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Directorate F - Food and Veterinary Office

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FINAL REPORT OF A MISSION CARRIED OUT IN THE UNITED STATES FROM 04 JUNE TO 11 JUNE 2008 IN ORDER TO EVALUATE THE CONTROL ACTIVITIES IN THE US FOR COMMISSION DECISION 2006/601/EC AS AMENDED REGARDING EMERGENCY MEASURES FOR RICE EXPORTS TO THE EU

Please note that factual errors in the draft report have been corrected. A clarification provided by the Competent Authority is given in an endnote.

Executive Summary

The mission was undertaken to evaluate the United States (US) Government and industry actions related to Commission Decision 2006/601/EC, as amended, on 'LL RICE 601'. The mission team met with the Central Competent Authorities with responsibility for the authorisation of Genetically Modified Organisms (GMOs) in the US and their export to the European Union (EU). In addition, visits were made to an export point for sampling, a rice mill and 2 laboratories, 1 of which organises the proficiency testing programme for rice and the other participants in this scheme.

The national policy in place in the USA for agricultural biotechnology is based on pre-existing health and safety laws developed to address specific product classes.

The US government agencies responsible for the oversight of products of agricultural biotechnology are the United States Department of Agriculture (USDA) –Animal and Plan Health Inspection Service (APHIS), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Depending on its characteristics a product may be subject to review by one or more of these agencies.

Within the USDA, a memorandum of understanding has recently been signed to improve communication between APHIS, the Grain Inspection, Packers and Stockyard Administration (GIPSA) and the Agricultural Marketing Service (AMS). There was no other information made available to the mission team on the other proposals to improve field trial oversight and prevent a future episode similar to the LL rice contamination.

There are more than 75 GMOs which have been deregulated since 1987, although not all of these have been subject to commercial cultivation in the USA.

The State of Arkansas produces more than 50% of total US rice and the varieties of rice found to be contaminated with 'LL RICE 601' have been banned from cultivation there since 2007.

GIPSA is responsible for official sampling for GMOs at the points of barge loading for exports of rice, in line with the requirements of Decision 2006/601/EC.

There are 6 laboratories in the GIPSA rice proficiency programme that have been approved by Bayer Crop Science to conduct GMO analysis. The private laboratory visited by the mission team, participating in this programme is well organised and accredited to ISO 17025.

There is a system of controls in place to ensure that rice exported to the EU fulfills the requirements of Decision 2006/601/EC. This includes official controls of the rice seed in some states (legal measures to prevent use of contaminated seed in Arkansas), private sector controls and official sampling for laboratory testing by laboratories participating in the official proficiency testing programme. Limited information was available to the mission team on the follow up of revisions being considered for the Biotechnology Framework regarding prevention of a recurrence of an incident such as 'LL RICE 601'.

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
AMS	Agricultural Marketing Service
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
ASTA	American Seed Trade Association
ASTB	Arkansas State Plant Board
BRS	Biotechnology Regulatory Services
CA	Competent Authority
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
FAS	Foreign Agricultural Service
FFDCE	Federal Food, Drug and Cosmetic Act
FGIS	Federal Grain Inspection Service
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FVO	Food and Veterinary Office
GIPSA	Grain Inspection, Packers and Stockyards Administration
GM	Genetically Modified or Genetically Engineered (GE used in US)
GMO	Genetically Modified Organism(s)
IP	Identity Preserved
ISO	International Organisation for Standardisation
LL	Liberty Link
LLP	Low Level Presence
LOD	Limit of Detection
NEPA	National Environmental Policy Act
PAT	Phosphinotricin Acetyltransferase (protein expressed by LL GM rice events)

Abbreviation	Explanation
RASFF	Rapid Alert System for Food and Feed
TARIC	Tarif Intégré de la Communauté (Integrated tariff of the Community)
TSCA	Toxic Substances Control Act
US	United States
USDA	United States Department of Agriculture

1 INTRODUCTION

The mission took place in the USA from 4 to 11 June 2008. The mission team comprised two inspectors from the Food and Veterinary Office (FVO), one policy officer from the Directorate General of Health and Consumers and one expert from a European Union (EU) Member State.

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

The inspection team was accompanied, during the mission, by representatives from the United States Department of Agriculture (USDA) and the USA Rice Federation.

An opening meeting was held on 4 June 2008 with the representatives of the USDA bodies concerned with the scope of this mission, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). At this meeting, the inspection team confirmed the objectives and the itinerary of the mission.

2 OBJECTIVES OF THE MISSION

The overall objective of the mission was to evaluate the US government and industry control activities related to Commission Decision 2006/601/EC.

The sites visited and meetings held in pursuit of these objectives are outlined in Table 1 below:

Table 1: Mission visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	3	USDA, EPA, FDA
Regional	1	Arkansas State Plant Board,
Laboratories		
Public Private	1 1	GIPSA laboratory organising proficiency tests Participates in rice testing for GMO prior to export to EU
Food and feed establishments		
Export service provider	1	Private service for sampling and IP systems in exports at Port of New Orleans
Rice miller	1	Private miller which exports to EU
Official sampling point	1	Barge loading at port of Helena for sampling

3 Legal Basis for the Mission

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

- Article 46 of 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 Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism "LL RICE 601" in rice products as amended.

Details of the above legislation, and all other relevant EU legislation are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

This report is the third mission to a third country to evaluate the control systems which are in place for the export of GMO food, feed or seed to the EU. Missions took place to Argentina in 2006 and to Brazil in 2007. However this mission focused specifically on rice exports from the USA to the EU (in the light of the above mentioned Commission Decision).

A series of missions to Member States (MS), concerning the evaluation of the implementation of EU Regulations on official controls for GMOs in food, feed and seed has been undertaken during 2006 and 2007. The final reports of these and the above mentioned missions are available on the DG Health and Consumers Internet site:

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

According to the report "Global Status of Commercialized Biotech/GM crops 2007" (http://www.isaaa.org/resources/publications/briefs/37/executivesummary/default.html) the cultivation area of biotech crops has continued to increase year on year from 1.7 million hectares in 1996 to 114.3 million hectares in 2007. The main producers of biotech crops are outside Europe, and are led by the USA and followed by Argentina, Brazil, Canada, India and China. The most important crops are soya beans, maize, cotton and rapeseed.

GM rice is not commercialised in the EU or the USA at present but field crops in the USA were found to contain traces of GM rice in recent years. In August 2006 the European Commission was informed by the US Secretary of Agriculture that trace amounts of a GM variety of rice were detected in samples of commercial rice and may have entered the food and feed supply in the US. The GM variety largely concerned LL RICE 601 which was not intended for commercialisation. According to EU legislation, even traces of unauthorised GMO are illegal and products containing them cannot be marketed.

Decision 2006/601/EC, requires that the original of an analytical laboratory report confirming that products do not contain "LL RICE 601" along with an official document from the Grain Inspection, Packers and Stockyards Administration (GIPSA) of USDA accompany each consignment of rice exported to the EU. In addition MS are to take random samples for analysis to verify the absence of LL RICE 601. The GM rice LL RICE 62, de-regulated in 1999, was found to a much smaller extent and received a favourable opinion by EFSA on 30 November 2007 as part of an application for authorisation in the EU.

There were a large number of rapid alert notifications in the EU regarding GM rice from the USA in 2006 and the number has decreased in subsequent years see table 2 below.

Table 2: Rapid Alert Notifications for GM rice from USA

Year	LL rice 62	LL rice 601
2006	2	99
2007	4	19
2008	2	1

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

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

4.1 ECONOMIC STATISTICS

According to EUROSTAT, imports of rice from the USA in 2007 accounted for 15 % of imports of rice in husk and 9% of milled rice imports compared to 62 % and 24 % for the same commodities in 2005. Table 3 below summarises the volumes imported from 2005 to 2007. The sharp decline of rice imports to the EU from the US over these 3 years is due to the LL rice contamination. There is no distinction at import as to whether a food or feed commodity contains GMO, as they are imported under the same TARIC code.

Table 3: EU Imports of rice from USA 2007, 2006, 2005 (source EUROSTAT).

	Year	Rice in husk	Brown rice	Milled rice	Broken rice
TARIC code		100610	100620	100630	100640
% share of EU imports	**2007**	15.2	0.9	9.1	0.6
	2006	61.5	18.4	18.6	1.4
	2005	62.3	26.9	23.9	3.2
Volume (tons)	**2007**	100	7,898	27,828	1,163
	2006	1,220	131,948	44,728	2,637
	2005	1,130	193,104	44,054	4,056

5 MAIN FINDINGS

5.1 RELEVANT NATIONAL LEGISLATION

Established as a formal policy in 1986, the Coordinated Framework for Regulation of Biotechnology describes the Federal system for evaluating products developed using modern biotechnology. The Coordinated Framework is based upon health and safety laws developed to address specific product classes. The U.S. Government has written new regulations, policies and guidance to implement these laws for biotechnology as products developed.

The major laws currently used to regulate the products of modern biotechnology are the Plant Protection Act (PPA), the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA). In addition, other legislation is considered when required such as the National Environmental Policy Act (NEPA), the Endangered Species Act; the Clean Water Act; and the Migratory Bird Treaty Act.

New regulations have been developed under these statutes to address GMO products. The mission team was informed by the USDA that new regulations, policy statements and guidelines will continue to be developed as needed.

The governing statutes for the USDA Federal Grain Inspection Service (FGIS) within GIPSA include the US Grain Standards Act which covers among others wheat, corn (maize), soybeans etc and the Agricultural Marketing Act of 1946 which covers among others rice, peas, beans, lentils.

There is no legal requirement in the USA for food, feed, or seed derived from GMO to be labelled as such. Voluntary labelling to indicate that foods are or are not derived from GM plants is permitted so long as the labelling is not false or misleading. However, although not specific to GMOs, labelling is required if there is any change to the composition of the food or feed as a result of genetic modification.

When it is deregulated, food and feed derived from GM plants have the same legal status as conventional food and feed. However, prior to marketing of food and feed derived from GM plants, there is a voluntary consultation process with the FDA to determine if the food or feed is as safe as food or feed already on the market and to examine the possibility of issues such as reduction of important nutrients, new allergens or the presence of unapproved food additives. A guidance document on this consultation procedure is available on the FDA website: http://www.cfsan.fda.gov/~lrd/consulpr.html

Legislation specifically dealing with the contamination of long grain rice with 'LL RICE 601' has been produced in the states of Arkansas, California and Louisiana (see section 5.4.2 below).

5.2 COMPETENT AUTHORITIES

5.2.1 Structure and responsibilities

The Federal Competent Authorities for this mission include the USDA, EPA and the FDA. Within the USDA there are 3 bodies under the authority of the Undersecretary for Marketing and Regulatory programmes: APHIS, GIPSA and the Agricultural Marketing Service (AMS).

5.2.1.1 Animal, Plant Health Inspection Service

APHIS is responsible for protecting agriculture from pests and diseases. Under the Plant Protection Act (PPA), APHIS has regulatory oversight over products of modern biotechnology that could potentially pose such risks. In order to protect plant health, the Biotechnology Regulatory Services (BRS) implements the PPA for GMO that may pose a risk to plant health. The BRS includes four programme divisions; Policy Coordination Programmes, Environmental Risk Analysis, Regulatory Operations Programmes, and Resource Management Programmes.

APHIS coordinates the regulatory responsibilities for GMO that may pose risks to plant health in cooperation with the other Federal agencies (mentioned below) as part of the Federal Coordinated Framework for Biotechnology. APHIS exerts its regulatory authority through a system of permits and notifications. GMO events subject to these controls are called "regulated articles." APHIS regulates the import, handling, interstate movement, and release into the environment of regulated organisms that are products of biotechnology, including organisms undergoing confined experimental use or field trials. APHIS regulations have a process by which GM plants can be “de-regulated” once data has been provided that demonstrate that the GM plant does not pose a risk to plant health.

5.2.1.2 Environmental Protection Agency

The EPA, through a registration process, regulates the sale, distribution and use of pesticides in order to protect health and the environment, regardless of how the pesticide was made or its mode of action. This includes the regulation of those GM varieties that mitigate pests in crops. Biopesticides and Pollution Prevention Division of the Office of Pesticide Programmes, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), regulates the distribution, sale, use and testing of pesticides produced in plants and microbes. The EPA also sets tolerance limits (Maximum Residue Limits) for residues of pesticides in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act.

5.2.1.3 Food and Drug Administration

The FDA is an agency within the Department of Health and Human Services and is responsible for protecting public health by assuring the safety of, among other products, of the US food supply.

The FDA is responsible for ensuring the safety and proper labelling of all plant-derived foods and feeds, including those developed from GMO. All foods and feeds, whether imported or domestic and whether derived from crops modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards. Under the Federal Food, Drug, and Cosmetic Act, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labelled. In addition, any food additive, including one introduced into food or feed by way of any plant breeding methods, must receive FDA approval before marketing. (The term "food additive" refers to substances introduced into food that are neither pesticides nor generally recognized as safe by qualified scientific experts).

5.2.1.4 Grain Inspection, Packers, Stockyard Administration

The Federal Grain Inspection Service (FGIS) of GIPSA facilitates the marketing of food and feed grains, which includes rice. One of their many roles is to develop sampling and testing methods. GIPSA is not a regulatory administration with regard to agricultural biotechnology. FGIS inspectors in each state undertake quality inspections of grain, rice and pulses. They provide official services which can include stowage examination, weighing, sampling, quality inspection, observation of loading and certification. A range of methods used to ensure that samples are representative was presented to the mission team. The role of FGIS following the LLRICE601 contamination included:

- The standardisation of testing in the market place,
- The development of the proficiency testing scheme for private commercial laboratories,
- The development of the protocol proposed to the Commission and reflected in Commission Decision 2008/162/EC which amended Decision 2006/601/EC on emergency measures for rice,
- The provision of sampling and certification services for rice.

5.2.2 Co-ordination and Communication

The mission team was informed that APHIS works in partnership with FDA and EPA in order to ensure that the development, testing and use of the products derived from GMO take place in a safe manner for plant, animal and human health and the environment.

In October 2007, during the aftermath of the 'LL RICE 601' problem, USDA-APHIS informed the Commission of revisions under consideration for the Biotechnology Regulatory Framework to strengthen its oversight over field trials. The published document (http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/LessonsLearned10-2007.pdf) identified up to 10 areas under consideration to enhance the regulatory framework:

- A requirement to create and retain additional records for quality and completeness
- Revision to the PPA to provide APHIS with the authority to subpoena physical evidence for investigation

- Convene an expert advisory panel to implement the above point
- Require applicants for experimental release of GMO to submit a contingency plan
- Require applicants to submit written corrective action plans
- Recommendations for resources, memoranda of understanding agreements and collaborations between the 3 USDA Marketing and Regulatory Programme agencies (APHIS, AMS and GIPSA)
- Require business agreements between GM technology researchers to be in writing
- Consider the sufficiency of isolation distances between experimental crops and nearby field crops
- To encourage the use of quality management systems throughout the biotechnology research community
- Electronic storage of all information associated with permits and notifications

As part of this review, an interagency memorandum has been recently signed to strengthen the collaboration and information flow between APHIS, AMS and GIPSA. A copy of the memorandum was supplied to the mission team. It indicates how cooperation can be achieved through the sample analysis, storage and germination facilities of AMS and the sampling and inspection of grains (including rice and oilseeds) pulses and legumes of GIPSA. The aim of this memorandum is to reduce time and resources required to address any future sampling and testing events. There were no details available to the mission team as to the level of progress with the nine remaining proposals.

5.3 GMO REGULATION PROCEDURE

5.3.1 Authorities involved in GMO regulation

The US government agencies responsible for the oversight of products of agricultural biotechnology are USDA-APHIS, EPA and the FDA. Depending on its characteristics a product may be subject to review by one or more of these agencies.

The mission team was informed by USDA that more than 75 GM crop lines have been de-regulated since 1987. Not all of these deregulated events have subsequently been commercialised by the developer.

The Biotechnology Regulatory Service (BRS) implements the regulations of APHIS regarding GMO which may pose a risk to plant health. All regulated introductions of GMO must be authorized by APHIS-BRS under either its permit or notification procedures. APHIS permits are for GMOs that may pose a plant pest risk (includes plants, insects or microbes). Details of the scientific information needed for review by APHIS for issue of a permit are available on the APHIS website. The notification procedure is an alternative process whereby the GM plant must meet specific eligibility criteria with pre-defined performance standards. Applications for permits and notifications can be made on line and guidance to applicants on the requirements is

available on the APHIS website (http://www.aphis.usda.gov/biotechnology/permits.shtml).

APHIS-BRS reviews the regulated articles both under permits and notifications to ensure that, under the proposed conditions of use, they do not present a plant pest risk through ensuring appropriate handling, confinement and disposal.

Under the APHIS regulations there is provision for a petition process to apply for "deregulated status". The developer or researcher who has the permit for field trials must supply scientific information to APHIS as part of the petition for deregulation. APHIS evaluates the information and allows for public input prior to making a decision. Non regulated status can be granted by APHIS through a simplified procedure if a regulated article is very similar to a GMO that has already been deregulated. "Non regulated status" indicates that permits or notifications are no longer required for the cultivation of that GMO.

The EPA informed the mission team that generally, "Experimental Use Permits" are issued by them for field testing where the trials are greater that 10 acres (4.05 ha) for GMO coming under the provisions of FIFRA. Such GM plants are classed as plant-incorporated protectants. Applicants must register these products prior to full commercial sale and distribution, and the EPA may establish conditions for use as part of the registration.

Under the Toxic Substances Control Act (TSCA), the EPA acquires information in order to identify and regulate potential hazards and exposures. TSCA applies to the manufacturing, processing, importation, distribution, use, and disposal of all chemicals in commerce, or intended for entry into commerce, that are not specifically covered by other regulatory authorities, (e.g. substances other than food, drugs, cosmetics and pesticides). The application of TSCA to the regulation of products of biotechnology is based on the interpretation that organisms are chemical substances under TSCA. The EPA's TSCA Biotechnology Programme of the Office of Prevention and Toxic Substances currently regulates micro-organisms intended for general industrial uses. The programme conducts a pre-market review of "new" microorganisms, (i.e. those microorganisms formed by deliberate combinations of genetic material from organisms classified in different taxonomic genera.) Developers must notify the EPA 90 days prior to manufacture or 60 days prior to field testing of a product regulated by TSCA.

The mission team was informed that EPA along with APHIS consult with the states as needed on experimental environmental release of GM plant material.

The FDA ensures that food and feed manufacturers meet their obligations through its enforcement authority under the Federal Food, Drug, and Cosmetic Act. However, unlike APHIS or EPA, the FDA has no specific role in the regulation or deregulation of GM plants. Food and feed production has to meet certain standards regardless of how it is produced. However, in order to help producers of foods and feeds derived from GM crops comply with their obligations; the FDA encourages them to participate in its voluntary consultation process. The FDA informed the mission team that it is not aware of any foods and feeds from GM crops intended for commercialization in the U.S. market that have not completed this consultation process. It is only if food or feed is considered to contain a "food additive" that prior approval is required prior to marketing.

5.3.2 Regulatory status of rice

In October 2007 the US provided an overview of the extensive investigations carried out in the attempt to identify the source of the LL rice contamination (http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf). While the exact mechanism of the contamination could not be established, the possible locations where the contamination could have occurred were confirmed. For 'LL RICE 601', the origin of the contamination could either have been cross-pollination (they were cultivated during the same years, but fields of 'LL RICE 601' and Cheniere always fulfilled the distance requirements) or mechanical admixture. For 'LL RICE 604', the most reasonable mechanism of contamination is mechanical admixture. Lack of available records beyond the prescribed period of 5 years was stated to have hampered more thorough investigation.

In March 2007, APHIS published is policy on the Low Level Presence (LLP) (http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/fs_llppolicy3-2007.pdf) of regulated GM plant material. The policy describes how the Agency responds to such occurrences in commercial seeds and grain. If APHIS determines that an incident involving a GM plant would result in the introduction of material that could pose a risk to plant health or the environment, the Agency will use its authority under the Plant Protection Act (PPA) to mitigate that risk. This authority includes holding, seizing, quarantine, treatment, applying other remedial measures to, destroying, or otherwise disposing of regulated materials if it is determined that such measures are necessary to prevent the dissemination of a plant pest within or throughout the US. Any remedial action is determined on a case by case basis. Even if APHIS determines that no remedial action is necessary to mitigate the low-level presence of a regulated GM material, the Agency can still take legal action for violations of the Agency's biotechnology regulations. 'LL RICE 601' has been subject to the application of this LLP policy.

APHIS works in cooperation with EPA and FDA to provide regulatory oversight of the development of GMO consistent with Coordinated Framework for Regulation of Biotechnology to ensure the safety of biotechnology research and products. In line with FDA's guidance on early food safety evaluations (http://www.cfsan.fda.gov/~dms/bioprgu2.html), the FDA made a statement on its website early in 2007 *regarding LL Rice 604* as follows, "FDA has previously evaluated the PAT protein for safety on a number of occasions through the Agency's voluntary biotechnology consultation process. Therefore, FDA has concluded that the presence of rice from the LL Rice 600 series at low levels in food and feed would pose no food or feed safety concerns. The FDA also made a similar statement on its website regarding LL Rice 601 in 2006 (http://www.cfsan.fda.gov/~lrd/biorice.htm).

An extension process can be used in cases where a GM plant is similar to a previously deregulated plant. The extension process, which was established in 1997 and has been used numerous times since, is based on the premise that a GM plant that is similar to a previously deregulated plant with respect to plant genotype and the expressed protein(s) is also similar in terms of any potential risk. Based on a thorough review of information in the extension request, which includes data showing similarity, APHIS may conclude that the new GM plant, like the previously deregulated GM plant, does not pose a plant

pest risk and therefore will no longer be regulated. This extension process was applied to 'LL RICE 601' and it now has deregulated status since November 2006 (http://www.aphis.usda.gov/brs/aphisdocs/06_23401p_ea.pdf).

5.4 CONTROLS TO ENSURE ABSENCE OF LL RICE 601 IN SEED

5.4.1 Industry controls

The USA Rice Federation representing the rice industry (growers, merchants, millers and exporters) developed a "seed plan" in December 2006 in response to the LL rice contamination. The aim of this plan was to eliminate LL rice traits from the commercial market. Rice markets disrupted by the LL rice incident in 2006 included not alone the EU but also other US export markets such as Cuba, Korea and Russia. Furthermore, the testing of rice for LL content were made a requirement by many US rice customers such as the EU, Japan, Iraq, Cuba, Korea, Philippines, Taiwan and Russia. This "seed plan" was a US rice industry recommendation to the rice growing state authorities and included:

- Seed testing so that all seed used for 2007 crop had tested negative for any LL traits
- Certification for mills so that only 2007 crop rice grown from seed certified as negative was purchased. In this respect, millers requested from farmers appropriate documents for each rice delivery.
- Education to ensure that all sectors of the industry understood the requirements

Test results from the 2007 long grain rice crop detected adventitious presence of LL traits at a level of 0.55% for total rice tested (0.6 % in Arkansas and 1.2 % in Louisiana) according to the Rice Federation see table 4 below. The legislation in Arkansas requires that any lots testing positive for LL traits do not get a second test and are removed from the seed market with proper identification.

Table 4: Test results of the 2007 US long grain rice crop * (final 31/10/2007)

State	Samples tested	Tons of rice tested	Tons with negative result	Tons with positive result	Positive results as % of total rice tested	States share of US long grain rice crop 92004-2006 average)
Arkansas	526	1,419,479	1,411,227	8,252	0.6	58%
Louisiana	23	46,161	45,617	544	1.2	16%
Texas	30	25,767	25,767	0	0	8%
Mississippi	13	82,899	82,899	0	0	9%
Missouri	16	46,320	46,320	0	0	8%
Total	608	1,620,626	1,611,830	8,796	0.5	100% ^

Source: USA Rice Federation

* Test results of harvested rice ("green rice") at first point of delivery. Testing is performed by laboratories participating in GIPSA proficiency test scheme.

^ Individual state percentages do not add to 100% due to rounding.

The mission team met with the American Seed Trade Association (ASTA). ASTA focuses on 3 areas of importance to the seed industry: regulatory and legislative matters, new technologies and communication and education of members and the public on science and policy issues. Seed production and commercialisation is regulated at state level and this does not affect the interstate movement of seed however, any seed bought across state lines from a different state must meet the regulatory requirements of the recipient state.

5.4.2 Official Controls

In the state of Arkansas the mission team met with the Arkansas State Plant Board (ASPB) which is a regulatory authority concerning seeds, plants, plant pests and fertilizers, among others. 50% of US rice production comes from Arkansas and the mission team could observe how the "seed plan" is implemented. See table 5 below on rice production by state for 2007.

ASPB started the testing of file samples of foundation seed rice produced in the state of Arkansas for 'LL RICE 601' in 2006 as soon as they were informed of the contamination issue. These samples were sent to the USDA AMS reference laboratory in Gastonia, North Carolina. Although not visited, the mission team were informed that this laboratory has additional equipment to facilitate the testing of large numbers of samples. As a result of testing these samples, the ASPB established that the source of the contamination was in the varieties of Cheniere and Clearfield131.

Arkansas has state legislation in place as follows: Rice of the varieties Cheniere, that was produced from seed tracing back to the 2003 Foundation Class from Louisiana State University, and Clearfield 131 tracing back to registered or certified classes produced in 2005, 2006 or 2007, shall not be offered for sale, sold, planted, produced, harvested, stored, distributed, transported, subjected to conditioning processes or handled in any manner for grain production in 2007 and 2008. This was adopted in the framework of a regulation for the production of rice having characteristics of commercial impact previously established in Arkansas in 2005.

There are 30 inspectors (agricultural specialists) in the seed division of ASPB with responsibility for official control including sampling rice seed at point of sale for purity and germination (quality parameters). Each inspector is allocated a specific area though out the state. These inspectors undertake official sampling of all rice seed produced in Arkansas or brought into Arkansas which is subject to mandatory testing for 'LL RICE 601' according to the above mentioned state legislation.

Currently, in Arkansas 1 ASPB inspector has been trained by APHIS BRS in a pilot programme to inspect field trials with regulated entities (GM events). It is planned that a further 2 ASPB inspectors will be trained by BRS to do these inspections. The number of BRS permits granted for regulated GM events in 2008 to date is 30; during 2007 it was approximately 50 permits. None of these field trials include rice.

Seed certification is voluntary and granted on the basis of grower application, which provides field crop history for the previous 2 years and details of the lot planted over 4 generations (breeder, foundation, registered and blue tag). The mission team was informed that up to 90% of US rice seed is certified.

The Association of Official Seed Certifying Agencies (AOSCA) includes agencies from 45 states and it inspects 3.75 m acres (all seed crops) annually. These include 3 types of agencies: state, universities and private crop improvement associations.

Table 5: US Rice Production 2007 Crop

State	**Area Harvested (1,000 Acres)**	**Yield (pounds)**	**Production (1000 cwt)**
Arkansas	1325	7130	94487
California	533	8220	43822
Louisiana	378	6140	32222
Mississippi	189	7450	14081
Missouri	178	6900	12279
Texas	146	6600	9565
United States	**2748**	**7185**	**197456**

Source: US National Agricultural Statistics Service

Both California and Louisiana issued regulations similar to the one adopted in Arkansas. The mission team was informed that the states of Mississippi, Missouri and Texas tend to follow the legislative requirements of Arkansas, as otherwise they could not trade in the state of Arkansas. The USA Rice Federation recommended the extension of the industry "seed plan" into 2008. Both Arkansas and Louisiana states are known to have extended seed testing regulations into 2008. In Arkansas penalties have been set for non compliance such as fines of up to $250,000 per day. An example of the documentation necessary for the implementation of the seed plan in Arkansas was provided to the mission team. This included detailed instructions on the required testing of all Arkansas rice varieties, the record sample sheet for LL testing and the form for the verification of previous rice crops. Copies of the documentation required from the grower for the miller were also made available to the mission team. Test results from the 2008 rice seed performed in Arkansas did not show adventitious presence of LL traits according to the ASPB (results as of 6 May 2008, 679 lots tested).

5.5 CONTROL PROCEDURES FOR RICE EXPORTS TO THE EU

5.5.1 Rice processing (milling)

The mission team visited one rice mill, which produces rice that may be exported to the EU. This facility is part of a large conglomerate of companies producing rice products and other food commodities. When the rice contamination arose in 2006 the company identified growers who had not grown Cheniere or Clearfield131 rice in the last 2 years. During 2007 the company required the growers to provide the following documents to ensure the rice was free of 'LL RICE 601': seed certificate, sales receipt from the seed merchant and Farm Services Agency documents of certified acres planted. These documents are all required as part of the rules under the ASPB. The rice mill purchases "green rice" which it can dry in its own drying facilities and it also purchases dried rice from farms and commercial elevators. The latter is also required to provide the above mentioned documents.

As part of the rice milling company's own in house quality control procedures rice was sampled at farm storage silos, at intake at the rice mill and during the final stages of the rice milling process. These samples are sent by the company to one of the private laboratories participating in the GIPSA proficiency testing programme for 'LL RICE 601'. All rice production is tested in this way regardless of the destination of the product. During 2007, at least 1 batch of rice was found positive for the presence of 'LL RICE 601' at the final milling sample. As part of the company's procedures the plant had to be flushed out with 'clean rice' and the company made sure itself that the resulting rice was placed on the US home market.

5.5.2 Rice export procedure

To fulfil the requirements of Decision 2006/601/EC, the exporters of rice to the EU can

request GIPSA to sample the consignments for analysis at barge loading for export. GM sampling of rice for export to the EU, in earlier steps of the production chain, may be performed by private services or by companies own controls, as noted by the mission team at the rice mill visited. GIPSA estimates that approximately 13,560 metric tons of rice has been tested officially under this protocol up to mid June.

The US Rice Federation disseminates information and guidance on the requirements for rice testing for export to the EU to all of its members (from growers through to exporters).

The mission team observed the official sampling of rice by a GIPSA inspector at the loading of a barge for export at the port of Helena on the Mississippi. The inspector was equipped with an "Ellis cup" to sample from the conveyer belt, as the rice was loaded from the truck to the barge. He used a divider to uniformly divide the rice into even amounts giving a better representative sample. He had sample seals which can only be used by GIPSA officials to seal the samples. Routinely GIPSA are notified in writing when a consignment is being loaded on a barge for export to the EU.

GM sampling in other commodities for export to the EU can be undertaken by private services at the request of the exporter. At the port of New Orleans (the largest US port for export of grain) there are four private companies which provide sampling services. The mission team visited one of these companies that are involved in Identity Preserved (IP) systems for the export of maize and soya. This company is certified by 2 internationally recognised certifying bodies (Grain and Feed Trade Association and Federation of Oils, Seeds and Fats Association). The company is aware of the official requirements for the export of rice to the EU.

5.6 LABORATORIES

According to the US food legislation, the labelling of unregulated GMO indicating that the specific food item contains GMO or is made from GMO is not necessary in the US. For rice, the EU requires testing of the lot to be exported to Europe. An accompanying document is issued by GIPSA based on officially taken samples. The analysis of GM rice in the US is performed by private laboratories which take part in an official proficiency scheme on a regular basis. In addition to the analysis of samples taken for export to the EU, the US Rice Federation has as part of the "seed plan" identified several stages during the production of long grain rice where samples are taken and analysed for the presence of rice containing the LL traits. This procedure aims to enable the industry to channel out any GM rice at several stages before the sampling and testing procedure for export to the EU.

5.6.1 GIPSA laboratory

The GIPSA laboratory in Kansas City is a governmental laboratory. It comprises an overall staff of 70 people. One part of the GIPSA laboratory is the Biotechnology department serving as coordinating facility in the field of GMO analysis. The Biotechnology department is responsible for the independent verification of methods used in testing, providing proficiency programme for GM in rice, corn, and soybean and also the verification of commercial test kits.

The laboratory does not provide testing services for GMO. There is a quality management system in place following the principles of ISO 9001:2000 and ISO 17025:2005. There is a quality management handbook in place as well as written methods for the analysis to be performed and for maintenance of the equipment.

The Biotechnology department has an overall staff of four trained persons, three of them with Ph.D. degrees. It is capable to perform molecular methods as well as immunological tests; and has also grinding and sample preparation facilities.

The equipment is up to date and adequate for the analysis required. There are three different real-time PCR instruments and modern equipment for DNA quantification is available.

The layout of the facilities and equipment is sufficient to prevent cross-contamination. The methodological steps, starting with grinding the test material, are performed in separate rooms and follow the principles of forward flow. In each room, designated equipment is used.

The verification of the method supplied by Bayer Crop Science for GM rice was done at the Biotechnology department (also verified by the EU Joint Research Centre see Annex II to Decision 2006/601/EC). This method verification comprised preparation of the test material, DNA extraction, real-time PCR and evaluation of the results. The studies led to improving the proposed procedure by a more adequate DNA extraction method. The method verification as executed by GIPSA included determination of the limit of detection (LOD) using grain material and DNA mixtures, resulting in a LOD of 0.01%. Ruggedness tests were performed by applying the procedure to 20 real samples including samples with degraded DNA to observe the impact of degraded DNA on the LOD. The principles of the method verification and the execution were done correctly and exceeded the requirements.

The GIPSA organises proficiency programmes for GMO tests of corn (11 varieties), soybean (line GTS 40-3-2), and rice (Liberty Link varieties LL RICE 62 and LL RICE 601) for private test laboratories. More than 150 laboratories worldwide participate in the programme for corn and soybean. At present, this programme comprises qualitative detection and quantitative determination of the relevant crop varieties setting a standard for proficiency programmes in this field.

Regarding the programme for rice, the six test laboratories were designated and authorised by Bayer Crop Science who supplies the method. The proficiency program for rice administered by GIPSA includes only the six laboratories designated by Bayer Crop Science. In this programme, the application of the 35S-bar real-time PCR method is predefined.

In September and October 2006, the proficiency study was done weekly, from November 2006 on the tests of LL rice are organised on a monthly basis. The tests material comprises six coded samples of ground rice flour prepared from conventional rice and from GM rice supplied by Bayer Crop Science. The fortification level is 0.03% of LL RICE 601 and LLRICE 62 (two samples each) in ground rice. Two samples are ground conventional rice. Up to the date of this mission, all participating laboratories correctly identified all samples (~1800 individual samples) correctly verifying that all laboratories are capable of detecting LL rice in ground rice at a detection level of 0.03 %.

5.6.2 Private testing laboratory

During the mission, a private test laboratory performing the tests for LL rice was visited. It is one of the six laboratories designated by Bayer Crop Science for testing rice to be exported.

The laboratory is accreditated according to ISO 17025:2005 by the American Association for Laboratory Accreditation for performing analysis of GMO since 2002. The documents are clearly structured and up-to-date.

The laboratory has a staff of 30. The head of the laboratory has post graduate qualification; the other staff performing analysis has as minimum a Bachelor degree. The personnel is trained on a regular basis, training records are maintained. The additional on-the-job training requires about two years for all methodological steps performed in this laboratory. The training records are kept correctly and include the raw data which each person produced during the training sessions.

The overall laboratory structure follows the principle of forward flow with separation of the methodological steps in different rooms. The well equipped rooms for sample grinding are separated from the rooms for DNA extraction and PCR setup. The DNA extraction area is very well equipped according the needs of the methods performed as there are facilities for a higher throughput of samples. There are several thermal cyclers and real-time instruments available. Gel electrophoreses is separated completely from the other parts of the laboratory in a different section of the building to prevent artificial contamination of samples.

When samples arrive at the laboratory they are coded with a five digit number and the relevant data entered into the laboratory information system (LIMS). In this LIMS, the methods to be applied to the samples including the number of replicates are predefined according to the clients needs.

DNA extraction is done according to the laboratories proprietary methods; the extraction procedure includes a quality check and the application of extraction negative controls in a pre-defined manner.

For molecular analysis of LL rice, the 35S-bar method, developed by Bayer Crop Science and verified by the Biotechnology department of GIPSA is applied. All test results generated by the real-time PCR instruments are verified by double checking the raw data including the amplification plots by a laboratory manager who signs the analytical report. The analytical results are qualitative results; the analytical report includes in addition to the test result also the size and the number of the test portions.

During the whole procedure, the sample is traceable, every methodological step is signed by the responsible staff member. The material is kept for three months so additional tests can be performed.

The laboratory participates in the GIPSA organised proficiency tests of GM corn and soybean twice a year and GM rice monthly with good results.

6 CONCLUSIONS

6.1 LEGISLATION

- There is a legislative framework in place for the regulation of biotechnology and it is based on pre-existing health and safety laws developed to address specific product classes.
- Rice specific regulations dealing with the LL rice contamination have been produced in the states of Arkansas, Louisiana and California.

6.2 COMPETENT AUTHORITIES

- The competencies of the various bodies within USDA and the authorities involved in the assessment and regulation of GMO events are well defined.
- The role of GIPSA in the official sampling of rice for export to the EU as required by Decision 2006/601/EC is clearly defined.
- The scope for the improvement of communication between APHIS, GIPSA and AMS was recognised with the recent signing of a memorandum of understanding
- The level of progress with the 9 other proposed revisions to the Biotechnology Regulatory Framework under consideration to strengthen field trial oversight and prevent a recurrence of an incidence such as the LL RICE 601 contamination is not available to the mission team. (see Endnote)

6.3 GMO REGULATION PROCEDURE

- There are more than 75 GMO events which are deregulated under US Federal legislation, the subsequent commercialisation of such events is at the discretion of the developer.
- The regulation procedures for GMOs including the experimental release are dependant on the classification of the GMO event of concern such as plant pest, pesticide or food additive.
- The "deregulated status" of a GMO event can only be granted as a result of a petition process usually brought by the developer to APHIS and must include the relevant scientific information required by APHIS to make an informed decision.
- In line with the low level presence policy of APHIS, and the application of the extension procedure, the low level presence of 'LL RICE 601' in the US domestic food chain has been deregulated. The FDA concurs that there is no food or feed safety issue. Currently 'LL RICE 601' is not in commercial use in the USA.

6.4 CONTROLS TO ENSURE ABSENCE OF LL RICE 601

- There is a strong legal framework in the state of Arkansas to prevent the cultivation of varieties of rice identified to have been contaminated with LL rice traits.
- Inspectors in Arkansas are well organised to check the quality parameters of rice seed as well as the sampling of rice for GM testing.
- The USA Rice Federation "seed plan" to eliminate LL rice from the long rice for export to the EU and other international customers is a comprehensive plan that covers the various stages of rice production and is proving to to be a good solution to the contamination problem.
- It is considered a positive initiative to extend the seed plan to the 2008 rice crop.

6.5 CONTROLS PROCEDURES FOR EXPORTS

- GIPSA inspectors are well placed to undertake the official sampling of rice for export to the EU.
- The inspector undertaking official sampling for GIPSA at barge loading was well equipped and knowledgeable of the procedures to follow. These procedures were in line with the requirements of Decision 2006/601/EC.

6.6 LABORATORIES

- The GIPSA laboratory organising the proficiency testing schemes for rice, corn and soybean was well staffed and equipped to carry out this function.
- The private laboratory undertaking GM analysis as part of the GIPSA proficiency testing scheme was accredited to ISO17025.
- This private laboratory was very well organised with regard to staffing and equipment to undertake GMO analysis techniques and participated in proficiency test schemes for rice, corn and soybean with good results.

6.7 OVERALL CONCLUSION

There is a system of controls in place to ensure that rice exported to the EU fulfils the requirements of Decision 2006/601/EC. This includes official controls of the rice seed in some states (legal measures to prevent use of contaminated seed in Arkansas), private sector controls and official sampling for laboratory testing by laboratories participating in the official proficiency testing programme. Limited information was available to the mission team on the follow up of revisions being considered for the Biotechnology Framework regarding prevention of a recurrence of an incident such as 'LL RICE 601'.

7 CLOSING MEETING

A closing meeting was held on 11 June 2008 with representatives of USDA, EPA and

FDA. At this meeting, the preliminary findings and conclusions of the mission were presented by the FVO inspection team. The representatives took note of these findings and offered some clarifications and comments.

8 RECOMMENDATIONS

The competent authorities are invited to provide, within 25 working days of receipt of the draft report, an action plan containing details of the actions taken and planned, including deadlines for their completion, to address the following recommendations:

No.	Recommendation
1	Continue with the proposed revisions of the Biotechnology Regulatory Framework under consideration to strengthen field trial oversight in order to prevent the recurrence of an incident such as the "LL RICE 601" contamination.
2	Encourage other rice producing states to follow the measures taken by Arkansas State Plant Board to eliminate the risk of 'LLRICE 601' in subsequent rice crops.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_the_united_states_7857_2008.pdf

9 ENDNOTES

Concerning	Detail
Section 6.2	In their response to the draft report the competent authorities noted that these potential revisions to policy have been legislatively mandated in the 2008 Farm Bill which was passed June 18, 2008. Action on each of the items must be completed by December 18 2009.

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Decision 2006/601/EC	OJ L 244, 7.9.2006, p. 27–29	2006/601/EC: Commission Decision of 5 September 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products
Regulation (EC) No 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Regulation (EC) No 1829/2003	OJ L 268, 18.10.2003, p. 1–23	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
Regulation (EC) No 1830/2003	OJ L 268, 18.10.2003, p. 24–28	Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
Regulation (EC) No 178/2002	OJ L 31, 1.2.2002, p. 1–24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Directive 2001/18/EC	OJ L 106, 17.4.2001, p. 1–39	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC