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Directorate F – Food and Veterinary Office

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FINAL REPORT OF A MISSION

CARRIED OUT IN BELGIUM

FROM 13 TO 17 FEBRUARY 2006

IN ORDER TO

EVALUATE OFFICIAL CONTROL SYSTEMS FOR FOOD AND FEED CONSISTING OF OR PRODUCED FROM GENETICALLY MODIFIED ORGANISMS (GMOs)

Please note that factual errors in the draft report, identified by the Competent Authorities of Belgium, have been corrected in the text of this final report. Clarifications, provided by the Competent Authorities of Belgium, are given as footnotes, in italics, to the relevant part of this final report.

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1. EXECUTIVE SUMMARY

The mission was carried out as part of a series of missions to a number of Member States to evaluate official control systems on food and feed consisting of or produced from genetically modified organisms (GMO). The mission team met with the Central Competent Authority and 2 regional authorities. Visits were also made to 1 control laboratory, 1 Border Inspection Post (BIP) and one visit each to a food and feed business.

Responsibilities were clearly defined, and controls on GMO in food and feed were well organised. There was good communication and cooperation with most stakeholders. Annual control plans did not cover foodstuffs controls at the point of entry for food, and it was noted that there is currently no communication with customs administration. Reports of GMO food and feed controls in 2004 and 2005 were available, with a number of samples exceeding the legal threshold of 0.9%. In such cases appropriate follow-up of actions of infringements was taken.

Inspectors availed of documentation for inspection and sampling, outlining GMO policy and working procedures and the main legal requirements operators have to comply with. On 3 occasions, the mission team observed inspection visits, which were in conformity with the Community legal requirements.

National legislation rather than Commission Recommendation 2004/787 on technical guidance for sampling and detection of GMOs is followed for sampling food and feed.

The laboratory of the Institute for Agricultural and Fisheries Research visited was accredited according to ISO 17025 for GMO analysis and was assessed by the mission team as to be adequate within the framework of official controls of GMO in food and feed.

Overall, there is a good system in place for official controls within the scope of Regulation (EC) No 1829/2003 and 1830/2003. Controls were well planned and executed, inspectors were aware of the applicable legislation concerning labelling and traceability of GMO in food and feed. Where non-compliances were found appropriate follow-up measures were taken.

The report provides a number of recommendations to the competent authorities in Belgium.

ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

BIP	Border Inspection Post(s)
CA	Competent Authority/ies
CRL	Community Reference Laboratory
CRM	Certified reference material
DNA	Deoxyribonucleic acid
EC	European Commission
EFSA	European Food Safety Authority
ELISA	Enzyme-linked-immuno-sorbent assay
ENGL	European Network of GMO Laboratories
EU	European Union
AFSCA	*Agence Fédérale pour la Sécurité de la Chaîne Alimentaire*
SPF	*Service Public Fédéral Santé Publique, Sécurité de la chaîne alimentaire et Environnement*
FTE	Full Time Equivalent
FVO	Food and Veterinary Office
GeMMA	Genetically Modified Materials Analysis Scheme
GM	Genetically Modified
GMO	Genetically Modified Organism(s)
HACCP	Hazard Analysis and Critical Control Points
ILVO	*Instituut voor Landbouw en Visserij Onderzoek*
IRMM	Institute for Reference Materials and Measurements
ISTA	International Seed Testing Association
JRC	Joint Research Centre (Ispra)
LIMS	Laboratory Information Management System
MS	Member State
PCR	Polymerase Chain Reaction
UPC	*Unité Provinciale de Contrôle*
RASFF	Rapid Alert System for Food and Feed
SD	Standard deviation

2. INTRODUCTION

The mission took place in Belgium from 13 to 17 February 2006. The mission team comprised of two inspectors from the Food and Veterinary Office (FVO), and one Member State expert.

The mission was undertaken as part of the FVO's planned mission programme.

The inspection team was accompanied during the whole mission by representatives from the central competent authority, the Federal Agency for the Safety of the Food Chain (AFSCA).

An opening meeting was held on 13 February with representatives of the Federal Public Service of Public Health, Food Chain Safety and Environment (SPF), the AFSCA and the Walloon and Flemish region. At this meeting, the inspection team confirmed the objectives and the itinerary of the mission.

3. SCOPE AND OBJECTIVES OF THE MISSION

The overall objective of the mission was to evaluate the official control systems for food and feed containing, consisting of or produced from genetically modified organisms (GMO). Within this context the mission team evaluated the following:

- the supervision performed by the competent authority (CA) to ensure that the placing on the market of genetically modified (GM) food and feed complies with Regulation (EC) No 1829/2003 of the European Parliament and the Council[1], with the exception of the authorisation procedure;
- the application of Regulation (EC) No 1830/2003 of the European Parliament and the Council concerning the traceability and labelling of genetically modified organisms (including GM seeds, or the presence of GM seeds in conventional seeds) and the traceability of food and feed products produced from genetically modified organisms;
- the implementation of Council Directive 2002/53/EC in so far as it relates to the placing on the market of varieties of GM agricultural plant species contained in the common catalogue, and Commission Decision 2004/842/EC in so far as it relates to national authorisations for placing on the market of GM varieties not yet entered in this common catalogue;
- any action taken by the competent authorities in order to comply with the requirements of Commission Decision 2005/317/EC.

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

[1] All legal references refer, where applicable, to the latest amended version. Full references to the acts quoted in this report are given in the Annex.

Table 1 Mission visits and meetings

Visits/meetings		Comments
COMPETENT AUTHORITIES		
Central	4	SPF, AFSCA, Walloon and Flemish Region
Provincial and point of entry/import	2	Provincial AFSCA services of West Flanders and East Flanders
LABORATORIES		
Laboratory of the Flemish Region	1	Institute for Agricultural and Fisheries Research (ILVO) laboratory
FOOD AND FEED ESTABLISHMENTS		
Feed mill	1	56 Full Time Equivalent (FTE)
Food processor	1	400 FTE

4. LEGAL BASIS FOR THE MISSION

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

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

5. BACKGROUND

5.1. Summary of previous mission series results

Prior to this mission, the FVO carried out a number of missions to Member States in order to evaluate the implementation of previous EU legislation on GMO products. The final reports of these missions can be found on the DG Health and Consumer Protection Internet site:

http://europa.eu.int/comm/food/fvo/index_en.htm

Overall, it was found that the level and scope of enforcement in Member States varied and analytical activities, if carried out, were impeded by the lack of quantitative GMO detection methods and certified reference materials. Prior to the entry into force of current Regulations imported GMO raw materials such as grains and milling products were not covered by EU legislation and the findings of the mission series indicated that these commodities were infrequently inspected and/or sampled.

5.2. Background to present mission series

This report is part of a series of missions to Member States with similar objectives concerning the evaluation of the implementation of new EU Regulations on official controls for GMOs in food, feed and seed. The final reports of these missions are also available on the DG Health and Consumer Protection Internet site.

According to the report "Global Status of Commercialized Biotech/GM crops 2005"[2] the cultivation area of biotech crops increased from 1.7 million hectares in 1996 to 90 million hectares in 2005. The main producers of biotech crops are outside Europe, led by the USA and followed by Argentina, Canada, Brazil and China. The most important crops are soy beans, maize, cotton and rapeseed. It is estimated that GM crops cover almost 4% of total global arable land[3].

Several authorisations for placing on the market and for deliberate release into the environment of GM plants have been granted under previous and current legislation. The current situation is shown on the following website:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/index_en.htm

6. MAIN FINDINGS

6.1. Economic statistics

In response to the pre-mission questionnaire and based on information provided by a professional feed association in Belgium, the annual production of GM and non-GM compound feed in Belgium is 6.1 million tons. According to the same association, the share of compound feed labelled as containing GMO is 70%.

Imports from third countries are summarized in Table 2, focussing on commodities potentially consisting of, containing, or produced from GMO. The main countries of origin for maize in 2004 were France, Brazil and Argentina, whereas in 2005 France was the main country of origin. The main countries of origin for soy beans and products thereof were the USA, Canada, Brazil, and The Netherlands for 2004 and 2005. No information was available concerning the amount of GM food and feed imported, as the combined nomenclature of the World Customs Organisation does not foresee specific classification for these products.

Since 2003, an application for one field trial was received by Belgium authorities, under notification number B/BE/03/V1, but not authorised. No further cases of applications for experimental or commercial cultivation of GMO crops in Belgium in 2004 and 2005 were reported by the authorities.

Table 2: Relevant imports into Belgium originating from non-EU countries in metric tons (source: EUROSTAT/ AFSCA)[4]

Quantities imported GMO products	2004 EUROSTAT	2004 AFSCA	2005 EUROSTAT	2005 AFSCA
Soya beans (excl. for sowing)	563,547	6,090	653,172	51,717

[2] James, C. 2005. Preview: Global Status of Commercialized Biotech/GM Crops: 2005. ISAAA Briefs No. 34. ISAAA; Ithaca, NY

[3] WHO biotechnology report 2005 http://www.who.int/foodsafety/publications/biotech/biotech_en.pdf

[4] ***In their response to the draft report AFSCA added that maize and rape seeds imported are used in the processing industry and not for cultivation.***

Quantities imported GMO products	2004 EUROSTAT	2004 AFSCA	2005 EUROSTAT	2005 AFSCA
Soya beans for sowing	0	0	0	0
Soya bean flour and meal	1	0	206	30
Oilcake/pellets from extraction of soy-bean oil	818,558	660976	752,183	711,800
Rape seeds	0	0	95	43.3
Oilcake/pellets from extraction of rape seed oil	0	1845*	0	0
Cotton seeds	0	0	0	0
Oilcake/pellets from extraction of cotton seeds	805	0	214	0
Maize (excl. seed)	146,652	53,526	7,044	21,746
Maize seeds	19,919	0	401	0
Corn gluten feed	0	0	0	0
Brewers grain	2,093	0	0	0

*including cotton seeds

A large discrepancy between the import data provided by the AFSCA and EUROSTAT data was noted. AFSCA representatives explained that their data referred to feed products.

6.2. Legislation

Regulations (EC) No 1829/2003 and 1830/2003 of the European Parliament and the Council are directly applicable in Belgium. Royal Decree of 04 May 2004 amended Royal Decree of 08 February 1999 in that it replaced the existing national provisions on feed labelling by those provided by the Regulation (EC) No 1829/2003 and 1830/2003. In order to sanction infringements of the aforementioned Regulations, Royal Decree of 22 February 2001 and Royal Decree of 16 December 2002 are applicable.

Labelling of food and feed as “GM-free” or as to contain GMO when actually not present in the product is not permissible according to the SPF. Relevant communication was sent to professional organisations.

For sampling of foodstuffs in general, Royal Decree of 05 December 1990 “on sample taking in foodstuffs and other products” is applicable. For feed stuffs, Royal Decree of 08 November 1998 on “the official control of substances destined for animal feeding” is applicable (transposition of EU Directive 76/371/EEC).

6.3. Competent authorities

The competencies of those organisations with responsibility for the official control within the scope of this mission are summarised in the following table:

Table 3: Structure and responsibilities

Levels Institutions	**Central**	**Regional**	Competencies
Food & Feed			
Ministry of Public Health and Ministry of Environ-ment	Federal Public Service Health, Food Chain Safety and Environment (SPF)		- Policy making - Preparation of legislation - Competent Authority for authorisation of GMO within the meaning of Articles 5 and 17 of Regulation (EC) No 1829/2003
Ministry of Public Health	Federal Agency for the Safety of the Food Chain (AFSCA)		- Implementation of Regulation (EC) No 1829/2003 and 1830/2003 - Setting up of annual control plans and procedures to be followed by inspectors of Provincial Control Units (UPC) - Central department in Brussels responsible for supporting inspectors in the UPC regarding legislative questions and to submit RASFF notifications to Commission Services
		11 Provincial Control Units (UPC) of the AFSCA throughout Belgium	- Executing annual control plans and reporting to headquarter
Federal Public Service of Finance	Administration of Customs and Excise		- Policy making and instructions
		7 Regional Inspectorates	- Documentary control and customs clearance
Seed			
		Flemish and Walloon Region	- Both regions competent for preparation of legislation, and planning and execution of controls regarding propagating materials commercialised and/or produced on their territories

The AFSCA has approximately 1350 staff, of which 74 are working in the "control policy" department, 608 working in the central "control department" and the UPCs, of which 522 staff in the UPC carry out inspection and sampling. Five internal laboratories provide analytical service in the area of food and feed. They avail of 170 staff and perform 200,000 laboratory examinations annually.

Within the AFSCA at the central authority in Brussels, the "Policy Control Department" is responsible for preparing the annual control programme for food and feed. The "Control Department" is responsible for the elaboration of the annual control plan of the UPC and supervises its execution by the 11 UPC. Furthermore, the department is responsible for providing working instructions and protocols to be used by inspectors on the spot. All 11 UPCs have specialised departments to deal with the implementation of EU legislation on food and feed. Control activities for feed include all stages of processing and marketing, including imports, whereas controls of foodstuffs at import are generally not planned. For further information on structure and responsibilities of the AFSCA see report SANCO 7060/2004 and SANCO 9060/2003.

6.4. Controls on GMO in Foods

6.4.1. Planning of controls

Planning of annual controls is undertaken by the central control department of the AFSCA and submitted to the UPCs. These plans include information about the scope of inspection and/or sample to be taken, the timing and what technical instruction is to be used by inspectors. All information is available to UPC inspectors via an intra-service IT-system. Each UPC assigns individual inspectors to execute the plans and prepares monthly reports to the central control department. In 2004 and 2005, for food the main objectives were to focus on

- the labelling of authorised GMO,
- the absence of non-authorised GMO,
- proof of adventitious or technically unavoidable presence of GMO by the processor, if GMO presence was not indicated on the product label.

Mainly maize and soya products (already on the market) in the retail and processing sector were targeted, potentially containing GM material. Because of analytical limitations regarding the detection of GMO in highly processed foodstuffs, in 2006 inspectors were instructed not to take samples from materials such as lecithin and food additives.

GMO inspections consist of sampling and traceability checks of the product sampled, as provided by the technical instructions.

AFSCA representatives explained that there are no controls planned for foodstuffs at import as there is no legal requirement for such controls. However, discussions with customs administration to coordinate and set up these controls are currently ongoing and expected to be implemented in 2007.

For 2006, the following activities were planned by the central control policy department:

Table 4 Control plan 2006 GMO food – sampling and inspection

Inspection and sampling of	Processing	Distribution
Foodstuffs on the basis of maize	69	40
Foodstuffs on the basis of soya	69	40

In the retail sector, controls on GMO in food focus on sampling of aforementioned products. It was explained by AFSCA representatives that if non-compliances were found, follow-up activities would be carried out at the producer of the product (if domestic producer), checking if traceability requirements of Regulation (EC) No 1830/2003 were met.

For carrying out controls, UPC inspectors received training and technical instructions as follows:

- Training given to 2 delegates of each UPC on 26 April 2005 by the control policy department of the AFSCA, on Regulation (EC) No 1829/2003 and 1830/2003 and subsequent training of inspectors within each UPC.
- Technical instructions provided by the central control department and to be followed by inspectors when executing control plans. In addition to the information provided by the annual control plan, the instructions provided a checklist for inspectors to perform checks regarding adventitious or technically unavoidable presence of GMO.

6.4.2. Communication among the authorities and with other relevant Ministries and stakeholders

Communication among the authorities and other relevant actors is organised through different channels:

- A central level committee of the AFSCA supports UPC's inspectors on interpretation of legislation or when non-authorised GMO have been detected and specific follow-up is necessary
- Cooperation of the CA with professional organisations in the form of a seminar on 20 January 2004, where the SPF and the AFSCA gave a lecture on the new Regulations (EC) No 1829/2003 and 1830/2003
- A guidance document was prepared based on the cooperation between the aforementioned professional and public organisations, available under http://www.favv-afsca.fgov.be/p/images/cereus/nl/pdf/ogm/ggoGids.pdf
- Info on SPF website http://www.ogm-ggo.be relating to GMO events authorised in the EU
- Quarterly meetings to coordinate analytical work, organised by the central AFSCA laboratory department and representatives of its 5 laboratories.
- A "Steering Group GMO" has the objective to assure the coordination between the different services and colleagues who work with GMOs at federal level. Representatives from the food, medicinal and environmental division of the SPF, collaborators of the Ministers, the permanent representation of Belgium at the EU level, AFSCA and scientific institutes tale part in the meetings.

6.4.3. Performance of inspection and sampling

The mission team evaluated an inspection performed by an inspector of the UPC West-Flanders at a producer of products based on soy beans. The producer operated its own identity preservation system, which was also certified by an independent private body. Raw materials were sourced from non-EU countries such as Brazil, China and Canada. Previous inspections and samplings in the context of EU legislation on GMO in food took place in January 2004 and November 2005. During the inspection demonstrated, the mission team took note of the following.

- The inspector followed the technical instruction for inspection and sampling TRA/591, provided by the central control department and was equipped with all necessary tools.
- Based on the Royal Decree of 05 December 1990, the inspector took all 11 incremental samples from a foodstuff of 6 tons total size at the same time. He explained that the timing of sampling is decided on an individual basis. Commission Recommendation 2004/787/EC was not used.
- In parallel to sampling and in line with TRA/591, the inspector acquired further information related to the lot sampled, such as delivery documents, type of commodity, type of labelling of end products and type of system applied to ensure traceability of GM products within the company.
- Within the scope of the mission, inspectors are not required to gather specific information on the internal traceability in companies, i.e. the possibility to establish a direct link between incoming materials and outgoing products.
- The inspector required information on actions undertaken by the company in order to verify the information received from suppliers.

6.4.4. Results of controls on GM (Inspection and sampling)

Results of samples taken by UPC inspectors are compiled annually by the AFSCA in the form of annual reports (see e.g. http://www.favv-afsca.fgov.be/p/images/cereus /nl/pdf/rapport/AV2004_S.pdf).

Of the 181 samples taken in 2004, 14 were found to contain GMO. Only one sample of fried shrimp cake originating from the USA contained GMO in excess of 0.9% and in addition one GM ingredient (GA21) not authorised for marketing within the EU at that time. The product concerned was withdrawn from the market, a RASFF notification was launched and the importer was sanctioned. In all other cases, follow-up performed by the UPC inspectors showed that the GMO presence was adventitious or technically unavoidable. Examples of follow-up activities were provided to the mission team. During 2005 9 samples were found to contain GMO, but all were below 0.9%. Follow-up of these samples was similar to those activities described for 2004[5].

[5] ***In their response to the draft report the Belgium competent authorities added that only those food and feed samples are considered positive for the presence of GMO where the content of GMO exceeded the analytical limit of detection.***

Table 5: Overview of results of GMO analyses of food in 2004 and 2005 as provided by the AFSCA

	2004: Number of samples analysed and results	2005: Number of samples analysed and results
No. of samples	181	207
No. of samples where extraction of DNA was not possible	49	36
% Positive and type of GMO	7.7 (14 samples) 13 RR soya ; 1 sample mixture of Bt 11, Bt 176, MON 810, GA 21	4.3 (9 samples) 9 RR soya;
% non compliant	0,5 (1 sample)	0

6.4.5. Follow-up of infringements

The only infringement found in Belgium refers back to 2004, when one sample of fried shrimp cake containing authorised and non-authorised GMO was found. The case is described under the previous heading. In general, the infringement procedures are based on national legislation described under 6.2.

6.5. Controls on GMO in Feed

6.5.1. Planning of controls

Planning of feed stuffs controls follows the same principles as for foodstuffs, in so far as it concerns the procedure of setting up and communication of plans and reporting of execution. The mission team noted that

- Controls focussed in 2004 (since coming into force of Regulation (EC) No 1829/2003 and 1830/2003) and 2005 on compound feed producers.
- Mainly raw materials were subjected to controls, containing or potentially containing GMO, whether authorised or not.
- Controls included import of feed stuffs.
- UPCs were informed by the AFSCA on 19 May 2005 about checks to be performed on commodities covered in Commission Decision 2005/317/EC.
- Technical instruction TRA 018 from April 2005 based on Regulation 1829/2003 and national Royal Decree of 08 February 1999, was available for feed stuff controls in 2005. No information on quantities to be sampled was indicated in TRA 018.
- For samplings to be performed in 2006, inspectors were provided with a technical instruction TRA 053. It contained detailed information on products to be sampled and follow-up in case of non-compliances. No information on the procedure of sampling apart from a general sample size of 500g was given. Furthermore, no reference was made in TRA 053 to the Royal Decree

of 08 November 1998 concerning official controls (and sampling) of feed stuffs[6]. Commission Recommendation 2004/787/EC was not used.

For 2006, the following activities were planned by the central control department:

Table 6 Control plan 2006 GMO feed – sampling and inspection

Inspection and sampling of	Raw materials	Compound feed
On the basis of maize	44	22*
On the basis of soya and /or rapeseed	66	*
Others than maize and soya	22	0

* 22 samples to be taken from products containing maize, soya and/or rapeseed

6.5.2. Communication among the central, regional and local authorities and with other relevant Ministries

With regard to communication, the same general activities and principles are applicable for feed as for food outlined under 6.4.2. In addition, the following was noted by the mission team.

- A letter was sent to professional bodies by the SPF on 04 November 2004 concerning the products labelled as to contain GMO while actually not present in the product. This letter explained SPF's standpoint that such cases would not be in line with Regulation (EC) No 1829/2003.
- Controls at import covered products that can be used for animal nutrition, based on a list prepared by the AFSCA and available to UPC inspectors and customs.
- On 19 May 2005, the AFSCA issued a note informing UPC inspectors about products potentially containing the non-authorised GM event Bt 10 and describing special import conditions as required by Commission Decision 2005/317/EC.
- The SPF on a regular basis provides the AFSCA with updated and summarizing tables containing all relevant information concerning GMO and derived products actually authorised for use in food and feed.

6.5.3. Performance of inspection and sampling

The mission team evaluated 2 inspections performed by inspectors of the UPC East-Flanders at a transhipment and storage facility and at a feed mill. The responsible inspectors availed of the 2 instructions mentioned under 6.5.2, the necessary equipment, and clothing to perform the inspections. It was noted by the mission team that

- Sampling of feed stuffs by the inspectors was in line with Royal Decree of 08 November 1998, which details the sampling in so far as it links different batch sizes to the number of increment samples to be taken.

[6] ***In their response to the draft report the Belgium competent authorities explained that the Royal Decree is the basis of the inspector's work and thus needs no mentioning in the technical instruction, as these should provide specific recommendations.***

- The timing of sampling was not specified in the aforementioned Decree and thus the inspector took all required increments at once.
- Sampling of materials in bulk (e.g. in a silo) as demonstrated, was limited to those areas accessible. It was explained by the UPC inspector that in cases of positive findings, the sampling would be repeated in order to achieve a sample representative for the whole batch. However, no written instruction was available for such case.
- For the documentary control demonstrated at the feed mill no specific instruction or checklist was available for the inspector. However, the inspector was aware of the legal requirements and checked documentation related to incoming and outgoing products. AFSCA representatives explained that a checklist for controls on the adventitious or technically unavoidable presence of a GMO is under preparation for 2006.

6.5.4. Results of controls on GM (Inspection and sampling)

Results of samples taken by UPC inspectors are compiled annually by the AFSCA in form of annual reports (see e.g. http://www.favv-afsca.fgov.be/p/images/cereus/nl/pdf/rapport/AV2004_S.pdf).

Between 2004 and 2005 the rate of non-compliances was down from 17.5% to 5.6%, whereas the sample number taken was down from 183 to 160. No non-authorised GMO had been found in feed stuffs.

Table 5: Overview of results of GMO analyses of feed in 2004* and 2005 as provided by the AFSCA

	2004: Number of samples analysed and results	2005: Number of samples analysed and results
No. of samples	183	160
No. of samples where extraction of DNA was not possible	0	0
% Positive and type of GMO	49 (90 samples) 87 RR soya, 2 maize T25, 1 MON810	22 (35 samples) 29 RR soya, 6 MS 8, 4 GT 73, 1 MON810, 1 Bt176
% non compliant	17.5	5.6

6.5.5. Follow-up of infringements

Most common infringements was the mislabelling of feed stuffs containing GMO, what was not indicated on the label. Furthermore, use of terms other than provided by Regulation (EC) No 1829/2003 had been found. In cases where the GMO content was below 0.9%, the UPC inspectors performed a follow-up inquiring documentary evidence concerning the adventitious or technically unavoidable presence of GMO. Evidence in the form of written follow-up and sanctioning of cases was presented to the mission team where the GMO content in the product was not labelled and above 0.9%.

6.6. Controls on GMO in propagating materials

For controls on propagating materials, including GMO, the Directorate for Agricultural Quality of the Flemish region and the Directorate-General for Agriculture of the Walloon Region are responsible within their territories.

For the Flemish region, a control plan put in place before 2002 is in principle still valid. Mainly imported seeds were subjected to controls in 2001 – 2003. No controls on these imports have taken place concerning the presence of GMO in propagating materials in 2004 and 2005. It was stated that this is due to the low amount of seeds destined for marketing in Belgium and a lack of funds to undertake the sampling and analysis. Inspectors of the Walloon region sampled 9 maize lots in 2003 and 6 maize lots in 2005 for the presence of GMO without any positive findings.

In 2002 1 import lot coming from the USA via Antwerp and destined for marketing in Italy was found to contain GMO. The Italian authorities were informed, but no further action was taken. For 2006, the Flemish region expressed its intention to resume testing of seed lots for the presence of GMO.

There are no GMO varieties, as listed in the common catalogue, grown for food, feed or seed cultivation in Belgium, and no requests have been made to the Commission Services for national authorisations for experimental growing under Commission Decision 2004/842/EC.

6.7. General import control procedures

At the time of the mission, there were controls at the point of entry for foodstuffs of plant origin within the scope of the mission.

For feed stuffs, the import control procedure as described in report SANCO 9060/2003 was applicable. It requires importers to notify imports 72h in advance of the arrival of the goods to the AFSCA, however in one case presented to the mission team, the import was notified to the AFSCA only after arrival. Furthermore, imports of feed stuffs are checked by UPC inspectors responsible for feed stuffs only in case they are declared as such.

6.8. Laboratories

There are three public laboratories providing official GMO analysis in the area of food, feed and seed in Belgium. These are the Institute of Public Health (IPH), the Walloon Agricultural Research Centre (CRA-W), and the Institute for Agriculture and Fishery Research (ILVO). The mission team was informed that the three labs are working as a Consortium and function as the National Reference Laboratory.

The three laboratories and the AFSCA meet on a quarterly basis to coordinate work in this area.

The IPH lab is accredited under ISO/IEC 17025 for GMO screening. The ILVO is accredited under the same European standard for the quantitative analysis of GMO. The CRA-W has received the accreditation audit and is awaiting the formal accreditation letter. The ILVO laboratory was visited by the mission team.

6.8.1. ILVO

In 2006 official analysis regarding GMO is performed by the ILVO. The ILVO is a public funded research institute. The laboratory is a member of the European Network of GMO laboratories (ENGL), and cooperates with several European Institutions and fora in this field (such as the European Food Safety Authority, the Community Reference Laboratory, the European Committee for Standardization). Furthermore it takes part in and performs research studies.

The scope of accreditation according ISO/IEC 17025 covers Real-Time Polymerase Chain Reaction (RT-PCR) analysis for detection and quantification of Roundup Ready soya and various maize transformation events (Bt 11, Bt 176, MON 810, T 25, GA 21). Further analytical methods for genetically modified maize (NK 603, MON 863, TC 1507, TC 1507 x NK 603) and canola (MS 8 X RF 3, MS 8, R 3, GT 73) lines shall be accredited in 2006. Qualitative tests for genetically modified canola are also performed, although not yet within the scope of accreditation. Maize containing samples are screened with RT-PCR for all specific maize lines in parallel for which accredited methods were set up. Additional information was given regarding the future inclusion of 35S and tNOS in screening tests for GMO analysis.

For analysis commercially available GMO detection and quantification kits are used. Standard curves are generated with commercial available plasmid standard solutions of defined absolute copy numbers. Certified reference materials (CRM) are in place for all methods within the scope of accreditation. Usually 1 % (w/w) GMO containing CRM powder material is used as positive control for each analytical run. Furthermore reagent and extraction blank controls are included for each analysis. Per sample four replicates over two extraction samples are analysed whereof the % RSDr (relative standard deviation) or % CV (coefficient of variation) is calculated and reported.

Regarding the results of GMO quantification, the measurement uncertainty (SD, standard deviation) is taken into account depending on the matrix type investigated.

For a simple matrix the SD was found to be 0.55 % which was estimated by experiments at the ILVO and 1.3 % for a complex matrix which was taken from proficiency test results. A simple matrix is defined as to contain one plant species within the scope of accreditation (soya or maize). A complex matrix consists of more than one species, i.e. soya and maize. Feed are routinely considered as complex matrix and tested for GM soya, maize and canola.

The different stages of the analytical procedure were separated to prevent carry-over contamination, and detailed documentation throughout sample reception, analysis and reporting of results was available. Registration of samples and analytical results are administered through a “Laboratory and Information Management System (LIMS)”.

The laboratory is well equipped and avails of knowledgeable staff which consists of three academic and four professional degrees. Additionally the laboratory participated in international proficiency tests on a regularly basis with satisfactory results (GeMMA, ISTA, FSA).

The internal quality control includes the analysis of control materials (reference material) to monitor trueness and the replication of measurements (repeatability, intra-laboratory reproducibility) to monitor precision once a year.

7. CONCLUSIONS

7.1. Legislation

1) Necessary steps have been undertaken to fulfil the requirements of Regulation (EC) No 1830/2003, Article 11, concerning rules on penalties.

2) The SPF has established and widely communicated their interpretation of the legal requirements regarding "GMO-free" labelling of food and feed and regarding labelling of products as to contain GMO when actually not present.

7.2. Competent authorities

3) Competencies for policy making, legislation, planning and execution of controls for GMOs in food, feed and propagating material are clearly defined.

4) Horizontal and vertical communication within the AFSCA and with other stakeholders involved is adequate.

7.3. Controls on GMO in Foods

5) Annual control plans, covering the areas of processing and distribution, were established and implemented, and addressed the legal requirements within the scope of the mission.

6) UPC inspectors met during the mission were aware of the applicable legislation and an inspection demonstrated to the mission team was well structured and sufficiently addressed the legal requirements concerning traceability and labelling.

7) Sampling of foodstuffs as demonstrated was in line with national legislation; however the applicable national legislation does not take account of point 2.1 of of Part IV of Commission Recommendation 2004/787/EC.

8) Where the presence of GMO had been established by analytical means, follow-up undertaken by UPC inspectors sufficiently addressed the legal requirements of Regulation (EC) No 1830/2003, Article 4 (C) (7).

7.4. Controls on GMO in Feed

9) Annual control plans, covering the areas of import, processing and distribution, were established and implemented, and addressed the legal requirements within the scope of the mission.

10) UPC inspectors met during the mission were aware of the applicable legislation and inspections demonstrated to the mission team were well structured and sufficiently addressed the legal requirements concerning traceability and labelling.

11) Sampling of feed stuffs as demonstrated was in line with national legislation; however the applicable national legislation does not take account of point 2.1 of Part IV of Commission Recommendation 2004/787/EC.

12) Where the presence of GMO had been established by analytical means, follow-up undertaken by UPC inspectors sufficiently addressed the legal requirements of Regulation (EC) No 1830/2003, Article 4 (C) (7).

13) A decrease in the number of non-compliances found in 2005 compared to 2004 was noted by the mission team.

7.5. Controls on GMO in propagating material

14) Currently there are no controls in place for the presence of GMO in propagating material[7].

7.6. General import control procedures

15) Currently, there are no import controls implemented for foodstuffs within the scope of the mission.

16) For feed stuffs, the import procedure as described in previous report SANCO 9060/2003 was applicable.

7.7. Laboratories

17) The ILVO laboratory visited was well equipped and staffed in the area of GM food and feed analysis. There was a good physical separation of the various stages of GMO analysis.

18) The current scope of accreditation of the ILVO is in accordance with ISO 17025, and covers all authorised GM events. Plans are in place to widen the scope of accreditation with regard to GMO analysis within the near future.

19) The ILVO laboratory participated regularly with acceptable results in international proficiency tests for GMO analysis.

Overall conclusion

Overall, there is a good system in place for official controls within the scope of Regulation (EC) No 1829/2003 and 1830/2003. Controls were well planned and executed, inspectors were aware of the applicable legislation concerning labelling and traceability of GMO in food and feed. Where non-compliances were found appropriate follow-up measures were taken.

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[7] ***In their response to the draft report the Belgium competent authorities explained that the controls in propagating material will still be done by the regions as in the past (following the old regional instructions). However, a federal ministerial decree that will clarify the controls on seeds is in preparation.***

8. CLOSING MEETING

A closing meeting was held on 17 February 2006 with the SPF and the AFSCA. At this meeting, the main findings and conclusions of the mission were presented by the inspection team. The representatives of the AFSCA provided a number of clarifications during the meeting, which were incorporated into the report.

9. RECOMMENDATIONS

9.1. To the competent authorities of Belgium

(1) with regard to Third country imports of foodstuffs within the scope of this mission, provide guarantees that these imports are subject to official controls at an appropriate place in accordance with Articles 15 and 16 of Council Regulation (EC) 882/2004 on official controls.

(2) for the organisation of official controls on the introduction of food within the scope of this mission from third countries, the competent authorities and the customs services shall cooperate closely (Art 24 Reg (EC) 882/2004).

(3) Should take account of Commission Recommendation 2004/787/EC for sampling of large quantities of food and feed for GMO analysis.

An action plan in response to the recommendations should be forwarded to the Commission within 2 months of dispatch of the report. This action plan should clearly set out the manner and deadline by which the competent authorities will address each recommendation.

10. ADDENDUM

In the response to the draft report, the Belgium authorities addressed all of the aforementioned recommendations as follows:

(1) The annual programme for food and feed will be adopted in the course of the last trimester of 2006 and will be send to the UCP. It will clearly indicate sampling at, amongst others, entry points.

(2) The general protocol of cooperation of customs and the AFSCA is foreseen to be finalised until end of 2006. The adoption of the protocol will permit planning of import controls for GM food and feed, which will be part of the control plan for 2007.

(3) In relation to the sampling plan for 2007, instructions are under preparation for controls at BIPs and at entry points for food and feed potentially containing GMO, taking into account Commission Recommendation 2004/787/EC.

ANNEX - LEGISLATION

European Legislation	Official Journal	Title
Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003	OJ No L 268, 18/10/2003, p. 0001-0023	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003	OJ No L 268, 18/10/2003, p. 0024-0028	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
Council Directive 2002/53/EC of 13 June 2002.	OJ L 193, 20/07/2002, p. 0001 – 0011	Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species
Commission Decision 2004/842/EC of 1 December 2004	OJ L 362, 09/12/2004, p. 0021 - 0027	Commission Decision 2004/842/EC of December 2004 concerning implementing rules whereby Member States may authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of varieties of agricultural plant species or vegetable species has been submitted
Commission Decision 2005/317/EC of 18 April 2005	OJ L 101, 21/04/2005, p. 0014 - 0016	Commission Decision 2005/317/EC of 18 April 2005 on emergency measures regarding the non-authorised genetically modified organism Bt 10 in maize products
Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004	OJ L 165, 30/04/2004. Corrected and re-published in OJ L 191, 28/5/2004, p. 0001-0052	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
Commission Recommendation 2004/787/EC of 4 October 2004	OJ L 348, 24/11/2004, p. 0018 – 0026	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 1830/2003
Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000	OJ L 109, 06/05/2000, p. 0029 – 0042	Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs