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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

HUNGARY

FROM 27 NOVEMBER TO 05 DECEMBER 2012

IN ORDER TO EVALUATE THE OFFICIAL CONTROLS FOR 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 an audit carried out by the Food and Veterinary Office (FVO) in Hungary, from from 27 November to 5 December 2012, in order to evaluate the official controls for genetically modified organisms (GMOs), including their release into the environment.

The objective of the audit was to evaluate the control systems in place for food, feed and seed containing, consisting of, or produced from 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.

The report concludes that, overall, there is a comprehensive system of official controls in place for genetically modified organisms in food, feed and propagation material as well as for their environmental release. Minor shortcomings were identified in the implementation of controls, the threshold for adventitious or technically unavoidable presence of GMOs in food and feed and the performance of the official 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
BIP	Border Inspection Post
CA(s)	Competent Authority/ies
CGO(s)	County Government Office(s)
DFCSAH	Directorate for Food Chain Safety and Animal Health
DG SANCO	Directorate-General for Health and Consumers of the European Commission
DRDS	Department of Rural Development Strategy of the Ministry of Rural Development
EC	European Community
EN	European Standard
ENGL	European Network of GMO Laboratories
EU	European Union
EURL-GMFF	European Union Reference Laboratory for GM Food and Feed
FFSD	Food and Feed Safety Directorate
FVO	Food and Veterinary Office
GeMMA	Genetically Modified Material Analysis Scheme
GM	Genetically modified
GMO(s)	Genetically Modified Organism(s)
ISO	International Organisation for Standardisation
ISTA	International Seed Testing Association
LOD	Limit of Detection
MON810	GM maize authorised for placing on the market on the basis of Commission Decision 98/294/EC
MRD	Ministry of Rural Development
NFCSO	National Food Chain Safety Office
NRL	National Reference Laboratory
PCR	Polymerase Chain Reaction
RASFF	Rapid Alert System for Food and Feed (http://ec.europa.eu/food/food/rapidalert/index_en.htm)
SNIF	Summary Notification Information Format

1 Introduction

This audit took place in Hungary from 27 November to 5 December 2012 and was undertaken as part of the Food and Veterinary Office's (FVO) planned audit programme.

The FVO team consisted of three auditors from the FVO and one expert from a European Union (EU) Member State. Representatives from the competent authorities (CAs) accompanied the FVO team for the duration of the audit.

An opening meeting was held on 27 November 2012 in Budapest with the CAs, during which, the objectives, scope and itinerary for the audit were confirmed, and the CAs provided a description of the control systems for genetically modified organisms (GMOs).

2 Objectives and scope

The objective of the audit was to evaluate the control systems in place for food, feed and seed containing, consisting of, or produced from 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.

The scope of the audit included the designation of CAs responsible for the official controls of GMOs, the organisation of the controls, implementation of checks, 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	2	Ministry of Rural Development National Food Chain Safety Office (NFCSO)
Regional	2	Csongrad and Gyor County Government Offices
Local	1	Pest County
Laboratories		
Official	2	NFCSO Central Seed Testing Laboratory NFCSO National Reference Laboratory, Food and Feed Safety Directorate
Inspection visits		
GMO trial	2	(Meeting with) Central Environmental and Food Science Research Institute
Feed processor	1	Gyor County
Seed establishment	1	Pest County

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 second audit carried out by the FVO to Hungary in order to evaluate the official controls relating to GMOs. The previous audit was carried out from 22 to 26 May 2006 in order to evaluate the official control systems for food, feed and seed consisting of or produced from genetically modified organisms (Ref: DG(SANCO)8109/2006). The reports of FVO audits are available on their website: http://ec.europa.eu/food/fvo/index_en.cfm.

The current audit was the tenth of a new series carried out in Member States that include an evaluation of the official controls for the deliberate release of GMOs for trial and cultivation, in addition to those for GMOs in food, feed and propagating material.

All data in this report was provided by the CAs unless stated otherwise.

4.2 Country profile

The FVO publishes country profiles for all EU Member States, which describe the control systems for food and feed safety, animal health, animal welfare and plant health and also provide an overview on the state of play of recommendations from previous FVO missions. Country profiles are available at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm

4.3 Authorised GM products

Details of those GMO products that have been authorised for use in feed and food and for cultivation in the EU, can be found in the biotechnology section of DG SANCO's website: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

4.4 Production and trade data

There is no cultivation of GMOs in Hungary.

The National Food Chain Safety Office (NFCSO - see section 5.2.1 below) stated that no information on the import of GM food products into Hungary is available, as the collection of such information is not obligatory. But by reason of experience of official controls, no GM food products are imported into Hungary.

There is no import of rice products originating in China into Hungary.

GM feed products are authorised for use in Hungary and GM feed products, mainly soya beans and flour and meal of soya, are imported from Serbia via the Roszke border point and Ukraine via the Eperjeske border point.

The data collected on entry does not enable distinction between non-GMO and GMO materials. In 2010, 410 tonnes of flour and meal of soya were imported from Serbia and 10,096 tonnes of soya beans were imported from Serbia and Ukraine. In 2011, 146 tonnes of flour and meal of soya were imported from Serbia and 898 tonnes of soya beans were imported from Serbia and Ukraine. In addition, 2,600 tonnes of oil seed rape and 640 tonnes of maize were imported in 2011 from Ukraine.

