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Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6306 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ROMANIA

FROM 11 TO 20 SEPTEMBER 2012

IN ORDER TO EVALUATE THE OFFICIAL CONTROLS OF GENETICALLY MODIFIED ORGANISMS, INCLUDING THEIR DELIBERATE RELEASE INTO THE ENVIRONMENT

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 a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office audit in Romania, carried out from from 11 to 20 September 2012 under the general provisions of EU legislation in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

The objective of the audit was to evaluate the system of official controls of genetically modified organisms (GMOs) including their deliberate release into the environment, and the action taken to address the shortcomings identified during the previous audit related to GMOs (DG(SANCO)2009-8138), carried out in March 2009.

Overall, there is a structured system of official controls for GMOs in place. Good progress has been made since the previous GMO mission in 2009 concerning the official control systems for food and feed. Appropriate controls are in place regarding GMO trials, GM maize MON810 cultivation, GM food, feed and seed. However, two recommendations regarding GMO threshold in seed have not been adequately adressed. Other shortcomings were found regarding the GMO laboratories.

The report makes a number of recommendations to the competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
Bt	*Bacillus thuringiensis* subsp. *Kurstaki*
CA(s)	Competent Authority/ies
CCA	Central Competent Authority/ies
CDA	County Directorate for Agriculture
CVSFSD	County Sanitary Veterinary and Food Safety Division
DG SANCO	Directorate-General for Health and Consumers of the European Commission
DNA	Deoxyribonucleic acid
EC	European Community
ELISA	Enzyme-linked immunosorbent assay
EN	European Standard
ENGL	European Network of GMO Laboratories
EU	European Union
EURL-GMFF	European Union Reference Laboratory for GM Food and Feed
FVO	Food and Veterinary Office
GM	Genetically modified
GMO(s)	Genetically Modified Organism(s)
IDAH	Institute for Diagnosis and Animal Health
IFB	Institute of Food Bioresources
ISO	International Organisation for Standardisation
ISTA	International Seed Testing Association
ISTIS	State Institute for Variety Testing and Registration
LCCSMS	Laboratory for Seeds Quality and Propagating Material
MARD	Ministry of Agriculture and Rural Development
MON810	GM maize authorised for placing on the market on the basis of Commission Decision 98/294/EC
MS	Member State
NACP	National Authority for Consumers Protection
NEG	National Environment Guard
NEPA	National Environment Protection Agency
NRL	National Reference Laboratory
NSVFSA	National Sanitary Veterinary and Food Safety Authority
p35S	Genetic element promoter 35S

PCR	Polymerase Chain Reaction
RASFF	Rapid Alert System for Food and Feed (http://ec.europa.eu/food/food/rapidalert/index_en.htm)
PT	Proficiency test
RENAR	Romanian Accreditation Association
SNIF	Summary Notification Information Format
TISQ	Territorial Inspectorates for Seed Quality
tNOS	Genetic element terminator NOS

1 Introduction

This audit took place in Romania from 11 to 20 September 2012. The audit formed part of the Food and Veterinary Office's (FVO) planned programme.

The team comprised two auditors from the FVO and one expert from a European Union (EU) Member State (MS).

Representatives from the competent authorities (CAs) accompanied the FVO team for the duration of the audit. An opening meeting was held on 11 September 2012 with the CAs. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the FVO team and the control systems were described by the authorities.

2 Objectives and scope

The objective of the audit was to evaluate:

a) the control system in place for food, feed and seed containing, consisting of, or produced from genetically modified organisms (GMOs) including their deliberate release into the environment under Regulations (EC) No 882/2004, No 178/2002, No 1829/2003, No 1830/2003 and Directive 2001/18/EC of the European Parliament and of the Council, and

b) the action taken to address the shortcomings identified during the previous audit related to GMOs (DG(SANCO) 2009-8138), carried out in March 2009.

In terms of scope, the audit reviewed the designation of competent authorities (CA) for official control of GMOs, their co-operation, audits and resources for performance of controls, as well as the organisation and implementation of the controls, including controls of GMO trials, cultivation of GM crops, GM food, feed and seed, sampling and laboratory performance.

In pursuit of this objective, the following sites were visited:

Table 1: Audit visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central Regional Local	2 2	NSVFSA, MARD, NEPA, NEG and NACP Targoviste and Timis counties
Laboratories		
Public Private	2	IFB and IDAH
Inspection visits		
GMO trial Cultivation of GM crops	2 2	One site in Calarasi and one site in Timis counties One GM maize MON810 grower for commercialisation and one GM maize MON810 seed grower

Food processor	1	Targoviste county
Feed processor	1	Timis county
Import point	1	Constanta
Seed establishment	1	Seed processor

3 Legal Basis

The audit was carried out under the general provisions of EU legislation, in particular Article 45 of Regulation (EC) No 882/2004.

EU 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 Audit series

This was the seventh of a series of audits to be carried out in MSs which include an evaluation of the controls for the deliberate release of GMO for trial and cultivation into the environment in addition to the controls of GM food and feed.

A mission to Romania dealing with GMOs was last carried out in 2009 (DG (SANCO)/8138-2009). The report of this mission can be found at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

4.2 Country profile

The FVO has published a country profile for Romania, which describes in summary form the control systems for food and feed safety, animal health, animal welfare and plant health and includes an overview of the state of play of the recommendations of the previous FVO audits. The country profile can be found at:

http://ec.europa.eu/food/fvo/country_profiles_en.cfm

4.3 Authorised GM products

The list of the GM products authorised in the EU can be found at:

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

The genetically modified maize MON810 was authorised for placing on the market and use in food, feed and cultivation on the basis of Commission Decision 98/294/EC. The authorisation is in the process of renewal. MON810 is cultivated in Romania. The official control system for the cultivation of this maize is covered in section 5.2.3.3 below.

4.4 Production and trade data

The GM, *Bacillus thuringiensis* subsp. *Kurstaki* insecticide toxin producing (Bt.) maize line MON810 is commercially cultivated and MON810 seed is multiplied in Romania. There were 701ha and 588ha of GM maize MON810 grown in 2010 and 2011, respectively. In 2012, the surface of commercial MON810 hybrids was 217ha and 103ha of MON810 seed was multiplied by 12 farmers in five counties. For compareson, based on FAOSTAT data, a total of some 2-2.4 million ha of maize are grown in Romania each year.

The production area of non-GM soya was 2,340ha in 2010. The area of non-GM soya seed multiplication amounted to 2,340ha and 1,748ha in 2010 and 2011, respectively. MON40-3-2 (Roundup ready) soya has not been cultivated since 2006.

EUROSTAT figures do not make a distinction between GM and non-GM products. According to the CA, 1,755t and 2,475t of GM maize seed was imported in 2010 and 2011, respectively. The CA further stated that 162 t of GM food and 1,439,640t of GM feed was produced in Romania in 2010. In 2011, no GM food was produced and the GM feed production amounted to 1,549,463t.

