



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Health and food audits and analysis

DG(SANTE) 2015-7640 - MR

FINAL REPORT OF AN AUDIT  
CARRIED OUT IN  
CHINA  
FROM 18 NOVEMBER 2015 TO 26 NOVEMBER 2015  
IN ORDER TO  
EVALUATE THE CONTROLS SYSTEMS FOR GENETICALLY MODIFIED  
ORGANISMS IN RESPECT OF FOOD AND FEED INTENDED FOR EXPORT TO THE  
EUROPEAN UNION

*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 a footnote.*

## ***Executive Summary***

*This report describes the outcome of an audit in China carried out from 18 to 26 November 2015 as part of the published DG Health and Food Safety audit programme in order to evaluate the control systems for genetically modified organisms (GMOs) in respect of food and feed intended for export to the European Union (EU).*

*The audit was carried out in response to the Rapid Alerts for Food and Feed due to the presence of GMOs in rice products exported from China to the EU.*

*Overall, there is a comprehensive export control system in place to ensure that food, feed and feed additives exported to the EU are compliant with the EU legislation regarding GMOs.*

*A detailed supervision system is implemented by the Chinese authorities to ensure compliance with the requirements of Decision 2011/884/EU. The system is supported by a well-established and up-to-the standard laboratory capacity and includes procedures to follow up on RASFF notifications. The number of GMO related RASFF alerts has decreased and attempts have been made to combat illegal trade which is currently stated by the Chinese authorities to be the main reason for EU non-compliances detected in the EU.*

*The GMO field trials are adequately controlled and extensive controls are in place in Hubei Province aiming to ensure that rice cultivation is not contaminated with GMO. Some GMO controls of rice cultivation are performed in other rice growing provinces. It is known that GM rice is present in the rice cultivation in China. Therefore there is a potential risk that GM rice enters in the production of commodities other than those regulated and controlled for EU export. Some efforts are made to mitigate such risk.*

## Table of Contents

1	Introduction .....	1
2	Objectives and scope .....	1
3	Legal Basis .....	2
4	Background .....	2
4.1	Trade data .....	3
5	Findings and Conclusions .....	4
5.1	National legislation regarding GMO and Competent authorities .....	4
5.2	GMO/GMM related authorisation procedures and status of GMOs, GMMs and GM feed and food products in China .....	6
5.3	GMO and GMM related domestic controls .....	7
5.3.1	<i>Field trials, including confined release</i> .....	7
5.3.2	<i>GMO controls of seed and rice cultivation</i> .....	8
5.3.1	<i>GMO/GMM controls of food and feed including fermentation products obtained with GMM</i> .....	9
5.4	Export controls related to GMOs .....	10
5.4.1	<i>GMO controls of feed exported to the EU</i> .....	10
5.5	GMO Laboratory .....	14
5.5.1	<i>Quality management system</i> .....	14
5.5.2	<i>Detection methods for Chinese rice products intended for EU export</i> .....	15
5.5.3	<i>Laboratory organisation</i> .....	15
5.6	Action taken in response to non-compliance and EU RASFF notifications (including Bt63 rice in choline chloride feed additives and GM Bacillus subtilis in vitamin B2 feed) .....	16
5.6.1	<i>Follow up of EU RASFF notifications</i> .....	16
6	Overall Conclusions .....	17
7	Closing Meeting .....	18
8	Recommendations .....	18

## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AOCS	American Oil Chemists' Society
AQSIQ	General Administration of Quality Supervision, Inspection and Quarantine
Bt	As used in this report, refers to GMO that include genetic elements from the bacterium <i>Bacillus thuringiensis</i> .
Bt63	Refers primarily to the Bt rice line Shanyou 63 ( <i>cryIAb/Ac</i> )
CAIQ	Chinese Academy of Inspection and Quarantine
CIQ	Entry-Exit Inspection and Quarantine Bureau of AQSIQ
CNCA	China National Certification and Accreditation Administration
DNA	Deoxyribonucleic Acid
E-Cert	AQSIQ database for official certification
EU	European Union
EU-RL GMFF	European Union Reference Laboratory for GM Food and Feed
EUROSTAT	Statistical Office of the European Union
Event	Transformation event
G	gram
GM	Genetically Modified
GMM	Genetically Modified Microorganism
GMO	Genetically Modified Organism
IRMM	Institute for Reference Materials and Measurements
ISO	International Organisation for Standardisation
Kefeng 6 and 8	GM rice lines expressing the <i>cryIAc+CpTI</i> genes
KMD1	GM rice line Kemingdao 1 (expressing the <i>cryIAb</i> gene)
MoA	Ministry of Agriculture
NBC	National Biosafety Committee
Tnos	Terminator deriving from the <i>nos</i> gene of <i>Agrobacterium tumefaciens</i>
PCR	Polymerase Chain Reaction
P35S	Promoter derived from the 35S gene of Cauliflower mosaic virus
RASFF	Rapid Alert System for Food and Feed
TARIC	<i>Tarif Intégré de la Communauté</i> (Integrated tariff of the Community)

## 1 INTRODUCTION

This audit took place in in China from 18 to 26 November 2015, as part of DG Health and Food Safety' planned audit programme.

The audit team comprised two auditors from DG Health and Food Safety and a scientific officer from the Joint Research Centre of the European Commission. Representatives from the central competent authorities accompanied the team for a part of the audit.

An opening meeting was held on 18 November 2015 at with the Ministry of Agriculture (MoA), and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ), in Beijing, during which, the objectives and itinerary for the audit were confirmed, and additional information, necessary for the conduct of the audit, was requested.

## 2 OBJECTIVES AND SCOPE

The objective of the audit was to evaluate the control systems for Genetically Modified Organisms (GMOs) in respect of food and feed, intended for export to the European Union (EU).

The audit focused on the following:

- (1) Implementation of Commission Implementing Decision 2011/884/EU.
- (2) Measures taken to prevent the presence of non-authorized Genetically Modified (GM) events in feed/feed additives and food, and in particular rice and rice products, intended for export to the EU, including during the trial, authorisation and production phases, and any action taken in response to relevant EU Rapid Alert System for Food and Feed (RASFF) notifications.
- (3) Measures taken to prevent the presence of non-authorized GM events in fermentation products obtained with Genetically Modified Microorganism (GMM).

In pursuit of these objectives, the following sites were visited:

Visits and meetings	No.	Comments
Central Competent Authorities	2	MoA and AQSIQ
Department of Agriculture	1	Wuhan, Hubei province
CIQ (feed)	3	2 local CIQs at Guangdong province
CIQ (food)	2	Local CIQs in Jiangxi province (1) and Fujian province (1)
GMO laboratories	1	Xiamen CIQ, Fujian
Control sites		

Export point (Sea Ports) Airports	1	Xiamen sea port
Field trial base at the inspection and Testing Centre (Wuhan) of Environmental Biosafety of Transgenic Plants of MoA	1	Xiaogan, Hubei province
Feed additive producer	3	Hubei province (1) and Guangdong province (2)
Food producer (rice)	2	Jiangxi province (1) and Fujian province (1)

### 3 LEGAL BASIS

The audit was carried out in agreement with the Chinese authorities, under the general provisions of European Union legislation and in particular, Article 46 of Regulation (EC) No 882/2004.

### 4 BACKGROUND

This was the third audit carried out by DG Health and Food Safety to China to evaluate the official controls for GMOs in food and feed intended for export to the EU. The reports of audits are available at: [http://ec.europa.eu/food/fvo/index\\_en.cfm](http://ec.europa.eu/food/fvo/index_en.cfm).

The previous audit (ref: DG(SANCO)2011/6208) was undertaken from 29 March to 08 April 2011. The audit was carried out in response to the ongoing Rapid Alerts for Food and Feed due to the presence of GMOs in rice products exported from China to the EU, in particular 'Bt63', 'Kefeng' and 'KMD1'.

This third audit was undertaken as the findings of GM events in rice products originating in China have continued.

The number of RASFF notification involving unauthorised GM rice in rice products originating from China are summarised in table 2:

**Table 2: RASFF notifications involving unauthorised GMO/GMM from China, 2012-2015**

Year	2012	2013	2014	2015 (January-October)
RASFF notifications	42	27	28	5

In 2014, 25 out of the 28 RASFF notifications were related to feed additives originating in China: 22 due to Bt63 rice in choline chloride (all between January and April) and three

concerning the presence of GM *Bacillus subtilis* in vitamin B2 feed additives (all between September and December). Further three notifications were issued as a result of controls carried out under Decision 2011/884/EU and involved rice products for food. In 2015 between January and October, all the five alerts were in relation to rice products for food under Decision 2011/884/EU.

The RASFF portal is available via: [http://ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm).

The European Commission adopted an emergency measure on Bt63 rice in 2008 (Commission Decision 2008/289/EC). This measure required that consignments of rice products originating from China be accompanied by a certificate demonstrating the absence of Bt63 rice and that EU Member States carry out random sampling and analysis.

In 2010, the number of RASFF notifications increased and further unauthorised GM rice events, in addition to Bt63, were reported.

In 2011, Commission Implementing Decision 2011/884/EU was adopted repealing Commission Decision 2008/289/EC, in order to:

- a. Update the list of products falling under the scope of the emergency measures;
- b. Set the frequency of sampling and analysis by MS at 100% of all consignments;
- c. Provide for harmonised methods of sampling and a testing approach, based on screening methods, capable to detect a number of potentially GM rice events in addition to Bt63.

In 2013, Commission Decision 2013/287/EU was adopted, amending Decision 2011/884/EU with respect to:

- a. The list of products falling under the scope of the emergency measures;
- b. Prior notifications of consignments;
- c. Sampling methodologies for processed products.

#### 4.1 TRADE DATA

According to EUROSTAT data, the following quantities of rice and the main rice products of concern, which are defined in the Annex to Commission Implementing Decision 2011/884/EU by TARIC code, were imported to the EU between 2013 and 2015 by the time of the audit:

**Table 3: Imports of rice and rice products (in tonnes) originating in China to the EU between 2013 and 2015 by the time of the audit (source: EUROSTAT)**

	2013	2014	Jan-Oct 15
<b>100630</b>	48	504	1 085
<b>11029050</b>	96	26	149
<b>19021100</b>	2 629	3 078	2 572
<b>190219</b>	7 969	9 144	5 049
<b>190220</b>	2 893	2 345	2 000
<b>190230</b>	51 557	50 498	36 163
<b>19041030</b>	156	75	100
<b>19059045</b>	184	176	148
<b>19059055</b>	6 763	6 088	4 013
<b>19059060</b>	7 599	9 010	5 986

19059090	13 548	13 712	10 761
----------	--------	--------	--------

**Key:**

- 100630= SEMI-MILLED OR WHOLLY MILLED RICE, WHETHER OR NOT POLISHED OR GLAZED
- 11029050= RICE FLOUR
- 19021100= UNCOOKED PASTA, NOT STUFFED OR OTHERWISE PREPARED, CONTAINING EGGS
- 190219= UNCOOKED PASTA, NOT STUFFED OR OTHERWISE PREPARED, NOT CONTAINING EGGS
- 190220= PASTA, STUFFED WITH MEAT OR OTHER SUBSTANCES, WHETHER OR NOT COOKED OR OTHERWISE PREPARED
- 190230= PASTA, COOKED OR OTHERWISE PREPARED (EXCL. STUFFED)
- 19041030= PREPARED FOODS OBTAINED BY SWELLING OR ROASTING CEREALS OR CEREAL PRODUCTS BASED ON RICE
- 19059045= BISCUITS (EXCL. SWEET BISCUITS)
- 19059055= EXTRUDED OR EXPANDED PRODUCTS, SAVOURY OR SALTED (EXCL. CRISPBREAD, RUSKS, TOASTED BREAD, SIMILAR TOASTED PRODUCTS AND WAFFLES AND WAFERS)
- 19059060= FRUIT TARTS, CURRANT BREAD, PANETTONE, MERINGUES, CHRISTMAS STOLLEN, CROISSANTS AND OTHER BAKERS' WARES WITH ADDED SWEETENER (EXCL. CRISPBREAD, GINGERBREAD AND THE LIKE, SWEET BISCUITS, WAFFLES AND WAFERS, AND RUSKS)
- 19059090= PIZZAS, QUICHES AND OTHER UNSWEETENED BAKERS' WARES (EXCL. CRISPBREAD, GINGERBREAD AND THE LIKE, SWEET BISCUITS, WAFFLES AND WAFERS, RUSKS AND SIMILAR TOASTED PRODUCTS, BREAD, COMMUNION WAFERS, EMPTY CACHETS FOR PHARMACEUTICAL USE, SEALING WAFERS, RICE PAPER AND SIMILAR PRODUCTS)

There were negligible or no imports of the other commodities listed in Decision 2011/884/EU, which are not included in the table above.

The data in table 3 show that, with the exception of the first two categories, there has been a decrease of import into the EU of the listed rice and rice products from China between 2013 and October 2015.

The audit report DG (SANCO) 2014-7074 provides, among other things, information regarding the chain of feed additives.

**5 FINDINGS AND CONCLUSIONS**

**5.1 NATIONAL LEGISLATION REGARDING GMO AND COMPETENT AUTHORITIES**

**Legal requirements**

Art. 46 (1) (a) (b) and (c) of Regulation (EC) No 882/2004 stipulates that Community controls shall have, inter alia particular regard to the legislation, the competent authorities, to the training of staff in the performance of official controls of the Third Country.

**Findings**

1. The national legislation in relation to GMO was described in the previous audit report (for details see audit report DG (SANCO) 2011-6208).
2. The MoA confirmed that the scope of the GMO safety management legislation includes plants, animals, microorganisms and their products.
3. The following changes were made since the previous audit:
  - a. The MoA stated that an amended legal act "Safety Evaluation Measures for Agricultural GMOs" had been drafted. It was under public consultation and had also been sent to the WTO. The aim of the amendment is, among other things, to



improve the GMO approval system and the management of field trials, to clearly identify responsibilities and to strengthen the biosafety management of GMOs.

- b. The Food Safety Law of the People's Republic of China was amended and entered into force in March 2015. Article 69 requires mandatory labelling of authorised GMOs and Article 125 specifies responsibilities and how to manage cases where GMO is present but not labelled.
  - c. The amended Seed management Law was adopted and entered into force on 1<sup>st</sup> January 2016; it requires labelling of GM seed and increased GMO monitoring and more information to the general public regarding GMOs.
  - d. Since 2011, 75 GMO safety standards were issued by the MoA.
  - e. In response to Commission Implementing Decision 2011/884/EU, the AQSIQ issued several Notices. Notice No 56 of 2012 specifies obligatory registration of agricultural fields to produce for export, including rice for EU export. Notice No. 99 of 2012 requires strengthening of Entry-Exit Inspection and Quarantine Bureaus (CIQ) controls of rice products for EU export. Notice No 149 of 2012 lists the foodstuffs for export for which the registration of the place of primary production is mandatory, including rice. Notice No 191 of 2013 was issued by AQSIQ to address Decision 2013/287/EU amending Commission Implementing Decision 2011/884/EU.
  - f. The AQSIQ issued a notice in April 2015 to their regional services. The notice is entitled "Enhance the GMO Safety Control on Import and Export Agricultural Products". In addition, "Guidance on GMO Risk Surveillance of Imported and Exported Agricultural Products" was introduced to ensure that products are compliant with the requirements of importing countries. The notice requires further enhanced GMO controls of imported and exported products, enlargement of the range of crops to be checked and increasing the sampling frequency for GMO analysis.
4. There were no changes regarding the competent authorities since the previous audit on GMOs. In summary, the MoA is the lead authority for GMOs. The AQSIQ is responsible for the control of imported and exported seed, food and feed. GMO related controls mainly involve the Department of Supervision on Animal and Plant Quarantine and the Bureau of Import and Export Food Safety. The AQSIQ supervises 35 provincial CIQs who are responsible for planning, monitoring and reporting to the AQSIQ. They also impose fines in the case of non-compliances. The local CIQs are responsible for implementation of controls and are supervised by the provincial CIQs. The AQSIQ has technical branches located in the provinces responsible for analytical testing. (For further details regarding the competent authorities see audit report DG SANCO 2011-6208).

### **Conclusions on national legislation regarding GMO and competent authorities**

5. Comprehensive national legislation regarding GMO is in place in China. Additional measures in relation to GMO biosafety management have been introduced since the previous GMO audit in 2011. The measures address the requirements of Decision 2011/884/EU including the Decision's amendment in 2013 aiming to strengthen the GMO related control system.
6. There is a clear structure and division of responsibilities for the competent authorities in charge of controls of GMOs.

## **5.2 GMO/GMM RELATED AUTHORISATION PROCEDURES AND STATUS OF GMOs, GMMs AND GM FEED AND FOOD PRODUCTS IN CHINA**

### **Legal requirements**

The following EU legislation provided a basis for the evaluation of the national system:

- Directive 2001/18/EC, Directive 2009/41/EC, Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003.

### **Findings**

7. The authorisation system of GMOs was described in the audit report DG (SANCO) 2011-6208. There have been no significant changes since then. In summary, there are generally five stages for GMO safety assessment: laboratory research, confined pilot field testing, environmental release field testing, pre-production testing and application for the grant of a safety certificate. Applications for all the five stages are evaluated by the National Biosafety Committee (NBC). As GMO safety management legislation includes GMMs, their authorisation system follows the same stages.
8. The MoA informed the audit team that the safety certificate for trial purposes of GM Bt63 rice expired in 2014. Before issuing a new safety certificate in 2014, a more comprehensive environmental and food safety re-evaluation was carried out compared to the assessment performed in 2009. The environmental assessment was extended compared to the previous one and included insect resistance, ecological invasiveness, pesticide/herbicide resistance, consequences of gene flow and tests regarding non-target organisms including soil organisms. The food safety assessment included component analysis, allergenicity and toxicity. There are four biosafety categories ranging from level one with very low risk to level four representing high risk. The NBC classified the Bt63 rice as level 2, corresponding to a low safety risk, but requiring additional precaution because China is the centre for the genetic origin of the species. The MoA stated that they do not intend to grant approval for commercial cultivation of Bt63 rice in the near future because the general public in China is concerned about GMOs and rice is a key crop. At the time of the audit, Bt63 rice was not authorised anywhere outside China either.

9. In addition to Bt63, further GM rice field trials had been performed in China for insect resistance, herbicide tolerance and quality improvement involving genes such as Cry2A and bar.
10. The MoA informed the audit team that in 2015, assessments of 10 GM events involving rice, rape seed, and maize, and one GMM trial were authorised in total in China.
11. China has issued safety certificates for 42 GM events (out of which one has expired) developed outside China, including five types of crops for food/feed uses: cotton, maize, soya, rape seed, sugar beet.
12. Safety certificates have been issued for 88 GMMs. GM *Bacillus subtilis* is not authorised in China.
13. Bt cotton and virus resistant papaya are the only GM crops currently authorised and in commercial cultivation in China.

**Conclusions on GMO/GMM related authorisation procedures and status of GMOs, GMMs and GM feed and food products in China**

14. There is ongoing research and development of GM crops in China, including GM rice. No commercial production of GM rice is permitted in China.
15. Since the previous audit, new parameters based on scientific developments have been taken into account during the assessment procedures of GMOs which further strengthens the authorisation system of GMOs.

### **5.3 GMO AND GMM RELATED DOMESTIC CONTROLS**

#### **Legal requirements**

Articles 46 (1) (e) and (b) of Regulation (EC) No 882/2004 stipulate that Community controls shall have, inter alia, particular regard to the existence and operation of documented control procedures and control systems based on priorities, and the competent authority's capability to enforce applicable legislation.

#### *5.3.1 Field trials, including confined release*

#### **Findings**

16. The Department of Agriculture in Hubei Province informed the audit team that 40 approved GMO trials in various testing stages and locations (laboratory research, environmental release field testing, pre-production testing) were carried out in total in the Province in 2015. The trial included two GM rice lines: Huihui1 and Bt63 rice, which was also the case at the time of the previous audit. Hubei is the only Province where GMO rice field trials are currently performed. The Department further stated that at least three inspections are carried out annually during the growing season, including sowing and harvesting.

17. The audit team visited the testing centre of the Oil Crop Research Institute of the Chinese Academy of Agricultural Sciences in Wuhan, Hubei Province. The centre has an eight ha area to carry out field trials involving GM rape seed and GM rice in 2015. The area is fenced, supervised by cameras and a strict access policy is applied. There is no agricultural production in the vicinity as there are ponds around the station serving as spatial isolation. The centre is accredited by the China National Certification and Accreditation Administration (CNCA) and re-accreditation audits, carried out jointly with the MoA, are carried out every three years. An approval of the MoA needs to be obtained before conducting any trial. The Provincial Department of Agriculture carries out regular inspections to ensure that the GMO trials are carried out in compliance with the approval. In 2015, the GM rice trials were for pest resistance. The representative of the testing station stated that GM and non-GM material is destroyed after the completion of each trial.
18. The audit team visited the Huazhong Agriculture University where GMO rice research and testing is carried out. The representative of the university explained the GMO safety management system which includes internal GMO safety control. Safety management protocols are in place for the GMO laboratories, in vitro cultivation rooms, greenhouse and testing fields. All residues and seeds are treated as potentially hazardous material and are safely destroyed. Post experimental control measures for field trials include two years monitoring for volunteers and their destruction. The University conducts self-control checks at all testing stages and keeps records and receives regular inspections from the Provincial Department of Agriculture and the MoA including the GMO Office affiliated to the MoA. No irregularities had so far been identified.

#### *5.3.2 GMO controls of seed and rice cultivation*

19. The Department of Agriculture of Hubei Province informed the audit team about their GMO safety management system which includes controls for the adventitious presence of GMOs in rice seed and rice cultivation. A steering committee was set up in 2003 to manage and implement the control system at provincial level in order to implement a biosafety system in line with the national requirements. In 2015, the controls covered 400 towns and villages involving 40 rice producing counties, 100 seed producing companies, 30 markets and 7 000 retailers selling agricultural inputs.
20. The Department of Agriculture of the Hubei Province provided data for the GMO controls of rice seed from 2013 to 2015. In each year, around 40 seed companies were controlled and around 200 samples were taken. They informed the audit team that in 2013 no non-compliances were detected in rice seed controls. In 2014, they had detected GMO contamination of conventional rice seed. Some 200 kg of seed contaminated with Bt63 was confiscated and destroyed and involved persons were prosecuted. A similar case was discovered in spring 2015 when some 100 kg of seed contaminated with Bt63 was confiscated and destroyed and investigation of the case was still on-going.

21. For the rice cultivation controls, the Department of Agriculture of the Hubei Province controlled some 100 enterprises annually in 2013, 2014 and 2015, and took 117, 264 and 106 samples, respectively. In 2014, in one case, they detected one sample containing Bt63. The Department stated that they had seized the harvested rice and carried out investigations of the case.
22. It is known that<sup>1</sup> GM rice is present in rice production in China. The MoA informed the audit team that they implement supervision and controls of GMO presence in each province that cultivates rice. The MoA issues an annual supervision plan which is implemented by the provinces and adapted to the provincial conditions. The MoA also stated that GMO controls in rice are carried out in all seven rice growing provinces similar to the controls in the Hubei Province (see above). An example was given by the MoA that in Jiangxi Province, 85 rice samples were taken in 2015 and no non-compliances were identified. No details of any additional GMO controls in China were provided to the audit team.

*5.3.1 GMO/GMM controls of food and feed including fermentation products obtained with GMM*

## **Findings**

23. The MoA stated that the use of GMM is allowed for feed additives including vitamins. The GMM that is used have to come with GMO Biosafety Certificates according to the relevant laws. Moreover, feed additive producers need to obtain a production certificate from the Departments of Agriculture and if they use microorganisms they have to organise GMM testing to ensure that no GMM is present in the final product. The testing must be done by an independent GMO laboratory.
24. The audit team visited Hubei province and met the Department of Agriculture in Wuhan. They stated that the Department carries out GMO controls of the production of agricultural products (food, feed and seed) before placing on the market.
25. Market controls of food are carried out by the Food and Drug Agency whom the audit team did not meet. Data provided by the MoA following the audit indicated that no details are available regarding GMO control of food in China.
26. Regarding GMO/GMM controls of feed and feed additives, the Provincial Departments of Agriculture manage the monitoring of feed and feed additives based on the instructions received from the MoA.
27. The audit team visited a large manufacturer of feed additives using GMM and met representatives of the local Departments of Agriculture and noted that:

---

<sup>1</sup> In their comments in response to the draft audit report, the competent authority noted that "it is known that China is a large rice producer, and has conducted in-depth experimental research on GM rice, yielding world-leading technologies". "...illegal trade has resulted in potential risks of the illegal spread of GM rice...".

- a. Although the company visited does not export to the EU, official controls carried out by the local Departments of Agriculture were stated to be the same for manufacturers exporting to the EU and were explained to the audit team during the visit.
- b. The local Department carries out annual inspections of the production of feed additives and does additional spot checks. Related inspection reports were provided to the audit.
- c. The production process of enzymes involves two filtrations, therefore the risk of finding genetically modified bacteria in the final product is deemed to be negligible. The company verified the production method when it was introduced to ensure that no GMM is present in the final product.
- d. The company is certified by various private standards and operates an internal control system of the production which includes GMM safety.

#### **Conclusions on GMO and GMM related domestic controls**

28. A control system is in place to ensure that research and testing of GMO, including field trials are carried out in compliance with the national requirements and to prevent adverse effects on the environment.
29. Extensive controls are in place in Hubei Province aiming to ensure that rice cultivation is not contaminated with GMO. GMO controls of rice cultivation are implemented in other provinces growing rice, however, apart from one example, the audit team was not provided with any details. Therefore, those controls could not be evaluated. Details of GMO controls of food in China are not available.
30. The establishment using GMM to produce feed additives visited is under official supervision and has an appropriate internal control system in place to ensure that the end product does not contain GMM.

## **5.4 EXPORT CONTROLS RELATED TO GMOS**

### **Legal requirements**

Art. 46 (1) (h) of Regulation (EC) No 882/2004 stipulates that Community controls shall have, inter alia, particular regard to the assurances which the TC can give regarding compliance with, or equivalent to, Community legislation.

Decision 2011/884/EU specifies emergency measures regarding genetically modified rice in rice products originating from China.

#### 5.4.1 GMO controls of feed exported to the EU

##### **Findings**

31. Since 2012, local CIQ inspectors carry out risk-based official controls at manufacturers exporting feed in accordance with instructions issued at national level by the AQSIQ. The risk categorisation takes into account the type of products manufactured and the production process. A minimum inspection frequency and a sampling plan are implemented and adapted to the specific product of each establishment. This approach is known as “one enterprise, one product, one surveillance plan”. The use and potential presence of GMO are included in the risk evaluation. The producers of food, feed and feed additives have to submit an application for registration to the local CIQ for approval. The application is evaluated and an initial inspection is carried out by the local CIQ. If necessary, the local CIQ suggests changes to be adopted by the producer. After having made the necessary corrections, the provincial CIQ carries out the final inspection for registration. A database of producers is maintained by AQSIQ and the authorisation is valid for five years. Any changes to the production profile need to be notified to the local CIQ and may require a new safety assessment and certification. Exporters are recorded by the AQSIQ and are not subject to registration or controls. The local CIQs carry out annual inspections of producers and controls of each batch of feed to be exported.
32. The AQSIQ prepares an annual monitoring framework taking into account a number of criteria, including GMO. Based on this, the provincial CIQ prepares the provincial plan, which is implemented by the local CIQs.
33. The audit team visited two manufacturers of feed additives exporting to the EU and met the Guangdong provincial CIQ and two local CIQs in the same province.
34. In Guangdong province, some 1 006 tonnes of feed additives were exported to the EU by six producers in 2014 and some 3 000 tonnes by three producers in 2015. No feed products from this province had been subject to GMO RASFF notifications so far.
35. The feed and feed additives exported to the EU must comply with the Chinese legislation on feed and feed additives, the Chinese GMO legislation and the EU GMO legislation.
36. The Guangdong CIQ stated that their sampling plan does not include GMO sampling because, on the basis of the profiles of the producers for EU export in the region, the GMO related risk is low.
37. Annual inspections are carried out based on a risk based monitoring plan tailored for each producer. A report is issued after each inspection.
38. Evidence was provided that the inspector keeps copies of the GMO analytical reports of the company and checks whether the laboratory used within the self-control system of the producer is accredited according to EN ISO/IEC 17025.

39. The audit team noted that both producers apply a stringent quality control system which includes GMO.
40. The CIQ staff and feed/feed additive producers receive regular training regarding new developments provided by AQSIQ.

*5.4.2 GMO controls of food exported to the EU including unauthorised rice [Decision 2011/884/EU]*

## **Findings**

41. The framework of GMO controls of food for EU export is largely the same as for feed which was described in the previous section. The AQSIQ stated that the control system for food is based on two elements: supervision and random inspection. Additional controls are carried out by the provincial and local CIQs at food producers to ensure that rice products exported to the EU comply with Decision 2011/884/EU.
42. The audit team visited Jiangxi and Fujian provinces, one producer of rice products for EU export in each province, and met the provincial and local CIQs.
43. In Jiangxi province, there is one producer currently exporting rice products to the EU out of the two producers authorised for EU export. The provincial CIQ stated that the number of such producers has decreased from over 10 since 2012 due to the introduction of Decision 2011/884/EU, due to which more stringent requirements were put in place by AQSIQ. The producer visited stated that their production and export to the EU had decreased since 2012.
44. The local CIQs carry out controls at the food producer for EU export at various stages including the cultivation of rice, transport, storage and processing. They check:
  - a. the agricultural inputs used in particular seed. The company must ensure that the seed used is non-GM. The surrounding area of the field is also checked to ensure that there is no risk of GMO cross-contamination.
  - b. whether there are dedicated storage places and transport vehicles for rice products for EU export. The records of the incoming and outgoing material of the warehouse are also checked.
  - c. whether there is a dedicated production line for rice products for EU export.
  - d. the GMO testing within the framework of the internal control system of the producer.
45. Evidence was provided that each batch of rice products for EU export is sampled and tested in a CIQ laboratory. The sampling is based on the requirements specified in the EU legislation.



46. The audit team reviewed the CIQ monitoring plan for the producer visited in Jiangxi, and inspection and analytical reports in Jiangxi and Fujian provinces.
47. The audit team noted that detailed records of the observations by the CIQ inspector regarding the rice cultivation, processing, transport and storage were kept. An inspection report summarising all checks carried out in a rice growing season is issued.
48. Both food processors visited produce for export only and a small proportion of their production is for EU export. They operate a quality control system which includes GMOs and they work under various internationally recognised private certification schemes.
49. The audit team noted at the two food producers exporting rice products to the EU visited that:
  - a. They consider the prevention of GMO in their productions as a priority and apply a non-GMO policy.
  - b. The companies have their own rice cultivation or work with contracted farms and carefully select the rice variety and seed for sowing.
  - c. Dedicated drying, transport and storage facilities for the rice to be processed and a processing line dedicated for EU export are used.
  - d. GMO controls are applied throughout the rice cultivation, and the rice products' production process which include GMO testing where CIQ or private GMO laboratories are used. In the case of one company, the seed, the rice before processing and the final product are sampled and analysed for GMO presence. In the other case, random sampling for GMO is carried out as part of the internal quality controls.
  - e. Based on the laboratory reports reviewed, the samples were analysed by one of the 29 CIQ laboratories (see section 5.5) or by a private laboratory. The private laboratory used is accredited according to EN ISO/IEC 17025 and the testing methods have a detection limit of 0.01%.
50. Each batch of the final rice product to be exported to the EU is sampled in the warehouse of the producer. In one case the sampling is done by the company in the presence of the CIQ inspector. In the other case the CIQ inspector carries out a short spot check of the processing, a documentary check of the batch to be exported and takes samples for GMO analysis.

## **Conclusions on export controls related to GMOs**

51. There is a comprehensive export control system of feed and feed additives which ensures compliance with EU legislation.
52. Based on stringent requirements for EU exporters of rice products, a detailed control system has been implemented by the Chinese authorities and by the producers in response to the introduction of Decision 2011/884/EU.

## **5.5 GMO LABORATORY**

### **Legal requirements**

Art. 46 (1)(d) and (c) of Regulation (EC) No 882/2004 specifies requirements with regard to resources including diagnostic facilities, and the training of staff in the performance of official controls. Article 12 of the same Regulation requires that laboratories charged with the analysis of GMO in products for export to the EU are accredited according to EN ISO/IEC 17025, or an equivalent international standard.

### **Findings**

53. The audit team visited the technical centre affiliated to one of the CIQs and located in Xiamen in the Fujian province. This technical centre provides various testing services.
54. The GMO testing is part of the micro-organisms laboratory which was certified for this activity by the CNCA in 2001.
55. The scope of the GMO testing covers 382 categories of food, but also plants, feed and seed, depending on the client's requests. The laboratory is also active in research and development (including on GMOs), and has participated in the development of several national (and Asian) testing standards, including sampling of plants and plant products, and real-time PCR methods.

#### *5.5.1 Quality management system*

56. The GMO testing laboratory is one of the 29 national laboratories which are also recognised by the EU for GMO testing of rice products intended for export to the EU. The laboratory is accredited according to EN ISO/IEC 17025 by the CNCA. The scope of the accreditation covers many screening, gene-specific and event-specific real-time PCR methods. Nearly all of these methods are qualitative methods.
57. The technical centre operates a quality management system covering all aspects of its activities, including staff management and training of staff, environmental safety (e.g. waste management), equipment inspection and maintenance, sample registration and barcoding throughout the analytical processes, internal and external audits, and the management of testing results. All these aspects are based on the relevant national standards issued by the AQSIQ.

58. The GMO testing is carried out by four staff members, three of which have a PhD and one a bachelor's degree.
59. The GMO laboratory regularly participates in training sessions organised by the EU (e.g. European Union Reference Laboratory for GM Food and Feed (EU-RL GMFF) in 2012) and by the AQSIQ (2012-2014). It has also been participating in national proficiency testing programmes organised by CNCA since 2004. During recent years, participation covered PCR methods for Bt63–TT51-1 in rice (2011), P35S and Bt176 detection in maize (2013), and P35S, Tnos, and event-specific methods for MIR162 and MON89034 in maize feed used for liquor production (certificate of January 2015). The laboratory completed all proficiency tests with satisfactory results.

#### *5.5.2 Detection methods for Chinese rice products intended for EU export*

60. For the analysis of rice products intended for EU export, the GMO testing laboratory strictly follows the requirements specified under Decision 2011/884/EU, as amended by Decision 2013/287/EU. The laboratory follows the national standards for sampling, in line with the revised EURL GMFF guidance of 2014, which requires one sample to be taken from processed rice products. The 'CTAB' method is used for DNA extraction.
61. The PCR methods used for analysis of the presence of unauthorised GM events include the 'SybrGreen' methods for PLD, P35S, Tnos and CryIAb/c, and 'TaqMan' real-time PCR methods (only qualitative methods) for the same targets. The methods are in-house validated, using positive control materials consisting of Kefeng 6 rice flour (containing all three GM targets), and 40-3-2 soybean (P35S and Tnos), and Bt11 and MON810 maize certified reference materials (CryIAb/c). The Kefeng 6 positive control materials are provided in limited quantities by the Chinese Academy of Inspection and Quarantine (CAIQ), which is affiliated to AQSIQ, and contain 1%, 0,1% and 0,01% (on mass basis) Kefeng 6 rice, and instructions are provided for the extraction of DNA from these materials. All the three methods have a limit of detection of 0,01%. Reference materials are obtained from the Institute for Reference Materials and Measurements (IRMM) of the EU or the American Oil Chemists' Society (AOCS), and the DNA diluted to obtain an unspecified GMO concentration providing a cycle threshold < 30, as required under the Standard Operating Procedures.
62. The audit team verified the validation report of 2012 issued for the analysis of rice products using the PCR methods specified in the EU Decision, which showed that the laboratory was competent to perform these analyses.
63. For GMO testing according to Decision 2011/884/EU, the laboratory has analysed 19 rice noodle samples for EU export during 2012-2015. All of these were tested negative for all three screening methods (P35S, Tnos and CryIAb/c).

#### *5.5.3 Laboratory organisation*

64. The laboratory has separate rooms for the different activities from sample preparation, DNA extraction to PCR analysis, following the forward-flow principle. The rooms are

not under different pressure conditions to avoid cross-contamination. Following sample reception at the entrance of the building, the material is transferred to the sample preparation room. The sample is registered in the electronic system and receives a barcode, allowing the status of the sample to be followed throughout the analysis processes. The sample is stored in an adjacent room. Sample grinding is done by dedicated staff using a Retsch GM200 grinder (max capacity 500 g); for rice noodles, generally 125 g samples are ground, then two samples of each approximately 1 g are taken for further analysis. The DNA extraction is performed in a separate room. PCR preparation and analysis are performed on another floor in separate rooms following a forward-flow principle to avoid contamination. Following PCR using 'ABI' or 'Stratagene' real-time PCR instruments, the samples are put into the waste without opening. Gel electrophoresis is performed in a separate room.

65. Laboratory coats and special shoes are used by the staff during working hours. Reagents are prepared in separate rooms, and primers, probes and reference materials are clearly labelled and stored in dedicated freezers.

#### **Conclusions on laboratory organisation and management for GMO testing**

66. The GMO testing facilities of the technical centre of the CIQ in Xiamen and their operation under ISO/IEC 17025 accreditation are appropriate for the testing of rice products intended for export to the EU.
67. The detection methods used follow the national standards in place for this qualitative testing according to the EU Decision 2011/884/EU.

#### **5.6 ACTION TAKEN IN RESPONSE TO NON-COMPLIANCE AND EU RASFF NOTIFICATIONS (INCLUDING BT63 RICE IN CHOLINE CHLORIDE FEED ADDITIVES AND GM BACILLUS SUBTILIS IN VITAMIN B2 FEED)**

##### **Legal requirements**

Point 6 of Guidelines of Codex Alimentarius CAC/GL 25-1997 establishes principles for the exchange of information between countries on rejections of imported food.

##### *5.6.1 Follow up of EU RASFF notifications*

##### **Findings**

68. The AQSIQ has an established procedure to follow up on EU RASFF notifications. The Guangdong provincial CIQ stated that they check the internet for EU RASFF notifications relevant to their province, they follow up on alerts forwarded to them by AQSIQ and in the cases where the producers notify them.
69. The number of GMO RASFF notifications involving products from China has been reduced from over 40 in 2012 to five in 2015 up to the time of the audit.

70. Evidence was provided that RASFF notifications are followed up on and corrective actions are taken. The AQSIQ stated that in most of the cases, the GMO RASFF notifications are due to illegal trade which means the producer involved is not registered with the AQSIQ and falsified certificates are used.
71. In Xiamen, there is Memorandum of Understanding signed between the CIQ, Customs and the Police services to combat illegal trade.
72. The MoA informed the audit team that there are nine producers in seven provinces registered with them for vitamin B2 production. In response to the three RASFF notifications involving GM *Bacillus subtilis* in vitamin B2, the relevant Departments of Agriculture carried out investigations at all registered vitamin B2 producers. No irregularities regarding GMM presence were identified. The MoA came to the conclusion that there was one pharmaceutical establishment located in inner-Mongolia linked with the three RASFF notifications and illegal use of GMM had been involved. Investigations are still ongoing.
73. In relation to RASFF notifications regarding GMO presence in choline chloride feed additives issued in 2014, the follow up actions taken by the Chinese authorities were explained in the audit report DG(SANCO) 2014-7074.

#### **Conclusions on export controls related to GMOs**

74. GMO RASFF notifications involving Chinese products are followed up and corrective actions are taken. There are initiatives to combat illegal trade.

## **6 OVERALL CONCLUSIONS**

Overall, there is a comprehensive export control system in place to ensure that food, feed and feed additives exported to the EU are compliant with the EU legislation regarding GMOs.

A detailed supervision system is implemented by the Chinese authorities to ensure compliance with the requirements of Decision 2011/884/EU. The system is supported by a well-established and up-to-the standard laboratory capacity and includes procedures to follow up on RASFF notifications. The number of GMO related RASFF alerts has decreased and attempts have been made to combat illegal trade which is currently stated by the Chinese authorities to be the main reason for EU non-compliances detected in the EU.

The GMO field trials are adequately controlled and extensive controls are in place in Hubei Province aiming to ensure that rice cultivation is not contaminated with GMO. Some GMO controls of rice cultivation are performed in other rice growing provinces. It is known that GM rice is present in the rice cultivation in China. Therefore there is a potential risk that GM rice enters in the production of commodities other than those regulated and controlled for EU export. Some efforts are made to mitigate such risk.

## **7 CLOSING MEETING**

A closing meeting was held on 26 November 2015 at the headquarters of the Ministry of Agriculture in Beijing, during which the main findings and preliminary conclusions of the audit team were presented. The Ministry of Agriculture and the AQSIQ provided clarifications and provisionally accepted these preliminary findings and conclusions.

## **8 RECOMMENDATIONS**

No recommendations are made to the competent authorities in China.

The competent authority's response on the draft Report can be found at:

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2015-7640](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2015-7640)

## ANNEX 1 – LEGAL REFERENCES

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 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
Reg. 1829/2003	OJ L 268, 18.10.2003, p. 1-23	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
Reg. 1830/2003	OJ L 268, 18.10.2003, p. 24-28	Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
Dir. 2001/18/EC	OJ L 106, 17.4.2001, p. 1-39	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
Dir. 2009/41/EC	OJ L 125, 21.5.2009, p. 75-97	Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast)

Dec. 2011/884/EU	OJ L 343, 23.12.2011, p. 140- 148	2011/884/EU: Commission Implementing Decision of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC
------------------	---	--