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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE NETHERLANDS

FROM 19 TO 23 NOVEMBER 2012

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office audit in the Netherlands, carried out from from 18 to 23 November 2012 under the general provisions of EU legislation in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

The objective of the audit was to evaluate the system of official controls of genetically modified organisms (GMOs) including their deliberate release into the environment.

Overall, the Dutch control system ensures the implementation of the EU GMO legislation. Controls are generally risk based and supported by competent laboratories. However, a threshold is applied for authorised GMO presence in seeds, which is not in line with the EU legislation and it is not ensured that each consignment, subject to Commission Decision 2011/884/EU on rice and rice products from China, is controlled.

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
CA(s)	Competent Authority/ies
CED	Common Entry Document
CN	Combined Nomenclature
COGEM	Dutch Committee on Genetic Modification
Customs	Dutch Customs Service
DG SANCO	Directorate-General for Health and Consumers of the European Commission
DNA	Deoxyribonucleic acid
EC	European Community
ESO	Environmental Safety Officer
EU	European Union
FTE	Full Time Equivalent
FVO	Food and Veterinary Office
GM	Genetically modified
GMO(s)	Genetically Modified Organism(s)
ILT	Human Environment and Transport Inspectorate
ISO	International Organisation for Standardisation
ISTA	International Seed Testing Association
MEA	Ministry of Economic Affairs
MI&M	Ministry of Infrastructure and Environment
MON810	GM maize authorised for placing on the market on the basis of Commission Decision 98/294/EC
MS	Member State
NAK	Dutch General Inspection Service for agricultural seed and seed potatoes
NRL	National Reference Laboratory
NVWA	Netherlands Food and Consumer Product Safety Authority
PCR	Polymerase Chain Reaction
RASFF	Rapid Alert System for Food and Feed (http://ec.europa.eu/food/food/rapidalert/index_en.htm)
RIKILT	Dutch Institute of Food Safety
SNIF	Summary Notification Information Format
VGC	Veterinary Border Control
VWS	Ministry of Health, Welfare and Sports

1 Introduction

This audit took place in the Netherlands from 18 to 23 November 2012. The audit formed part of the Food and Veterinary Office's (FVO) planned programme.

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

Representatives from the competent authorities (CAs) accompanied the FVO team for the duration of the audit. An opening meeting was held on 19 November 2012 with the CAs. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the FVO team and the control systems were described by the authorities.

2 Objectives and scope

The objective of the audit was to evaluate 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.

In terms of scope, the audit reviewed the designation CAs for official control of GMOs, their co-operation, audits and resources for performance of controls, as well as the organisation of the controls, including controls of GMO trials, GM food, feed and seed, sampling and laboratory performance.

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

Table 1: Audit visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central Regional	2 1	NVWA, MEA, MI&M, VWS, ILT and Customs NVWA Zwijndrecht
Laboratories	2	
Public Private	1 1	NVWA RIKILT
Inspection visits	3	
GMO trial Import point Seed establishment	1 1 1	Apple and potato Rotterdam Seed establishment (maize)

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 eighth of a series of audits to be carried out in MSs that include an evaluation of the controls for the deliberate release of GMOs into the environment for trial and cultivation, in addition to the controls of GM food and feed.

A mission to the Netherlands dealing with GMOs was last carried out in 2005 (DG (SANCO)/7666/2005). 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 the Netherlands, which describes in summary form the control systems for food and feed safety, animal health, animal welfare and plant health and includes an overview of the state of play of the recommendations of the previous FVO audits. The country profile can be found at:

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

4.3 Authorised GM products

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

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

The genetically modified maize MON810 was authorised for placing on the market by Commission Decision 98/294/EC. MON810 is not cultivated in the Netherlands.

4.4 Production and trade data

Based on Dutch customs data submitted to EUROSTAT, which is not able to distinguish between GMO and non-GMO products, the Netherlands imported 3,491,386t and 2,944,829t of grain, flour and meal of soya in 2010 and 2011, respectively. The import of soya oilcake/pellets amounted to 5,628,050t and 5,188,043t in 2010 and 2011, respectively. There were 428,120t and 1,121,309t of maize (grains) imported in 2010 and 2011, respectively. The rape seeds import was 6,253t in 2010 and 943t in 2011. The corn gluten feed import amounted to 21,203t and 154,791t in 2010 and 2011, respectively.

The import of maize seed for sowing was 8,145t in 2010 and 10,295t in 2011.

Regarding rice and rice products from China imported under Combined Nomenclature (CN) codes listed in Decision 2011/884/EU, the import amounted to 32,470t and 28,165t in 2010 and 2011, respectively. The volume imported January-July 2012 was 9,387t.

5 Findings And Conclusions

5.1 Relevant national legislation

Legal requirements

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

Findings

The applicable national legislation is set out in section 6.2 of the last GMO mission report (DG(SANCO)/7666/2005). The national legislation regarding GM food and feed has not been amended since then.

The Decree of 25th of January 1990 establishes general measures pursuant to Article 24 of the Environmental Management Act and transposes Directive 2001/18/EC. This decree is also the legal basis for GMO controls of seed. The 'Regulation on Genetically Modified Organisms', which is annexed to the Decree, provides for implementing measures.

Rules on co-existence of GM, conventional and organic maize, potato and sugar beet crops are set by the Product Board of Arable Crops, which are mandatory for members of the organisation (there is a mandatory Product Board membership in the Netherlands). As there is no cultivation of GM crops, currently, it is not applied.

Conclusions

As far as the audit team could ascertain, appropriate national legislation is in place to implement 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 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

A number of the CAs for GMO controls has recently been re-organised and re-named.

The Ministry of Health, Welfare and Sports (VWS) is responsible for the GMO policy on food and the Ministry of Economic Affairs (MEA) for feed.

The Netherlands Food and Consumer Product Safety Authority (NVWA) under the MEA is the CA for GMO controls of food and feed including imports.

The Ministry of Infrastructure and Environment (MI&M) is the CA for the deliberate release of GMOs into the environment and for GMO controls in seed.

The GMO Office and the Human Environment and Transport Inspectorate (ILT), both under the MI&M, are tasked with handling applications for GMO trials and the control of GMO field trials, respectively.

The Dutch General Inspection Service for agricultural seed and seed potatoes (NAK), which is an independent administrative body, carries out GMO controls of seed under an annually renewable agreement with the ILT and the MEA.

Conclusions

Competent authorities falling within the scope of this audit have been designated together with the respective tasks allocated to them.

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

There are 1.5 Full Time Equivalent (FTE) staff dealing with GMO related market controls of food, 3 FTE responsible for import controls of food (mainly rice products from China) and an additional 1.8 FTE are involved in GMO analysis at the NVWA. Sampling for GMO presence in feed are performed together with other feed controls. At the ILT, 2.3 FTE are involved in GMO controls of field trials and co-ordination of GMO controls of seed. The FTE are generally distributed between several individuals in the different authorities.

There was a training session organised by the NVWA regarding the implementation of Decision 2011/884/EU on 30-31st of January 2012 with the participation of all staff involved.

The CA issued written instructions regarding GMO controls. The audit team noted that the inspectors met followed the instructions during the demonstration of inspection.

The audit team further noted that the number of food samples increased from previous years to 2012 due to the implementation of Decision 2011/884/EU. Not all food samples had been analysed for GMO presence in 2012 as the laboratory capacity remained unchanged (See section 5.2.9 below).

Conclusions

The staff performing controls are adequately trained and generally appropriate facilities are available.

However, the laboratory capacity is not adequate to analyse all food samples, which is not in line with Article 4(2)(c) of of Regulation (EC) No 882/2004.

5.2.3 Controls of the deliberate release of GMOs

Legal Requirements

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

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

Legal Requirements

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

Findings

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

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

There are three categories of GMO field trials. Category 1 concerns GMOs where there is limited knowledge of their characterisation and confinement measures (e.g. isolation distance) are required. The trial is limited to five locations and to 1ha at each location. In the case of category 2, no confinement measures are required, as the environmental aspects of the GMO are characterised to some extent. The total area of the field trial is limited to 10ha. In the case of category 3, the GMO is fully characterised and there is no area limit to the field trial.