According to the data provided by the CA and based on EUROSTAT figures, 550,892t and 498,954t of soya pellets was imported in 2010 and in 2011, respectively. The import of maize amounted to 66,560t in 2010 and 507,573t in 2011.

Regarding rice and rice product from China, the import amounted to 51t and 57t in 2010 and 2011, respectively based on EUROSTAT figures.

5 Findings And Conclusions

5.1 Relevant national legislation

Legal requirements

Article 291 of the Treaty on the functioning of the EU establishes that MSs shall adopt all measures of national law necessary to implement legally binding Union acts.

Findings

The main national legislation regarding GM food and feed has not been changed since the last GMO mission (DG(SANCO)/2009-8138).

The following new national legislation has been put in place regarding seed and deliberate release of GMOs since the last GMO mission:

- Order No 1718/2009 of Ministry of Environment on the approval of the authorisation and import permits formats on the deliberate release into the environment of genetically modified organisms,
- Order No 1205 /2009 of Ministry of Environment on the establishment and functioning of the National Register regarding the locations of the release of genetically modified organisms,
- Order No 1160/2010 of Ministry of Environment and the Ministry of Finance on the approval the control procedure of the import, export and transit of genetically modified

organisms.

- Order No. 61/2012 of Ministry of Agriculture and Rural Development (MARD) regarding the licensing and inspection of GM plant growers and the measures taken to ensure the coexistence of GM plants with conventional and organic crops,
- Order No. 232/2010 of MARD, amending MARD Order No. 631/2006 regarding the inspection and certification of seed quality through the testing of non-GM varieties that can be contaminated with GM varieties. This order lowered the threshold of authorised GMO in seed to 0.3% in the case of free pollinated species (e.g. maize) and 0.5% in the case of self-pollinated species (e.g. soya), (see section 5.2.4 below, for further details).

Conclusions

As far as the audit team could ascertain, national legislation is in place to implement the EU legislation relevant to the scope of this audit.

5.2 Organisation and Implementation of Official Controls

5.2.1 Designation of Competent Authorities

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 and article 4(4) of Directive 2001/18/EC require Member States (MSs) to designate the CAs responsible for official controls and for complying with the requirements of the Directive, respectively. Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies.

Findings

The central competent authorities regarding GM food, feed, seed and cultivation of GM crops have not changed since the last GMO mission in 2009.

The National Sanitary Veterinary and Food Safety Authority (NSVFSA) is the competent authority (CA) for GMO controls regarding food and feed including import controls.

The National Environment Protection Agency (NEPA) is the CA for the deliberate release of GMOs into the environment.

The MARD is responsible for GMO controls of seed, GM maize MON810 cultivation, GMO controls in soya bean cultivation and GMO trials and finally for the maintenance of official registration of transgenic varieties.

The National Environment Guard (NEG) is responsible for controls of GMO trials and GMO cultivation together with MARD.

In Romania, no official controls on GMOs are delegated to control bodies, consequently the provisions of Article 5 of Regulation 882/2004 are not applicable.

Conclusions

Competent authorities within the scope of the audit are identified and tasks are allocated.

5.2.2 Resources for performance controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure that they have access to a sufficient number of suitably qualified and experienced staff and that appropriate and properly maintained facilities and equipment are available. Article 6 requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

At county level, there is at least one inspector at each authority who carries out GMO related controls regarding food, feed, seed, trial and cultivation.

Evidence was provided that NSVFSA inspectors involved in the activity of GM food and feed controls received training in 2011 and 2012 (17 -18.11.2011 – Braşov, 08.12.2012 - Galati, 24 – 25.05.2012 – Braşov). All staff responsible for GMO import controls at the Constanta harbour were last trained on 23.08.2012. The training sessions included updates regarding the legislation, inspection and sampling procedures.

The GMO inspectors at the County Directorates for Agriculture (CDA) under MARD participated in a 2-day training in 2011.

The inspectors and laboratory staff met by the FVO team were generally informed and prepared for their tasks.

Not all necessary reagents and materials were available at the IFB laboratory. Apart from that, the FVO team did not identify any cases of facilities or equipments being inadequate.

Conclusions

Adequate facilities are generally available. Staff met were by and large adequately trained.

5.2.3 Controls of the deliberate release of GMOs

Legal Requirements

Article 4(1) of Directive 2001/18/EC requires MSs to ensure that adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs are avoided. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively of the Directive. Article 4(3) requires MSs to ensure that the potential adverse effect on human health and the environment of GMO release are accurately assessed on a case by case basis. Article 4(5) requires MSs to ensure that the CA organises inspections and other control measures to ensure compliance with this Directive. In the event of a release of GMOs or placing on the market as or in products for which no authorisation was given, the MS concerned shall ensure that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform its public, the Commission and other Member States. Article 31(3) requires MSs to establish registers for recording the location of GMOs released under part B and C of this Directive.

5.2.3.1 Authorisation of the deliberate release of GMOs for purposes other than placing on the market (field trial)

Legal Requirements

Article 6 of Directive 2001/18/EC specifies the standard authorisation procedure for the deliberate release of GMOs into the environment for any other purpose than for placing on the market. Article 8 regulates the handling of modifications and new information regarding the deliberate release of GMOs. Article 9 specifies the consultation of and information to the public, which MSs shall carry out.

Findings

Authorisation for deliberate release of GMOs into the environment under Part B of Directive 2001/18/EC (field trials) is issued by NEPA.

The CA stated that each application for authorisation of a proposed GMO trial is assessed on a case by case basis.

The notifier submits the application dossier together with the Summary Notification Information Format (SNIF) to NEPA. NEPA submits the SNIF to the European Commission and consults the public. The SNIF is published on the web page of NEPA, the web page and the information board of the local environmental protection agency and the information board of the local municipality. NEPA consults the Bio-safety Commission which is an inter-disciplinary scientific body composed of 12 permanent members and four substitutes from public institutions. Each notification for GMO trial shall contain a risk assessment aiming to identify and evaluate, on a case by case basis, the potential adverse effects of the GMO, both direct and indirect, immediate or delayed, on human health and on the environment. The Bio-safety Commission evaluates the risk assessment submitted by the notifier and issues a scientific opinion, which is submitted to NEPA. NEPA also consults with MARD for approval. The comments submitted by the public during the public consultation are considered by NEPA when the authorisation decision is made. The socio-economic aspects (e.g. whether neighbours would be against), and the characteristics of the biodiversity of the intended location of the GMO trials (e.g. it is not in a protected area) are also taken into account.

NEPA issues the authorisation in the cases where the notification is in compliance with Directive 2001/18/EC and the necessary approvals have been received from MARD. The authorisation is generally valid for more than one year.

