation covers qualitative and quantitative real time PCR tests for Roundup Ready soya.

In the IDAH, seven specialists are involved in GMO analysis. The staff is well trained and skilled. Documented job descriptions for personnel are in place and are kept up-to-date. The high number of samples analysed for GMO annually, 474 in 2008, ensures that the competence of the personnel is maintained.

The organisation of the laboratory facilities for GMO testing is in compliance with the general laboratory requirements laid down in EN ISO 24276. Incompatible activities are carried out in separate rooms to prevent cross contamination and adequate PCR controls are used to reveal possible cross-contamination.

The laboratory possesses all the necessary equipment to be able to perform GMO testing and each item of equipment is uniquely identified. The equipment is properly maintained

and procedures for planned maintenance are in place.

Methods in place include qualitative screening methods for commonly used DNA elements in GMOs, as well as a PCR method for detection of the Cauliflower Mosaic Virus (CaMV) to reveal potential false positive results. In addition, the laboratory has implemented quantitative modification-specific or event-specific methods for Roundup Ready soya, MON810 maize and Bt11/Bt10 maize, using commercially available kits. Currently, the laboratory is in the process of validating and implementing methods for several additional maize events. Methods are applied on both raw materials and on complex processed food products. PCR controls to expose reduced amplification efficiency in unknown samples are used in quantitative analyses. Adequate procedures for validation or verification of methods, before they are being put into use, are available. Methods for GMO detection of other genetically modified species than soya and maize, such as rapeseed and rice, are not in place.

To assure the quality of GMO tests, the laboratory uses certified reference materials from the Institute for Reference Materials and Measurements (IRMM). Quality control data are analysed, but not recorded in such a way that trends are easily detectable. IDAH has not yet participated in proficiency testing for quantitative GM analysis, but is planning to take part in one proficiency test for quantitative determination of Roundup Ready soya in 2009.

The results from GM tests are reported accurately, clearly and objectively and test reports include all necessary information such as the limit of detection and the estimated uncertainty of quantitative measurements.

The laboratory has the managerial and technical personnel and resources needed to carry out its duties. The organisation and management structure of the laboratory is sufficient and responsibilities of personnel are well defined. The management system established is implemented and appropriately maintained.

5.7.2 IBA-Institute of Food Bioresources

IBA, which is a member of the ENGL, is a public body under the MAFRD. The main activity of IBA is food research. The microbiology-ELISA laboratory of IBA is accredited according to EN ISO/IEC 17025 by RENAR. The scope of accreditation covers detection and quantification of CP4 EPSPS protein from Roundup Ready soya using a commercially available ELISA test kit.

The team of the microbiology-ELISA laboratory consists of six persons. The staff is highly qualified, well trained and possesses the necessary competence in the specific field of GMO analysis using ELISA. The number of samples analysed annually, 105 seed samples in 2008, is sufficient to maintain the competence of the personnel.

The facilities where the analytical work is carried out are appropriate for the tasks and sufficiently furnished with the equipment required for the correct performance of the tests. The equipment is identifiable and properly maintained.

The laboratory uses a commercially available ELISA test kit for detection and quantification of the CP4 EPSPS protein from Roundup Ready soya. Controlled standard operating procedures, based on the kit manufactures' instructions, are in place. The

method used has been properly validated in the laboratory using certified reference materials.

To monitor the validity of tests performed, the laboratory uses certified reference material from IRMM. Procedures for internal quality control in quantitative analyses include calibration standards in triplicate, samples in duplicate and certified reference material recovery but control charts to uncover bias and trends are not in place. In 2006, the laboratory took part in 2 international proficiency tests for qualitative and quantitative determination of Roundup Ready soya and MON810 maize and the results were satisfactory. The laboratory intends to participate in one proficiency test round in 2009.

Suitable internal procedures to ensure traceability are present for samples from reception until release of results. Test reports were found to be appropriate and included all the information necessary for the interpretation of the test results, including a statement on the estimated measurement uncertainty associated with a specific test result.

