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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SPAIN

FROM 21 TO 30 NOVEMBER 2011

IN ORDER TO ASSESS 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 Spain, carried out from 21 to 30 November 2011 and 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 mission related to GMOs (DG(SANCO)7632/2005), carried out in March 2005.

Overall, there is a clearly structured system of official controls for GMOs in place. However, shortcomings were found in the actual implementation of controls, in particular, the use of non-accredited laboratories and the absence of procedures specific to GMO related controls at regional level. Furthermore, the 'de minimis' threshold for adventitious and technically unavoidable presence of GM material in non GM seeds contravene the EU legislation, since such a presence below 0,5% is not subject to labelling and traceability requirements. Two out of the three outstanding recommendations of mission report DG(SANCO)/7632/2005 have been adequately addressed. One recommendation regarding laboratory accreditation is still to be addressed.

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
AC	Autonomous Community
AESAN	Spanish Food Safety and Nutrition Agency
Bt	*Bacillus thuringiensis*
CA(s)	Competent Authority/ies
CCA	Central Competent Authority/ies
CIOMG	Inter-ministerial Council on GMOs
CNA	*Centro National de Alimentación* – National food Centre
CNB	Spanish Commission on Biosafety
DG SANCO	Directorate-General for Health and Consumers of the European Commission
DNA	Deoxyribonucleic acid
EFSA	European Food Safety Authority
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
FAPAS	Food Analysis Performance Assessment Scheme
FVO	Food and Veterinary Office
GeMMA	Genetically Modified Material Analysis Scheme
GM	Genetically modified
GMO(s)	Genetically Modified Organism(s)
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
ISTA	International Seed Testing Association
LAA	*Laboratorio Arbitral Agroalimentario* – Agri-food Arbitration Laboratory
LSV	*Laboratorio de Sanitat Vegetal* – Plant Health Laboratory
MARM	Ministry of Environment, Rural and Marine Affairs
MON810	GM maize authorised for placing on the market by Commission Decision 98/294/EC
MS	Member State
MSPSeI	Ministry of Health, Social Policy and Equality
NRL	National Reference Laboratory

OEVV	Spanish Plant Variety Office
PCR	Polymerase Chain Reaction
PNCOCA	National Official Control Plan of the Food Chain
RASFF	Rapid Alert System for Food and Feed (http://ec.europa.eu/food/food/rapidalert/index_en.htm)
SGASCF	Sub-directorate General for Health Agreements and Border Controls
SGCRAA	Sub-directorate General for Conservation of Resources and for Animal Feed
SNIF	Summary Notification Information Format

1 Introduction

This audit took place in Spain from 21 to 30 November 2011. 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 21 November 2011 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

The objective of the audit was to evaluate 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 the action taken to address the shortcomings identified during the previous mission related to GMOs (DG(SANCO)7632/2005), carried out in March 2005.

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

Table 1: Audit visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	3	MSPSeI, AESAN, MARM, OEVV
Regional	2	Aragón and Catalonia
Import point	1	Tarragona
Laboratories		
Public	3	*LAA*, *Laboratory Semillas aragón, Laboratori de Sanitat Vegetal*
Inspection Visits		
Controls of GMO trial	3	Two GM maize sites in Aragon and one GM maize site Catalonia
Controls of GMO cultivation	2	One GM maize site MON810 in Aragon and Catalonia each

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 of the European Parliament and of the Council.

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 Mission series

This was the fourth 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 Spain dealing with GMOs was last carried out in 2005 (DG (SANCO)/7632/2005). 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 Spain, 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 missions. The country profile can be found at:

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

4.3 Authorised GMO products

The list of the GMO 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 is of particular relevance to this audit. This maize includes the cryIA(b) gene from *Bacillus thuringiensis* (Bt) subsp. *kurstaki,* which provides insect resistance, in particular against the European corn borer. The event was authorised for cultivation and use in food and feed, by Commission Decision 98/294/EC. The official controls system for the cultivation of this maize are covered in section 5.2.4.3 below.

4.4 Production and trade data

GM maize MON810 has been grown in Spain since 2003. Currently, there are 106 varieties containing GM maize MON810 registered in Spain. The cultivation area was 76,575 ha and 97,346 ha in 2010 and 2011, respectively. The CA stated that the recent increase of the production area of maize MON810 is due to the increase of the maize production as a whole.

The GM maize MON810 seed production was 605.7 and 476 ha in 2009 and 2010, respectively.

Based on EUROSTAT data, which does not enable the distinction between GM and non-GM products, Spain imported 2,877,855 tonnes and 3,066,438 tonnes of grain, flour of soya in 2009 and 2010, respectively. The import of oilcake/pellets from soya amounted to 2,561,600 tonnes and 2,249,832 tonnes in 2009 and 2010, respectively. There were 1,266,806 tonnes and 1,562,014 tonnes of maize imported in 2009 and 2010, respectively.

Based on the information provided by the CA, 29,736,319 tonnes of feedstuffs were produced in 2010 in Spain.

Regarding rice products from China, subject to Commission Decision 2008/289/EC, the import amounted to 47.4 tonnes and 22.5 tonnes in 2009 and 2010, respectively.

The CA stated that the import of GM material is not systematically recorded, as there is no such obligation. In the case of GM soya, 782,007 tonnes and 794,800 tonnes were reported by trade

companies to be imported in 2009 and 2010, respectively. In the case of maize reported as GM, the volumes imported in 2009 and 2010 were 213,755 tonnes and 444,135 tonnes respectively.

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

Law 17/2011 on food safety and nutrition has been put in place in Spain including, among other things, GM food and feed related issues since the previous FVO mission dealing with GMOs.

Law 9/2003 and its implementing Royal Decree 178/2004 establish the legal framework for contained use, deliberate release and placing on the market of GMOs.

Autonomous communities (AC(s)) put in place additional GMO legislation regarding the CA(s) in their region and establishing procedures in their territory.

Conclusions

There is national and regional legislation 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 Spanish Food Safety and Nutrition Agency (AESAN) is responsible for co-ordination regarding food safety including GMO controls in food. The Sub-directorate General for External Health of the Ministry of Health, Social Policy and Equality (MSPSeI)[1] is responsible for the control of food imports including GMO in food.

Within the Ministry of Environment, Rural and Marine Affairs (MARM)[2], the Sub-directorate

1 In their response to the draft audit report, the competent authority noted that as a result of the changes of the names of ministry departments, the Ministry of Health, Social Policy and Equality is now called the Ministry of Health, Social Services and Equality.

2 In their response to the draft audit report, the competent authority noted that as a result of the changes of the names of ministry departments, the Ministry of the Environment and Rural and Marine Affairs is now called the Ministry of Agriculture, Food and the Environment.

General for Conservation of Resources and for Animal Feed (SGCRAA) is responsible for coordinating GMO controls in feed other than imports. The Sub-directorate General for Health Agreements and Border Controls (SGASCF) is responsible for controls of feed imports including GMO in feed.

The ACs are responsible for the implementation of controls regarding GM food and feed excluding import.

The Inter-ministerial Council on GMOs (CIOMG) under MARM is responsible for authorisation of the deliberate release of GMO into the environment under Part B of Directive 2001/18/EC for variety registration and is the CA for GMO cultivation.

The Spanish Plant Variety Office (OEVV) is responsible for the co-ordination of controls of GMO presence in conventional seeds. Furthermore, it is responsible for controls of GMO release into the environment under part B of Directive 2001/18/EC for variety registration of GM crops in the national catalogue.

ACs are responsible for authorisation and controls of trials other than those for variety registration to be carried out on their territory under part B of Directive 2001/18/EC.

Importing companies hire specialised samplers to perform own controls at the port visited by the audit team (see 5.2.5 for details). These samplers are also involved in official controls. A private laboratory is used to perform analysis of both official and private samples for GMO presence in feed samples taken at the same port. No detailed written agreements have been signed including an accurate description and conditions to carry out the control tasks where they are performed by the private samplers or private laboratory.

Conclusions

The CAs within the scope of this audit have been clearly designated and tasks are clearly allocated.

It is not guaranteed that specialised private samplers and private laboratory used at Tarragona port to perform official control tasks are free from any conflict of interest and meet the requirements of Article 4(2)(b) of Regulation (EC) No 882/2004.

5.2.2 Resources for performance of 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; 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

Staff met by the audit team carrying out official controls of GMOs had the necessary qualification to perform their job. However, no training specific to GMO controls has been provided to the staff met by the audit team.[3]

Staff responsible for regular food and feed controls are involved in GMO related controls as well.

3 In their response to the draft audit report, the competent authority noted that the Spanish „authorities involved in official feed controls regularly organise courses on such controls and on animal feed legislation for staff carrying out inspections. These courses normally cover matters related to official controls of GMOs in feed, among many other aspects."

There is one inspector of the OEVV carrying out GMO trial controls full time. There are 4 seed inspectors involved in GMO trial controls in Aragon and in Catalonia, respectively. In Aragon, the inspector met by the audit team performs this job nearly full time.

The FVO team did not identify any cases of facilities or equipment being inadequate.

Conclusions

The staff met by the audit team are sufficiently experienced and adequate facilities are available.

5.2.3 Controls on specific import requirements

Legal Requirements

Article 2 of Commission Decision 2008/289/EC specifies conditions for first placing on the market of rice products from China. Article 3 requires MSs to take appropriate control measures, including random sampling and analysis of rice products originating in or consigned from China. Article 4 requires products that are found to contain, to consist or to be produced from genetically modified rice Bt63 are not placed on the market.

Findings

Based on an annual control program managed by the Sub-directorate General for External Health, there were 9 and 10 samples taken from rice products originating from China in 2009 and 2010, respectively in Spain. The CA reported that in 2011, 7 samples were taken by the time of the audit.

The audit team visited Tarragona port suggested by the CA based on the volume of GM products - mainly maize and soya - imported via this point of entry. No rice products were sampled in recent years because no such consignments were imported. The CA stated that the instructions of circular 1/2008 are known and would be followed requiring documentary control and to sample 10% of the consignments of rice products from China under Decision 2008/289/EC.

Conclusions

The CA perform sampling under Decision 2008/289/EC, however, the audit team was not able to verify that all requirements of the Decision are followed, because in the harbour visited no rice consignments are imported from China.

5.2.4 Controls on 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 grown under part B and C of this Directive.

5.2.4.1 Authorisation of deliberate release of GMOs for purposes other than placing on the market

Legal Requirements

Article 6 of Directive 2001/18/EC specifies the standard authorisation procedure of 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 is issued by the CIOMG in the cases when the deliberate release is for variety registration. The ACs issue authorisation for trials to be carried out on their territory when agronomical characteristics of the GMOs are evaluated for purposes other than variety registration.

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

In the case of trials for variety registration, the notifier submits the application together with the Summary Notification Information Format (SNIF) to the CIOMG. The CIOMG requests the Spanish Commission on Biosafety (CNB) to prepare the environmental risk assessment. The CNB is composed of experts of scientific institutions, technical representatives from government departments, and representatives of the 17 ACs. The CIOMG submits the SNIF to the European Commission and it is also published on the website of the MARM for public consultation. The CNB checks the completeness of the dossier submitted and requests additional information from the notifier as necessary. It carries out the risk assessment based on the information submitted. The CNB stated that the aim of the risk assessment is to identify characteristics which may cause adverse effects on human health and the environment, evaluate the consequences of each adverse effect if it occurs, evaluate of the likelihood of the occurrence of each adverse effect, estimate the risk posed by each characteristic of the GMO, apply management strategies for risk from deliberate release of the GMO and determine the global risk of the GMO. The comments received during the public consultation are considered by the CNB when preparing the risk assessment. The CA informed the audit team that generally no or very few such comments are received. Based on the risk assessment, the CIOMG takes the decision on the deliberate release and issues the authorisation. The authorisation requests the consent holder to observe the possible effects of the deliberate release on biodiversity in most cases in the form of a recommendation. The authorisation is published on the website of the MARM.

