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FINAL REPORT OF A MISSION CARRIED OUT IN CHINA FROM 27 NOVEMBER TO 03 DECEMBER 2008 IN ORDER TO EVALUATE OFFICIAL CONTROL SYSTEMS FOR COMMISSION DECISION 2008/289/EC ON EMERGENCY MEASURES REGARDING THE UNAUTHORISED GMO "BT 63" IN RICE PRODUCTS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected;any clarification appears in the form of an endnote.

Executive Summary

The mission was undertaken to evaluate the Chinese government actions related to Commission Decision 2008/289/EC, on "Bt63" in rice products.

The mission team met with the Central Competent Authorities with responsibility for the authorisation of Genetically Modified Organisms (GMOs) in China and their export to the European Union (EU). In addition, visits were made and meetings were organised with the authorities from one province, one university research centre, 2 companies exporting rice products and 3 laboratories.

There is legislation in place regulating research, testing, production, processing, labelling, import and export of GMOs.

The Ministry of Agriculture is responsible for the assessment and regulation of GMO events and the General Administration of Quality Supervision Inspection and Quarantine (AQSIQ) is the competent authority for the official control of rice products for export to the EU, under Commission Decision 2008/289/EC.

China has not approved the commercial cultivation of GM rice. On the other hand, multiple GM rice events have been approved for pilot tests and GM rice events for insect resistance, disease resistance and quality improvement have been approved for production trials. Regarding "Bt63", the Competent Authority took appropriate action to prevent illegal commercialisation of GM rice, after the incident of illegal cultivation in Hubei province.

The rice product export procedures are well defined and in line with Commission Decision 2008/289/EC. However, the lack of practical simplified guidelines for sampling of rice products, available to inspectors, is detrimental to the representativeness of the sample. Regarding illegal exports of rice products, which account for several Rapid Alert System for Food and Feed (RASFF) notifications, the mission team was not informed of further measures envisaged.

There are 29 laboratories nominated to perform the official control analyses of "Bt63" in rice products. The laboratories visited were well staffed, structured and equipped. The lack of implementation of screening methods prevents the detection of GM rice events other than "Bt63". In addition, the lack of testing of the performance of the "Bt63" construct-specific method on finished rice products decreases the sensitivity of the method for this matrix.

There is a system of controls in place to ensure that rice products exported to the EU fulfil the requirements of Commission Decision 2008/289/EC. There are some shortcomings, regarding lack of practical simplified sampling instructions available to inspectors, lack of knowledge of specific details of the methodology for "Bt63" detection, lack of implementation of screening methods and control of fraud and illegal exports.

The report makes a number of recommendations to the competent authorities of China to address the deficiencies noted.

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
AQSIQ	General Administration of Quality Supervision, Inspection and Quarantine
CA	Competent Authority
CIQ	Entry-Exit Inspection and Quarantine Bureau
CNCA	Certification and Accreditation Administration
ct	cycle threshold
DNA	Deoxyribonucleic Acid
EU	European Union
EUROSTAT	Statistical Office of the European Communities
FVO	Food and Veterinary Office
GM	Genetically Modified
GMO	Genetically Modified Organism(s)
ISO	International Organization for Standardization
LOD	Limit of Detection
MoA	Ministry of Agriculture
MS	Member State
PCR	Polymerase Chain Reaction
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operating Procedures
TARIC	Tarif Intégré de la Communauté (Integrated tariff of the Community)

1 INTRODUCTION

The mission took place in China from 27 November to 4 December 2008. The mission team comprised two inspectors from the Food and Veterinary Office (FVO), one official from the European Commission Delegation in China, 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 Chinese Ministry of Agriculture (MoA) and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

An opening meeting was held on 27 November 2008 with the representatives of the MoA and AQSIQ concerned with the scope of this mission. 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 Chinese government and industry control activities related to Commission Decision 2008/289/EC on emergency measures regarding the unauthorised GMO "Bt 63" in rice products.

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	2	MoA,AQSIQ
Provincial	1	Hubei Agriculture Department
Laboratories		
Public	3	Entry-Exit Inspection and Quarantine Bureau (CIQ) of Fujian,CIQ of Xiamen, Oil Crop Research Institute
Food and feed establishments		
Food processor	1	Private company which exports to the EU
Rice miller	1	Private miller which exports to EU
GM rice research institution		
University	1	Huazhong Agriculture University

3 Legal Basis for the Mission

The mission was carried out in agreement with the the MoA and the AQSIQ 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;

The legislation relevant for this mission is Commission Decision 2008/289/EC on emergency measures regarding the unauthorised genetically modified organism "Bt63" in rice products.

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 result of the fourth mission to a third country to evaluate the control systems which are in place for the export of GM food, feed or seed to the EU. Missions took place in Argentina in 2006, in Brazil in 2007 and in USA in 2008. This mission focused specifically on rice products' exports from China 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 soybeans, maize, cotton and rapeseed.

Genetically modified (GM) rice is not authorised for commercialisation in the EU or China but rice products originating from China were found to be contaminated with GM rice in recent years. In September 2006, the United Kingdom, France and Germany notified to the Rapid Alert System for Food and Feed (RASFF) the discovery of unauthorised GM rice "Bt 63" in Chinese rice products. The Chinese Competent Authority (CA) informed the Commission that the GM rice "Bt 63" is not authorised on the Chinese market, conducted checks on the cases notified in the RASFF, carried out testing on exported rice and rice products and required exporting companies to strengthen controls over raw material purchasing. Despite the measures announced by the Chinese CA, several other alerts concerning the presence of "Bt 63" rice were subsequently reported. According to the EU legislation, even traces of unauthorised GMOs are illegal and products containing them cannot be marketed.

Commission Decision 2008/289/EC provides that MS shall allow the first placing on the market of rice products, listed in the Annex of the Decision, only when the original of an analytical laboratory report, confirming that products do not contain, consist or are not produced from the GM rice "Bt 63", accompanies each consignment of rice products originating in or consigned from China. In addition MS shall take random samples for analysis to verify the absence of "Bt 63".

There was an increase to 14 in the number of rapid alert notifications regarding GM rice products from China in 2008. In 2006 and 2007, the alerts for GM rice and rice products from China were 11 for each year. According to investigations conducted by the Chinese CA previous to this mission, most alerts were related either to illegal exports and fraud or to discrepancies between the analytical results of Chinese and MS laboratories. The Spanish CA notified one rapid alert regarding rice products positive to GMO screening tests but negative to "Bt 63". This would suggest the presence of other GM events in Chinese rice, besides "Bt 63"(see Endnote).

Regarding illegal exports and fraud, an Arrangement for the Cooperation on Joint Prevention of Illegal Action for Import and Export of Food between the European Commission's Directorate General for Health and Consumer Protection (DG SANCO) and AQSIQ was signed in September 2006. The Arrangement, within the framework of the Memorandum of Understanding on Administrative Co-operation Arrangements between DG SANCO and AQSIQ, provides for information exchanges, disposal of illegal food and preventive measures against illegally imported and exported food.

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 and rice products from China in 2006 and 2007 accounted for 4.3 and 4.9 % of imports into the EU of the same commodities. However, some rice products reached much higher percentages such as cooked or prepared rice pasta that amounted to 41 and 40% of imports in 2006 and 2007. Annex II summarises the volumes imported from 2006 to 2008.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.

5 MAIN FINDINGS

5.1 RELEVANT NATIONAL LEGISLATION

Decree 304 of the State Council on Regulations on the Safety Management of Agricultural GMOs is the framework legislation regarding research, testing, production, processing, import and export of GMOs. This framework legislation has been developed through several ministerial orders:

Order No. 8 of the MoA on Implementing Regulations on Safety Assessment of Agricultural Genetically Modified Organisms provides for safety grading and evaluation, application and approval, supervision and safety monitoring of GMOs.

Order No. 10 of the MoA on Implementing Regulations on Labelling of Agricultural GMO, which lists the GM products to be labelled and the labelling requirements.

Order No. 59 of the MoA on Implementing Regulations on Approval of Agricultural GMO for Processing, which establishes the requirements to be fulfilled by operators processing GMOs.

Order No. 62 of the AQSIQ on Measures for the Entry and Exit Inspection and Quarantine Administration of GM Products, which provides for official controls of GMOs at import and export.

Regarding export of foodstuffs, Regulation No. 20 of the AQSIQ on Sanitation Registration for Export Food Production Enterprises lays down the requirements for application and delivery of certificates to establishments wanting to export foodstuffs.

Announcement No. 85 of AQSIQ on the Inspection and Quarantine Labelling on Export Foods provides for the labelling with inspection and quarantine tags of certain foodstuffs that have fulfilled export requirements.

5.2 COMPETENT AUTHORITIES

5.2.1 Structure and responsibilities

The Chinese CAs for this mission are the MoA and the AQSIQ. In addition, the Ministry of Public Health is responsible for food safety on the market, including GM foodstuffs. All these CA have their counterparts at provincial, prefecture and county level.

5.2.1.1 Ministry of Agriculture

Under the Regulations on the Safety Management of Agricultural GMOs, the MoA is responsible for the supervision and management of the safety of national agricultural GMOs. Within the MoA, a specific department and division are dealing with this subject. The MoA has established a Safety Committee for Agricultural GMOs, which is responsible for the safety assessment of agricultural GMOs. The Agricultural Administration at the county level or above is responsible for the supervision and inspection of the agricultural GMOs. The MoA may commission a qualified technical inspection organisation to conduct an inspection depending on the needs for safety assessments, supervision and management.

5.2.1.2 General Administration of Quality Supervision, Inspection and Quarantine

Within AQSIQ, the Entry-Exit Inspection and Quarantine Bureaus (CIQ) are responsible for inspection and quarantine of GM foodstuffs entering or exiting China. AQSIQ has 35 bureaus at provincial level.

5.2.2 Co-ordination and Communication

Decree 304 of the State Council provides for the establishment of an Inter-ministerial Joint Conference System for the Safety Management of Agricultural GMOs. This Committee includes representatives from 11 ministries and is coordinated by the MoA. The Committee is responsible for the decision-making and coordination of key issues on safety management of agricultural GMOs

5.3 GMO REGULATION PROCEDURE

5.3.1 Authorities involved in GMO regulation

The Chinese ministry responsible for the oversight of products of agricultural biotechnology is the MoA.

The MoA is responsible for the implementation of Decree 304 of the State Council

regarding supervision and safety management of agricultural GMOs. Under this legislation, any organisation engaged in laboratory research or field testing of agricultural GMOs shall establish an Agricultural GMO Safety Team to implement the provisions below. After laboratory research, the testing of agricultural GMOs should proceed through three consecutives stages: pilot test (less than 0.27 hectares), environmental release (0.27-2 hectares) and production trial (more than 2 hectares). Pilot tests shall be reported to the MoA. On the other hand, applications for environmental releases and production trials have to be submitted in advance to the MoA. Approval of environmental releases and production trials may be granted after the Safety Committee for Agricultural GMOs issues a safety assessment. After production trials, an application for a safety certificate may be submitted to the MoA. The safety certificate may be granted after the Safety Committee for Agricultural GMOs issues a safety assessment. The safety certificate will enable operators to apply for GMOs production and processing licenses.

The mission team was informed by the CA that safety certificates have been provided for GM cotton, tomato, morning glory, pimiento and papaya, and a vaccine for avian influenza.

GMO producers or processors should be approved and are supervised by the MoA or the provincial, regional or local agricultural administrations. Operators can apply for GMO production licenses when fulfilling certain requirements such as applying safety management and prevention measures and cultivating or breeding the GMOs in a specified area. Applications from farmers breeding or cultivating GMOs may be handled by the sales organisations for seeds, livestock and poultry, or aquatic hatchlings. Operators can apply for GMO processing licenses when fulfilling certain requirements such as special production lines and closed storage facilities for GMOs, adequate waste treatment and control and appropriate safety management systems. GMO producers or processors shall forward reports on production, processing and safety management to the local agricultural administration. Operators handling GM seeds require a management license for seeds issued by the MoA.

The MoA is responsible for the approval, supervision and management of labelling of agricultural GMOs. Labelling is mandatory for all GMOs listed in Order No. 10 of the MoA. These are soybean, soybean seeds, soybean powder, soybean meal, soybean cake, maize seeds, maize, maize oil, maize meal, rape seeds, rapeseed, rapeseed oil, rapeseed cake, cotton seeds, tomato seeds, fresh tomato, tomato paste.The National Standard on Labelling of Agricultural GMOs details the wording of the labelling depending if the goods are GM propagating materials, GM foodstuffs or products processed using GMOs.

The MoA and the lower levels of the agricultural administration have inspection powers and can impose sanctions to research and field testing organisations and operators not complying with the legislation.The inspection organisations, accredited by the MoA, provide technical support for the administrative supervision of the agricultural sector and are further described in 5.6.

5.3.2 Regulatory status of GM rice

China has not approved the commercial cultivation of GM rice. Neither production

licenses nor safety certificates have been granted for GM rice. On the other hand, multiple GM rice events have been approved for pilot tests. Moreover, GM rice events for insect resistance, disease resistance and quality improvement have been approved for production trials. The surface of rice field trials for the gene Cry1A, for insect resistance, in Hubei and Sichuan provinces is of 81 hectares. No information was provided to the mission team about the number of GM rice events under different stages of development and the total surface of GM rice field trials in China.

Regarding GM rice "Bt63", the first application for a pilot test by Huazhong Agricultural University was in 1999. The environmental release testing took place in 2001 and 2002 and the production trial in 2003 and 2004. The application for a safety certificate was submitted in 2004. The Safety Committee for Agricultural GMOs has not yet finalised the safety assessment of GM rice "Bt63".

In 2005, the Hubei Agriculture Department found "Bt63" rice seeds in the market. The inquiry tracked the seeds to 3 seed companies, which had been entrusted by Huazhong Agricultural University with seed multiplication in a production trial of GM rice "Bt63". These companies illegally commercialized "Bt63" seed and 200 hectares of illegally cultivated "Bt63" were identified by Hubei Agriculture Department. Hubei Agriculture Department destroyed the GM rice and imposed financial and administrative penalties. Since then a provincial contingency plan was set up, efforts in supervision and inspection were increased and no positive cases have been found in the seed market in recent years. As far as the CA is aware, similar incidents have not happened in other places in China.

5.4 CONTROLS TO ENSURE ABSENCE OF "BT63" IN SEED

5.4.1 Official Controls

The mission team met with the Hubei Agriculture Department, which implements and controls the national legislation on agricultural GMO biosafety in the province. Its main functions are administrative licensing, supervision and inspection and imposing corrective actions in case of infringements. Regarding administrative licensing, the MoA is responsible for the approval of licences for environmental release and production trials, while Hubei Agriculture Department is responsible for the review and approval of GMO processing and GMO labelling. Regarding supervision and inspection, Hubei Agriculture Department controls GMO research and field trials and labelling. Regarding corrective action, under the Regulations on the Safety Management of Agricultural GMOs and implementing rules, Hubei Agriculture Department has the right to terminate trials and impose penalties when operators engage in environmental release and production trials without approval, or when they not adopt safety management measures or not implement preventive measures, or exceed the approved test scope.

There are around 2000 inspectors in the Hubei Agriculture Department, which have among their tasks the official controls of GMOs. In 2007, around 100 samples for official control of GMOs in food, feed and seeds were collected in Hubei province.

The Hubei Agriculture Department implements the field trial guidelines from the MoA. These guidelines include instructions regarding isolation measures, destruction of crop yield, surveillance after harvest and seed market inspection. At present, there are no

authorized production trials in Hubei province. In 2007, the MoA issued one license approving the environmental release of GM rapeseed in Hubei province.

Under Chinese law, the isolation distance for field trials of GM rice is of not less than 100 meters. According to the CA, this distance is above 200 metres in practice. The mission team was informed that research by Chinese experts has demonstrated that the isolation distance of 100 metres is enough to prevent cross-contamination. The mission team was also informed that field trials are usually separated from conventional crops by natural barriers such as rivers, mountains and lakes. Therefore, the CA considered that there is no need for laboratory analysis to check if contamination arises from field trials to nearby conventional crops.

5.5 CONTROL PROCEDURES FOR RICE EXPORTS TO THE EU

5.5.1 Rice export procedure

Establishments producing, processing or storing foodstuffs for export are required to apply for a sanitary certificate, under Regulation No. 20 of the AQSIQ. These certificates, under the Certification and Accreditation Administration (CNCA), are printed by AQSIQ and issued by the local CIQ, after inspection of the establishment. The CIQ will accept an application for inspection of foodstuffs to be exported only when the establishment holds a sanitary certificate. Some foodstuffs, amongst them rice and rice products, after being inspected by the local CIQ and when fulfilling export requirements must be labelled with an inspected and quarantined tag, as provided by Announcement No. 85 of AQSIQ. The number of tags issued by the CIQ corresponds to the number of items in a consignment. To ensure traceability, CIQ issues an official certificate which includes the manufacturer name, the product name, the batch number and the production date. This information is also included on the packaging, except the certificate number. In addition, the transportation packaging is labelled with a CIQ label. Inspected and quarantine tags are not mandatory for exports in bulk or when due to the type of packaging they cannot be attached.

Regarding export of non GMOs, Article 37 of Decree 304 of the State Council provides that if a certificate is required for the export of non GM farm products, the AQSIQ shall conduct an inspection and issue, if appropriate, the certificate. Moreover, Order No. 62 of the AQSIQ establishes that non-GM certificates will be issued after application by the operator and analytical testing of a sample of the product to be exported in a state certified, accredited and supervised laboratory.

To fulfill the requirements of Commission Decision 2008/289/EC the exporters of rice and rice products to the EU should request the local CIQ to sample and analyse the consignments for export. The analytical report accompanying the consignment, issued by one of the 29 nominated laboratories, should be endorsed by a certificate of the local CIQ to obtain clearance from Customs. There is a national information technology (IT) system linking AQSIQ with Customs and, according to the CA, there is a verification network system between the local CIQ and Customs.

The mission team was informed by AQSIQ that official control sampling for export of rice products was based on National Standard SN/T 1194-2003 on Sampling and

Preparation of Samples for Detection of GM Components in Plants and their Derived Products before 15 April 2008. According to the CA, after this date, the sampling of rice products is based on GB/T2828, which is equivalent to ISO 2859, and the sampling of rice is based on ISO 13690. These standards are taken into account in Commission Recommendation 2004/787/EC 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. Officials from one of the CIQ visited informed the mission team that sampling was based on Commission Recommendation 2004/787/EC. No practical simplified guidelines for sampling are available to inspectors.

GM sampling and testing of rice for export to the EU in earlier steps of the production chain may be performed by private companies. The mission team visited a food processor which exports rice products to the EU and met the managers of a company that exports rice to the EU. To avoid GM rice, these companies have selected reliable providers, set up traceability systems and tested rice in the paddy or rice deliveries for GMOs in the CIQ laboratories, as part of the companies' quality control system.

Regarding the rapid alert notifications related to GM rice and rice products, the investigations performed by AQSIQ indicate that several of them are related with illegal exports or fraud. The mission team was informed that AQSIQ could not proceed further with the investigations of some rapid alert notifications due to lack of enough information provided. The mission team was not informed by AQSIQ of further measures envisaged to prevent illegal exports and fraud, regarding rice products.

5.6 LABORATORIES

There are 29 AQSIQ laboratories nominated to analyse "Bt63" in rice products before export to the EU. The mission team visited 2 of them: the laboratories of the CIQ of Fujian and the CIQ of Xiamen. Following discrepancies between the results of the CIQ laboratory of Jiangxi and some EU laboratories, AQSIQ informed the mission team that it had suspended the capacity of the CIQ laboratory in Jiangxi to issue certificates for export of rice and rice products to the EU until the results of an inquiry launched were available. The mission team requested AQSIQ that this information was provided in writing to the European Commission services.

Under the MoA, 49 technical inspections organizations perform sampling and analysis of GMOs for food, feed and seed. The mission team visited one of them: the laboratory of the Oil Crop Research Institute in Hubei.

5.6.1 AQSIQ laboratories

5.6.1.1 Molecular laboratory of the Fujian CIQ

The molecular laboratory of the CIQ of Fujian is one of the 25 laboratories certified by the CNCA for general GMO detection. It was accredited to ISO 17025:2003 by CNCA in 2003.

There is a comprehensive quality management system in place. Incoming samples are

registered in a laboratory information system and coded with a unique number and a barcode. The code for official and private samples is different, so the responsible staff can discriminate between official and private samples.

The general structure of the molecular laboratory, with different areas for sample preparation, deoxyribonucleic acid (DNA) extraction, polymerase chain reaction (PCR)-setup and thermal cycling, and gel electrophoresis, is appropriate. The dedicated areas are physically separated. The work is carried out in the PCR-setup and thermal cycling area in ultraviolet cabinets.

The laboratory is well staffed with 2 PhD, 1 senior engineer with a master degree and 2 technicians. The equipment is up to date and is considered sufficient. It includes several instruments for sample grinding, thermal cyclers and modern real-time PCR instruments.

Written working procedures are available in the form of standard operating procedures (SOP) and were presented to the mission team.The SOPs follow the guidelines for qualitative DNA testing of GM rice in foodstuffs under the document No. [2006]892 distributed by AQSIQ and the detection method under Decision 2008/289/EC. Sample preparation is done in line with the national standard SN/T1194-2003, followed by Hexadecyl-trimethyl-ammonium-bromide (CTAB) extraction of 4 replicates. Reference samples are stored according to national provisions for 6 months. The real-time fluorescent PCR method for "Bt63" is applied. The laboratory assesses the method's sensitivity regularly by analysing serial dilutions of the 0.2% reference material provided by the Chinese Academy of Inspection and Quarantine in Beijing and self prepared 0.1% material.

Training of the laboratory staff is done on a regular basis several times a year. These training sessions are either organised by national bodies, international private companies or in-house. The laboratory takes part in national and international proficiency tests with satisfactory results. The mission team had access to the results of the last national proficiency test on "Bt63" rice powder. The fortification level of the test samples were not given to participating laboratories by the organising body, so the mission team could not obtain the "Bt63" level. The test report states that the laboratory is capable to detect GM rice at the 0.01 level.

The laboratory analyses mostly official samples but also samples from third parties. Since 15 April 2008, 95 official control samples were analysed for "Bt63". None of the samples were positive. The raw data of test samples provided to the mission team indicates that the analyses were performed according to the construct specific method under Commission Decision 2008/289/EC. The method development used ground rice and the same amount of DNA has been used for the analysis of processed rice products. This amount is not enough for a correct sensitivity of the method. In real time fluorescent PCR, the cycle threshold (ct) value of the rice reference gene for rice and products containing only rice shall be between ct 20 to ct 24 or even lower to achieve maximum sensitivity. These findings could most probably explain the different test results between Chinese and EU laboratories.

5.6.1.2 Molecular laboratory of the Xiamen CIQ

The molecular laboratory of the Xiamen CIQ is one of the 25 laboratories certified by CNCA for GMO detection. The laboratory was accredited under ISO 17025:2005 and certified for detection of GMO in food by CNCA. Laboratory staff is involved in the development of the national Chinese GMO detection standards.

From 1 September 2006 to 30 November 2008, the laboratory analysed 115 private samples and 71 official samples. Among those, 39 samples from consignments of rice products to be exported to the EU. None of the samples tested positive. The detection method for "Bt63" under Decision 2008/289/EU has been in place since April 2008. No screening methods for detection of GM events are applied to the samples from consignments to be exported to the EU since this date.

The quality management system is well organised with written working procedures in place. The laboratory regularly takes part in proficiency tests with satisfactory results. After an initial training by the Chinese Academy of Inspection and Quarantine, several in-house trainings were organised.

Incoming samples are registered in a laboratory information system and coded with a unique number and a barcode. The code for official and private samples is different, so the responsible persons can discriminate between official and private samples. In contrast to the molecular laboratory of the Fujian CIQ, reference samples are stored for a period of 3 months according to the quality management system.

The general structure of the molecular laboratory, with different areas for sample preparation, DNA extraction, PCR-setup, thermal cycling, and gel electrophoresis is appropriate. The dedicated areas are physically separated.

The laboratory is adequately staffed with 3 PhD and 2 master graduated scientists. The technical equipment including the real-time PCR machine in place is appropriate.

Sample preparation includes grinding of rice products in 100 grams portions. If the samples entail several pre-packed units, material is randomly taken from all packages. DNA extraction is done in 4 replicates with a commercial kit, using an amount of 200 mg ground sample. Written procedures were presented to the mission team.

The sensitivity of the test methods is assessed twice a year using ground rice. The limit of detection (LOD) was 0.01% in a national proficiency study. Decoding of the samples from the proficiency study was not available in the laboratory.

The mission team was provided with information on the analysis of the sample related to RASFF information notification 2008.0788. The sample processing and analysis were appropriately documented. This sample was analysed, prior to Decision 2008/289/EC entered into force, by applying the Real-Time Fluorescent PCR Method for Detection of GM Rice in Food Products, selected by AQSIQ for the detection of GMO in rice and rice products, intended for export to the EU, which targets the Bt cryIAb/c gene, and tested negative. The raw data of the sample, especially of the rice reference gene, indicated a possible false negative result due to sample dilution (see Endnote).

5.6.2 MoA laboratories

5.6.2.1 Oil Crop Research Institute

The laboratory of the Oil Crop Research Institute is one of the 49 technical inspection organisations of the MoA testing official samples for seeds and undertaking environmental studies for GMOs, prior authorisation. Additionally, the GMO laboratory is offering testing services to third parties.

The laboratory is certified according to the National Chinese Standard GB/T15481-2000, which corresponds to the previous version of ISO 17025, by CNCA. The laboratory is additionally certified by the MoA.

The staffing and the overall structure of the laboratory, with dedicated rooms for the different methodological steps of the molecular analysis, are adequate. The laboratory is well equipped to carry out conventional and real-time PCR. However, the grinding equipment is not appropriate. In addition, written instructions for sample preparation were not available in this area. The SOP, provided to the mission team, were detailed and contained the information necessary to carry out the molecular tests.

The laboratory analyses around 80 GM samples every year, 30 of those are official control samples for rice and rapeseed. The mission team was informed that cycling programmes and gel images are not stored in the equipment, because of confidentiality reasons. Therefore, neither raw data of analyses of official samples nor the documentation belonging to such samples could be checked.

The analysis of GM rice is done by conventional PCR targeting the screening elements and the coding region of the genes introduced. Construct specific or event specific test systems are not applied. The results of the conventional PCR are not verified, as required by ISO 21569 (Foodstuffs Methods of analysis for the detection of genetically modified organisms and derived products Qualitative nucleic acid based methods).

The LOD of the analytical methods was assessed as 0.05% by national proficiency testing schemes in 2007 and 2008. The evaluation of the laboratory's performance in these tests was not available in writing during the mission. Other tests of assessment of the LOD were not presented to the mission team.

6 CONCLUSIONS

6.1 LEGISLATION

There is legislation in place regulating research, testing, production, processing, labelling, import and export of GMOs.

6.2 COMPETENT AUTHORITIES

The competencies of the MoA regarding the assessment and regulation of GM events are well defined.

The competencies of the AQSIQ regarding the official control of rice and rice products for export to the EU, under Commission Decision 2008/289/EC, are well defined.

6.3 CONTROLS TO ENSURE ABSENCE OF "BT63" RICE

The CA took appropriate action to prevent illegal commercialization of "Bt63" rice, after the "Bt63" incident in Hubei province.

6.4 CONTROLS PROCEDURES FOR EXPORTS

The rice products export procedures are well defined and in line with Commission Decision 2008/289/EC.

The lack of practical simplified guidelines for sampling of rice and rice products, available to inspectors, is detrimental for the representativeness of the sample.

Several RASFF notifications were related to illegal exports and fraud but the mission team was not informed by the CA of further measures envisaged to prevent illegal exports and fraud, regarding rice products.

6.5 LABORATORIES

The laboratories visited were well staffed, structured and equipped.

The lack of implementation of screening methods and the use of only the construct-specific method developed by D. Maede et al, for detection of "Bt63", prevent the detection of GM rice events other than "Bt63"(see Endnote).

The testing of the performance of the construct-specific method developed by D. Maede et al, for detection of "Bt63", on rice but not on processed rice products decreases the sensitivity of the method for this matrix.

The European Commission services have not yet been provided with the updated list of Chinese accredited laboratories nominated to perform the analytical test required by Article 2 of Commission Decision 2008/289/EC.

6.6 OVERALL CONCLUSION

There is a system of controls in place to ensure that rice products exported to the EU fulfil the requirements of Commission Decision 2008/289/EC. There are some shortcomings regarding lack of practical simplified sampling instructions available to inspectors and lack of know-how on specific details of the methodology for "Bt63" detection in official control laboratories. Regarding the rapid alert notifications related with illegal export and fraud, the mission team has not received enough information to evaluate the size of the problem and possible actions.

7 CLOSING MEETING

A closing meeting was held on 3 December 2008 with representatives of MoA and AQSIQ. 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

No.	Recommendation
1	The Chinese CA are encouraged to put in place practical simplified sampling instructions, available to inspectors, which take into account chapters I, II, III and IV of Commission Recommendation 2004/787/EC 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, as provided in the recital (14) of Commission Decision 2008/289/EC.
2	The Chinese official control laboratories are encouraged to start with a screening method, to test whether GMOs are present or not, the analytical testing of rice products for export to the EU, as provided by chapter V.4 of Commission Recommendation 2004/787/EC 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, in line with the recital (14) of Commission Decision 2008/289/EC.
3	The Chinese official control laboratories are encouraged to test the performance of the construct-specific method developed by D.Maede et al., which is required by Article 2 of Commission Decision 2008/289/EC, on processed rice products, as provided by chapter V.5 of Commission Recommendation 2004/787/EC 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, in line with the recital (14) of Commission Decision 2008/289/EC.
4	The Chinese CA are encouraged to prevent and control fraud and illegal exports of rice and rice products exported to the EU, as established in the Arrangement for the cooperation on joint prevention of illegal action for import and export of food between the European Commission's Directorate General for Health and Consumer Protection (DG SANCO) and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ).
5	The Chinese CA are invited to provide the European Commission services with the updated list of Chinese accredited laboratories nominated to perform the analytical test required by Article 2 of Commission Decision 2008/289/EC.

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

http://ec.europa.eu/food/fvo/ap/ap_china_7834_2008.pdf

9 ENDNOTES

Concerning	Detail
Section 4	In their response to the draft report the Competent Authority noted that further investigations are needed to find out the actual conditions of this incident.
Section 5.6.1.2	In their response to the draft report the Competent Authority noted that it cannot be confirmed that the documentation that was provided to the mission team by the laboratory is from the goods related to RASFF information notification 2008.0788.
Section 6.5	In their response to the draft report the Competent Authority noted that this was the case for only two laboratories.

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Decision 2008/289/EC	OJ L 96, 9.4.2008, p. 29–34	2008/289/EC: Commission Decision of 3 April 2008 on emergency measures regarding the unauthorised genetically modified organism Bt 63 in rice products
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