The ELISA methodology used in the laboratory lacks the specificity to identify specific GM transformation events. However, IBA is in the process of establishing the molecular methodology required. IBA has the molecular biology competence and the equipment needed to do so. Personnel are currently validating PCR based methods for qualitative and quantitative detection of GMOs, and accreditation of PCR based tests is foreseen for 2009. This laboratory intends to participate in international proficiency testing in 2009. The equipment is of high standard and the layout of the rooms where the PCR methodology is used is acceptable, but the space is very limited. However, IBA intends to move into a new building with better facilities in two years.

The laboratory has an adequate management structure with defined responsibilities of personnel involved in analyses of sample taken from official controls. Internal audits are conducted to verify that the operations of the laboratory comply with the requirements of the management system and of the international standard ISO EN ISO/IEC 17025. However, internal audits are carried out by the laboratory quality manager, and not by personnel who are independent of the activity to be audited. Findings from internal audits and corrective actions that arise from them are not recorded(see Endnote).

5.8 FOLLOW-UP TO MISSION DG(SANCO)/2007-7186

Recommendation in 2007-7186	Follow-up in 2009-8138
(1) Proceed urgently with plans to fully transpose Directive 2001/18/EC of the European Parliament and of the Council.	Satisfactorily addressed. See section 5.2.
(2) Until such time as the threshold values for GMO in seed are set under Article 21 of Directive 2001/18/EC, ensure that national legislation on the adventitious presence of GMO in seed lots is brought into line with the practice of using the analytical limit of detection.	Not satisfactorily addressed. See section 5.2.
(3) Ensure that food and feed produced from GM soya fulfils the requirements of Articles 12 and 13 of Regulation (EC) No 1829/2003.	Satisfactorily addressed. See section 5.4.2.
(4) Extend official control activities to include products potentially containing additional authorised GMO and non authorised GMO to comply with the requirements of Articles 4.2 and 16.2 of Regulation (EC) No 1829/2003.	Not satisfactorily addressed. See section 5.4 and 5.7.
(5) Ensure that the central IDAH laboratory is sufficiently resourced in order to comply with the requirements for National Reference Laboratories as specified by Article 33 of Regulation (EC) No 882/2004.	Satisfactorily addressed. See section 5.7.1.
(6) Ensure that the IDAH laboratory can adequately analyse additional authorised GMO (under Regulation (EC) No 1829/2003) in order to comply with the requirements of Article 9.1 of Regulation (EC) No 1830/2003.	Satisfactorily addressed. See section 5.7.1.

6 CONCLUSIONS

6.1 LEGISLATION

All Community legislation within the scope of this mission has been transposed. The existence of national legislation setting labelling thresholds for adventitious presence of GM material in non-GM seeds contravenes the provisions set out in Article 21.2 of Directive 2001/18/EC. In addition, until a EU labelling threshold for the adventitious presence of GMO seed in conventional seed is set, under Article 30.2 of Directive 2001/18/EC, the limit of detection should be used.

6.2 COMPETENT AUTHORITIES

The CAs with responsibilities in the control of GM food, feed and seed are well defined and have not changed since the last mission in 2007.

6.3 CONTROLS ON GMO IN FOOD AND FEED

There is an operational system of control in place for GMO in food and feed in Romania. The inspections for traceability and labelling observed were well conducted and structured. However, the inspection in one of the establishments visited did not check the unique identifier assigned to the GMO, as required by Article 4 of Regulation (EC) No 1830/2003.

6.4 CONTROLS ON GMO IN SEEDS

There is an operational system of control in place for GMO in seed in Romania.

6.5 GENERAL IMPORT CONTROL PROCEDURES

The import of rice products originating from the USA is in compliance with Commission Decision 2006/601/EC, as amended. There are neither appropriate documentary checks nor sampling and testing of rice products, originating in or consigned from China, at import, as required by Commission Decision 2008/289/EC.

6.6 LABORATORIES

The laboratories visited are well structured, equipped and staffed. However, laboratories performing official controls do not participate regularly in proficiency tests, as required by Chapter V.2 of Commission Recommendation 2004/787/EC. In addition, eight regional molecular biology laboratories performing official controls are not accredited under EN ISO/IEC 17025 and 31 December 2009 is the deadline for accreditation, as provided by Article 12 of Regulation (EC) No 882/2004. There is no access to laboratory capacity for testing "Bt 63" and "LL RICE 601", as required by Article 3 of Commission Decision 2008/289/EC and Article 3 of Commission Decision 2006/601/EC.

6.7 OVERALL CONCLUSION

There is an operational control system in place for GM food, feed and seed in Romania. Four of the six recommendations from previous GMO mission 2007/7186 have been

satisfactorily implemented. However, there are no official controls on imports of rice products from China, the national thresholds of adventitious presence of GM in non GM seed contravene Directive 2001/18/EC, and shortcomings regarding laboratory capacity for GM rice testing were identified by the mission team.

7 CLOSING MEETING

A closing meeting was held on 6 March 2009 with the central competent authorities, NSVFSA, MAFRD, NACP, MESD, NEG, NEPA and NCA. At this meeting, the main findings of the mission were presented by the inspection team. The representatives of the CAs provisionally accepted these findings and informed the mission team of their willingness to proceed to a swift correction of the shortcomings identified. In addition, NSVFSA provided evidence that one of the rice products consignments from China, identified by the mission team as not fulfilling the requirements of Commission Decision 2008/289/EC, had already been withdrawn from the market.

8 RECOMMENDATIONS

The competent authorities are invited to provide, within 25 working days of receipt of the draft report, an action plan containing details of the actionstaken and planned, including deadlines for their completion, to address the following recommendations:

No.	Recommendation
1	Ensure that rice products originating in or consigned from China are allowed to be placed on the market only when they fulfil the requirements of Article 2 of Commission Decision 2008/289/EC.
2	Ensure that national provisions do not regulate a labelling threshold for the adventitious presence of GMO seed in conventional seed lots. Such threshold shall be established at EU level under the procedure laid down in Article 30.2 of Directive 2001/18/EC, as provided by Article 21.2 of the same Directive.
3	Ensure that until a labelling threshold for the adventitious presence of GMO seed in conventional seed is set, under Article 30.2 of Directive 2001/18/EC, the limit of detection is used.
4	Ensure the access to laboratory capacity for testing "Bt 63" and "LL RICE 601", as required by Article 3 of Commission Decision 2008/289/EC and Article 3 of Commission Decision 2006/601/EC.
5	Ensure that all laboratories performing official controls are accredited under EN ISO/IEC 17025 by 31 December 2009, as required by Article 12 of Regulation (EC) No 882/2004.
6	Ensure that laboratories performing official controls participate regularly in proficiency tests, as provided for by Commission Recommendation 2004/787/EC.
7	Ensure that official controls of traceability requirements for products consisting or

No.	Recommendation
	containing GMOs include the inspection of the unique identifiers assigned to the GMOs, as required by Article 4 of Regulation (EC) No 1830/2003.

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

http://ec.europa.eu/food/fvo/ap/ap_romania_8138_2009.pdf

9 ENDNOTES

Concerning	Detail
Section 5.7.2	In their response to the draft report the CA noted that internal audits will be performed by independent personnel and that findings from internal audits and corrective actions will be recorded.

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Regulation (EC) No 1829/2003	OJ L 268, 18.10.2003, p. 1–23	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
Regulation (EC) No 1830/2003	OJ L 268, 18.10.2003, p. 24–28	Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
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
Directive 2000/13/EC	OJ L 109, 6.5.2000, p. 29–42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
Directive 2001/18/EC	OJ L 106, 17.4.2001, p. 1–39	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
Directive 2002/53/EC	OJ L 193, 20.7.2002, p. 1–11	Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species
Decision 2004/842/EC	OJ L 362, 9.12.2004, p. 21–27	2004/842/EC: Commission Decision of 1 December 2004 concerning implementing rules whereby Member States may authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of varieties of agricultural plant species or vegetable species has been submitted
Decision 2006/601/EC	OJ L 244, 7.9.2006, p. 27–29	2006/601/EC: Commission Decision of 5 September 2006 on emergency measures regarding the non-authorised genetically modified organism

Reference	OJ Ref.	Detail
		LL RICE 601 in rice products
Decision 2008/289/EC	OJ L 96, 9.4.2008, p. 29–34	2008/289/EC: Commission Decision of 3 April 2008 on emergency measures regarding the unauthorised genetically modified organism Bt 63 in rice products