5 Findings And Conclusions

5.1 Relevant national legislation

Legal requirements

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

Findings

National legislation relating to GMOs has been in place since 1998.

Joint Decree 111/2003 (XI. 5.) of the Ministry of Agriculture and Rural Development, the Ministry of Economy and Transport, the Ministry of Health, Social and Family Matters and the Ministry of Environment and Water defines gene technological modification and processes, its products as well as on authorities which are entitled to supervise such activity. The definitions are consistent with those in relevant EU legislation.

The Fundamental Law of Hungary, which was adopted on 1 January 2012, establishes, in Article XX, the main objective of the Hungarian strategy on GMOs:

(1) Every person shall have the right to physical and mental health.

(2) Hungary shall promote the exercise of the right set out in Paragraph (1) by ensuring that its agriculture remains free from any GMO, by providing access to healthy food and drinking water, by managing industrial safety and healthcare, by supporting sports and regular physical exercise, and by ensuring environmental protection.

GM trials:

- Hungarian Act on gene technological activities (Act No. XXVII of 1998)

This Act applies to the genetic modification of natural organisms, to contained use, to deliberate release into the environment, to placing on the market, to import, export and transportation of GMOs and products thereof. The Act came into force in January 1999 and was amended in 2002 to transpose Directive 2001/18/EC, and again in 2006 in order to adopt rules for the co-existence of GM crops with conventional and organic farming.

- Decree 82/2003. (VII. 16.) of the Ministry of Agriculture and Rural Development on the registering and supply of data regarding the gene technological activity.

This Decree determines which documents and information shall be enclosed to the notification for the authorisation of the gene technological activity.

- Decree 128/2003. (XII. 19.) of the Ministry of Agriculture and Rural Development on the organisation and the activity of the Gene Technological Advisory Committee.

The Act on Gene Technological Activity establishes a scientific advisory body in order to support the decision process on the authorisation of GMOs. The Decree establishes rules on the operation of the Gene Technology Board (former name: Gene Technological Advisory Committee).

- Government Decree 148/2003. (IX. 22.) on penalties relating to gene technological activities.

This Decree establishes penalties for non-compliance relating to gene technological activities. The penalty ranges from 300 000 HUF to 1 million HUF at the first occasion, from 1 million HUF to 10

million HUF if repeated.

The main elements of the Act are detailed in section 5.2.3.1. below.

- Government Decree Nr. 132/2004. (IV. 29.) on the authorisation procedure for gene technological activity as well as on liaison with the European Commission

This Decree establishes the authorisation process for gene technological activity and designates the former Ministry of Environment and Water, which is responsible for the liaison with the European Commission in gene technological issues. The Decree includes detailed rules regarding the authorisation of contained use of GM micro-organisms, the deliberate release of GMOs into the environment – including placing on the market – as well as the authorisation process for GM food and feed.

- Decree 142/2004. (IX. 30.) of the Ministry of Agriculture and Rural Development and the Ministry of Economy and Transport on conditions of gene technological activity in the field of agriculture and industry

This Decree establishes the conditions of gene technological modification including the obligations of the notifier as well as rules on the labelling and transportation of GMOs and the list of accredited national laboratories for determining the gene technological origin. Annex 1 to the Decree includes the methods and principles of the environmental risk assessment. Annex 2 to the Decree provides guideline on how to carry out post market monitoring of GMOs and products thereof.

- Decree 14/2008. (IV. 17.) of the Ministry of Health on the designation of the competent authority dealing with gene technological activities related to human-health, production of human medicines, and chemicals in contact with the human body; and designation of the special authority contributing to the authorisation procedures relating to agricultural, food production and other industrial uses of gene technology.

This Decree designates the National Institute of Quality and Organisational Development of Healthcare and Medicines as competent authority, in case of gene technological activities related to human health, to the production of human pharmaceutical products and to cosmetics in direct contact with the human body. The Decree also designates the National Institute of Quality and Organisational Development of Healthcare and Medicines as a special/technical authority which gives an expert opinion in a human health point of view in case of in the authorisation process of gene technological activities in the agricultural and food sector (including process additives used in food production) and in contained use, as well as in the case of other industrial gene technological activities.

<u>GM cultivation</u>

- Decree 86/2006. (XII. 23.) of the Ministry of Agriculture and Rural Development on coexistence measures on the cultivation of genetically modified, conventional and organic plants

This Decree describes establishes rules for the cultivation of GMOs. Producers who wish to produce GM plants or a person employed by such person must attend training on co-existence. The exam certificate must be enclosed with the application for a licence to produce such plants. Annex 3 lists the sample documents for the declaration and consent necessary to issue a licence to produce plants. The consent and declaration must be completed by the land-owner and the actual user of the land. The table in Annex 2 specifies the minimum size of buffer zone, which is 400 m in case of maize, and other conditions that must be complied with. Producers must maintain a record of all activities carried out in the field as specified in Annex 5 to monitor the compliance with the

provisions for the production of GM crops.