The authorisation includes, among other things, the description, the detection and identification methods of the GMO, the conditions of the release, the locations of the trial, the obligations of the consent holder and the validity of the authorisation.

The obligations of the consent holder include requirements regarding isolation distances, training of personnel, waste management and cross border movement of the GM material, monitoring, reporting, labelling and co-operation with MARD and NEG.

NEPA manages a register, accessible to the public via the internet, of the notifications received and rejected by them and the authorisations issued for GMO trials. The location of the trials is also recorded in the register. The risk assessment submitted by the notifier, the SNIF and the scientific opinion are published on NEPA's website (www.anpm.ro).

There were seven and four new authorisations issued for GMO trials in 2010 and 2012, respectively. No authorisations were issued in 2011 due to the unavailability of the Bio-safety Commission during its reconstitution.

Once a trial has been terminated, the consent holder has to submit a report, which NEPA checks to see whether the authorisation conditions have been fully followed. In mid-December, the consent holders submit the monitoring report to NEPA. After having verified and analysed, NEPA forwards them to the European Commission. The Format of the report for field trials is according to the relevant requirements.

Conclusions

A system for authorisation regarding the deliberate release of GMO for trial purposes is in place in line with Directive 2001/18/EC.

5.2.3.2 Controls of the deliberate release of GMOs authorised for purposes other than placing on the market (field trial)

Legal Requirements

Article 6(8) of Directive 2001/18/EC requires that the notifier may proceed with the release only when he has received the written consent of the CA, and in conformity with any conditions required

in this consent. Article 6(9) requires MSs to ensure that no material derived from GMOs which are deliberately released in accordance with part B is placed on the market, unless in accordance with part C. Article 10 specifies the reporting by notifiers on releases to the CA after the completion of the GMO release.

Findings

The consent holder needs to register the exact location of the GMO trial with CDA every year and an annual cultivation authorisation for growing the GM crop is issued. A map of the location of the trial is included in the documentation submitted by the consent holder. The CDA submits the data regarding the locations of the GMO trials to the NEPA, at their request, each year. NEPA uses these data to maintain their database of environmentally protected areas.

GMO trials of maize and soya bean were carried out involving 17 and 11 GMO events in 2010 and 2011, respectively. In 2012, only GM maize trials have been performed involving three GMO events.

A thematic instruction for controls is issued by the MARD each year. This guidance includes details of controls regarding GMO trial including timing of inspections. It is addressed to the CDA.

Official controls of GMO trials are carried out by the CDA and NEG of the location of the trial. There were 37 and 42 inspections carried out in 2010 and 2011, respectively. In 2012, 14 inspections have been performed by the time of the audit. Non-compliances have not been identified.

The audit team visited GM maize trials performed under two authorisations by the State Institute for Variety Testing and Registration (ISTIS) in Calarasi county and a GM maize trial carried out by a farmer in Timis county. A partnership agreement was signed between the performer of the trial and the consent holder in each case.

The trial in Calarasi county is inspected three times a year. Inspectors explained that inspections are carried out after sowing, during the growing season and after harvest by the CDA and the NEG. The CDA stated that they check the isolation distances between the GM maize and maize grown in the neighbourhood. The consent holder stated that they obtain a prior agreement of the neighbouring farmers in order to respect at least 200 m isolation distance prior to sowing. The NEG and the CDA inspectors are present when the leftover of the GM seed is destroyed after sowing. They check whether the seed is duly buried in the GMO field. During the growing season the CDA inspectors checks the vegetative status of the crop. Another joint inspection is carried out by the CDA and NEG after harvest to verify whether the entire GMO material has been properly destroyed and incorporated in the soil. An inspection report is drawn up after each visit by each authority.

The CDA controls of the GMO trial visited in Timis county followed the same principle as in Calarasi. However, the NEG inspector did not carry out inspections in 2011 and 2012 at the time of sowing. The inspector stated that they operate based on a centrally prepared control plan. The plan did not include controls specific to GMO these years[1]. An inspection was carried, based on the notification received from the farmer after harvest in 2011. The conditions of the consent were checked including verification of the surface of the GMO trial and isolation distances. Similar inspections are planned in 2012.

Conclusions

The GMO trials are inspected at an appropriate frequency and it is verified that the conditions of the

1 In their response to the draft report the competent authority noted that inspectors can carry out inspections based on request received from the consent holders.

consent are met.

5.2.3.3 Controls of deliberate release of GMOs authorised for placing on the market (cultivation)

Legal Requirements

Article 19(4) of Directive 2001/18/EC requires MSs to take all necessary measures to ensure that the conditions specified in the written consent and the approval decision are complied with.

MON 810 is an existing product in the sense of Regulation (EC) No 1829/2003 (Articles 8 and 20). It is currently the subject of an application for renewal under that Regulation. At the time of this audit, no decision on the renewal has been adopted by the Commission. In such cases, Articles 11(4) and 23(4) of the Regulation foresee that the duration of the authorisation is prolonged until a decision is taken.

According to Articles 8(5) and 20(5) of the same Regulation, existing products in the sense of Articles 8(1) and 20(1) are subject to the provisions of that Regulation.

Findings

Order 61/2012 of MARD regulates the cultivation of GM crops. Where GM maize MON810 is grown, at least 200m isolation distance is required from other maize crops. The grower has to declare the location of the MON810 field sown and then the harvested surface to the CDA.

Each year, annual authorisations are issued upon request to farmers for GM maize MON810 cultivation. A map of the location of the fields has to be included in the farmer's request. The CDA compiles a register, which is submitted to MARD who forwards it to NEPA. It is accessible to the public via internet.

The consent holder works on the basis of a partnership agreement with farmers growing GM maize MON810. The farmers are required to have a refuge area sown with non-GM maize, which is at least 20% of the surface sown with MON810. The activity of the farmer is regularly monitored by the consent holder.

<u>Controls of GM maize MON810 cultivation</u>

Under Order No. 61/2012 of MARD, in counties where GM maize MON 810 is cultivated, one person at the CDA is in charge of issuing the annual cultivation authorisation and one person is responsible for carrying out inspections.

A thematic instruction for controls is issued by MARD each year. The instruction includes details of controls regarding cultivation of GM maize MON810 including timing of inspections. It is addressed to the CDAs.

The audit team visited one grower of GM maize MON810 for commercial use in Arad county and one GM maize MON810 seed grower in Braila county (see also section regarding seed below).

The farmer in Arad county grew 46ha and 182ha GM maize MON810 in 2010 and 2011, respectively. In 2012, he initially declared 140 ha, but he could not ensure the isolation distance of 200m from other maize crops for the full area, therefore, the planted area was 59ha. The farmer also grows conventional maize. He stated that the GM maize seed is stored separately from the conventional seed. The harvested GM crop is directly transported to the trader, it is not stored on the farmer's premises.

In 2012, the CDA inspector in charge of controls of GM maize MON810 carried out 5 inspections

at the farmer visited. The first inspection was carried out before sowing. The inspector checked whether the GM seed was stored separately from non-GM maize seed. The designation of the refuge areas were verified using the map submitted with the request for the cultivation authorisation. The inspector also reminded the grower to declare the planted surface to the CDA within 7 calendar days after sowing. The following visit took place after sowing. The documents of the seed supply were checked to verify the origin and the planted surface. During the next visit in July, the inspector checked the isolation distance between GM and non GM maize crops. One further inspection was dedicated to estimate the yield before harvest. The latest inspection was observed by the audit team after harvest. The inspector verified the harvested surface and whether the entire GMO material had been properly incorporated in the soil. An inspection report using a standardised format was drawn up after each visit.

The farmer stated that it is indicated on every document accompanying the harvested crop that it is GMO.

The CDA inspectors report their activity, including GMO related controls to the MARD monthly.

Controls carried out for GMO presence in non-GM soya bean

The CA stated that the CDA inspectors carried out 89 and 37 GMO related controls of conventional soya crops in 2010 and 2011, respectively. The controls included checking the documents attesting the origin of conventional soya seed, making an inventory of the areas planted. In order to verify the area indicated in the documentation, the amounts of seed used for sowing and the cultivation area were compared. Sampling of soya bean leaves were also carried out in the case of suspicions of impurities with GM plants. In 2011, 21 controls were carried out using side-flow Trait√RUR Grain strip tests in Mures and Teleorman counties, where conventional soya was grown. Eight tests were performed at conventional soya growers in Mures county in 2012. All of these test results were negative. (See also section 5.2.12, below).

Conclusions

A detailed and intensive control system is in place for GM maize MON810 cultivation, which is made possible by the very limited area grown.

Some controls continue to be carried out to verify that no GM soya bean is being cultivated in Romania.

5.2.4 Controls of GMOs in seed and propagating material

Legal Requirements

Article 4 of Regulation (EC) No 1830/2003 details the traceability and labelling requirements for products consisting of or containing GMOs. Article 9 requires that Member States carry out inspections and other controls measures, including sample checks and testing, to ensure compliance with this Regulation.

Article 21(1) of Directive 2001/18/EC requires that labelling and packaging of GMOs comply with provisions specified in the consent. Article 21(2) envisages the possibility to set at Union level thresholds below which technically unavoidable or adventitious traces of authorised GMOs cannot be excluded from conventional products and they do not need to be labelled. Such thresholds may only be set by means of Union action.

Article 4(5) of the same Directive requires, in the event of a release of GMO(s) or placing on the market as or in products for which no authorisation was given, that the MS concerned ensures that necessary measures are taken to terminate the release or placing on the market, to initiate remedial

action if necessary, and to inform its public, the Commission and other MSs.

Findings

The 2009 mission report included two recommendations:

(Rec. 2) to *'ensure that national provisions do not regulate a labelling threshold for the adventitious presence of GM seed in conventional seed lots. Such threshold shall be set 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.'*

(Rec. 3) to *'ensure that until a 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 is used.*

Since the previous FVO mission, the tolerance threshold for authorised GMOs in seed was reduced. However, threshold values are still applied: 0.3% in the case of free pollinated species (e.g. maize) and 0.5% in the case of self pollinated species (e.g. soya).

Controls of GM seed are carried out by the Laboratory for Seeds Quality and Propagating Material (LCCSMS) and the Territorial Inspectorates for Seed Quality (TISQ) under MARD at cultivation, processing and marketing level. In practice the laboratory ability allows only to evaluate the presence of maize event MON810 and soya bean event MON40-3-2.

In 2010, 74 soya bean and 39 maize samples were taken from non-GM seed for GMO presence. In the case of soya bean, two samples were non-compliant and in the case of maize, non-compliant samples were not identified. No samples were taken in 2011. In 2012, it is planned that each lot/production site of non-GM maize seeds produced in the counties where GM maize MON810 has been grown in 2012, shall be sampled. 109 samples are planned to be taken.

In the case of first trans-boundary movement of GM seed under Part B of Directive 2001/18/EC into Romania, the consent holder must notify NEPA to obtain a licence. The subsequent trades during the validity of the licence, have to be notified to NEPA, in form of a notification submitted by the consent holder on a yearly basis.

<u>Controls of GM maize MON810 seed multiplication</u>

Controls of GM maize MON810 seed multiplication are carried out by the CDA and the TISQ. Farmers intending to multiply GM maize MON810 seed have to be registered with both authorities.

The audit team visited a GM maize MON810 seed multiplier in Braila county. The farmer cultivated this crop on a 40 ha plot.

The TISQ inspector stated that they carry out controls for seed certification based on the centrally prepared annual multiplication plan. These inspections also include GMO related controls. At least five inspections are carried out in a growing season at each grower of GM maize MON810 seed. As it is required under the seed certification system, the controls include checking the isolation distance (200 m) between the seed and other maize crops and whether traceability is ensured. Checks for volunteers are carried out within 200 m of the GM seed field. Controls are carried out according to the a harmonised check list. A standardised inpection report is completed after each inspection. The TISQ issues documents, which accompany the harvested GM seed. On these documents, it is indicated that the seed is GM.

Based on an annual thematic instruction issued by the MARD, inspections are carried out by the CDA following the same principles as indicated in chapter 5.2.3.3 above, regarding controls of GM maize MON810 cultivation.

The GMO inspector of the CDA in Braila stated that in 2012, the first inspection was carried out

after sowing. The inspector verified, among other things, the surface sown, the quantity of seed used and the location of the field. The following inspection was carried out before harvest to assess the yield. The audit team observed an inspection carried out after harvest. The inspector checked the harvest declaration of the seed multiplier, which includes information on the name of the hybrid, the harvested quantity, the location and that the product was entirely delivered to the consent holder. He verified in the field whether the material left in the field after harvest is properly incorporated in the soil. An inspection report was drawn up.

GMO controls of seed processing

The controls at seed processors are carried out based on the national seed legislation and include also checks regarding GMO presence in seed and checks of GM maize seed MON810.

The audit team visited a large seed processor dealing with both GM and non-GM maize seed in Ialomita. The company deals with only maize at the premises visited and GM maize processing forms a small part of their activity. The company stated that in order to prevent contamination of non-GM seed with GMO, they generally use, at their processing plant, a thorough cleaning of the production line with pressurised air between varieties and they process GM seed at the end of the processing season. In practice, they are currently using a separate processing facility to process GM seed. Samples are taken by the company for seed certification purposes and for adventitious presence of GMOs from each lot. The samples are analysed in the laboratory of the company, where the Limit of Detection is approximately 0.26 %. Samples of 3,000 kernels are analysed. The company stated that GMO presence was detected in some 1% of their samples.

The inspection observed by the audit team was carried out by an official of the LCCSMS. It included a demonstration of a sampling of seed (see section 5.2.8 below on sampling).

Sampling of seed can also be carried out by the 27 samplers employed by seed companies officially approved and supervised. The authorisation is made according to the provisions of EC Directive 66/402/EEC (for maize) by the LCCSMS and TISQ. They are trained and after having passed an exam successfully they receive a licence which is valid for three years. They receive regular training in particular if the legislation changes.

The inspection observed also included checking the label of the seed packages. In the case of GM maize MON810 seed, the inspector checked whether the label indicates that the product is GMO.

The audit team noted that the label of GM maize seed indicated the words "Genetically modified variety". The CA stated at the closing meeting that GM seed is labelled as required by the EU legislation regarding marketing of seeds.[2]

Controls carried out for GMO presence in non-GM soyabean seed

Controls of non-GM soya bean seed have been carried out to follow up on non-compliances (see section 5.2.12 below, for further details).

Conclusions

Detailed control measures are in place to ensure compliance of seed with the requirements of Regulation (EC) No 1830/2003 and Directive 2001/18/EC.

The *de minimis* labelling threshold applied in Romania for adventitious and technically unavoidable presence of authorised GM material in non-GM seed contravene Article 21 of Directive 2001/18/EC

2 In their response to the draft report the competent authority noted that “on labelling issue we would like to state that Romania apply the EU legislation on the marketing of seeds (e.g Directive 66/402/EEC - art. 11a "In the case of seed of a variety which has been genetically modified, any label or document, official or otherwise, which is affixed to or accompanies the seed lot, under the provisions of this Directive, shall clearly indicate that the variety has been genetically modified")”.

and Article 4 of Regulation (EC) No 1830/2003.[3] Therefore, recommendations (2) and (3) of the previous report have not been adequately addressed.

GM seed is labelled, although not exactly in line with the wording of Article 4 of Regulation (EC) No 1830/2003.

5.2.5 Controls of GMOs in food and feed

Legal Requirements

Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 require that no person shall place on the market a GMO for food or feed use or GMO food or feed unless it is covered by an authorisation granted in accordance with the Regulation and the relevant conditions of the authorisation are satisfied.

Articles 12, 13, 24, and 25 of the same Regulation require that food and feed is labelled as containing GMO when it contains, consists of or is produced from GMOs, except if the proportion is no higher than 0.9% of the food ingredient or of each feed considered individually and the presence is adventitious or technically unavoidable. Article 12(3) and 24(3) require that in order to establish that the presence is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

Article 9.1 of Regulation (EC) No 1830/2003 requires that Member States carry out inspections and other control measures, including sample checks and testing, to ensure compliance with this Regulation. Articles 4 and 5 specify the information to be transmitted in writing to the operator receiving GMO products or food and feed products produced from GMOs, and information to be indicated on the label, or in connection with the display of the product.

Findings

The 2009 mission report included a recommendation:

(Rec 7) to *'ensure that official controls of traceability requirements for products consisting or containing GMOs include the inspection of the unique identifiers assigned to the GMOs, as required by Article 4 of Regulation (EC) No 1830/2003.*

On this recommendation, the NSVFSA stated that the issue of unique identifier checks also was identified by an internal audit report of June 2012. Following this audit, it is planned to update the standardised inspection form for GM food and feed control by 31 December 2012. Checks of the unique identifiers assigned to the GMOs will be included. The inspectors met by the FVO team were already aware of the requirements.

The system of controls regarding GM food and feed has not significantly changed since the previous FVO audit in 2009. A national plan for the GMO controls in food and feed is prepared by the NSVFSA in consultation with the National Reference Laboratory (NRL) and the County Sanitary Veterinary and Food Safety Divisions (CVSFSD). The latter generally carry out the controls as specific GMO controls and not in conjunction with other food or feed safety controls. They focus on verification and enforcement of the traceability and labelling rules for authorised GMOs. Testing was only carried out for soya products until 2009, when maize was added. It is the policy of NSVFSA to encourage operators to take their own samples and have them analysed, in

3 In their response to the draft report the competent authority noted that in the case of soybean seed, Romania multiplies only conventional varieties which are placed on the market according to the provisions of Directive 2002/57/EC on the marketing of seed of oil and fibre plants. In the last two years no 'impurification' of GMO in conventional soyabean seed was detected. The MARD Order no 232/2010 stipulates that for self pollinated species (e.g. soya), a threshold value of 0.5%, this threshold is applied only for authorised GM events. In fact, in the case of soyabean, the threshold is zero, because no GM soya is authorised for cultivation.

order in the longer term to be able to reduce the amount of official samples. The elements that are taken into account when preparing the control plan include, coverage of the entire food chain (except primary production) for maize and soya, number of relevant operators in the counties, volume of products processed there, laboratory capacity, results of previous years' controls, degree of self control by operators, amount of imported products regardless of origin. From 2011, documentary controls for products of rape seed, cotton seed and sugar beet pellet were included. Controls for unauthorised events are carried out if there are RASFF notifications of relevance for Romania from other Member States. An example of such was a notification of non-authorised GM linseed in bakery products sold in Romania. Except for controls of Chinese rice products under Decision 2011/884/EU, imports are inspected as part of the above mentioned controls of domestic operators. The NSVFSA stated that when relevant commodities are imported, the inspection staff at the border notify the CSVFSD in the county of destination for them to take this into account in their targeting of controls.

Food

The authorities stated that about 160 t of oil from GM soya beans was produced in 2010. Since then, there has been no production of GM food in Romania. It is common that importers and producers of food require statements from their suppliers that the supplies are GM free.

The operators under surveillance and control include soya bean and maize warehouses, soya oil factories, food processors that produce food or food ingredients containing soya or maize and retailers, such as supermarkets. Samples are only taken from non-GM products. The controls carried out the last three years are summarised in table 2 below.

The FVO team observed an inspection and sampling carried out at a food processor that used various soya ingredients in non-GM meat products for the local market. A thorough documentary check was done for the supply of the soya ingredients. The producer had requested GM-free declaration from the suppliers and the inspector verified that it was stated on all the relevant supply documents. For the sampling, see section 5.2.8.

Table 2: GMO controls 2010 to 2012 of food with soya or maize content

	Soya products				Maize products			
Year	Checks	Samples	Positive samples	Above 0.9%*)	Checks	Samples	Positive samples	Above 0.9%*)
2010**)	1,182	379			726	301		
2011	1,019	365	50	18	633	271	1	1
2012 (until 30/7)	337	74	20	1	159	52	5	1

*) Only products not labelled as GM were tested and only authorised events were detected. Thus, non-compliance relates to GM content over 0.9%.