In the case of trials for evaluation of the agronomic characteristics of the GMO for purposes other than variety registration the notifier submits the application to the competent authority in the AC where the trial is to be carried out. The authorisation procedure is similar to the one co-ordinated by the CIOMG. The competent authority of the relevant AC requests the CNB to carry out the risk assessment, which is taken into account when the authorisation decision for deliberate release of GMOs into the environment under part B of Directive 2001/18/EC is made. The authorisation is published on the website of the MARM.

The consent is issued generally for one growing season. It includes measures to be taken to avoid potential risk (e.g. isolation distance of GM crop from conventional crop of the same species). The consent holder has to submit a report on the result of the trial in a standardised form at the end of

the growing period in accordance with the authorisation by the CA. The report is submitted to the CIOMG and is made publicly available on the website of the MARM, furthermore it is also received by the CNB. When the AC is responsible for the trial, the report is submitted to them, published on the website of the MARM and also submitted to the CNB. The CNB takes into account the report when the company submits another notification for the same trial and informs the CA if any risks have been identified regarding the performance of the trial.

The public was not consulted before the authorisation was granted for GMO trials by the Catalan Authorities.

The location of GMOs grown under part B of Directive 2001/18/EC is recorded in a national register maintained by the CIOMG. Information regarding the location of GMO trials is available to the public upon request.

5.2.4.2 Controls on deliberate release of GMOs authorised for purposes other than placing on the market

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

In the case of GMO trials carried out for the purposes of inclusion in the Register of Varieties the OEVV, and in the case of GMO trials carried out for agronomical evaluation and not for variety registration, the competent authority at the AC, carry out the controls regarding the deliberate release.

There were 54 deliberate releases of GMO carried out in Spain under part B of Directive 2001/18/EC in 2009, 43 in 2010 and 21 in 2011. They involved maize, cotton and sugar beet.

Regarding GMO trials carried out for the purposes of inclusion in the Register of Varieties, the OEVV stated that each trial is inspected by them during sowing, before pollination, during harvest and the destruction of the crop. Inspections are carried out mainly by one inspector dealing with this task full time. In the case of sowing and harvest, a date is agreed with the consent holder and the inspector is present throughout the process and carries out controls. At sowing and at harvest, it is checked whether the machinery is cleaned and the waste is destroyed by burial in the trial field. Additional inspections are carried out to check the isolation distance from other non-GM fields of the same crop and the isolation zone planted with conventional crop surrounding the GM crop. A standardised report is drawn up on visits carried out during sowing and harvest including details of destruction of the GM crop. Volunteers are checked during the two growing seasons following the trial.

In Aragon, five GM maize trials not for variety registration were carried out under the responsibility of the AC at four sites in 2011. GMO trials are inspected by four inspectors out of which one inspector performs this job full time. Each trial is inspected generally four times.

In Catalonia, there was only one GMO trial not for variety registration carried out under the responsibility of the AC on one site involving maize in 2011. GMO trials are inspected at sowing, at pollination and at harvest.

In both ACs visited, the inspector had the consent including conditions and a recommendation of the deliberate release available. During the inspections it is verified whether the conditions of the consent are met. However, the recommendation of authorisation regarding the impact of the GMO release on the biodiversity is not checked.[4] An inspection report is drawn up at visits except for some of the unannounced inspections, voluntary controls and visits made at pollination in Aragon. Inspections follow the same principles as controls performed by the OEVV.

The audit team noted that the potential negative effects on the biodiversity including non-target organisms are not checked by the consent holder and are not verified either by the ACs or by OEVV.[5] The consent holder stated in Catalonia, that the company carries out such studies when trials involve new events. These studies were stated to be carried out in parallel with the trial involving the new event and are performed in different European countries depending on the resources available.

There have been a number of public research studies carried out addressing the environmental impact of deliberate release of GMOs into the environment in Spain. Studies involving herbicide tolerant maize and cotton have been carried out between 2006 and 2010 in order to identify the potential indirect effects on non-target organisms due to weed management. No adverse effects were identified during these studies.

5.2.4.3 Controls on deliberate release of GMOs authorised for placing on the market

Legal Requirements

Article 19(4) of Directive 2001/18/EC requires MSs to take all necessary measures to ensure that the 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 (Article 8 and 20). It is 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.

Findings

The cultivation area of maize MON810 is calculated based on the quantity of seed sold by seed companies in each region. Farmers are generally not obliged to report their MON810 growing areas to the competent authorities.

4 In their response to the draft audit report, the competent authority noted that the recommendation of the consent „is not mandatory and only informs and reminds the notifier, it is not a matter requiring inspection. It is appropriate, however, for the notifier to include the recommendation in the objectives of the trial, carry out the study and present the results in the report at the end of the trial. The report would then indeed be studied by the competent authorities."

5 In their response to the draft audit report, the competent authority noted that „trials involving notifications for variety registration concern a very limited surface area and that herbicide-resistant maize varieties are not even treated with that specific herbicide, since resistant and sensitive varieties are found in the same trial. Weeds are therefore treated with conventional herbicides. Thus, we do not consider it OEVV's mission to evaluate the possible impact on biodiversity as this will be so minimal as to be unquantifiable using existing methods. However, the notifying company carries out these tasks in parallel in different European locations".

In Catalonia, the estimated cultivation area of MON810 is approximately 50% of the growing area of maize. Farmers receiving subsidies in Catalonia, which is almost always the case, have to report the area, variety and the exact location of the MON810 maize production to the competent authority in the AC under the cross-compliance requirements; 5 % of the subsidised farmers are randomly selected for cross-compliance checks. Based on the information provided by the farmers, inspections are carried out, in accordance with the cross-compliance requirements, regarding the GM maize MON810 cultivation and the relevant documentation. The farmers met in the region, have never been controlled under the cross-compliance scheme.

The National Association for Plant Breeders issued recommendations to be taken into account when growing maize varieties of MON810. This information is attached to each seed bag of MON810 varieties in the form of a brochure. It includes suggestions regarding measures to avoid insect resistance to the Bt toxin, measures ensuring traceability and proper co-existence with other maize crops.

Farmers met by the audit team in both regions visited stated that when growing MON810 varieties, they take into account the recommendation regarding the insect resistance, they apply a refuge zone where conventional maize is planted. They do not apply any isolation distance from non-GM maize crops. This is not required in Spain. All farmers met by the audit team stated that all their crops are sold exclusively to feed manufacturers labelled as GMO.

Annual monitoring reports on the cultivation of MON810 in 2009 and 2010 have been provided by the consent holder to the European Commission and have been published. The reports have been evaluated by the CNB. Based on the 2009 report, there were 100 farmer's questionnaires completed in Spain in order in order to monitor potential adverse effects on the environment of MON810 cultivation. No adverse effects were identified.

The CA stated that national legislation is under finalisation regarding a public register of the location of production areas of GM maize. Under this legislation, the farmer will have to report to the regional CA the area and the exact location of every field sowed with GM maize. He will also have to submit information concerning the coexistence measures taken.

As mentioned in 5.2.4.2 above, there have been a number of private and public research studies carried out addressing the environmental impact of authorised GMOs released into the environment. Studies on MON810 were carried out between 2003 and 2010 with financial support of the MARM. They included the ecology of corn borers and their susceptibility to Bt maize and Bt toxin, ecological risk assessments specifically on adverse effects of GM maize on non-target organisms, co-existence studies and gene transfer from GM maize to the microbial organisms in the soil and effects on the soil organisms. In addition, monitoring of unintended release of GMOs authorised in the EU for food and feed has also been performed. No significant risks were identified during these studies.

Conclusions

A system for authorisation regarding the deliberate release of GMO for trial purposes is in place. Article 9 of Directive 2001/18/EC specifying consultation of the public on the proposed deliberate release is implemented in most cases checked by the audit team.

Each GMO trial is inspected at an appropriate frequency during the growing season.

The official controls consist of the evaluation of the annual monitoring report on the cultivation of GM maize MON810.

5.2.5 Controls of genetically modified 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 Regulation (EC) No 1829/2003 requires that food and feed be labelled as containing GMO when they contain, consist of or are produced from GMOs in a proportion higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient, of the feed and of each feed of which it is composed of, provided that this presence is adventitious or technically unavoidable. Article 12 (3) requires that in order to establish that the presence of GMO material 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. Article 4 and Article 5 specify the information to be transmitted in writing to the operator receiving GMO products or food and feed produced from GMOs, and information to be indicated on the label, on or in connection with, the display of the product.

Findings

The 2005 mission report included two relevant recommendations:

(No 1) that '*all imports of food or feed products containing or potentially containing GMOs are checked in accordance with Article 9 of Regulation (EC) 1830/2003 and Article 4.3 of Council Directive 89/397/EEC. In particular, attention should be given to imported products not declared as feed stuffs and not destined or ready for human consumption.'*

The CA stated that importers must declare whether their product is intended for food or feed in all cases. The customs clearance only takes place once they have received the certificate of the inspection authority at the point of entry. In this way it is ensured that products which may potentially contain GMOs are subject to official controls.

(No 4) that '*the regions report consistently on inspection activities and follow-up actions to the central competent authority, AESAN.*

The CA stated that the relevant information is sent once a year to the AESAN using the application 'ALCON', which is designed to gather and analyse data on official controls including measures adopted in the cases of non-compliances. In the case of imports, points of entry send the relevant information in form of an annual report.

The new multi-annual 'National Official Control Plan of the Food Chain' (PNCOCA) 2011-15 provides the framework of official controls of food safety and includes programs for controls of GMO in food and feed.

The ACs prepare their control plan based on the PNCOCA 2011-15. GMO controls carried out by the regions include inspections performed at food and feed business operators and samples to be taken for GMO analysis. The risk assessment for planning controls is the responsibility of the ACs.[6]

6 In their response to the draft audit report, the competent authority noted that 'since feed control plans have been implemented under Regulation 882/2004 (both in the previous and the current programming periods), a multi-annual control programme for feed has been drafted centrally by the national feed coordinating committee, including *inter alia*

In Catalonia, the CAs stated that in the case of both food and feed, unauthorised GMO events are not tested for.

GM food

Programmes III.1 on 'General Control of Food Establishments' including traceability and labelling requirements, programme III.2 on 'Control of Self-control System' including sampling plan III.12 and programme on 'Control of Biotechnological Foods in Foodstuffs' of PNCOCA 2011-15 provide a framework of GMO related controls in food.

The total number of samples taken and analysed for GMO presence in food in Spain including those taken during import controls was 237 in 2009 and 233 in 2010.

In Aragon, 20 samples were planned to be taken for GMO analysis in food in 2011 implementing the plan developed by the regional CA based on the PNCOCA 2011-15. The CA stated that GMO related checks are carried out at establishments processing raw materials with potential GMO presence.

In Catalonia, 50 samples were planned, taken and analysed for GMO presence both in 2009 and 2010 during the label controls of packaged food for final consumers. In 2011, 70 samples were taken and the plan for this year has been fully implemented. Inspections are carried out to check raw material and food production whether products labelled as GMO are involved. In such cases it is checked whether the traceability and labelling requirements are met. Evidence was provided that follow up actions are taken in response to relevant RASFF notifications.

Regarding import controls, the centrally prepared annual Coordinated Programme of External Health Controls 2011 includes reference to GMO controls. The plan is implemented by the points of entry in Spain. Regarding food other than rice products from China, maize and soybean products can also be sampled in Spain. There were 26 and 40 such samples taken at import points in 2009 and 2010, respectively. No maize or soybean products have been sampled for GMO presence since 2009 at the Tarragona port visited by the audit team.

GM feed

The centrally co-ordinated 'Official Control Programme for Animal Feed 2011-15' is a framework document for carrying out feed related controls including for GMOs. This document is an integrated part of the PNCOCA 2011-15.

The total number of samples taken at the domestic market and analysed for GMO presence in feed in Spain was 207 and 208 in 2009 and 2010, respectively.

In Aragon, which produced 3,479,473 tonnes of feed in 2010 and was the third largest feed producing region in Spain, 25 and 27 samples were planned and taken for GMO analysis in feed in 2009 and 2010, respectively, implementing the plan developed by the regional CA based on the PNCOCA 2008-10. The CA stated that GMO related controls are carried out at 274 feed establishments to check traceability and labelling regarding GM materials and feed; unauthorised GMO events are tested for. All establishments are visited at least once every five years. The CA further stated that feed processors in the region deal only with GM materials.

In Catalonia, which produced 7,254,711 tonnes of feed in 2010 and is the largest feed producer in Spain, 18 and 21 samples were taken for GMO analysis in feed in 2009 and 2010, respectively from maize products. In 2010, in the case of 11 samples of feed not labelled as GMO (52%), the presence of MON810 were detected in a quantity higher than 0.9%. The CA stated that sanction procedures were initiated as a consequence of each non-compliance. In 2011, 10 out of the planned 41 samples

a section on risk assessment for planning controls. This document is used as a framework document by CAs, as the bodies responsible for implementing controls, to draw up their own control programmes within their respective remits.'

had been taken by the time of the audit. No results were yet available. The CA further stated that labelling and traceability requirements regarding GMOs are checked in the case of products labelled as GMO. They further stated that they do not verify whether the feed establishment ensures that in the case of presence of authorised GMO under 0.9% in products not labelled as GMO, that presence is adventitious or technically unavoidable. It was further stated that the CA requests testing for MON810 maize only.

Regarding import control of feed, the SGASCF prepares an annual control plan, which is communicated to the points of entry. On the basis of this plan sampling for presence of GMO in feed is carried out by inspectors at the points of entry. The audit team visited the Tarragona port where two inspectors are in charge of performing GMO related controls, including sampling. Sampling is also carried out by specialised samplers hired by the importing companies following guidelines given by the SGASCF. Only some 25% of the samples are taken by the inspectors, the remainder are taken by the service providers hired by the importing companies in the presence of the inspector, who normally observes some part of the sampling process. The total number of samples taken was 12 and 14 in 2009 and 2010, respectively. The inspectors at Tarragona port stated that the transmission of unique identifier assigned to the GMO of the imported consignment is only requested by the CA in the case of maize consignments.

Conclusions

Recommendations No 1 and No 4 of mission report DG(SANCO)/7632/2005 have been adequately addressed.

A control system is in place regarding GMO food and feed.

It is not verified that the presence below 0.9%of authorised GMO in material not labelled as GMO is actually adventitious or technically unavoidable, which is not in line with Article 24 of Regulation (EC) No 1829/2003.

Since authorised events other than MON810 are not tested for in feed, it is not ensured that requirements in Regulation 1829/2003, in particular Section 2, Chapter III and in Regulation 1830/2003 are complied with for those authorised events.

As unauthorised events are not consistently tested for, the MS can not ensure that obligations in Article 4 (2) and 16(2) of Regulation (EC) No 1829/2003 are complied with.

Unique identifiers are not systematically transmitted when GMO lots are imported which is not in compliance with Article 4 (1) of Regulation (EC) No 1830/2003.

5.2.6 Controls of GMO 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 of Regulation (EC) No 1830/2003 of the European Parliament and of the Council 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) of the Directive 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.

Findings

A joint control plan for GMO presence in seeds is prepared annually in the form of a resolution by the authorities involved at national and AC level and coordinated by the OEVV. Based on the current resolution, samples are to be taken for GMO presence of conventional seeds of maize, cotton and soya bean. The resolution requires that all seeds of these species of over 500 kg lot size introduced into Spain or produced domestically can only be certified and put on the market in Spain if accompanied by an analytical certificate stating that the product does not contain GMO. Once the seeds have been sealed or introduced and placed in the seed processor's warehouses, at least 10% of the batches are sampled randomly as a check on previous analyses. All batches of seeds for which no analytical certificate is available are officially sampled for GMO presence. The OEVV stated that 5% of GM maize MON810 seed lots are also checked to verify the event and to check whether there are other events present in the lot.

In the cases where the analytical results exceed 0.5% and events authorised for food and feed in the EU are involved, the seed can not be marketed in Spain and they are either returned to their country of origin, destroyed or used for purposes other than seed for sowing. Seed lots are rejected where non-authorised events are detected above 0.1% which is considered as the limit of detection. No seed lots with GMOs unauthorised for food and feed in the EU have been detected yet.

There were 1,149 and 689 seed samples taken and analysed for GMO presence in 2009 and 2010, respectively. Mainly maize seed lots were sampled. The CCA stated that the ACs have a team of seed inspectors which perform sampling according to the requirements of the International Seed Testing Association (ISTA) system.

In Aragon, 218 samples were taken in 2011 and GMO presence below 0.1% was detected in the case of 3 samples. As this level was below 0.5% no actions were taken.

In Catalonia, 281 and 98 samples from non-GM maize seed lots were taken and analysed in 2009 and in 2010, respectively. GMO presence of events authorised for food and feed in the EU was detected in over 20% and over 40% of samples analysed in 2009 and 2010, respectively. In the vast majority of the cases, the GMO presence was below 0.5%.

Conclusions

A system is in place for the control of GMOs in seeds. However, the *de minimis* threshold for adventitious and technically unavoidable presence of authorised GM material in non GM seeds contravene Article 21 of Directive 2001/18/EC and Article 4 of Regulation (EC) No 1830/2003, since such a presence below 0,5% is not subject to labelling and traceability requirements.

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

Under the PNCOCA 2011-15, risk assessments have been carried out regarding food and feed

including GMOs at regional level in order to better address the risks since 2011 (see 5.2.5 for details). The risk assessment takes into account, among other things, the activity of the company, the product processed, the self-control, the past records of controls, and the size and the volume of production. GMO events other than MON810 are not systematically considered in the official controls[7].

The small number of feed samples for GMO analysis taken during the domestic market control is not proportionate to the volume of feed production in the ACs visited and the low number of samples was maintained even though a high degree of non-compliances was found in one of the ACs visited.

Conclusions

In the case of feed, the risk assessment carried out on the basis of Article 3 of Regulation (EC) No 882/2004 does not take adequately into account the size of production and level non-compliances identified.

5.2.8 Sampling

Legal Requirements

Article 9 of Regulation (EC) No 1830/2003 of the European Parliament and of the Council 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[8] 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 (EU) No 619/2011 harmonises sampling and testing controls in the EU regarding GMO feed materials, which are authorised for commercialisation in a non-EU country, have a valid EFSA application and the authorisation has been pending for more than 3 months, or have an expired authorisation under Regulation (EC) No 1829/2003. A 'Minimum Required Performance Level' for GM detection in the laboratory is set at 0.1%. For results below this level, a decision of non-compliance of the feed should not be taken.

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

Findings

No sampling was observed by the audit team because no consignment was available for sampling for GMO presence in food and feed at Tarragona port when visited by the audit team. The inspectors explained that they follow Commission Recommendation 2004/787/EC, sampling

7 In their response to the draft audit report, the competent authority noted that since the feed control programmes have been applied in accordance with Regulation (EC) No 882/2004, a multi-annual control programme is drawn up within the national feed coordinating committee. This programme contains, among other things, a risk assessment of control planning, which forms the basis for CAs to draw up their own control programmes within their respective remit.

8 Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003Text with EEA relevance. Official Journal L 348, 24/11/2004 pg18 - 26

methods referred to in Regulation (EC) No 152/2009 and Regulation (EU) No 619/2011.[9] In the case of cotton seeds in big bags as an example, incremental samples are taken from each bag with a probe and an aggregate sample is produced. It is mixed by hand and three final samples of 1 kg each are taken from the aggregate sample. One is sent to the laboratory, one is kept by the business operator, and one is kept by the authority. A report is completed following each sampling.

The inspector stated that the size of the final sample is always 1kg. The audit team noted that 10.000 seeds/grains can weigh more than 1 kg, depending on the species. Therefore, based on Regulation (EU) No 619/2011, the sample size should be more than 1 kg for some species.

Conclusions

When sampling is carried out based on Regulation (EU) 619/2011, the methods of sampling referred to in the Regulation are not fully complied with.

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

Findings

The 2005 mission report included one relevant recommendation:

(No 5) that '*official GMO laboratories are complying with the general criteria of standard ISO 17025 as required by Article 3.1 of Council Directive 93/99.*

In Spain, 21 laboratories were stated to be involved in official control activities regarding GM presence in food, feed and seeds. There are 4 food and 3 feed laboratories performing GMO analysis of official samples, which are not accredited. In addition, one out of the three laboratories performing analysis of official samples for GMO presence in seeds is not accredited. Therefore, the total number of non-accredited GMO laboratories is 8.

Laboratorio Arbitral Agroalimentario (LAA) together with *Centro National de Alimentación* (CNA) are the two national reference laboratories (NRL) appointed under article 33 of Regulation (EC) No. 882/2004 in Spain. The two NRLs jointly co-ordinate the activities of official GMO laboratories in Spain and provide training. They also organise comparative tests and transfer information from the EURL-GMFF to the Spanish official GMO laboratories.

The *Laboratorio Central de Sanidad Animal* in Algete, which is appointed to carry out analysis of GMOs in seed for cultivation and the *Laboratori de Sanitat Vegetal* in Barcelona are part of the GMO working group of the LAA-CNA, which co-ordinates GMO analysis at national level. Both

9 In their response to the draft audit report, the competent authority noted that the Department of Animal Feed and Safety of Livestock Production of the Autonomous Government of Catalonia had drawn up technical instructions on sampling and identification of GMOs (the document was attached to the CA comments to the draft report of this audit).

laboratories are actively involved in the working group's activities. The audit team noted, that the activity of *Laboratorio Semillas Aragón, Zaragoza* has not been co-ordinated by any NRL appointed under Regulation (EC) No 882/2004. The LAA stated that this laboratory started to perform official tests for GMO presence in seeds only in 2011, their activity is planned to be co-ordinated in the next monitoring plan.

Laboratorio Arbitral Agroalimentario, Madrid

The first laboratory visited, LAA works under the supervision of the MARM and is a member of the European Network of GMO Laboratories (ENGL). Three well trained staff are working in the laboratory with GMO analyses.

The LAA has been accredited for GMO analyses by the Spanish National Accreditation Body. The scope of the analysis is fixed, but a flexible scope is anticipated in 2012. Samples analysed for official control purposes include samples of food, feed and its vegetable raw materials, in addition to the analysis of seed for the OEVV.

The different methodological steps involved in the production of the results are performed in dedicated work areas with their own apparatus to minimise the risk of accidental DNA contamination.

The laboratory has equipment of high quality and documented procedures for maintenance, control, and calibration of equipment in place.

LAA uses end-point Polymerase Chain Reaction (PCR), followed by agarose gel electrophoresis for screening of the P35S and T-nos DNA elements. Identification and quantification of individual GM events is performed by real time PCR. The range of quantitative methods includes most (not all) authorised GM maize events and RoundUp Ready Soya. The laboratory has also implemented methods for the unauthorised events Bt10 maize, Bt63, Kefeng6, and LL601 rice events. However, the laboratory has not yet implemented any methods for GM material under the scope of Regulation (EU) No 619/2011.

Documented procedures for validation of new methods are implemented. The laboratory applies well documented procedures for estimating uncertainty of measurement based on internal validation data.

The laboratory uses certified reference materials whenever possible, and adequate controls are used in the analyses at relevant steps.

LAA participates in proficiency testing schemes organised by FAPAS/GeMMA and by EURL-GMFF and the performance in these tests is good.

Laboratorio Semillas Aragón, Zaragoza

The *Laboratorio Semillas Aragón* is dedicated to perform analysis for seed certification. It became operational for GMO analyses in mid 2011 and has analysed 80 seed samples for official control purposes so far. Three staff are involved in GMO analyses of seeds and the personnel has received training in GMO analyses.

The laboratory is not accredited and it does not have a quality system in place.

The layout of the rooms in the laboratory is good with devoted areas for grinding of seeds, DNA

extraction, PCR setup and PCR. The laboratory is equipped with all the necessary apparatus required.

The methods used for DNA extraction and qualitative real time PCR are based on commercially available kits. The PCR GMO screening kit includes all relevant controls, and the system detects the P35S and T-nos DNA elements. The audit team noted that in the case of seed non-authorised events for food and feed in the EU are not tested for.[10]

The operational procedures, although technically and scientifically sound, are only passed on orally or laid down in non controlled documents.

The laboratory has neither participated in any proficiency tests, nor has it been audited internally, or externally.

Laboratori de Sanitat Vegetal, Barcelona

The *Laboratori de Sanitat Vegetal* (LSV) belongs to the Generalitat de Catalunya. It is a small laboratory with nine employees. The main focus of the laboratory is diagnosis of various plant diseases using chromatography, Enzyme-linked immunosorbent assay (ELISA) and PCR based methods. Since 2009 the laboratory is accredited for GMO analyses in maize seeds, maize grains and maize flour, and the accreditation covers qualitative detection of P35S and maize event MON810 using end-point PCR followed by agarose gel electrophoresis. Three persons are involved in the GMO work, which is considered sufficient taken the number of samples analysed annually into account. The personnel is highly qualified and have received specific training in GMO analyses.

The laboratory facilities for GMO analyses are satisfactory, and incompatible activities are physically separated to minimize the risk of accidental DNA contamination. LSV is furnished with all the necessary equipment and apparatus to be able to perform the GMO tests in a correct way. The laboratory has and applies procedures for maintenance, control and calibration of its equipment. Methods used are validated and documented operational procedures covering all necessary steps are in place, including controls at relevant steps throughout the procedures.

LSV uses certified reference materials and participates in proficiency testing schemes organised by the Spanish NRLs and by FAPAS/GeMMA with good results.

Samples identified as GM positive, are at the moment sent to other accredited laboratories in Spain for quantitative analyses. However, the laboratory has acquired quantitative PCR equipment and an extended scope of accreditation, including also quantitative GMO methods, is foreseen in 2012, when the laboratory also will move into a new location.

Conclusions

Eight GMO laboratories are not accredited therefore the requirements of Article 12 of Regulation (EC) No 882/2004 in respect of official GMO analysis are not fulfilled in all cases.

Recommendation No 5 of mission report DG(SANCO)/7632/2005 regarding laboratory accreditation has not been addressed.

10 In their response to the draft audit report, the competent authority noted that the quantification of positive samples from all seed controls was done in the Ministry's own laboratory at Algete which does carry out tests to detect unauthorised events, but it was not visited during the audit.

Regulation (EU) No 619/2011 has not been fully implemented in Spain yet, however it entered into force on 15 July 2011.

Not all laboratories performing GMO analysis of official seed samples are co-ordinated by an NRL, which is not in compliance of Article 33 (2) (b) Regulation (EC) No 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 of the above Regulation 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

The written procedures put in place by the AC Catalonia related to food and feed controls do not include requirements specific to GMOs.

No checklists or guidance documents are available for inspectors performing controls regarding GMO trials in the two ACs visited by the audit team.

There are no documented procedures in place regarding controls of cultivation of GM maize MON810.

Generally, reports of official controls related to GMO controls were drawn up and made available to the audit team. However, in the case of GMO trials carried out in Aragon no reports were issued during pollination, unannounced inspections and volunteer controls (see 5.2.4.2 for details).

Conclusions

Documented procedures are not consistently in place, therefore Article 8 of Regulation (EC) No 882/2004 is not fully implemented. Reports are not consistently drawn up as required by Article 9 of Regulation (EC) No 882/2004.

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 and co-operation between CAs.

Article 4(5) of Regulation (EC) No 882/2004 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

In addition to the central co-ordination of the control activities of the ACs, there are mechanisms such as joint meetings to prepare control plans, information exchanges via phone and e-mails in place to ensure co-operation between and within authorities dealing with GMOs.

Inspectors from the CCA and ACs demonstrated a good co-operation during the field visits

observed by the audit team. However, in one of the ACs visited, the high number of non-compliant test results was not reported to the CCA (see 5.2.7 for details).

Conclusions

Procedures are in place to enable efficient and effective co-ordination and co-operation between and within competent authorities in line with Regulation (EC) No 882/2004.

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 Regulation (EC) No 882/2004 states that MSs shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare 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 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 Mss.

Article 33 of Directive 2001/18/EC 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

Law 17/2011 on food safety and nutrition and Law 9/2003 provide for actions to be taken in case of non-compliances including sanctions.

AESAN stated that sanctions imposed as a result of inspections carried out at food and feed establishments when checking the traceability and labelling requirements do not specify whether the non-compliance relates to GMO.

The CA stated that no sanctions were imposed as a result of food samples taken and analysed for GMO presence during the recent years.

In the case of feed, two and one non-compliances were identified and reported to MARM in 2009 and 2010 in Spain, respectively. However, not all non-compliant cases were reported by the AC to the MARM. In Catalonia, 11 out of 21 feed samples were found to be non-compliant in 2010. The CA stated that sanction procedures were initiated in all the cases.

In the case of GMO trials, the CAs stated that if non-compliances are identified the trial is cancelled and destroyed on the trial field.

Conclusions

Generally, there is a system in place to ensure that enforcement measures are taken if necessary.

5.2.13 Verification procedures and audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 competent authorities 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

Chapter 10 of the PNCOCA 2011-15 includes general information regarding verification procedures and audits. Annex IX lists the documented procedures relevant to food and feed controls and Annex X lists topics of audits planned to be carried out between 2011-15. There is no reference in PNCOCA specific to GMO related controls.

Conclusions

There is a system for verification procedures and audits in place as required by Regulation (EC) No 882/2004, however GMO controls are not specified.[11]

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 AESAN and the SGCRAA are the contact points for GMO RASFF notifications regarding food and feed, respectively. There were 12 RASFF notification issued in 2009. No notifications were issued in 2010 and 2011. 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 to the Commission and follow up of RASFF notifications is taking place.

6 Overall Conclusions

Overall, there is a clearly structured system of official controls for GMOs in place. However, shortcomings were found in the actual implementation of controls, in particular, the use of non-accredited laboratories and the absence of procedures specific to GMO related controls at regional level. Furthermore, the 'de minimis' threshold for adventitious and technically unavoidable presence

11 In their response to the draft audit report, the competent authority noted that GMO controls are not covered by a specific official control programme. Rather they are part of the official animal feed control programme, together with the controls relating to the remaining animal feed legislation. These animal feed control programmes have their own verification processes for controls and are subject to audit processes as laid down in Regulation 882/2004. This does not apply to each section of the programme, but to the control programme as a whole, which is the basis for planning official controls.

of GM material in non GM seeds contravene the EU legislation, since such a presence below 0,5% is not subject to labelling and traceability requirements. Two out of the three outstanding recommendations of mission report DG(SANCO)/7632/2005 have been adequately addressed. One recommendation regarding laboratory accreditation is still to be addressed.

7 Closing Meeting

A closing meeting was held on the 30 November 2011 with representatives of the CCA. 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 Spain should ensure that:

N°.	Recommendation
1.	Requirements of Article 4(2)(b) of Regulation (EC) 882/2004 are met when private samplers and private entities perform official control tasks
2.	The public is consulted in all the cases in particular when the authorisation is issued for GMO trial by an Autonomous Community as required by Article 9 of Directive 2001/18/EC.
3.	For products with presence of approved GMO material below the threshold of 0.9%, exemptions from the labelling requirements are allowed only when this presence is adventitious or technically unavoidable as established in Article 24 of Regulation (EC) No 1829/2003.
4.	The control system allows to verify that non-authorised GM food and/or feed is not placed on the market in order to ensure that Articles 4(2) and 16(2) of Reg. 1829/2003 are complied with.
5.	Information on unique identifiers is transmitted when GMO lots are imported as required by Article 4 (1) of Regulation (EC) No 1830/2003.
6.	Official controls in feed and in particular sample checks and testing required in Art. 9(1) of Regulation (EC) No 1830/2003 include authorised events other than MON810, in order to verify compliance with requirements in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003.
7.	Regulation (EU) No 619/2011 is fully implemented.
8.	Any detectable adventitious or technically unavoidable presence of GM in non GM seed is subject to labelling and traceability requirements of GMOs in line with Article 21.1 of Directive 2001/18/EC and Article 4 of Regulation (EC) No 1830/2003.

N°.	Recommendation
9.	All laboratories involved in official GMO analysis are accredited in line with Article 12 of Regulation (EC) 882/2004.
10.	All laboratories involved in GMO analysis of official seed samples are co-ordinated by an NRL as required by Article 33 (2) (b) of Regulation (EC) 882/2004.
11.	The risk assessment is reviewed on the basis of Article 3 of Regulation (EC) 882/2004 to adequately take into account the size of production and level of non-compliances so that the number of samples are proportionate the risk.
12.	Documented procedures regarding controls of GMO cultivation, all the cases of GMO trials, procedures specific to GMO in the case of GM food and feed controls performed are put in place in accordance with Article 8 of Regulation (EC) 882/2004 by for the relevant CA.
13.	Reports are always drawn up when GMO trial inspections are performed as required by Article 9 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=2011-8982

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
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
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. 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
Dec. 2008/289/EC	OJ L 96, 9.4.2008, p. 29-34	2008/289/EC: Commission Decision of 3 April 2008 on emergency measures regarding the unauthorised genetically modified organism Bt 63 in rice products
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

Legal Reference	Official Journal	Title
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
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