Conclusions

National legislation, necessary for the implementation of EU legislation relevant to the scope of this audit, is in place.

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 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

In Hungary there has been no delegation of official controls relating to GMOs.

The Ministry of Rural Development (MRD) includes two Departments that have responsibilities relating to GMOs:

- Department of Food Chain Control is responsible for the policy for the whole food chain, for the provision of legislation on food and feed safety, animal health, animal welfare and plant health, and for the international relations except for areas where specific legislation is applied.
- The CAs regarding the field trials of GMOs were changed in the course of 2010, because the two previously responsible Ministries – Ministry of Agriculture and Rural Development and the Ministry of Environment and Water were merged. The Department of Rural Development Strategy (DRDS) of MRD is responsible for authorising the environmental release of GMOs for trial or cultivation.

Since 1 January 2011, all CAs involved in official controls related to the food chain, function as part of the 19 County Government Offices (CGO). At local level, the administrations consist of 95 district offices; staff are responsible for decision making on first level, collection of samples, inspection of establishments and retailers.

Administratively, CGOs are under the direction of the Ministry of Public Administration and Justice; however each CGO Directorate operates under the direction of their respective CA.

Governmental Decree 22/2012, which entered into force on 15 March 2012, created the National Food Chain Safety Office (NFCSO) under the MRD, which has taken over the responsibilities of the former Central Agricultural Office.

The NFCSO is the central competent authority responsible for implementation of official controls in relation to food safety and food quality requirements. It includes four directorates that are involved in the official controls for GMOs:

- Directorate for Plant Protection, Soil Conservation and Agri-environment is responsible for co-ordination of the work of the primary plant product inspectors. The Directorate issues guidelines for sampling and controlling and organises trainings for the inspectors.
- The Food and Feed Safety Directorate (FFSD) has overall operational responsibility for

establishing the control plans for GMOs in food and feed. FFSD is responsible for the implementation of administration and controls, co-ordinates and supervises the official controls performed by the CGO Directorates for Food Chain Safety and Animal Health (DFCSAH).

The Department for the Supervision of Feed Production and Distribution of the FFSD is responsible for the central planning, coordination and supervision of feed businesses, including their compliance with GM feed requirements.

- Plant Production and Horticultural Directorate is responsible for the certification of seed and plant reproductive material and their official control. Its laboratory, the Central Seed Testing Laboratory is responsible for testing of seed lots for GM contamination (see section 5.2.9 below).

  The Directorate has been designated as the CA for field trials. Their power is to carry out official control as well as to make a first level decision regarding posing gene technological penalties.

  The CGO Directorates of Plant Protection and Soil Conservation are responsible for carrying out inspections and checks at local level.

- Directorate for Food Safety and Risk assessment which was formerly the Hungarian Food Safety Office is now part of the NFCSO. The Directorate's responsibilities include the operation of scientific committees and acting as the contact point for RASFF and European Food Safety Agency. The Directorate contributed to the development of the guideline for sampling of GMOs in food.

Conclusions

The Competent Authorities within the scope of this audit have been designated and their responsibilities have been clearly defined.

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

The NFCSO informed the FVO team that the staff carrying out official controls related to GMOs are required to have at least a university level degree in a relevant subject.

No specific training on GMOs has been provided to staff performing controls, except for those responsible for sampling feed. The DRDS informed the FVO team that there has been no specific training of the current staff because of the ongoing changes to the organisation of the department.

The NFCSO stated that it had access to a sufficient number of qualified staff. The FVO team did not identify any cases of facilities or equipment for performing controls being inadequate during their site visits.

Conclusions

The CA has access to suitably trained and qualified staff and adequate facilities to perform controls

in line with EU legislation.

5.2.3 Controls of the deliberate release of GMOs

Legal Requirements

GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively of Directive 2001/18/EC.

Article 4(1) of the Directive requires Member States 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. Article 4(3) requires Member States 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 Member States to ensure that the CA organises inspections and other control measures as appropriate to ensure compliance with this Directive.

Article 31(3) requires Member States 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 of the same Directive 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 Member States shall carry out.

Findings

The DRDS provided detailed information on the authorisation procedures for the environmental release of GMOs for trial in Hungary. The FVO team noted that this is consistent with that established by Directive 2001/18/EC. In summary:

Applications for release must be submitted to the DRDS, together with a sample of the propagation material to be used in the trial. The DRDS seeks the opinion of Gene Technology Board, which acts as an independent biotechnology committee, including members from the Hungarian Academy of Sciences, competent ministries and non-governmental organisations. The National Institute of Quality and Organisational Development of Healthcare and Medicines acts as a special technical authority for applications where there may be implications for human health.

The DRDS informed the FVO team that a risk assessment is necessitated in each case in view of the new ecological region – the Pannonian Plain biogeographic region, created following Hungary and adjacent countries accession to the EU.

The authorisations for release include conditions intended to minimise risk to the environment and human health. For trials involving GM maize, a minimum genetic protection/isolation zone of 500m is required. The site is required to have secure fencing. All plant residues must be destroyed at the end of the trial, either by ploughing or incineration. The trial sites are controlled by the NFCSO at key risk periods (see section 5.2.3.2 below).

A summary of each application ('SNIF') is published on the MRD website. The draft consent is published in the official journal of the MRD, for public consultation.

Authorisations are valid for 5 years, subject to annual review, based on an environmental impact report, which consent holders are obliged to submit annually for each trial. The review is carried out by the DRDS and the Gene Technology Board.

The final consents are published made available on the following website: http://biosafety.abc.hu/biosafe_eng.html The location of the trials, including the address is made available to the public on the MRD website.

The DRDS informed the FVO team that there has been a continuous decrease in the number and area of GMO field trials in recent years:

Six consents were granted in 2010, all were for one applicant, and terminated before the end of the period of consent. The trials involved the following GM maize hybrids: 1507; 1507×59122; 1507×NK603; 59122; 59122×NK603; 59122×1507×NK603 in a total area of 44 886 m^2, consisting of GM: 21 600 m^2, isogenic plots: 14 400 m^2, and isogenic pollen trap maize - 4 170 m^2. The release was carried out in Pest county.

In 2011, three consents were issued; two were terminated before the end of the consent period and one was suspended by the consent holder.

The two terminated trials involved MON 810 and E4497.59.22 (DAS-59122) GM maize, notified by Hungarian Academy of Sciences, Plant Protection Institute in Nagykovácsi. The total area of the trial was 153 m^2 (MON810) and 1 015 m^2 (DAS-59122).

The suspended trial involved the *in vivo* back-cross transformation of Martonvásár maize lines using NK603 Round up Ready GM maize event. The total area of the trial was 4,500 m^2 with a 1 500 m^2 buffer zone.

In 2012, two consents were issued for trials involving two GM maize varieties MON 810 and E4497.59.22 (DAS-59122) at one location. The maximum total area permitted is 5 000 m^2.

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 10 specifies the reporting by notifiers on releases to the CA after the completion of the GMO release.

Article 6(9) of the same Directive requires Member States 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.

Findings

GMO field trials are subject to supervision by the relevant Directorate of Plant Production and Horticulture.

The FVO team met with the persons responsible for the two field trials authorised in 2012. Evidence was provided that the conditions specified in the consent, in particular relating to size of plots, their isolation and security was in line with the consent.

Inspections had been carried out by the Directorate of Plant Production and Horticulture on 7 June

to confirm that the trial complied with the planting plan and that security measures were in place. A second inspection was carried out on 16 November, in order to ensure the correct destruction of plant material.

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 Member States 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

The cultivation of GMOs in Hungary is prohibited.

A statement was issued by the Minister of Agriculture and Rural Development on 20th January 2005 prohibiting the production, use, marketing and import of sowing seeds of the inbred lines and hybrids deriving from maize line MON 810 in Hungary/to Hungary. The ban covers also the successor plants produced by cross-breeding with any traditionally cross-bred maize varieties.

The prohibition does not apply to the use of maize containing the gene construction MON 810 in the food industry and in feed, as well as to its transit shipment through the area of Hungary without repacking and further treatment if it is guaranteed that this maize may not get out into the environment.

The CA issued two Decisions in 2010 (ref: XXI/442/3/2010. and XXI/442/4/2010) pursuant to Article 23 of Directive 2001/18/EC and Article 34 of Regulation 1829/2003/EC, which prohibited the cultivation, placing on the market and use of, including for industrial purposes and feed, of 'Amflora' GM potato.

MRD stated that controls are carried out in order to ensure compliance with this prohibition, including the control of seed and propagation material. These controls and the action taken in case of GM contamination is detailed in section 5.2.4. below. No contamination has been confirmed in maize crops in Hungary. In the case of contamination identified in seed after sowing, no samples are taken from the growing crops.

Conclusions

A system for the authorisation of the deliberate release of GMOs for trial purposes is in place and is in line with EU legislation.

Conditions are included in each consent intended to ensure that any 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. These are subject to supervision at appropriate times, in line with EU legislation.

Official controls are in place to ensure that GMO crops are not cultivated in Hungary.

5.2.4 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

GM food and feed are permitted to be marketed in Hungary.

Controls for GMOs in food and feed are carried out by the Food Chain Control Units at Regional level, based on a plan developed centrally by the NFCSO Food and Feed Safety Directorate. focussing on the hygiene rules.

The sampling plans include the specific numbers of samples that must be taken on a monthly basis for each type of product being targeted. In Csongrad County, which was visited by the FVO team, there was a target of 5 samples; 1 in maize, 2 from American rice and 2 from Chinese rice. If the target cannot be fulfilled, it is carried over to the following month, or are allocated to another CGO.

The NFCSO informed the FVO team that samples of food and feed are taken on the market; no food samples have been taken at border inspection posts and the last feed sample collected at a border inspection post was in 2008. The Food and Feed Safety Directorate stated that a BIP sampling plan for feed was being established at the time of the audit.

Samples are sent to the National Reference Laboratory for Food and Feed in Budapest for analysis. The analytical certificate is sent to the inspector who took the sample, who is responsible for interpreting the results, including confirming whether any GM events that are identified are authorised in the EU. Although a guideline has been issued to assist inspectors in interpreting the results, this does not specify how to decide whether any GM events that are identified are authorised or not. The inspectors met by the FVO team stated that they checked against the list of authorised events published on the DG SANCO website.

The CGO inspectors are required to investigate any unlabelled GM presence identified. The NFCSO has adopted a threshold of 1.35% for adventitious or technically unavoidable presence of GMOs. This is based on the limit of 0.9% contained in EU legislation, with a further 0.45% for analytical uncertainty.

<u>Food</u>

As detailed in section 4.4 above, no GM food products are imported into Hungary. The NFCSO

reported that in 2010, 356 samples of food stuffs not labelled as containing GMO, excluding rice and rice products, were taken from the market for GMO analysis. GMOs (Roundup ready soya) were present in 29% of samples. In 2011, 354 samples were taken, 18% of which were confirmed to contain GMO (Roundup Ready Soya and in one case, MON810). The level of contamination was reported to be below 1.35%; no action was required.

The Food Chain Control Unit in Csongrad County provided details of the investigation carried out following laboratory confirmation of GMOs at a level of 0.71% in porcine pate (canned meat food). The inspector had assessed information provided by the processor and supplier that indicated that measures had been taken at each stage of the supply chain to exclude the presence of GMOs. The GM presence was subsequently determined to be adventitious. The inspector stated that the headquarters had required that the product be labelled as containing GMOs or be withdrawn from the market. However the inspector stated that it was not known what action, if any, was taken; no evidence was found that the product remained on the market, but no confirmation of the withdrawal or labelling had been requested. The inspector confirmed that there are no clear guidelines for the action to be taken in such cases.

Feed

The NFCSO reported that in 2010, 81 samples were taken of feed stuffs not labelled as containing GMO, from processors and packers. 65% of samples were found to contain GMOs, at a level of less than 1.35%. In 2011, 48 samples were taken; 47% were found to contain GMOs, at a level of less than 1.35%. No action was required as all GMOs identified are authorised for use in feed.

Conclusions

Inspections, sampling and other controls are carried out to ensure compliance with the EU requirements for GMOs in food and feed. In the event that GMOs are found in food or feed not labelled as containing GMOs, an investigation to determine whether the presence of adventitious or technically unavoidable is carried out as required, however the threshold of 1.35% exceeds that established by Articles 12(2) and 24(2) of Regulation 1829/2003.

5.2.5 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 Member States including documentary checks and sampling.

Findings

The NFCSO stated that there are no imports of Chinese rice or rice products into Hungary. Samples have been taken of American and Chinese rice and rice products at retail level.

Ten samples of rice were analysed in 2010 and further 29 in 2011. None of these were of Chinese rice or rice products. No GMOs were found.

The NRL for Food and Feed tested 37 samples of rice and rice products in 2012 until the date of the audit. Eight of the samples were of Chinese rice products on the market. All samples tested negative for GMO.

Conclusions

There are no imports of Chinese rice products into Hungary. Market controls are carried out to ensure compliance with the conditions of Decision 2011/884/EU.

5.2.6 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 Member States.

Findings

The NFCSO stated that GM seed, or seed contaminated with GMOs, may not be marketed or supplied for public cultivation in Hungary.

The CGO Directorates for Plant Protection, Soil Conservation and Agri-Environment perform field inspections and sampling of seed as part of the certification process and for ISTA certification. They are also responsible for performing controls to ensure compliance with the prohibition on GMOs. Samples for testing for GMOs may be taken from seed on the market, during packaging or at time of planting.

The NFCSO informed the FVO team that in 2010, samples were taken from 41 lots of maize seed to test for the presence of GMO. Four lots, all originating in South America, were found to be contaminated with GMO.

As a result of these findings, an intensive sampling programme for GMOs was initiated; a further 535 seed lots were sampled by 31 August 2011. Fifteen of these samples (10 maize and 5 soya) were found to contain GMO. The seed involved originated in Chile, Romania, Slovenia and Canada. The contaminated lots and approximately 5 000ha of growing crops planted with seed from the same lots, were destroyed.

By the end of 2011, 740 samples had been tested, 3.78% of which were found to be contaminated. Each sample had less than 0.1% GMO.

The MRD stated that, in order to increase the likelihood of identifying GM contamination in seed prior to planting, the national legislation relating to the production and marketing of arable land seed (Decree 48/2004) was amended in April 2011. Decree 16/2011 introduced rules concerning the import of more than 2kg of seeds of maize, soya, oil seed rape and linseed into Hungary. These included:

- For seed produced in Hungary, the producer is responsible for ensuring that the seed is free from GM contamination.
- For seed produced outside of Hungary, advanced notification of import must be provided.
- An analytical certificate indicating freedom from GMO must be provided for each seed lot. For third country seeds, the analysis must be performed by an official laboratory in Hungary. For EU origin seeds, the analysis may be performed by an accredited laboratory.

Obligations for the owners of GM contaminated lots were also introduced, including immediate notification of contamination to the Plant Production and Horticultural Directorate, formerly the Central Agricultural Office, the isolation of contaminated seed and the traceability and notification of preceding and following parties in the seed supply chain.

The Decree also authorised the Plant Production and Horticultural Directorate to order the sequestration and destruction of contaminated seed lots and any plants cultivated from them. The destruction is carried out by the Directorate, at the owner's expense.

The Decree was amended in 2012 to introduce *inter alia* sampling based on a risk assessment i.e. 10% of non-Hungarian seed lots and 5% of Hungarian seed lots. The FVO team met with inspectors from the Directorate for Plant Protection, Soil Conservation and Agri-environment in one CGO, who explained that the non-Hungarian seed lots to be sampled are determined centrally by the Plant Protection and Horticulture Directorate. For Hungarian origin seed, every twentieth lot entered for certification in each region is sampled.

Importers of non-Hungarian seed lots are also permitted to provide a declaration of freedom from GMO ('Annex VI declaration') instead of providing an analytical certificate from an accredited laboratory.

The FVO team were informed by the Plant Protection and Horticulture Directorate that prior to September 2012, the advance notification of import and Annex VI declarations were either not systematically provided by importers, or were provided in formats that could not be used. The Annex VI declarations were said not to be provided due to the nature of the statement contained in that Annex. As a result, no reliable data is available regarding imports prior to September 2012. However, since that date, a total of 20,921 tonnes of seed entered Hungary.

The Plant Protection and Horticulture Directorate stated that samples should be taken within 5 days of notification, and that the results of the analysis should be available within 30 days. Marketing of seed lots is prohibited pending the results of the analysis. The results of the analysis performed by the Central Seed Testing Laboratory, and if appropriate the NFCSO's Food and Feed Directorate Laboratory are sent directly to the CGO inspector who took the sample. The action taken is determined by the inspector.

Table 2 below provides details of the number of lots, by origin, subject to analysis for presence of GMO in 2011 and 2012.

Table 2: Seed lots subjected to GMO testing 2011 - 2012

Country of origin:	**HU**		**EU**		**3rd countries**		**Origin not known**	
Year:	**total**	+	**total**	+	**total**	+	**total**	+
2011	106	0	213	8	264	20	157	0
2012 (until 30 June)	224	0	277	13	65	4	292	1
Total:	**330**	**0**	**490**	**21**	**329**	**24**	**449**	**1**

The GMO events detected in the sampled seed lots are detailed in table 3 below:

Table 3: GMO events detected by origin of seed in 2011 – 2012 (until 30 June)

GM event	2011			2012 (to 06/12)		
	HU	EU	3rd country	HU	EU	3rd country
Mon 810	0	7	4	0	7	1
NK 603	0	0	10	0	2	0
Mon 88017	0	0	0	0	2	1
GA 21 and Mon 810	0	0	0	0	1	0
Roundup Ready	0	0	5	0	0	0
TC 1507	0	0	0	0	0	0
Not identified	1	0	0	0	1	2

According to the Plant Protection and Horticulture Directorate, 34 of the 46 GMO contaminated seed lots (+) in table 2 above, were destroyed and 7 were moved, under official control, to other EU member states. The remaining five maize lots are held in the warehouse.

The Plant Protection and Horticulture Directorate informed the FVO team that CGOs carry out sampling at the time of sowing, in order to detect forgery. The samples are taken from opened bags and from the the seed drills. A total of 74 samples were taken for laboratory analysis in 2012.

The Plant Protection and Horticulture Directorate provided details of one case of GMO contamination that was identified as a result of a sample being taken at time of sowing. One sample was taken in Békés County of a hybrid maize seed lot, variety Montoni. The sample was taken 10 May, 2012. Traces of GMO were found in the original sample; the check sample taken for certification purposes was subsequently analysed and also found to contain GMO.

The company responsible for the seed provided a customer list and a list of places were the seed lot had been planted. The NFCSO formally notified the owners that the seed and therefore the planted crops were GMO contaminated. No samples were taken of the growing crop. The NFCSO stated that producers had the right to request that samples be taken from the crops, however this was not requested. The crops were required to be destroyed by harrowing or smashing the stems, but on request ensiling was also permitted till before the plants began flowering. The CGO inspectors carried out site visits to confirm that destruction had been carried out. The MRD provided compensation to affected producers at that time; the government intends to claim this from the provider of the seed lots.

Conclusions

Official controls are carried out, on a risk basis, to ensure that GMO presence in non-GMO seed is avoided. No threshold for adventitious or technically unavoidable presence is applied.

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

The NFCSO System Management and Supervision Directorate (SMSD) is responsible for the coordination of the establishment control plan and monitoring programs for food and feed. Controls are carried out based on a risk assessment, which includes the following factors:

- basic categorisation of the establishments:
  - general type of the establishment,
- various risk factors:
  - size, capacity, production data, sanctions etc.
- results of previous inspections:
  - results of the control check lists (considering hazards and exposure)
- time elapsed since last inspection

Based on these factors, each establishment is given a risk score, which is used to form a priority list. A threshold is set annually, based on the resources available; controls are carried out at all establishments above the threshold.

As described in section 5.2.4 above, 10% of non-Hungarian origin seed lots and 5% of Hungarian origin seed lots are sampled for GMO analysis, based on a risk assessment. The Plant Protection and Horticulture Directorate stated that the sampling activity for non Hungarian origin seed lots was targeted at the countries of origin of seed lots that had previously been found to be contaminated with GMO, including Romania, Argentina and Chile.

Conclusions

Official controls regarding GMOs are carried out regularly and are risk based in line with 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 FVO team did not observe any sampling of food or feed materials being carried out. The NFCSO stated that the sampling procedures for these commodities are identical to those detailed in the EU legislation listed above.

The FVO team observed sampling of seeds being carried out at a processing and packing facility. The sampling is carried out using an automatic sampler in line with relevant ISTA standards. Samples may be taken manually if the automatic sampler is not functioning. The collected samples were divided into equal 1kg samples, in line with standard ISTA procedures. Three samples are taken for certification purposes, one of which is retained by the processor, 1 sample that is submitted to the seeds laboratory for germination and variety checks and 1 sample that is retained by the seeds authority. A fourth 1 kg sample is taken if analysis for GMO is required. No check, or duplicate sample is taken for GM purposes.

Conclusions

Sampling for GMOs is carried out in line with EU legislation, and for seeds, in line with ISTA standards.

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

<u>The Central Seed Testing Laboratory</u>

The Central Seed Testing Laboratory is responsible for analysing samples of maize and oilseed rape seeds for the presence of GMO. The laboratory also performs various analyses (germination, purity, moisture content, post certification control) on a wide range of seed species and varieties for seed certification purposes.

The laboratory is accredited to ISO 17025:2005. The method for the qualitative detection of the CaMV 35S Promoter is the only screening method included in the scope of accreditation. It is not a member of the European Network of GMO Laboratories (ENGL).

The laboratory has participated in proficiency testing schemes, including those organised by ISTA. However, it last participated in a scheme covering qualitative tests to detect the presence of GM maize in 2009. The NFCSO confirmed that the laboratory is in the process of extending the scope of its accreditation to include the detection of the NOS terminator by conventional Polymerase Chain Reaction (PCR) and to the duplex detections by real-time PCR of 35S promoter/NOS terminator, 35S promoter/CaMV specific sequence, NOS terminator/*Agrobacterium tumefaciens* specific sequence, 34S promoter/FMV and plant species specific gene/IPC.

No National Reference Laboratory has been designated for seeds; if a sample is found to contain the 35S promoter, it is sent to the National Reference Laboratory for Food and Feed (see below) for further analysis.

The laboratory is organised in 4 sectors according with the type of analysis performed. GM seed testing is included in the "Genetic Purity" sector together with variety and species purity testing.

Measures to ensure the quality of results according to the rules for accreditation by both ISTA and ISO 17025, are in place. The FVO team noted that the laboratory has suitable facilities and equipment to perform GM analysis on seeds. Four areas, physically distant, and the relevant instruments (e.g. pipettes) are dedicated to specific tasks such as: grinding, DNA extraction, PCR master mix preparation and PCR and electrophoresis.

Minor shortcomings were identified relating to the grinding room (the absence of a door and dedicated protective covers for shoes and hair and laboratory coats); Master-mix preparation room (storage for DNA extracts); PCR and electrophoresis room (storage for master mix and primers). It was also noted that the limit of detection (LOD) had not been determined.

National Reference Laboratory for Food and Feed

The NFCSO's Food and Feed Directorate Laboratory was designated as the National Reference Laboratory (NRL) for food, and the Feed Investigation Reference Laboratory as the NRL for feed. Since April 2012, the Feed Investigation Reference Laboratory has no longer acted as the NRL; all of its duties in this regard are now carried out by the NFCSO's Food and Feed Directorate Laboratory.

Since 2011, the NFCSO has also been responsible for the analysis of all samples that the Central Seed Testing Laboratory found to be positive for 35S promoter during the screening test. The two laboratories showed to have a good cooperation.

The GMO NRL of the Food and Feed Directorate is a member of ENGL and has been accredited under ISO 17025 standard by the Hungarian accreditation body, since 2008. The last re-accreditation was in 2011.

The scope of accreditation is fixed and includes qualitative screening methods for CaMVp35S, T-nos and CaMV and quantitative methods for maize (MON810, Bt11, MON 863, TC 1507, GA21, T25, DAS-59122, MIR604, MON 88017), soya (Roundup Ready-soy, MON 89788, A2704-12), rice (LLRice62, LLRice601, Bt63), linseed (FP967) and potato (EH92-527-1) using real time PCR. These methods apply to GMO analyses in food, feed and seed.

Several other methods as the P34S screening method and events specific quantification methods for maize (Bt176, 3272, MON 89034, MON 87460) and oilseed rape (Topas 19/2, T45, Rf2, Rf1, Ms1, GT/RT 73, RF3, Ms8) are implemented but are not covered by the accreditation. The laboratory carries out analysis of Chinese rice products; the methods are also not within the scope of its accreditation.

The LOD has been established for all methods; for the un-authorised events in food and feed covered by Directive 619/2011 the LOD is 0.01%.

Method descriptions, working instructions, and worksheets (eg. set up of Master mix volumes) and laboratory work registration are included in a document control system. The technical records produced by the laboratory in each analytical step were traceable to the specific sample and it was possible for the FVO team to identify the personnel responsible for each specific activity as well as the batch number of the reagents used.

The areas where the different methodological steps of the analytical procedures are performed are physically separated to minimise the risk of cross contamination. Procedures for maintenance and control of key equipment are in place.

The laboratory applies measures to assure the quality of their results. They participate in proficiency testing schemes organised by the EURL-GMFF, GeMMA and ENGL. The laboratory uses Certified

Reference Materials from either Institute for Reference Materials and Measurements or American Oil Chemists' Society, when available.

Acceptance criteria for quality control data and procedures to be put in to practice when the data are outside of the pre-defined criteria are in place and follow the EURL-GMFF recommendations.

Test reports produced by the laboratory do not contain opinions or interpretation of results.

Conclusions

The laboratories involved in analysing official samples for GMO have been designated and are accredited in line with EU legislation. However, not all of the detection methods used by the NRL for food and feed are included in the scope of accreditation, which is not in line with Article 12 of Regulation 882/2004.

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

Staff performing controls at CGO level are provided with guidelines and technical information by the relevant CAs. As noted in section 5.2.4. there are no clear guidelines on the action to be taken to ensure withdrawal from the market or labelling of non-compliant food material.

Reports on controls are prepared by district and regional level staff and provided to the relevant CAs on a monthly basis.

Conclusions

Documented procedures for the performance of official controls are in place, however these do not include guidelines to ensure that corrective action is taken, in the case of non-compliant feed.

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) of the same Regulation 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

With the exception of the DRDS, the CAs involved in this audit are all part of the NFCSO. Regular meetings are held between the CAs, in particular regarding the annual planning.

The NFCSO stated that in the event that a non-compliance is found with implications for other Counties or nationally, the CGO service who initially identified the non-compliance is responsible for coordinating the follow-up by other CGOs. The NFCSO coordinates the response if more than

two CGOs are involved.

Conclusions

Procedures are in place that should ensure effective and efficient coordination and cooperation between competent authorities.

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 Member States 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 Member States.

Article 33 of the same Directive requires Member States 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 Member States 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

The NFCSO stated that national legislation on administrative actions provides a legal basis for action in the case of non-compliance and the range of measures which could be undertaken by officials.

As detailed in sections 5.2.4 and 5.2.6 above, action has been taken following findings of non-compliance in feed and seed.

In the case of non-compliant food detailed in 5.2.4, the CA did not have evidence that the corrective action required, labelling or withdrawal from the market, had been complied with.

In the case of non-compliant seed detailed in 5.2.6 above, the CA carried out site visits to confirm that the corrective action had been implemented.

Conclusions

Legislation is in place to ensure that action may be taken in the event of a non-compliance. In the case of seeds, action is taken to ensure that the situation is remedied. This was not done for non-compliance in food, which is not in line with Article 54 of Regulation 882/2004.

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

According to NFCSO verification of official controls is carried out regularly by each CA, at regional level. Internal supervision and audits are carried out by heads of each County Directorate, including the control of inspection reports and by carrying out joint inspections with inspectors. The frequency and the number of controls carried out is established by each CGO.

Conclusions

There is a system in place to audit and verify the effectiveness of official controls.

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 NFCSO Directorate for Food Safety and Risk Assessment acts as the contact point for RASFF.

Evidence was provided to the FVO team that action had been taken following receipt of a RASFF alert for feed found to contain GM linseed in another member state, to trace the contamination and to remove associated material from the market.

Conclusions

Hungary operates the RASFF system.

6 Overall Conclusions

There is a comprehensive system of official controls in place for genetically modified organisms in food, feed and propagation material as well as for their environmental release. Minor shortcomings were identified in the implementation of controls, the threshold for adventitious or technically unavoidable presence of GMOs in food and feed and the performance of the official laboratories.

7 Closing Meeting

A closing meeting was held on 5 December 2012 with representatives of the Competent Authorities, during which, the FVO team presented the main findings and preliminary conclusions of the audit. The representatives of the competent authorities provisionally accepted these following some corrections and clarifications.

8 Recommendations

The Competent Authorities in Hungary should ensure that:

N°.	Recommendation
1.	The threshold for the determination of adventitious or technically unavoidable presence of a genetically modified organism in food or feed does not exceed the level of 0.9% established by Articles 12(2) and 24(2) of Regulation 1829/2003.
2.	Laboratories involved in analyses of official samples apply methods which are included in their respective scopes of accreditation as required by Article 12 of Regulation (EC) No 882/2004.
3.	Appropriate action is taken by competent authorities, following identification of a non-compliance in food, to ensure that the operator remedies the situation, as required by Article 54 of Regulation (EC) No 882/2004.
4.	Documented procedures for inspectors include guidelines for appropriate corrective action, in the case of non-compliant food, in line with Article 8 of Regulation (EC) 882/2004.

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=2012-6303

The Central Competent Authority in Hungary is 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