**) The analysis of the samples taken in 2010 was for the majority delayed and only completed in 2011. At the time of writing the report, information was not available as to how many of the samples taken in 2010 were positive/above 0.9%. Therefore, the figures in the table cannot be taken to indicate any trend 2010-2012 in the proportion of samples being positive or non-compliant

Feed

Like for most other Member States, a substantial proportion of the animal feed produced in Romania contains GMOs. The operators under surveillance and control include feed mills, store

houses, oil factories etc. that use or handle maize or soya. In addition, documentary checks were carried out in 2011 on food products containing rape seed (52 checks), cotton seed (18) and sugar beet pellet (11).

The controls carried out the last three years are summarised in table 3 below. Samples are only taken from non-GM products.

Table 3: GMO controls 2010 to 2012 of feed with soya or maize content

	Soya products				Maize products			
Year	Checks	Samples	Positive samples	Above 0.9%*)	Checks	Samples	Positive samples	Above 0.9%*)
2010**)	198	32			161	59		
2011	184	27	18	8	172	63	0	0
2012 (until 30/7)	46	11	3	3	38	7	0	0

*) Only products not labelled as GM were tested and only authorised events were detected. Thus, non-compliance relates to GM content over 0.9%.

**) The analysis of the samples taken in 2010 was for the majority delayed and only completed in 2011. At the time of writing the report, information was not available as to how many of the samples taken in 2010 were positive/above 0.9%. Therefore, the figures in the table cannot be taken to indicate any trend 2010-2012 in the proportion of samples being positive or non-compliant

The FVO team observed an inspection carried out at a feed processor and discussed sampling with the inspector. He did a documentary check for the supply of soya beans and maize. The producer uses GM soya beans and the inspector checked the unique identifier on the supply documents to verify that the event was authorised. GM indication was also verified on the documentation and labelling of the outgoing feed. For the sampling, see section 5.2.8.

Conclusions

Controls of GMOs in food and feed focus on verifying the required traceability and labelling of authorised GMOs. These controls are prioritised, planned and carried out across the food chain in compliance with EU legislation. Recommendation 7 of DG(SANCO)/2009-8138 has been addressed.

5.2.6 Controls of specific import requirements

Legal Requirements

Article 3 of Commission Implementing Decision 2011/884/EU requires prior notification of rice and rice products consignments from China. Article 4 sets out the import conditions each consignment shall meet. Article 5 specifies the official controls to be carried out by CAs of MSs including documentary checks and sampling.

Findings

The 2009 mission report included a recommendation:

(No 1) to *'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* [now applicable to Decision 2011/884/EC].

In order to ensure the implementation of Decision 2011/884/EU, a service note Nr. 237 of NSVFSA

was issued on 6th of January 2012. This note is addressed to the control services at the points of entry and summarises the main requirements of the Decision.

The audit team visited the import point at Constanta harbour. Since the Decision entered into force, three samples have been taken from three consignments of rice noodles from China. The consignments were from the same exporter and imported by the same company. The analytical results did not identify any GMOs. No rice consignment from China was available for inspection at the time of the audit, but the inspector who carried out the controls of the most recent consignment from China explained the control steps he had followed. He stated that the importer informed the NSVFSA three days prior to the intended date of the import. When the product arrived, the inspector checked the health certificate, the analytical certificate and the batch number indicated on them comparing it to the one indicated on the products. He also took a sample for analysis (see section 5.2.8 below).

In 2010-2011, there were four consignments of rice products from China controlled at Constanta harbour. The analytical certificates were checked, but no samples were taken.

Conclusions

Clear written instructions have been put in place for the implementation of Decision 2011/884/EU and controls are carried out in accordance with these instructions. The recommendation of the 2009 mission report has been addressed.

5.2.7 Prioritisation of official controls

Legal Requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency, taking account of (a) identified risks; (b) the food business operators' past record as regards compliance; (c) the reliability of any own checks that have already been carried out; and (d) any information that might indicate non-compliance. Some of those criteria are also included in Chapter I of Commission Recommendation 2004/787/EC concerning the controls to ensure compliance with Regulation (EC) No 1830/2003.

Findings

Controls of GM food and feed are prioritised based on "Programme for Surveillance and Food Safety". The programme includes the frequency of sampling and inspections to be carried out at storehouses, food and feed processors each trimester.

In the case of GMO trials, cultivation of GM maize MON810 and GMO controls of seed, the controls are carried out based on the national legislation and thematic instruction issued by the MARD.

The number GM food and feed inspections has been reduced since 2011 at establishments where non-compliances had not been identified in the previous years.

Conclusions

GMO controls are generally prioritised in line with the EU legislation.

5.2.8 Sampling

Legal Requirements

Article 9 of Regulation (EC) No 1830/2003 requires that Member States carry out inspections and other controls measures, including sample checks and testing, to ensure compliance with this Regulation.

Commission Recommendation 2004/787/EC establishes technical guidance for sampling and

detection of genetically modified organisms and material produced from genetically modified organisms. Article 11 of Regulation (EC) No 882/2004 establishes requirements for sampling and analysis.

Regulation (EC) No 152/2009 lays down the methods of sampling and analysis for the official control of feed.

Regulation (EU) No 619/2011 harmonises sampling and testing controls in the EU regarding, among other cases, GM feed materials, which are authorised for commercialisation in a non-EU country, have a valid application for authorisation and the authorisation procedure has been pending for more than 3 months, or have an expired authorisation under Regulation (EC) No 1829/2003. A 'Minimum Required Performance Limit' for GM detection in the laboratory is set at 0.1%.

Findings

The audit team observed a demonstration of sampling of non-GM maize seed at a seed processor performed by an inspector of LCCSMS in Ialomita county. An aggregate sample of approx. 10kg was taken in accordance with the ISTA rules. The CA stated that the sample is used for different seed tests. Two samples of 1kg are produced from the aggregate sample for GMO analysis. The CA further stated that the seed processor visited uses an automated sampler, which is checked annually by the LCCSMS for accuracy.

The audit team also observed a demonstration of sampling of two soya bean products at a food processor in Dambovita county. The lot of one product consisted of three 20kg bags and the lot of the other product consisted of 44 15kg bags. The inspector explained that, based on the Guidelines on sampling and analysis of GMOs (approved by Order No. 94/2006 of NSVFSA), all three bags for the one product are selected and ten for the other. Then, three incremental samples are taken from each of the selected bags. The incremental samples are mixed and divided into four equal parts with a divider. After the division, two parts are kept out of which, two aggregate samples of 2.5-5kg each are produced. One is for the laboratory and the other for the operator. The samples are put in bags, sealed and labelled. A standardised sampling form is completed in triplicates. One copy is handed over to the business operator together with the operator's sample. The latter can be analysed in an independent accredited laboratory in case of dispute. A standardised form for request of test addressed to the laboratory is also completed. The laboratory sample is delivered to the laboratory by the CSVFSD. The CA stated that the result of the analysis becomes available within a few days.