The procedure to obtain consent for the above field trials is as follows. The notifier first submits the application dossier together with the Summary Notification Information Format (SNIF) to the GMO Office. The GMO Office then submits the SNIF to the European Commission. The GMO office carries out the risk assessment and prepares a draft consent, also called a "concept decision" which it makes publicly available for a period of 6 weeks. The concept decision is published in two national newspapers, one agricultural paper, a regional newspaper from the intended location of the trial, in the Official Journal and on the web page of the MI&M. The public then has 6 weeks to submit comments on the concept decision. Each comment is evaluated and will be taken into consideration, if relevant to environmental issues of the planned trial. The GMO Office responds directly to each individual comment received from the public. In parallel, the Dutch Committee on Genetic Modification (COGEM) is requested to provide scientific advice regarding the planned field trial. This committee is an inter-disciplinary scientific body composed of members from public institutions and private companies. Private experts are used where special expertise is required. They are not involved in the assessment of their own notification.

The COGEM evaluates the risk assessment prepared by the GMO Office and issues a scientific advice. The concept decision is also forwarded to the relevant ministries for their approval. The GMO Office considers the advice issued by COGEM and prepares the final consent once they have received the approval from the MI&I and the MEA. The final consent is also made publicly available for 6 weeks before entering into force.

The consent is generally valid for more than one year. It includes, among other things, the description, detection and identification methods of the GMO, the conditions of the release, the locations of the trial, the obligations of the consent holder and the validity of the authorisation. The obligations of the consent holder include requirements regarding isolation distances if applicable, keeping records of the trial in a logbook, training of personnel, waste management, monitoring, reporting and labelling.

In relation to field trials, the notification, SNIF, risk assessment submitted by the notifier, scientific

advice on the notification by the COGEM, public comments and the final consent itself are all published on the website of the MI&M. The location of the trials is recorded in a public register, which is also accessible on this website.

Each year, the consent holder must notify the MI&I that a field trial with a valid consent will be performed and provide the exact location of the trial.

The consent holder has to submit an annual report on the results of the GMO field trial, which the GMO office then checks to see whether the consent conditions have been adhered to and if any adverse effects have been observed.

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

Legal Requirements

Article 6(8) of Directive 2001/18/EC requires that the notifier may proceed with the release only when he has received the written consent of the CA, and in conformity with any conditions required in this consent. Article 6(9) requires MSs to ensure that no material derived from GMOs which are deliberately released in accordance with part B is placed on the market, unless in accordance with part C. Article 10 specifies the reporting by notifiers on releases to the CA after the completion of the GMO release.

Findings

In the last three years, 4-5 GMO field trials were carried out annually, involving apples and potatoes. See table 2 for details.

Table 2: Overview of field trials for GM plants authorised under Part B of Directive 2001/18/EC and the field trials actually conducted 2010-2012

	Permit	Crop	Modification	Locations
2010	B/NL/04/04	Potato	Altered starch composition	4
	B/NL/07/01	Potato	Resistance to *Phytophthora infestans*	3
	B/NL/07/06	Potato	Altered starch composition	2
	B/NL/07/07	Potato	Resistance to *Phytophthora infestans*	2
2011	B/NL/07/04	Potato	Altered starch composition	3
	B/NL/09/02	Potato	Resistance to *Phytophthora infestans*	3
	B/NL/07/07	Potato	Resistance to *Phytophthora infestans*	2
	B/NL/10/05	Apple	Resistance to *Venturia inaequalis*	1
	B/NL/10/06	Potato	Resistance to *Phytophthora infestans*	3
2012	B/NL/10/05	Apple	Resistance to *Venturia inaequalis*	1
	B/NL/11/05	Potato	Resistance to *Phytophthora infestans*	1
	B/NL/09/02	Potato	Resistance to *Phytophthora infestans*	3
	B/NL/07/07	Potato	Resistance to *Phytophthora infestans*	2*
	B/NL/10/06	Potato	Resistance to *Phytophthora infestans*	3**

* The GMO trial at one location was destroyed due to vandalism.
** The GMO trials at two locations were destroyed due to vandalism.

A project plan for the control of GMO field trials is prepared annually by ILT. Inspectors from the ILT carry out at least one control at every trial location each year. A check-list has been prepared to assist the inspectors.

Table 3: GMO controls 2010 to 2012 of GMO field trials

Crop	2010	2011	2012
Potato	11 (on 11 sites)	11 (on 11 sites)	11 (on 9 sites)
Apple	-	1 (on 1 sites)	2 (on 1 sites)
Volunteer control on sites of previous potato GMO trials	4	14	25 (on 25 sites)

The audit team visited two consent holders of apple and potato field trials, respectively.

The ILT inspector explained that he had visited each trial site at least once in 2012. The locations of the potato trial were visited in May-June and the apple trial site was visited in June. The inspector stated that, in both cases, the records of the monitoring activities of the consent holder had been checked. The site of previous potato trials had also been checked for volunteers. A document called 'confirmation of non-infringement' was issued after each inspection. The inspector stated that the consents did not require any specific containment measures to be put in place. He further stated that, based on the experience of previous years, it was not considered necessary to perform a detailed control of the trial site and in 2012 only some records were checked.

Depending on the trial and the conditions of the consent, the inspector also checks the consent holder's records of the storage, transport and harvest of the GM material, as necessary.

The consent holders for the trials stated that they monitor their field trials at least twice a month. Over and above the checks for research purposes, anything unusual observed on the crop is recorded. Non-target organisms are also monitored (e.g. leaf miners in the case of apple).

An independent Environmental Safety Officer (ESO) is employed by each of the consent holders carrying out field trials. The role and obligations of the ESO are laid down in the national legislation 'Regulation on Genetically Modified Organisms'. They perform inspections to check whether the trial is being conducted in accordance with the consent. The ESOs met stated that they control the trial, at the beginning, middle and end of the growing season. The ESO gives advice on the environmental safety aspects of the trial and has a reporting obligation to the MI&I if they find non-compliance with the consent.

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

Legal Requirements

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

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

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

Findings

Currently, no GM crops are grown and never have been.

Conclusions

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

The GMO trials are controlled at an appropriate frequency and verifications are carried out to ensure that the conditions of the consent are met.

5.2.4 Controls of GMOs in seed and propagating material

Legal Requirements

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

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

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

Findings

A project plan and funding for controls of seeds are issued by the ILT and the MEA on alternate years. Based on the plan, 30 samples are taken from 3-5% of maize seed lots intended for the Dutch market or processing and certification in the Netherlands. Seed lots from countries considered at risk are targeted for sampling (e.g. Argentina, Brazil and United States).

Although a large amount of seed is imported into the Netherlands, the CA stated that, because the majority are forwarded, sealed, to other countries, they do not control them for GMO presence. Maize seed is not produced in the Netherlands and the CA is not aware of any GM seed being imported.

Seed inspectors of NAK carry out GMO controls of maize seed.

Table 4 summarises the GMO controls carried out between 2010 and 2012.

Table 4: GMO controls 2010 to 2012 of seed

	2010	2011	2012
No of maize seed samples	30	30	30
No of positive samples	1 (MON810 < 0.1%)	3 (35s promoter << 0.1%, not further identifiable)	2 (MON810 < 0.1%)
Considered non-compliant in the Netherlands	0	0	0

The audit team observed a sampling of maize seed for GMO presence (see section 5.2.8 for details).

The CA stated that a threshold of 0.5% is applied for the presence of GM maize MON810 in non-GM maize seed. Above this level, the seed should be labelled as GM. In practice, this value has never been applied as levels were always at or below the detection limit. In the case of GMO events not authorised for cultivation in the European Union, zero tolerance applies.

The Customs sample imported rapeseed for GMO presence. As the CN code of the rapeseed does not allow identifying the use of the seed, it is decided after the sampling, whether the sample contains seed for sowing or seed for other purposes.

The screening of samples taken by NAK is performed by their laboratory and the screening of the rapeseed samples is carried out by the customs laboratory. In the case of a positive screening result, the identification and quantification is carried out in the RIKILT laboratory. (See section 5.2.9 below).

In recent years, there have been no non-compliant samples identified.

Conclusions

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

However, the threshold applied in the Netherlands for the authorised GM material in non-GM seed contravenes Article 21 of Directive 2001/18/EC and Article 4 of Regulation (EC) No 1830/2003.

5.2.5 Controls of GMOs in food and feed

Legal Requirements

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

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

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

Findings

The system of controls regarding GM food and feed has not significantly changed since the previous FVO audit in 2005.

GMO controls of food and feed are carried out by the NVWA based on a national project plan prepared by them annually. Table 5 summarises the GMO controls of food and feed carried out between 2010 and 2012.

Table 5: GMO controls 2010 to 2012 of food and feed

No of samples	2010	2011	2012
Food	237	137 (most samples analysed in 2012)	90 (by 1st of October, not analysed yet due to use of laboratory resources for products subject to Decision 2011/884/EU)
Feed	143	160	137 (by 1st of October)
Non-compliant sample	5	0	1

Food

Products containing ingredients which can potentially be GMO are planned to be sampled at retail level and analysed for GMO presence.

The NVWA has temporarily suspended the sampling of food other than products falling under Decision 2011/884/EU, because the laboratory capacity is used for analysis of rice products from China.

Feed

The NVWA stated that the vast majority of raw material for feed imported to and produced in the Netherlands contains authorised GMOs and is labelled as such. In recent years, non-compliances with feed GMO labelling requirements had not been identified. As a result, the NVWA decided to stop verifying the labelling requirements and focus on checks for labelled GM feed for unauthorised GMO instead.

Conclusions

Controls of GMOs in food and feed are in compliance with EU legislation.

However, the GMO control of food is currently limited to checks under Decision 2011/884/EU.

5.2.6 Controls of specific import requirements

Legal Requirements

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

Findings

In order to ensure the implementation of Decision 2011/884/EU the NVWA has updated its work instructions regarding import controls.

Since Decision 2011/884/EU entered into force, the GMO controls of food are dedicated to the implementation of the Decision. There have been 219 samples taken from rice and rice products from China. Non-authorised GMO was detected in 18 samples (see section 5.3 for details).

Consignments subject to Decision 2011/884/EU are required to be notified before they enter the Netherlands. The prior notification has to be performed electronically using the Common Entry Document (CED) established by Regulation (EC) No 669/2009. Registered business operators can send the notification via a web based IT application called Veterinary Border Control (VGC). The

scanned copy of the analytical report issued in China and the Chinese health certificate has to be attached to the notification. The VGC allocates a unique identification number to each consignment. The business operator also has the possibility to notify the NVWA non-electronically. It may extend the control time as data need to be processed by NVWA.

Customs do not operate any system to verify whether all consignments subject to Decision 2011/884/EU have been notified.

The audit team visited the Customs at Rotterdam harbour.

The documentary check of products notified under Decision 2011/884/EU is carried out by the Customs, who have access to the VGC. They verify whether the analytical report and the health certificate are attached to the CED and are in compliance with the model documents of Decision 2011/884/EU. The original documents from China are not checked. In the case where the analytical report and the health certificate are not attached, the Customs inform the business operator that they can not proceed. The Customs stated that, based on the oral statements made by the operators, some consignments with prior notification had been imported without the report and certificate. It happened in the case of products of CN1902 and CN 190230, where a considerable part of the products does not contain rice.

The Customs further stated that, certain CN code categories in Annex I of Decision 2011/884/EU cover a broad range of products, large number of consignments and the majority of them do not contain rice. The audit team requested data to substantiate this claim, and to confirm that all consignments containing rice products had in fact been checked and sampled. At the time of drafting this report, the CA had not provided such data.

After the documentary check, the customs refer the product to the NVWA.

The audit team visited a warehouse where a consignment subject to Decision 2011/884/EU was sampled by an NVWA inspector (see section 5.2.8 for sampling details).

The NVWA inspector carries out an identity verification, checks the ingredient list of the product, if available, and the product is sampled if it contains rice. These controls are carried out at locations where suitable facilities are available.

The customs clearance may take place before the identity and physical controls, and in this case, the consignment remains under the supervision of the NVWA until the laboratory results have become available, which takes about two weeks**.**

Conclusions

There is a control system in place for the implementation of Decision 2011/884/EU. The system does not ensure that the CA verifies that all consignments subject to prior notification are actually notified by the operators. This is not in line with Article 3 of the Decision. Consequently, the CA cannot ensure that all the products referred to in Article 1 of this Decision are subject to documentary checks and meet the import conditions of its Article 4, which is not in line with Article 5 of the Decision.

The control system in place allows that products referred in Annex I to Decision 2011/884/EU be imported without the analytical report and health certificate based on oral statements made by the operators. Using oral statements does not fulfil the requirements of Article 4(2) of this Decision.

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

In the case of GMO trials, the main aim of the controls is to ensure that the conditions of the trial consent are met. Each trial location is visited at least once annually and the details of the controls depend on the requirements laid down in the consent and the control results of the same trial or same GMO event or crop.

The NVWA stated that as they did not identify non-compliances regarding labelling of GM food and feed in recent years, they focus their controls on unauthorised GMOs. Due to the large number of consignments subject to Decision 2011/884/EU the NVWA dedicate most of their GMO controls to implement this Decision and other GM food controls are currently suspended.

In the case of GMO controls of seed, priority is given to seed intended for the Dutch market or processed in the Netherlands.

Conclusions

Official controls of GMOs are prioritised in accordance with Article 3 of Regulation (EC) No 882/2004. However, currently, GM food controls only include controls under Decision 2011/884/EU.

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[1] 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

<u>Sampling of rice products from China</u>

The audit team observed a demonstration of sampling of rice crackers in carton boxes from China subject to Decision 2011/884/EU.

The sampling was carried out by an NVWA import inspector during the unloading of a container in a warehouse. The sampling procedure applied followed the instructions of section D.2.7.2 of Regulation 178/2010 (Sampling procedures for peanuts oilseeds etc. traded in vacuum packages).

1 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

The procedures of the Regulation are adequate for the purposes of taking representative samples from the consignment sampled and are considered as equivalent to CEN/TS 15568 by the audit team.

The inspector first carried out a number of documentary checks. Based on the lot size of 2,310 carton boxes she then calculated the number of units to be sampled and the number of increments to be taken from the lot. During the sampling process, 25 carton boxes were selected and 100 increment samples of 200g each were withdrawn from these boxes. The final sample size consisted of 20kg.

The samples taken were packaged, closed and sealed. Each sample received a unique identification number and was transported to the laboratory by the NVWA on the same day. A sampling report was drawn up.

Sampling of seed for sowing

The audit team observed a demonstration of sampling of maize seeds carried out by an inspector of NAK. The sampling procedure followed the rules of International Seed Testing Association (ISTA). Apart from the label attached to the seed sample, no sampling report was drawn up by the inspector. (See 5.2.10 regarding reporting).

The sampling procedures applied are based on sampling 3,000 kernels allowing a limit of detection of 0,1% GMO in the sample based on the seed calculations. Three laboratory samples of 3,000 kernels are formed: the 1st for the laboratory analysis by the NAK laboratory, the 2nd as counter sample for the business operator and the 3rd sample as reserve sample for confirmation by the RIKILT laboratory.

Sampling of feed

The CA informed the audit team that samples of feed ingredients and compound feed, taken in the framework of official feed controls (e.g. for mycotoxin analysis), have been used for GMO controls.

Conclusions

Sampling was carried out in compliance with the EU legislation.

5.2.9 Laboratory performance

Legal Requirements

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

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

Findings

The audit team visited the NVWA and the RIKILT laboratories. Both laboratories have been designated to perform GMO analysis of official samples and had been visited by the 2005 mission.

GMO analysis of food is carried out by the NVWA laboratory while the GMO analysis of feed by

the private laboratory RIKILT. Both laboratories work in close co-operation.

Samples of rice products from China under Decision 2011/884/EU are generally analysed by the NVWA laboratory. In the case of detection of unauthorised GMO, the analysis is repeated by RIKILT. The RIKILT laboratory carries out the analysis of some 10% of the rice products as a subcontractor for NVWA. The analysis is repeated by the NVWA laboratory where unauthorised GMO is detected. The samples are considered to be non-compliant where the result is confirmed by the other laboratory.

NVWA laboratory

The NVWA laboratory has been recently re-organised merging the five former regional laboratories.

The laboratory layout is functional with separated areas for the different methodological steps. This prevents possibilities of cross-contamination. The GMO laboratory is well organised and properly equipped with designated grinding facilities, sample preparation instruments and up-to-date real-time Polymerase Chain Reaction (PCR) instruments. The personnel are adequately trained and demonstrated a proper knowledge of the GMO analysis. Sufficient staff are available to carry out analysis of samples defined in the national control plan. Currently, most resources of the laboratory are used for analysing samples taken under Decision 2011/884/EU.

The laboratory is accredited under the flexible scope of ISO 17025. The quality management system of the laboratory allows a reliable analysis.

The relevant methods for the detection of authorised GMO are in place and properly validated. In 2012, only rice samples under Decision 2011/884/EU have been analysed. The laboratory informed the audit team that the SYBR® green based cryIA(b)/cryIA(c) detection method leads to positive signals that may cause problems in interpreting the results, therefore all positive results are verified by the RIKILT laboratory. Samples with verified results are considered as non-compliant.

RIKILT

RIKILT is the National Reference Laboratory (NRL) for GMO analysis.

The GMO analysis of samples and the verification of positive results of other laboratories are carried out under the contract with the Dutch government. Laboratory results requiring actions are immediately submitted to NVWA.

The laboratory is accredited under the flexible scope of ISO 17025. The quality management system of the laboratory allows a reliable analysis.

The laboratory layout has the same structure as the NVWA laboratory, the quality management system and the equipment are appropriate. The capacities of the laboratory allow analysing samples as sub-contractor for NVWA.

The methods are in place and the analytical strategy is designed for a reliable detection of both authorised and unauthorised GMO.

The RIKILT laboratory verifies positive findings of food samples for the NVWA laboratory and performs the identification and quantification of the GMO in the case of positive screening results of seed samples of the NAK and the Customs laboratories.

NAK and Customs laboratories

The CA informed the audit team that laboratories of NAK and Customs perform screening on GMO based on 35S-promoter and NOS-terminator. In the case of positive results the sample is to be analysed by RIKILT to specify the GMO.

Conclusions

Adequate laboratory procedures are in place to ensure that GMO analysis is performed in line with EU legislation.

The capacity of the laboratories is not adequate to handle both samples from the Chinese rice controls and samples from the controls of food products.

Analytical methods as provided in Annex II of Decision 2011/884/EU regarding rice from China are properly implemented.

Test methods for the purpose of Regulation (EU) No 619/2011 are implemented.

5.2.10 Procedures for performance and reporting of control activities

Legal Requirements

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.
Article 9 requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Findings

Written procedures and standardised forms are in place regarding official controls of GM food, feed, seed and GMO trials. GMO controls are based on project plans which are issued annually.

Control results are systematically reported by inspectors and annual reports regarding the results of GMO controls are prepared centrally by each authority.

However, no sampling report was drawn up by the NAK inspector in the case of sampling of seed for GMO presence.

Conclusions

Documented procedures are in place as required by EU legislation.

The absence of a report on seed sampling is not in line with 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 between CAs.

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

Findings

The authorities within the scope of the audit are centralised, generally one unit is competent to carry out GMO controls at each authority. There is a regular contact among the authorities involved in

GMO controls.

The co-ordination of the GMO controls carried out by the NAK and the RIKILT laboratory is ensured by annual written contracts. Control results are systematically reported to the competent authorities by the NAK and the RIKILT laboratory.

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

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

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

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

Findings

The applicable national legislation regarding sanctions is set out in section 6.2 of the last GMO mission report.

Generally, in recent years, only minor non-compliances have been identified during GMO controls, where the operators were required to rectify the deficiencies.

The audit team noted that in the case of some consignments subject to Decision 2011/884/EU, the confirmed analytical result was positive and the NVWA waited for the result of the counter sample by a private independent laboratory performed at the request of the sample owner. They rejected the consignment of the rice product only then.

Conclusions

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

5.2.13 Verification procedures and audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a

transparent manner. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure that corrective action is taken when needed and to update documentation as appropriate.

Findings

Internal audits are performed in the NVWA which can include GMOs. The CA stated that no audits had been carried out dedicated to GMOs in recent years.

A quality control system is under implementation at ILT, which is planned to include verification of the effectiveness of official controls.

Evidence was provided that the NVWA had carried out a documentary check to verify whether the Customs perform the documentary controls to ensure the adequate implementation of Decision 2011/884/EU in the case of consignments notified by using the CED.

Conclusions

There is a system for verification procedures and audits in place as required by Regulation (EC) No 882/2004, however, GMO controls have not been recently audited.

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 NVWA is the national contact point for GMO RASFF notifications regarding food and feed, respectively.

The audit team noted that NVWA identified 18 samples where unauthorised GMO was detected in rice products from China subject to Decision 2011/884/EU by the time of the audit. In the case of 10 samples, the result was confirmed by the other official GMO laboratory, therefore the NVWA considered them non-compliant. The NVWA stated that in the case where the operator appeals against the decision made based on positive laboratory results, the RASFF notification is issued only after the appeal procedures have been completed. The NVWA presented three cases of written complaint to the audit team. However, in total, four border rejection RASFF notifications have been issued concerning products subject to Decision 2011/884/EU.

Evidence was provided to the audit team that follow up actions are taken in response to relevant RASFF notifications.

Conclusions

RASFF border rejection notifications are not systematically issued, therefore, the operation of the RASFF does not ensure that food safety risks are notified.

Follow up on RASFF notifications is taking place.

6 Overall Conclusions

Overall, the Dutch control system ensures the implementation of the EU GMO legislation. Controls

are generally risk based and supported by competent laboratories. However, a threshold is applied for authorised GMO presence in seeds, which is not in line with the EU legislation and it is not ensured that each consignment, subject to Commission Decision 2011/884/EU on rice and rice products from China, is controlled.

7 Closing Meeting

A closing meeting was held on 23 November 2012 with representatives of the CA. 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 the Netherlands should ensure that:

N°.	Recommendation
1.	Any detectable presence of GMO in seed is subject to labelling and traceability requirements of GMOs in line with Article 21 of Directive 2001/18/EC and Article 4 of Regulation (EC) No 1830/2003.
2.	The obligations established for feed and food business operators or their representatives referred to in Article 3 of Decision 2011/884/EU are met in order to ensure compliance with the requirements of Article 5 of the same Decision.
3.	The import conditions established in Article 4(2) of Decision 2011/884/EU are met. In particular that the import of products referred in Annex I to this Decision without analytical report and health certificate is allowed only when these documents are replaced by a declaration issued by the operators indicating that the food or feed is not containing, consisting or produced from rice.
4.	The laboratory capacity is adequate to analyse both samples taken under Decision 2011/884/EU and samples from the controls of food products as required by Article 4(2)(c) of of Regulation (EC) No 882/2004.
5.	Reports are drawn up on sampling of seed for GMO presence as required by Article 9 of Regulation (EC) No 882/2004.
6.	A RASFF notification is always issued when non-authorised GMO is detected in line with Article 50 of Regulation (EC) No 178/2002.

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=2012-6312

The CA in the Netherlands 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
Reg. 669/2009	OJ L 194, 25.7.2009, p. 11-21	Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC