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FINAL REPORT OF A MISSION
CARRIED OUT IN GERMANY
FROM 06/03/2006 TO 10/03/2006
CONCERNING CONTROLS ON
FOOD AND FEED CONTAINING, CONSISTING OF OR
PRODUCED FROM GENETICALLY MODIFIED ORGANISMS

Please note that factual errors in the draft report have been corrected in the text. Clarifications provided by the German Authorities are given as footnotes in italic, type, to the relevant part of the 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 (GMOs). The mission team met with the central competent authority and two regional authorities. Visits were also made to a control laboratory, a designated import point and one visit each to both a food and a feed business.

Five GM maize varieties have been approved in Germany. Small areas of GM plants are cultivated for commercial and/or experimental purposes.

Whereas practically no GM food is produced, approximately 90% of compound feed is subject to labelling as containing GMOs.

Responsibilities for policy-making, legislation, planning and execution of controls for GMOs in food, feed and seeds are clearly defined at central level and in the two regions (Länder) visited during the mission (Hamburg and Saxony-Anhalt).

Controls and sampling for GMO food are planned and carried out at all the relevant levels of the food chain. However, controls on import carried out by the CA responsible for GM food under Regulations (EC) No 1829/2003 and No 1830/2003 are limited to controls of papayas.

Procedures for inspections for traceability observed at food and feed producers during the mission were regarded as satisfactory. A sampling procedure for GMO food has been drawn up on the basis of Commission Recommendation 2004/787/EC and applied so far for sampling food commodities in one of the 'Länder' visited (Saxony-Anhalt). Deviations from the Recommendation are in line with a draft CEN standard.

A large number of samples (6000 food and 600 feed samples in 2005) are analysed. Infringements concerning labelling or non-authorized GMOs have been detected.

In the regions visited samples of food and feed have been analysed for GMO contents. Infringements detected concerned labelling and were followed-up.

The laboratory of the Regional Office for Consumer Protection of Saxony-Anhalt (Landesamt für Verbraucherschutz Sachsen-Anhalt), visited during the mission, is accredited under ISO 17025. The facilities and equipment were regarded as adequate, while knowledge of staff, quality management procedures and scope of analysis were regarded as very good.

Overall, a sufficient structure is in place for the implementation of Regulations (EC) 1829/2003 and 1830/2003 within the scope of the mission, with very good expertise for GMO analysis.

The report provides recommendations to the German Authorities to address the deficiencies noted.

ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

ALB	Working Group on Foodstuffs and Utility Articles (<i>Arbeitsgruppe für Lebensmittel und Bedarfsgegenstände</i>)
ALS	Working Group of Food Chemistry Experts (<i>Arbeitskreis Lebensmittel-chemischer Sachverständiger</i>)
BBA	Federal Biological Research Centre for Agriculture and Forestry (<i>Biologische Bundesanstalt für Land- und Forstwirtschaft</i>)
BfN	Federal Agency for Nature Conservation (<i>Bundesamt für Naturschutz</i>)
BfR	Federal Institute for Risk Assessment (<i>Bundesinstitut für Risikobewertung</i>)
BMELV	Federal Ministry of Food, Agriculture and Consumer Protection (<i>Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz</i>)
BSA	Federal Office for Plant Varieties (<i>Bundessortenamt</i>)
BSU	Authority for Urban Development and Environment (<i>Behörde für Stadtentwicklung und Umwelt</i>)
BÜP	Federal Monitoring Plan (<i>Bundesüberwachungsplan,</i>)
BWA	Authority for Economy and Labour (<i>Behörde für Wirtschaft und Arbeit</i>)
BWG	Authority for Scientific and Health Affairs Hamburg (<i>Behörde für Wissenschaft und Gesundheit Hamburg</i>) ¹
BVL	Federal Office for Consumer Protection and Food Safety (<i>Bundesamt für Verbraucherschutz und Lebensmittelsicherheit</i>)
CA	Competent Authority
ENGL	European Network of GMO Laboratories
EC	European Community
EU	European Union
FVO	Food and Veterinary Office
GM	Genetically Modified
GMO	Genetically Modified Organism(s)
IHU	Institute for Hygiene and Environment (<i>Institut für Hygiene und Umwelt</i>)
IRMM	Institute of Reference Material and Measurement
ISO	International Standards Organisation
JRC	Joint Research Centre (Ispra)

¹ In their response to the draft report the German authorities noted: “New name from May 2006: Authority for Social, Family, Health and Consumer Affairs (*Behörde für Soziales, Familie, Gesundheit und Verbraucherschutz - BSG*)”

LAU	Regional Office for Environmental Protection Saxony-Anhalt – Laboratory for the Monitoring of Genetic Engineering (<i>Gentechnisches Überwachungslabor am Landesamt für Umweltschutz Sachsen-Anhalt</i>)
LAV	Regional Office for Consumer Protection Saxony-Anhalt (<i>Landesamt für Verbraucherschutz des Landes Sachsen-Anhalt</i>)
LLFG	Regional Institute for Agriculture, Forestry and Horticulture Saxony-Anhalt (<i>Landesanstalt für Landwirtschaft, Forsten und Gartenbau Sachsen-Anhalt</i>)
LVwA	Regional Administrative Office Saxony-Anhalt (<i>Landesverwaltungsamt des Landes Sachsen-Anhalt</i>)
MLU	Ministry for Agriculture and Environment Saxony-Anhalt (<i>Ministerium für Landwirtschaft und Umwelt Sachsen-Anhalt</i>)
MS	Ministry for Health and Social Affairs Saxony-Anhalt (<i>Ministerium für Gesundheit und Soziales Sachsen-Anhalt</i>)
PCR	Polymerase Chain Reaction
RKI	Robert Koch Institute (<i>Robert Koch Institut</i>)
TARIC	Tarif Intégré de la Communauté (Integrated tariff of the Community)

2. INTRODUCTION

The mission took place in Germany from 6 to 10 March 2006. The mission team comprised 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 a representative from the Federal Office for Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL*).

An opening meeting was held on 6 March 2006 with representatives from the Federal Ministry of Food, Agriculture and Consumer Protection (*Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz, BMELV*), the BVL, the Authority for Scientific and Health Affairs Hamburg (*Behörde für Wissenschaft und Gesundheit Hamburg, BWG*), the Ministry for Health and Social Affairs Saxony-Anhalt (*Ministerium für Gesundheit und Soziales Sachsen-Anhalt, MS*) and the Regional Institute for Agriculture, Forestry and Horticulture Saxony-Anhalt (*Landesanstalt für Landwirtschaft, Forsten und Gartenbau Sachsen-Anhalt, LLFG*). 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 (GMOs). 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,² 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 the placing on the market of GM varieties not yet entered in this common catalogue;

² 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 the Annex.

- 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:

Table 1: Mission visits and meetings

Visits/meetings		Comments
COMPETENT AUTHORITIES		
Central	2	BMELV, BVL
Regional	7	Hamburg: BWG, BWA, BSU Saxony-Anhalt: MS, MLU, LVwA, LLFG
Import Point	1	Port of Hamburg
LABORATORIES		
Public	1	Laboratory of the LAV, Halle
FOOD AND FEED ESTABLISHMENTS		
Food processor	1	Producer avoiding the use of genetically modified foods and food ingredients.
Feed processor	1	Producer of compound feed

4. LEGAL BASIS FOR THE MISSION

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

- Article 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 had 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 the 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 the 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”³ 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 land⁴.

Several authorisations for placing on the market and for deliberate release into 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

Trade statistics of maize, oilseeds and products thereof from EU Member States and Third Countries are presented in table 2 (source: EUROSTAT). No data are available on the percentage of GM material for these commodities.

To the knowledge of the German Federation for Food Law and Food Science (*Bund für Lebensmittelrecht und Lebensmittelkunde*) practically no GM food is produced.

A survey of the German Agricultural Cooperative Association (*Deutscher Raiffeisenverband*) showed that 93% of bovine and pig food respectively and 89% of poultry feed were subject to labelling as containing GMOs.

Table 2: Trade statistics of maize, oilseeds and products thereof from EU Member States and Third Countries (source: EUROSTAT)

	2003	2004	2005 (preliminary)
Soya beans (excl. for sowing)	4.552.812	3.754.974	3.886.409
Soya beans for sowing	263	63	88
Soya bean flour and meal	20.591	17.865	12.529

³ James, C. 2005. Preview: Global Status of Commercialized Biotech/GM Crops: 2005. ISAAA Briefs No. 34. ISAAA; Ithaca, NY

⁴ WHO biotechnology report 2005 http://www.who.int/foodsafety/publications/biotech/biotech_en.pdf

Oilcake/pellets from extraction of soy-bean oil	2.649.133	2.839.427	2.613.649
Rape seed	22.041	104.128	7.934
Oilcake/pellets from extraction of rape-seed oil	254.536	296.584	434.235
Cotton seed	81	0	0
Oilcake/pellets from extraction of cotton seeds	141	279	185
Maize (excl. for sowing)	1.036.568	1.324.827	1.676.971
Maize for sowing	44.567	47.058	41.477
Corn gluten feed	286.785	299.571	55.823
Brewers grain	68.533	36.425	43.121

6.2. Legislation

At federal level the CA for policy-making and legislation for GM food, feed and seeds is the BMELV. The competency of the supreme authorities at regional (*Länder*) level is restricted to legislation concerning the implementation of GM food, feed and seed controls.

The provisions of Regulations (EC) No 1829/2003 and No 1830/2003 and Commission Regulation (EC) No 641/2004 are transposed by means of the Act implementing European Community Regulations and amending the Ordinance on Novel Foods and Food Additives (*Gesetz zur Durchführung der Verordnungen der Europäischen Gemeinschaft und zur Änderung der Neuartige Lebensmittel – und Lebensmittelzutaten-Verordnung*). The Act lays down rules on penalties applicable to infringements of the provisions of Regulations (EC) No 1829 and No 1830/2003.

Legislative action is currently been taken to fully transpose Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms.⁵

The Directive on the labelling of foodstuffs (2000/13/EC) has been transposed by the Food Labelling Order of 15 December 1999 as amended (*Lebensmittel-Kennzeichnungs-verordnung*) and related legislation. A national order lays down, among others provisions for ‘GM-free’ labelling.

5 In their response to the draft report the German authorities noted: “ The process was completed by the adoption and publication of the 3rd Genetic Engineering (Amending) Act of 17 March 2006. This means Directive 2001/18/EC has been fully transposed into German law.”

6.3. Competent authorities

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

Table 3: Structure and responsibilities of CAs and laboratories

NATIONAL		
Ministry	Obere Bundesbehörden	Competencies
Federal Ministry of Food, Agriculture and Consumer Protection (BMELV)		Policy-making and legislation for GM food, feed, seeds.
	Federal Office for Consumer Protection and Food Safety (BVL)	Advisory function for law-making for GM food, feed and seeds. Coordination of the Federal Monitoring Plan (<i>Bundesüberwachungsplan</i> , BÜP) and of control activities for GM food and feed. Responsible authority for accepting, processing and forwarding applications under Articles 5(2) and 17(2) of Regulation (EC) No 1829/2003 and for approving applications for deliberate release into the environment under Directive 2001/18/EC.
	Federal Institute for Risk Assessment (BfR)	Assessment of applications for authorisation of placing on the market of GMOs.
	Federal Biological Research Centre for Agriculture and Forestry (BBA)	
	Robert Koch Institute (RKI)	
	Federal Agency for Nature Conservation (BfN)	
	Federal Office for Plant Varieties (BSA)	
HAMBURG		
‘Land’	Local	Competencies
Authority for Scientific and Health Affairs (BWG)		Policy-making and legislation for GM food and feed. Supervision of control activities in the 7 District Administrations and the departments of the Institute for Hygiene and the Environment regarding official food surveillance. Controls for GM feed, including import thereof. Import controls of GM foods of animal and non-animal origin by the Veterinary Office – Border Service.

	7 District Administrations/ Consumer Protection Offices	Controls on GM food and feed, including sampling and checks of labelling.
Authority for Economy and Labour (BWA)		CA responsible for GM seeds.
Authority for Urban Development and Environment (BSU)		Inspections including sampling, under the Genetic Engineering Act (<i>Gentechnikgesetz</i>).
Institute for Hygiene and Environment (IHU)		Laboratory analysis of GM food and feed. (1/3 of the feed samples are analysed in a private laboratory).
SAXONY-ANHALT		
Land level	Local	Competencies
Ministry of Health and Social Affairs (MS)		Policy-making and legislation for GM food.
Ministry for Agriculture and Environment (MLU)		Policy-making and legislation for GM feed and seeds.
Regional Administrative Office Saxony-Anhalt (LVwA)		Coordination of controls of GM food and feed and monitoring of the placing on the market of GMOs under the Genetic Engineering Act (<i>Gentechnikgesetz</i>).
	Local Veterinary and Food Monitoring Offices	Controls and sampling of GM food and feed.
Regional Office for Consumer Protection Saxony-Anhalt (LAV), Halle		Laboratory controls of GM food and feed and expert assessment of GM food.
Regional Institute for Agriculture, Forestry and Horticulture (LLFG)		Sampling and label checks of GM seeds. Label checks for seeds.
Regional Office for Environmental Protection Saxony-Anhalt – Laboratory for the Monitoring of Genetic Engineering (LAU)		Laboratory controls of GM seeds.

6.4. Controls on GMO in Foods

6.4.1. Structure and organisation of responsible authorities

Performance of GMO food monitoring is the responsibility of the regional (Länder) authorities.

In Hamburg the Department for Food Safety and Veterinary Affairs of the BWG is responsible for the monitoring GM food under Regulations (EC) No 1829/2003 and No 1830/2003. It supervises the control activities of the Offices for Consumer Protection (*Verbraucherschutzämter*) of the 7 District Administrations (*Bezirksämter*), with 60 posts for food inspectors and the laboratory of the Institute

for Hygiene and Environment (*Institut für Hygiene und Umwelt IHU*) regarding official surveillance of GM food.

Training for food inspectors in Hamburg for the monitoring of GM food is provided by the IHU and the BWG.

The Veterinary Office for Border Services (*Veterinäramt Grenzdienst*) with 55 employees, is part of the Department for Food Safety and Veterinary Affairs of the BWG. It is responsible for GM foods of animal and non-animal origin which are subject to obligatory checks at import (*Vorführpflicht*).

The Authority for Urban Development and Environment (*Behörde für Stadtentwicklung und Umwelt, BSU*) is responsible for inspections, including sampling, under the Genetic Engineering Act (*Gentechnikgesetz*). In this function it also samples food and feed for the analysis of non-authorised GMOs.

In Saxony-Anhalt under the supervision of the MS (2 food chemists and 1 administrator) the Regional Administration Office (*Landesverwaltungsamt, LVwA*, 3 technical and 1 administrative staff) is responsible for the coordination of controls of GMO food.

The controls are carried out by 95 food inspectors of the Local Veterinary and Food Monitoring Offices (*Veterinär- und Lebensmittelüberwachungsämter der Landkreise und kreisfreien Städte*).

Food inspectors in Saxony-Anhalt receive training, among other things, for controls of GM food during the initial two-year-training period, which includes laboratory work, during regular training (every two years) and during meetings (1-2 times a year).

6.4.2. Communication among the central, regional and local authorities and with other relevant ministries

The Regions (*Länder*) organise regular meetings of expert working groups which are also attended by representatives of the Federal Government and the BVL: the Working Group on Foodstuffs and Utility Articles (*Arbeitsgruppe für Lebensmittel und Bedarfsgegenstände, ALB*) and the Working Group on Monitoring of Genetically Modified Foods of the Working Party of Food Chemistry Experts (*Arbeitskreis Lebensmittelchemischer Sachverständiger, ALS*). Legal issues, sampling schemes, testing methods and labelling issues are discussed during these meetings.

In Hamburg meetings of representatives of the BWG and the heads of the Consumer Protection Offices are organised four times a year. Meetings of the Veterinary Office for Border Services (*Veterinäramt Grenzdienst*) and of the Customs Service take place monthly. Regular meetings also take place for the coordination of GM analysis between the IHU and the BWG, the BSU and the Veterinary Office for Border Services respectively. Further informal meetings and consultation take place between the services concerned as the need arises. The mission team was informed that the results of controls carried out by the Consumer Protection Offices (*Verbraucherschutzämter*) are not routinely reported to the BWG.

In Saxony-Anhalt clear lines for communication and reporting have been established between the Ministry of Health and Social Affairs (*Ministerium für Gesundheit und Soziales*, MS), the Administrative Office of Saxony-Anhalt (*Landesverwaltungsamt des Landes Sachsen-Anhalt*, LvWA) and the Local Veterinary and Food Monitoring Offices (*Veterinär- und Lebensmittelüberwachungsämter der Landkreise und kreisfreien Städte*). Regular meetings take place at regional level. Technical supervision is provided by staff of the Administrative Office and the MS respectively. One technical discussion per year is jointly organised by the MS and the Ministry of Agriculture and Environment (*Ministerium für Landwirtschaft und Umwelt*, MLU).

6.4.3. Planning of controls on GM (Inspection and sampling)

In 2005, the Federal Monitoring Plan (*Bundesüberwachungsplan*, BÜP), which targets the surveillance of all areas of food safety, was drawn up for the first time as a pilot project. It included the controls of 122 food businesses for GM labelling, including sampling for analysis of GMOs (participation of 6 regions).

The BÜP for 2006 consists of 36 programmes, one of which targets controls of food businesses for GMO labelling, including sampling for GMO analysis. Eight of the regions will participate and carry out controls at 133 businesses altogether, with 10 controls in Saxony-Anhalt and no controls in Hamburg. Primarily importers and first producers of soy, maize and rape will be controlled. A further programme includes controls of 181 food businesses for traceability. These controls do not specifically target GMOs.

The regional monitoring plan for Hamburg is planned quarterly. For the first quarter of 2006, sampling of 20 maize products for GMO analysis is scheduled. Plans are drawn up on the basis of results from previous years, RASFF notifications and information from mass media.

In addition to this monitoring plan, special risk-oriented programmes are planned. Twelve samples of food or feed consignments are sampled per quarter for controls of unauthorised products, such as GM papayas and maize Bt 10 (primarily for feed).

In addition to the controls under the BÜP, the regional plan in Saxony-Anhalt for 2006 includes collection of 300 food samples for GMO analysis and 100 controls for traceability and labelling.

Table 4: Overview table for planned controls on GM for 2006

Number of controls	Germany		Hamburg	Saxony-Anhalt
	BÜP	Total samples planned in the regions		
Controlled businesses	133	No information available	Not specified	100 + 10 (BÜP)
Sampling	Not specified	5051	20* (during first quarter of 2006)	300

* Additionally, sampling of 48 food and feed samples (for analysis of non-authorised GMOs) is planned by the BSU

6.4.4. Performance of inspection and sampling

The ALS has established a sampling scheme for GM food, which is based on Commission Recommendation 2004/787/EC, draft standard prCEN/TS 21568: 2005 and standards EN ISO 542 and 13690. It contains a procedure for the sampling of big bags, bags and other packaged material and a procedure for bulk consignments. The procedure for sampling bulk consignments departs from Commission Recommendation 2004/787/EC insofar as it provides for a simplified procedure for bulk consignments where GMO contents is not expected to be near the threshold. The deviation is in line with draft standard prCEN/TS 21568:2005.

Food inspectors in Hamburg informed the mission team that they had received the new sampling scheme during a training session, but that they did not yet apply it for the sampling of food.

Inspectors of the Consumer Protection Offices (*Verbraucherschutzämter*) carry out inspections on GM food at producer and retail level but not on import in the port of Hamburg.

The tasks of the Veterinary Administration of the Border Services (*Veterinäramt Grenzdienst*) of the BWG in Hamburg for food consignments within the scope of the mission are limited to checks of papaya consignments, for which in Germany GM analysis is obligatory before release into free circulation.

BSU inspectors carry out controls, including sampling, of food and feed on import for analysis of non-authorised GMOs. Each quarter 12 samples of food and feed consignments are taken. As the controls target non-authorised GMO events, random sampling is not regarded as required and samples are taken from only one part of the consignment. These samples are also analysed for authorised events and the results of the analysis are notified to the BWG. Representatives of the BWG responsible for food safety stated that they had no knowledge of any notification.

In Saxony-Anhalt the new sampling procedure for GMO analysis was applied during 10 controls at food businesses as a pilot project in 2005. These inspections were carried out by an inspection team consisting of an inspector of a Local Veterinary and Food Office, a food chemist from the LVwA and two specialists from the LAV. These visits also covered an inspection of the production area and

comprehensive documentary checks for traceability and labelling concerning GMOs.

A demonstration of an inspection at a food producer in Saxony-Anhalt who avoids the use of genetically modified foods and food ingredients was observed by the mission team. The observed sampling procedure of a 750 kg lot (30 bags of 25 kg) of ground maize followed the new German sampling procedure for GMO food. The inspector also checked the certificate of the supplier of the sampled product and the analytical results of previous lots of the same product and asked the manager of the company to request the analytical result of the sampled lot from the producer. The inspector informed the mission team that he would normally check the certificates and analytical reports of all products from maize, soy or rape which are used in the production. He would also check traceability in company documentation of products found during an inspection of the production area.

Food samples are sent to the laboratory of the IHU (Hamburg) and the LVA (Saxony-Anhalt) for GMO analysis. The laboratory reports include the results and an expert assessment of the results. The final decision of whether a consignment is compliant rests with the service which took the sample.

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

Table 5 summarises the results of GMO analyses in food in the years 2004 and 2005. Whereas the regional authorities are requested to report to the central CAs on controls carried out under the BÜP, no annual reports on the results of GMO analyses performed under the regional programmes are routinely drawn up at federal level. However, the respective data have been collated on request of the mission team, on the basis of the results as reported by the laboratories.

Reports by the IHU on results of GMO analyses of food in Hamburg in 2003 and 2004 and by the LAV on the results of GMO analyses in Saxony-Anhalt in 2004 and 2005 were provided to the mission team.

A report sent to the Commission pursuant to Article 3 of Commission Decision 2005/317/EC also included information on analyses of food products for Bt10. Some 1196 samples (15 samples in Hamburg and 75 in Saxony-Anhalt) were analysed, but Bt 10 was detected in none of these samples.

Documentation of a food sample taken in 2003 in Hamburg was given to the mission team. GM soy was detected in a product which was not labelled as containing GMOs.

Two infringements were detected in Saxony-Anhalt in 2004 and 2005. In both cases RR soy was detected in products which were not labelled as containing GMOs.

Table 5: Overview of results of GMO analyses of food in 2004 and 2005

	Germany*		Hamburg**		Saxony-Anhalt	
	2004	2005	2004	2005	2004	2005

No of samples	5438	6110	170	130	237	402
No. of samples where extraction of DNA was not possible	173	223	31	15	33	47
No of positive samples and type of GMO	710 RR soy, Bt176, Bt11, T25, papaya (E55-1 Sunup), GA21, MON863, MON810	808 RR soy, MON810, GA21, T25, Bt176, Bt11, MON863 papaya (E55-1 Sunup)	31 types not specifid	15 types not specifid	9 RR soy	61 RR soy, MON810, Bt176
No of non-compliant samples	67	60	0	0	1	1

* Results as reported by the laboratories in the 16 regions.

** Results as reported by the IHU (including samples from BWG and BSU)

6.4.6. Follow-up of infringements

Follow-up of the infringement cases described in chapter 6.4.5 included follow-up visits and written instructions.

Penalties applicable to infringements of the provisions of Regulations (EC) No 1829/2003 and No 1830/2003 are defined in the law (see chapter 6.2). Additionally the general provisions of the Law on Infringements (*Gesetz über Ordnungswidrigkeiten*, BGBl I 1968, 481) apply.

6.5. Controls on GMO in Feed

6.5.1. Structure and organisation of responsible authorities

The CAs in the regions (Länder) are responsible of controls for GM feed.

In Hamburg inspectors of the BWG carry out inspections concerning GM feed under Regulations (EC) No 1829/2003 and No 1830/2003. For the Veterinary Office for Border Services (*Veterinäramt Grenzdienst*) and BSU see chapter 6.4.1.

In Saxony-Anhalt the MLU and the Regional Administration Office (*Landesverwaltungsamt*, LVwA, 3 technical and 1 administrative staff) are the responsible central CAs for GMO feed. At the moment the posts of both services for feed monitoring are not occupied. The controls are carried out by inspectors of the Local Veterinary and Food Monitoring Offices (*Veterinär- und Lebensmittelüberwachungsämter der Landkreise und kreisfreien Städte*). 24 staff members (16 full-time posts) are responsible for feed monitoring. Feed inspectors receive similar training to the food inspectors (see chapter 6.4.1.).

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

As mostly the same CAs are involved in GMO food and feed control, communication lines are the same as described in chapter 6.4.2 for food, with the following main differences:

- The working group for feedstuffs (*Arbeitsgruppe Futtermittel*) performs similar tasks for feed to the ALS and the ALB for food.
- In Hamburg the Consumer Protection Offices (*Verbraucherschutzämter*) are not involved in feed controls as controls are carried out by BWG inspectors.
- In Saxony-Anhalt the MLU is the superior central authority for GM feed controls. As the posts for feed monitoring of the MLU and the Administrative Office are vacant, technical supervision for feed inspectors is not available at the moment.

6.5.3. Planning of controls on GM (Inspection and sampling)

The National Control Programme for Feed Safety for the Years 2005 and 2006 (*Nationales Kontrollprogramm Futtermittel für die Jahre 2005 and 2006*) does not schedule controls within the scope of the mission.

The mission team was provided with the sampling plans for 2006 for feed in Hamburg and Saxony-Anhalt. Details are presented in Table 6.

Table 6: Overview table for planned controls on GM feed for 2006

Number of controls	Germany		Hamburg	Saxony-Anhalt	
	National Control Programme for Feed Safety for the Years 2005 and 2006	Total samples planned in the regions	Sampling	Insp.	Sampling
Import (following release by the customs service)	0	964	13	-	-
Retail			12	1	15
Production of single component feed				-	15
Production of compound feed			11	1	30

6.5.4. Performance of inspection and sampling

In both regions visited the mission team was informed that sampling of feed consignments for GMO analysis is in accordance with the German Feed Sampling and Analysis Decree (*Futtermittel-Probenahme- und Analysen-Verordnung, FPA*) which transposes Commission Directive 76/371/EEC and further sampling Directives.

A copy of a guidance document for monitoring of the production, treatment, use and marketing of feed in connection with GMOs was provided to the mission team. It includes information on the relevant legislation, on GM feed approved in the EU and procedures for sampling and documentary checks concerning traceability. It also contains an amendment to the FPA concerning sample sizes to be taken for soy-beans and rape and maize kernels.

GM feed controls in Hamburg, including import controls, are the task of the Veterinary Office – Border Service (*Veterinäramt Grenzdienst*) of the BWG. This includes checks of consignments of corn gluten feed and brewers grain imported from the USA, which have to be accompanied by analytical certificates showing that they do not contain Bt 10 (Commission Decision 2005/317/EC).

BWG inspectors carry out random controls for GMO feed at two importers (after release by the customs services) and 4 producers of compound feed in Hamburg.

Feed inspectors of the BWG informed the mission team that they have received the quarterly information from the BSU concerning the results of food and feed consignments sampled for GMO analysis on import (see also chapter 6.4.4).

The mission team observed a demonstration of a sampling procedure (in accordance with the FPA) for extracted soy meal by an inspector of the BWG at an importer in the port of Hamburg. The inspector informed the team that he would randomly sample a 1600 t portion of the ship load, a portion which can be sampled within 4 hours during the unloading of the ship. 40 incremental samples (approx. 300 – 400 g) per hour are taken with a scoop (total of 160 individual samples). The incremental samples from one hour are mixed and 3 laboratory samples (at least 500 g each) are randomly taken from the mixture (one sample for the IHU and one reference sample each for the BWG and the importer).

GMO analysis of feed sampled in Hamburg is carried out by the IHU or a private laboratory.

In Saxony-Anhalt the mission team observed an inspection at a producer of compound feeding stuff. The inspector carried out a sampling procedure of a 25.000 kg bulk consignment of extracted soy meal in line with the FPA. She calculated that a minimum of 23 incremental samples had to be taken. The incremental samples were taken by a shovel and a probe respectively and combined as the bulk sample. Three laboratory samples (one for the company and 2 for the laboratory) were randomly taken from the bulk samples.

The inspector checked the delivery documents of the sampled consignment and the document of the truck that was used for transport. The truck document has to include information on the three previous consignments transported.

The inspector also demonstrated a documentary check for a compound feeding-stuff, comparing the delivery documents with the mixing report. She informed the mission team that she would trace back the product to the raw materials used only in the case of a special event.

GMO analysis of feed sampled in Saxony-Anhalt is carried out by the LAV in Halle.

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

Under the Commission Decision (2005/317/EC) on emergency measures regarding the non-authorised genetically modified organism Bt 10 in maize products, documents required for imports of the commodities concerned were checked in the port of Hamburg and found to be compliant.

Under Article 3 of Commission Decision 2005/317/EC, the BMEVL reported the analysis of Bt10 in 207 feed samples (72 samples of corn gluten feed and brewers grain, 52 samples of maize seeds and flakes and 83 samples of compound feed containing maize). Bt 10 was detected in none of these samples.

In Hamburg, for samples of a feed consignment taken by the BSU (not randomly sampled, see also chapter 6.4.4.) GMO content above 0.9% was found and these results were notified to the BWG. BWG inspectors then carried out random sampling of the consignment. The analytical results of these samples showed that the product was compliant.

In Saxony-Anhalt one sample was found to contain GMOs although the accompanying papers did not mention this fact. No feed samples were analysed for GMOs in 2005.

Table 7: Overview of results of GMO analyses of feed in 2004 and 2005

	Germany*		Hamburg**		Saxony-Anhalt	
	2004	2005	2004	2005	2004	2005
No of samples	996	632	30	15	80	-
No of samples where extraction of DNA was not possible	13	2	0	0	0	-
No of positive samples and type of GMO	576 RR soy, MON810, GT73, T25, Bt11	239 RR soy, NK603, TC1507, MON863, Bt11, Bt176, MON810, CBH351, T25, GA21	24	13	21 RR soy	-
No of non compliant samples	33	24	1	0	1	-

* Results as reported by the laboratories in the 16 regions.

** Results as reported by the IHU and a private laboratory (including samples from BWG and BSU)

6.5.6. Follow-up of infringements

In Saxony-Anhalt in the case of the infringement described in chapter 6.5.5 the producer was asked to rectify the accompanying papers.

For penalties applicable to infringements, see chapter 6.4.6.

6.6. Controls on GMOs in propagating materials

Three GM maize varieties (corn borer resistant) were approved in Germany in December 2005 and a further two in February 2006. They have been notified under the provisions of Article 16(1) of Council Directive 2002/53/EC.

The Federal Office for Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Gesundheit*, BVL) keeps a register of locations which provides areas under genetically-modified crops in Germany. In 2005, GM plants, largely derived from MON810, were cultivated on 342 ha. Samples for GMO analyses were taken from these fields to estimate the distances needed for the coexistence of GM and conventional maize. The crops were used for feed production. So far, approximately 1900 ha have been registered for 2006.⁶

In the growing season 2004/2005, five authorisations for a total of 455 dt of seeds and in 2005/2006 so far one authorisation for 50 dt have been issued under the Commission Decision (2004/842/EC) for the development of new varieties.

Seed consignments are preferably sampled at producers in parallel with the sampling for approval. For imported seeds controls are normally only possible when the consignments are on the market. Analysis of 818 seed samples is planned for 2006.

In Hamburg in 2004 and 2005 no seed samples were analysed for GMOs. In Saxony-Anhalt 31 and 34 seed samples were analysed for GMO contents in 2004 and 2005. No GMOs were detected.

Table 8: Overview of results of GMO analyses of seeds in 2004 and 2005

	Germany		Hamburg		Saxony-Anhalt	
	2004	2005	2004	2005	2004	2005
No of samples	717	771	-	-	31	34
No of samples where extraction of DNA was not possible	0	0	-	-	0	0
No of positive samples and type of GMO	15 MON810, GT73	12 Falcon GS40/90, T25, MON810	-	-	0	0
No of non compliant samples	1	3	-	-	0	0

⁶ In their response to the draft report the German authorities noted: " Following de-registrations, areas totalling around 950 ha remained in mid-June 2006."

* Results as reported by the laboratories in the 16 regions.

6.7. General import control procedures

Because of time constraints and the absence of a representative from the customs services during a meeting at the BWG in Hamburg the general import procedures were not evaluated during the current mission.

The mission team was informed by representatives of the BWG that import procedures for food and feed have not changed since the FVO inspections on import of food of plant origin in 2002 and 2004 and on import of feed in 2003 (see reports DG (SANCO)/5892/2002, DG (SANCO)/7068/2004 and DG (SANCO)/9171/2003).

During the closing meeting the mission team was informed by a representative of the Veterinary Administration of the Border Services (*Veterinäramt Grenzdienst*) that following the coming into force of Regulation (EC) No 882/2004, the competency of his service has been increased from the area of the port to the whole of Hamburg. The requisite changes were being prepared.

Customs officers are responsible for the release of imported food and feed consignments into free circulation. There is no obligation for customs to notify the BWG concerning imports of food or feed consignments within the scope of the mission. On the basis of an informal agreement the BWG is notified by FAX by the customs officers concerning the arrival of feed consignments.

For controls of food and feed consignments at the port and at importers see chapters 6.4.4 and 6.5.4 respectively.

6.8. Laboratories

The BMELV have proposed to designate the BfR together with the BVL as the National Reference Laboratory for the monitoring of GMO food and feed.

Five laboratories in Germany are members of the European Network of GMO laboratories (ENGL). Approximately 20 further laboratories will be designated as laboratories associated to the ENGL.

The regions (*Länder*) coordinated by the BVL develop and validate methods for GMO analysis. These methods are adopted and published in the Official Collection of Methods established pursuant to Article 64 of the Food and Feed Law (*Lebensmittel und Futtermittelgesetzbuch*).

Methods developed and validated by Germany have been adopted as CEN Standards and also annexed to ISO Standards.

At the moment Germany concentrates on the incorporation of EN ISO methods into the Official Collections of Methods under Article 64 of the Food and Feed Law.

Furthermore it focuses on the development and validation of new screening methods for unauthorised GMOs, Dublex and Multiplex methods and the analysis of GM rice.

6.8.1. *GMO laboratory of the Regional Office for Consumer Protection of Saxony-Anhalt in Halle*

The laboratory is accredited under ISO 17025 for GMO analysis. The tests for GMO in feed and food comprise only about 30% of all analyses carried out. In 2005 the laboratory analysed a total of 402 food samples for contents of GM material.

The laboratory has a staff of nine. The laboratory equipment is up to date and adequate for the analysis concerned. The layout of the facilities and equipment was regarded as sufficient to prevent cross-contamination.

The samples are recorded in a central reception office. The expert responsible decides on the scope of analyses and forwards the samples to the appropriate laboratories. A GMO laboratory expert determines the scope of methods, which always includes taxon-specific amplification control and a general screening.

Detection of GMO in a sample is followed by a construct- and an event-specific PCR to identify the type of GMO. The laboratory uses TaqMan technology to determine the GMO concentration.

Screening methods used are generally qualitative PCR followed by gel electrophoresis. Real-time PCR is used for identification and quantification. All results are verified by a biomolecular method, such as restriction analysis with two different enzymes, hybridisation with Southern Blotting, or sequencing. However, the verification process can be omitted when real-time PCR (hybridisation with a TaqMan probe) is applied.

The laboratory uses validated methods based on various CEN standards, on the method collection of the JRC and on personal notifications of the *Kantonales Labor Zürich*. There are quantitative methods for all authorised events in the European Union, but the laboratory can also verify Bt10 and StarLink as non-authorised events.

The positive and negative controls in the analyses are used in accordance with the requirements. Certified reference materials from the Institute for Reference Materials and Measurements (IRMM) in Geel, Belgium, are used as far as available.

For quality assurance the laboratory regularly participates in external testing schemes. The laboratory has taken part in several rounds of RR-Soya tests organised by the Institute of Food Research in Norwich. In the past three years it has attended successfully the USDA/GIPSA Proficiency Program, which takes place twice a year.

The laboratory staff is well trained and knowledgeable.

7. CONCLUSIONS

7.1. Legislation

- (1) The relevant legislation has been transposed with the exception of Directive 2001/18/EC. Outstanding legislation has been drafted.⁷

7.2. Competent authorities

- (3) Competencies for policy-making, legislation, planning and execution of controls for GMOs in food, feed and seeds at import and market level are clearly defined at central level and in the two regions (*Länder*) visited.
- (4) Horizontal and vertical communication between the competent authorities with responsibilities within the scope of the mission is adequate with some exceptions.

7.3. Controls on GMO in foods

- (5) The national monitoring plan only provides for a limited number of controls for GM labelling. Regional monitoring plans include a substantial number of samples of food products for GMO analysis.
- (6) Controls and sampling for GMO food are carried out at all relevant levels of the food chain. However, controls on import carried out by the CA responsible under Regulations 1829/2003 and 1830/2003 are limited to a single commodity (papayas).
- (7) Only in one of the *Länder* visited is a new German sampling procedure, based on Recommendation 2004/787/EC, applied. Departures from the Recommendation are in line with the respective draft CEN standard.
- (8) An inspection for traceability and labelling observed during the mission was regarded as adequate.
- (9) Reports on all results of GMO analyses are routinely collated only at regional level.
- (10) A large number of food samples were analysed for GMO contents in 2004 and 2005. Only few infringements concerning labelling and non-authorized GMOs (GM papaya) were detected.
- (11) Infringements detected in one of the regions visited concerned labelling. Follow-up measures were taken.

⁷ *In their response to the draft report the German authorities noted: " It entered into force on 23 March 2006."*

7.4. Controls on GMO in Feed

- (12) The national control plan on feed safety for 2005 and 2006 does not provide for controls for GM feed. Comprehensive sampling of feed for GMO analysis is planned at regional level.
- (13) Controls and sampling for GMO feed are carried out at all relevant stages of production, processing and distribution.
- (14) A guidance document for GM feed controls is in place, but was known only in one of the two regions visited.
- (15) The sampling procedure applied in both regions visited does not take account of Commission Recommendation 2004/787, but it is based on Commission Directive 76/371/EEC.
- (16) An inspection for traceability and labelling observed during the mission was regarded as adequate.
- (17) An adequate number of feed samples are analysed for GMO contents. Infringements detected concerned labelling or contents of non authorised GMOs.
- (18) The only infringement detected in the regions visited concerned labelling. Follow-up measures were taken.

7.5. Laboratories

- (19) The GMO laboratory of the Regional Office for Consumer Protection of Saxony-Anhalt in Halle is accredited under ISO 17025 for GMO analysis. It has well trained staff and adequate facilities and equipment. The layout of facilities and equipment is sufficient to prevent cross-contamination. It applies a wide range of validated methods. Analytical methods for all authorised and two non-authorised GM events are in use. The frequency and outcome of participations in proficiency tests indicate reliable and repeatable performance.

Overall conclusion

Overall, a sufficient structure is in place for the implementation of Regulations (EC) No 1829/2003 and No 1830/2003 within the scope of the mission, with very good expertise for GMO analysis.

8. CLOSING MEETING

A closing meeting was held on 10 March 2006 with representatives from the BMELV, the BVL, the BWG, the MS and the LLFG. At this meeting, the initial findings and conclusions of the mission were presented by the FVO inspection team. The representatives of the CAs offered a number of clarifications and comments and provisionally accepted the preliminary findings.

9. RECOMMENDATIONS

9.1. To the competent authorities of Germany:

- (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) Should take account of Commission Recommendation 2004/787/EC also for sampling of feed for GMO analysis.

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

10. ADDENDUM

In their response to the draft report the German authorities provided corrections and clarifications. In relation to Recommendation (1) they stated that changes to the procedure for import controls on foods of non-animal origin and planning of regular controls according to Article 15(1) of Regulation (EC) No 882/2004 are being implemented. In relation to Recommendation (2) the German authorities stated that an adaptation of the sampling procedure to Commission Recommendation 2004/787/EC is to be prepared for the whole of Germany.

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
Commission Directive 76/371/EEC of 1 March 1976	OJ L 102, 01/03/1976, p. 0001 - 0006	First Commission Directive of 1 March 1976 establishing Community methods of sampling for the official control of feedingstuffs (76/371/EEC)