The audit team visited the Constanta harbour where the inspector explained how he had carried out the sampling of the latest rice product consignment from China, which consisted of a lot of 15.6t of rice noodles (1,300 boxes, each of 30 400g packages). He stated that 37 boxes were randomly selected. From each, a 400g package was taken out and of these, five packages were selected for the laboratory sample and five for the importer's sample.

Conclusions

Sampling was in general carried out in compliance with the EU legislation. However, for pre-packed rice products the laboratory sample was not prepared correctly from the incremental samples. Article 2 (2) (c) of Decision 2011/884/EU stipulates that the bulk sample is obtained by combining and mixing the increments.

5.2.9 Laboratory performance

Legal Requirements

Article 12 of Regulation (EC) No 882/2004 requires that competent authorities only designate laboratories that operate and are assessed and accredited in accordance with the standards EN ISO/IEC 17025 and EN ISO/IEC 17011. Article 33 requires Member States to designate National Reference Laboratories (NRL) for each Community reference laboratory, and specifies tasks for the

National Reference Laboratory.

Chapter V.2 of Recommendation 2004/787/EC lays down guidance for laboratories performing testing for GMOs to ensure compliance with Regulation (EC) No 1830/2003.

Findings

The 2009 mission report included two recommendations:

(Rec. 5) to *'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.*

(Rec 6) to *'ensure that laboratories performing official controls participate regularly in proficiency tests, as provided for by Commission Recommendation 2004/787/EC.*

Official controls of GM food and feed are performed by a network of eight public laboratories under the NSVFSA. The Institute for Diagnosis and Animal Health (IDAH) was designated as NRL for GM food and feed and it has the responsibility to coordinate and assist seven county laboratories (Calarasi, Constanta, Iasi, Satu-Mare, Salaj, Suceava, Tulcea). The county laboratories are accredited by the national accreditation body RENAR for the qualitative analysis of MON40-3-2 in soya bean products (six county laboratories) or for GM maize and soya (one laboratory). They are in charge of performing qualitative analysis. In the case of positive results, the sample is transferred to the NRL for further investigations.

The Institute of Food Bioresources (IFB), under MARD, is responsible for GMO analysis of official seed samples.

The audit team visited the IDAH and the IFB laboratories. Both laboratories were visited by the 2009 mission.

National Reference Laboratory for GM seed (IFB)

The IFB is a public institute designated by MARD to conduct analysis of GMOs in seed samples based on the control programme for GMO in seeds. It is a member of the European Network of GMO laboratories (ENGL).

The laboratory is accredited to ISO 17025 by RENAR, the last audit took place in 2010 and the accreditation is valid until 2014. The scope of accreditation covers the quantification of CP4-EPSPS and CryIAb proteins through ELISA tests for the quantification respectively of the soya bean event MON40-3-2 and the maize MON810. The ELISA methodology used in the laboratory does not allow identifying specific GM transformation events or screening for detecting the possible presence of other GM events.

IFB set up a molecular biology laboratory, which uses PCR techniques and is accredited for the quantitative detection of soya bean event MON40-3-2. However, this laboratory analyses only private samples.

Six staff are involved in GMO analysis of official samples. They have a third level education and are adequately trained to perform their job.

Since the 2009 GMO mission, the laboratory moved into new facilities without any significant changes in the overall organisation.

The laboratory analysed 74 soya bean and 39 maize samples in 2010. No samples were analysed in 2011. Samples of the 2012 harvest are planned to be analysed.

The last proficiency test the laboratory participated in was in 2010, with satisfactory results.

The laboratory does not estimate measurement uncertainty, it reports only the standard deviation of the replicate measurements without applying any interval of confidence.

National Reference Laboratory for GM food and feed (IDAH)

The Molecular Biology Laboratory of IDAH is designated by NSVFSA as the NRL for GM food and feed and it is an ENGL member. The laboratory carries out analysis of official and private samples. It is accredited by RENAR in accordance with ISO 17025 and the scope of the accreditation covers GMO analysis.

In its function as NRL, the laboratory collaborates with the EURL-GMFF for the collaborative validation studies and attends their meetings; it also assists the CA to prepare the national control plans. It coordinates the activity of the county laboratories by dissemination of analytical protocols and organising training. The laboratory organises proficiency tests (PT) for the county laboratories in order to monitor their activity, in particular there have been three PT rounds organised in 2010-2011 for qualitative detection of MON40-3-2 soya bean and detection of p35S and tNOS elements.

The laboratory participated in one PT organised by the Food Analysis Performance Assessment Scheme in 2009 and in every comparative study organised by the EURL-GMFF since 2010, with satisfactory results.

There are two veterinarians, two biochemists, two technicians involved in GMO analysis who all are adequately and regularly trained to perform their job.

The laboratory is accredited for the identification of p35S and tNOS, the detection and quantification of MON40-3-2 soya bean and maize GM events MON810, NK603, GA21. Methods for detection of maize events Bt11, MON863, Bt176 and T25 are validated but not accredited while detection of maize events TC1507, MIR604, MON88017 and Starlink are performed using non-validated methods. Detection and quantification of all events are performed using commercially available kits. Other methods for detection of other events are implemented as necessary (e.g. EURL-GMFF comparative test for GT73/RT73 rapeseed).

As a general strategy the NRL is going to substitute kits with methods listed in the Compendium of methods for detection of GMOs published by the EURL-GMFF.

Regarding the screening step the laboratory has started implementing a multi-target approach with the aim to detect both authorised and un-authorised GM events, the accreditation is scheduled for the 2013.

For accredited methods the laboratory adopted appropriate procedures in order to ensure the appropriate number of replicates and controls; analytical flow include the possible detection of co-purified PCR inhibitors.

Methods of analysis for detection and quantification of GM events falling under Regulation (EU) No 619/2011 are not implemented, only the analysis of Bt176 event is in place.

An analytical procedure for the control of rice consignment from China, under Implementing Decision 2011/884/EU and the EURL-GMFF guidance document, is properly implemented including sample preparation, targeted screening elements, use of appropriate controls and consequently interpretation of results.

Report of analysis contain all relevant information including measurement uncertainty with a level of confidence of 95%.

Conclusions

All laboratories have now been accredited according to EN ISO/IEC 17025 and recommendation No 5 made in the 2009 mission report has been addressed.

The IFB laboratory does not participate in proficiency test in order to verify and maintain competence, which is not in line with Commission Recommendation 2004/787/EC. Therefore, recommendation No 6 has only been partially addressed.

Neither laboratories adopt methods approved by the EU-RL, which is not in line with Recommendation 2004/787/EC.

The IFB laboratory does not estimate measurement uncertainty properly and can therefore not report appropriately as required by EN ISO/IEC 17025.

Analytical methods provided for in Decision 2011/884/EU regarding rice products from China are properly implemented.

Test methods for the purpose of Regulation (EU) No 619/2011 are not implemented.

5.2.10 Procedures for performance and reporting of control activities

Legal Requirements

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Findings

Procedures and standardised forms are in place regarding each area within the scope of the audit.

They include guidelines to carry out inspection and a protocol for sampling of food and feed issued by NSVFSA. An annual thematic instruction is issued by MARD addressed to the CDAs, which includes GMO related controls. The TISQ operates based on a centrally prepared annual multiplication plan.

Control results are systematically reported by the county authorities to the CCA.

Conclusions

Documented procedures are in place as required by EU legislation.

5.2.11 Co-operation between and within competent authorities

Legal Requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination between CAs.

Article 4(5) requires that, when, within a CA, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

Findings

A Protocol of Cooperation (no. 3090/12.07.2006) was signed between NSVFSA, the National Authority for Consumers Protection (NACP), MARD and NEG regarding collaboration in the field of official control for GM food, feed and seeds, which includes the division of responsibilities in the entire GM food, feed and seed chain.

Controls of GMO trials are carried out by both the CDA and NEG at county level. They often perform joint inspections after sowing and harvest. They both verify that the conditions of the GMO trial consent are met.

GMO controls of seed are carried out by both the CDA and TISQ at county level.

Evidence was provided that co-operation between the CDA and NEG, NEPA and MARD, CSVFSD and CDA exists.

Conclusions

Procedures are in place to enable co-ordination and co-operation between and within competent authorities in line with Regulation (EC) No 882/2004. However, there appears to be some duplication of effort in the controls of GMO trial and cultivation including seed.

5.2.12 Enforcement measures

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA, which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

Article 55 of the same Regulation states that MSs shall lay down the rules on sanctions applicable to infringements of feed and food law and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Article 4(5) of Directive 2001/18/EC requires, in the event of a release of GMO(s) or placing on the market as or in products for which no authorisation was given, that the MS concerned takes the necessary measures to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform its public, the Commission and other MSs.

Article 33 of the same Directive requires MSs to determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive.

Articles 45 of Regulation (EC) No 1829/2003 and 11 of Regulation (EC) No 1830/2003 state that MSs shall lay down the rules on penalties applicable to infringements of those Regulations and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings

NSVFSA can impose sanctions under Government Decision No 173/2006 in the case of non-compliance with Regulations No 1829/2003 and No 1830/2003.

Non-GM seed lots containing GMOs above the threshold set in the national legislation are not allowed to be marketed as seed under Order No. 232/2010 of MARD.

Non-GM soya bean crops were tested for GMO presence as a consequence of complaints received by CDA in Botoşani. A team of experts from NEG and CDA inspected two growers and used side-flow Trait√RUR Grain strip tests to check the presence of GMO. The test results were negative.

Non-GM soya bean seed lots were sampled in Neamt county in 2009. GMO presence of over 2.5% was detected in two out of the 74 tested lots. The seed was redirected and used as feed. As a consequence, the soya bean seed of the company involved was also tested in 2010 and 2011. No MON40-3-2 soya was detected.

Sampling of non-labelled soya was carried out by Ialomita CSVFSD in October 2010. The result of analysis showed GMO presence of MON40-3-2 soya above 0.9%. The NEG was informed and followed up on the non-compliance. As a consequence, a 10,000 RON (approx. € 2,500) sanction was imposed and the CSVFSD was informed of the action taken.

Conclusions

There is a system in place to ensure that enforcement measures are taken if necessary in order to ensure compliance with the EU legislation.

5.2.13 Verification procedures and audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure that corrective action is taken when needed and to update documentation as appropriate.

Findings

The audit directorate of NSVFSA audited the directorate dealing with GM food and feed controls and IDAH in June 2012. The BIP Constanta was audited in March 2012. Audit reports were prepared including recommendations. The CA stated that every CSVFSD had carried out an internal audit in March 2012.

The authorities in Braila county stated that controls are carried out by MARD to verify whether inspections by TISQ and CDA are in compliance with the legislation. The latest control visit received by TISQ in Braila took place in September 2012.

Conclusions

Verification procedures are in place and generally audits are carried out as required by Regulation (EC) No 882/2004.

5.3 Rapid Alert System for Food and Feed

Legal Requirements

Article 50 of Regulation (EC) No 178/2002 requires Member States to immediately notify any information relating to the existence of a serious direct or indirect risk to human health deriving from food, to the Commission under the RASFF.

Regulation (EU) No 16/2011 establishes implementing measures for the Rapid alert System for food and feed.

Findings

The NSVSFA is the contact point for GMO RASFF notifications regarding food and feed. There has been one RASFF GMO notification issued by Romania since the last GMO mission in 2009. NSVFSA uses the RASFF system for communication with and between the CVSFSDs. Evidence was provided to the audit team that follow up actions are taken in response to relevant RASFF notifications.

Conclusions

The operation of the RASFF ensures that food safety risks are notified and follow-up on RASFF

notifications is taking place.

6 Overall Conclusions

Overall, there is a structured system of official controls for GMOs in place. Good progress has been made since the previous GMO mission in 2009 concerning the official control systems for food and feed. Appropriate controls are in place regarding GMO trials, GM maize MON810 cultivation, GM food, feed and seed. However, two recommendations regarding GMO threshold in seed have not been adequately adressed. Other shortcomings were found regarding the GMO laboratories.

7 Closing Meeting

A closing meeting was held on 20 September 2012 with representatives of the CCAs. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit. The representatives of the CA provided some corrections and clarifications.

8 Recommendations

The CAs in Romania should ensure that:

N°.	Recommendation
1.	Any detectable presence of GMO in seed is subject to labelling and traceability requirements of GMOs in line with Article 21 of Directive 2001/18/EC and Article 4 of Regulation (EC) No 1830/2003.
2.	The IFB laboratory regularly participates in proficiency tests in line with Commission Recommendation 2004/787/EC.
3.	GMO laboratories adopt methods approved by the EURL-GMFF in line with Recommendation 2004/787/EC.
4.	The IFB laboratory estimates measurement uncertainty and reports it as required by EN ISO/IEC 17025.
5.	Analytical methods for the purpose of Regulation (EU) No 619/2011 are implemented.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6306

The CCAs in Romania are requested to provide an action plan addressing all of the above recommendations. It should give details of the action taken and planned, including deadlines for their completion and it should be provided within 25 working days of receipt of this report.

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dir. 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
Reg. 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
Reg. 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
Reg. 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
Reg. 152/2009	OJ L 54, 26.2.2009, p. 1-130	Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed
Reg. 16/2011	OJ L 6, 11.1.2011, p. 7-10	Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed
Reg. 619/2011	OJ L 166, 25.6.2011, p. 9-15	Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired

Legal Reference	Official Journal	Title
Dec. 98/294/EC	OJ L 131, 5.5.1998, p. 32-33	98/294/EC: Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC
Dec. 2011/884/EU	OJ L 343, 23.12.2011, p. 140-148	2011/884/EU: Commission Implementing Decision of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC