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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

CHINA

FROM 16 TO 22 SEPTEMBER 2014

IN ORDER TO ASSESS THE CONTROL SYSTEMS IN PLACE TO CONTROL
MICROBIOLOGICAL CONTAMINATION IN SEEDS FOR HUMAN CONSUMPTION
INTENDED FOR EXPORT TO THE EUROPEAN UNION AND TO FOLLOW-UP AUDIT
DG(SANCO) 2013-6680

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in China from 15 September to 22 September 2014.

The first objective of the audit was to assess the official control systems in place for seeds for human consumption (in particular, mung beans and other seeds for sprouting and direct human consumption) for export to the EU in order to prevent microbiological contamination (Articles 11 and 14 of Regulation (EC) No 178/2002) and to assess whether these systems offer adequate assurance that the produce concerned is within the limits laid down in EU legislation. The second objective was to follow-up the previous audit DG (SANCO)/2013-6680. The audit focused on controls at primary production level. The objectives of the audit were met.

Significant progress was made by the Chinese Competent Authorities (CAs) since the last audit in 2013 and all six recommendations made in the report of that audit were fully addressed.

The CAs have implemented the requirements of the EU legislation on hygiene for exports of mung beans for sprouting. A new control system has been devised explicitly for seeds for sprouting for export to the EU. This is based on registration and approval of farms by regional CAs and the introduction of specific official controls of farms and processors/exporters. The processing facilities visited by the audit team followed Good Hygiene Practices. The laboratory visited was accredited and suitable for the purpose of official microbiological analysis including Shiga Toxin-Producing Escherichia coli.(STEC).

At the time of the audit there were no export certificates being issued by the CAs of China for seeds for sprouting to be exported to the EU. However, the system of official food safety controls currently in place can assure that the mung beans for sprouting were produced under conditions which comply with the general hygiene provisions for primary production and associated operations set out in Part A of Annex I to Regulation (EC) No 853/2004 as required by Article 3 of Regulation (EU) 211/2013. The system in place enables the CAs of China to issue the required export certificates. This applies already for the 2014 harvest.

The report contains no recommendations to China.

Table of Contents

1	<u>INTRODUCTION</u>	1
2	<u>OBJECTIVES</u>	1
3	<u>LEGAL BASIS</u>	2
	3.1 <u>LEGAL BASIS</u>	2
	3.2 <u>STANDARDS</u>	2
4	<u>BACKGROUND</u>	2
5	<u>FINDINGS AND CONCLUSIONS</u>	3
	5.1 <u>NATIONAL LEGISLATION</u>	3
	5.2 <u>COMPETENT AUTHORITIES</u>	5
	5.3 <u>OFFICIAL CONTROLS</u>	6
	5.3.1 <u>DOCUMENTED CONTROL PROCEDURES</u>	6
	5.3.2 <u>REGISTRATION OF FOOD BUSINESS OPERATORS</u>	7
	5.3.3 <u>CULTIVATION</u>	7
	5.3.4 <u>PROCESSING AND STORAGE</u>	8
	5.3.5 <u>NON- CONFORMING PRODUCTS</u>	10
	5.4 <u>METHOD OF SAMPLING</u>	10
	5.5 <u>LABORATORY SERVICES</u>	11
	5.6 <u>CERTIFICATION PROCEDURES FOR EXPORTING TO THE EU</u>	13
	5.7 <u>RESPONSE TO RASFF NOTIFICATIONS</u>	13
6	<u>OVERALL CONCLUSIONS</u>	14
7	<u>CLOSING MEETING</u>	14
	<u>ANNEX 1 - LEGAL REFERENCES</u>	15
	<u>ANNEX 2 - STANDARDS</u>	16

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AQSIQ	General Administration of Quality Supervision, Inspection and Quarantine
CA(s)	Competent Authority(ies)
CCA	Central Competent Authority
CIQ(s)	Inspection and Quarantine Agency(ies)
CODEX	Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization
DG SANCO	Directorate General for Health and Consumers of the European Commission
EFSA	European Food Safety Authority
EU	European Union
FBO(s)	Food Business Operator(s)
FNAO	Food of Non Animal Origin
FVO	Food and Veterinary Office
GAP	Good Agricultural Practices
GHP	Good Hygiene Practices
GMP	Good Manufacturing Principles
HACCP	Hazard Analysis and Critical Control Points
ISO	International Organisation for Standardization
LFS	Food Safety Law
MOA	Ministry of Agriculture
MS(s)	Member State(s)
PRC	People's Republic of China
PT(s)	Proficiency Test(s)
RASFF	Rapid Alert System for Food and Feed
STEC	Shiga Toxin-Producing <i>Escherichia Coli</i>
TC(s)	Third Country(ies)

1 INTRODUCTION

This audit took place in China from 15 September to 22 September 2014 to assess the official control systems in place for seeds for human consumption (in particular, seeds for sprouting e.g. mung beans and other seeds for sprouting) for export to the European Union (EU). The audit team comprised one auditor from the Food and Veterinary Office (FVO) and one National Expert from an EU Member State (MS).

The audit was undertaken as part of the FVO's annual audit programme. The audit team was accompanied throughout the audit by representatives of the Central Competent Authority (CCA) - the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

The opening meeting was held on 15 September 2014 with the CCA, including the representatives of the laboratories and Competent Authorities (CAs) from the Provinces of Inner Mongolia and Liaoning and the EU Delegation to China. During the meeting, the objectives of the audit, itinerary (including visits to farms) and the standard reporting procedures were confirmed.

2 OBJECTIVES

The objectives of the audit were:

1. To assess the official control systems in place for seeds for human consumption (in particular, mung beans and other seeds for sprouting and direct human consumption) for export to the EU in order to prevent microbiological contamination (Articles 11 and 14 of Regulation (EC) No 178/2002).
2. To assess whether these systems offer adequate assurance that the produce concerned is within the limits laid down in EU legislation.
3. To follow-up on the previous audit of the Directorate General for Health and Consumers of the European Commission (DG (SANCO))/2013-6680. The audit will focus on controls at primary production level.

In terms of scope, the audit reviewed the controls on production, processing and export, including national legislation in place, the organisation and operation of the CAs and their controls over Food Business Operators' (FBOs) compliance with hygiene rules.

Table 1: Audit visits and meetings

Meetings/visits	Comments	
Competent authorities		
Central	2	Opening and closing meeting was attended by representatives from the Ministry of Agriculture (MOA), AQSIQ, Inspection and Quarantine Agencies (CIQs) of Inner Mongolia and Liaoning Province, the Ministry of Commerce, China Chamber of Commerce for Import and Export of Foodstuffs, Native produce and Animal By-products and representatives of the

		European Seeds for Sprouting Association and exporting companies
Regional	2	CIQs of Inner Mongolia and Liaoning Province
Laboratories		
Official	1	CIQ laboratory in Dalian
Processors /Exporters/Farms		
Processors/Exporters	3	Main processors and exporters of seeds for sprouting to the EU in Inner Mongolia (1) and Liaoning (2)
Farms producing seeds for sprouting	2	The farms visited were based in Inner Mongolia

3 LEGAL BASIS

3.1 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation, in particular, Article 46 of Regulation (EC) No 882/2004 of the European Parliament and the Council which stipulates that EU controls in Third Countries (TCs) may verify compliance or equivalence of TC legislation and systems with EU feed and food law. These controls shall have particular regard to the assurances which the TC can give regarding compliance with, or equivalence to the relevant EU requirements.

A full list of the EU legal instruments referred to in this report is provided in Annex 1. EU legal acts quoted in this report refer, where applicable, to the most recently amended version.

3.2 STANDARDS

Additionally, the Guidelines and Codes of Practice of the Codex Alimentarius Commission of the Food and Agriculture Organisation of the United Nations and World Health Organisation (CODEX) were taken into account in the context of the audit, where relevant.

A full list of applicable standards referred to in this report is provided in Annex 2. Reference to specific provisions of these texts is provided at the beginning of relevant sections.

4 BACKGROUND

The European Food Safety Authority (EFSA) adopted a scientific opinion on the risk posed by Shiga toxin-producing *Escherichia Coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds, following the outbreaks of STEC in May 2011 in the EU. The EFSA report can be found at:

<http://www.efsa.europa.eu/en/efsajournal/pub/2424.htm>.

The EFSA indicated that as sprouted seeds are ready-to eat foods, the presence of pathogenic bacteria in seeds used for sprouting or in sprouted seeds represents a public health risk.

Microbiological testing alone may convey a false sense of security due to the statistical limitation of sampling plans. A negative sample result does not ensure the absence of the pathogen in the tested lot, particularly where it is present at low or heterogeneous prevalence.

In order to ensure an adequate level of protection of public health, it is appropriate that sprouts and seeds intended for the production of sprouts imported into the EU comply with the requirements as laid down in Regulation (EC) No 852/2004. Appropriate certification requirements are therefore laid down for such commodities imported into the EU.

In view of the number of large outbreaks and the volume of imports from China the FVO decided to carry out a follow-up audit to China in 2014 on the previous audit (DG (SANCO)/2013-6680 on control systems in place to control microbiological contamination in seeds for human consumption and sprouting intended for export to the EU).

Table 2 : Exports of mung beans for human consumption from China to the EU (*)

Year	Export of mung beans to EU in tonnes	No of lots
2012	10900	296
2013	9400	272
2014	3600	118

(*) Data provided by the Chinese authorities

5 FINDINGS AND CONCLUSIONS

5.1 NATIONAL LEGISLATION

Legal requirements

Article 46(1)(a) of Regulation (EC) No 882/2004 stipulates that EU controls are to have, *inter alia*, particular regard to the legislation of the TCs.

Findings

The Food Safety Law (LFS) of the People’s Republic of China (PRC) designates the CAs responsible for official food safety control. Requirements for official controls on imported and exported food are also laid down in the LFS. According to these requirements, FBOs and growers whose produce is intended for export need to be registered with the provincial CIQs. Provisions for enforcement measures to be undertaken in the case of non-compliances identified and sanctions to be imposed are also laid down in the LFS.

The LFS of the PRC and the Law of the PRC on Import and Export Commodity Inspection and its implementing regulations establish rules for export and import of Food of Non Animal Origin (FNAO).

The Law of the PRC on the Entry and Exit Animal and Plant Quarantine describes the general food import and export conditions.

The Law on Quality and Safety of Agricultural Products provides the legal framework for official controls at primary production for both foods of animal and non-animal origin.

A circular on strengthening the administration of the registration of plant product exporting enterprises (Guo Zhi Jian Dong Han [2008] No. 106) establishes rules for registration of FNAO exporting facilities. Under these provisions, the food processing enterprises for export shall establish and maintain food safety control systems focusing on hazard analysis and preventive control measures.

Since the publication of the new EU sprouts/seeds for sprouting legislation AQSIQ has published three legislative acts.

AQSIQ published on 17.06.2013 Directive Nr. 176 in which the four regulations (EC) No 208/2013, 209/2013, 210/2013 and 211/2013 were announced. The original and translated legislation were sent to CIQs. The CIQs sent the legislation to all related operators, such as processors/exporters and producers.

On 12.12.2013 AQSIQ published Directive Nr. 113. In this directive it indicated that as the result of the FVO audit was not satisfactory, more strict controls should be implemented in order to comply with EU requirements.

On 19.08.2014 AQSIQ published Directive Nr. 114. According to the legislation and the outcome of the training session provided on 25.07.2014 by the Directorate General for Health and Consumers of the European Commission (DG SANCO) and the private sector, specific controls for the hygienic production of seeds for sprouting were formulated. The Directive covers the whole chain from primary production to export.

In part two of the directive a new sampling standard was published according to the Chinese national legislation and based on Chinese national standards and Codex General Guidelines on sampling (CAC/GL 50-2004).

In addition to the new legal acts, AQSIQ decided in January 2014 to extend the application of the Administrative Regulation for Filing of Plantations for export of Food Raw Materials (AQSIQ Announcement 56/2012) to seeds for sprouting plantations that are contracted by exporters to the EU. Contract farming was an existing system, which was already used for controlling the primary production of other agricultural products. By applying this system of approved contract farmers, traceability can be achieved. The plantations must be registered and approved by the provincial CIQ and AQSIQ is informed of such plantations.

The CIQ inspectors were informed about legislation in the form of letters from AQSIQ. The inspectors and FBOs met were aware of the existence of both national and new EU legislation on seeds for sprouting.

Conclusions

There is a legal framework in place for food safety which designates the CAs and their competences. New legislation on the production of seeds for sprouting intended to be exported to the EU was published. The national legislation for the control of seeds for sprouting is in place and is properly disseminated. The legal requirements in the national legislation are in line with EU requirements for seeds for sprouting to be exported to the EU.

5.2 COMPETENT AUTHORITIES

Legal requirements

Articles 46(1)(b) and (c) of Regulation (EC) No 882/2004 stipulate that EU controls shall have, *inter alia*, particular regard to the organisation of the TC's CAs, their powers and independence, the authority they have to enforce the applicable legislation effectively, and the training of staff in the performance of official controls.

Findings

There were no changes in the structure of the CAs since the last audit.

The State Council has established a Food Safety Commission to analyse the food safety situation, co-ordinate and guide food safety work, propose major policy measures.

The National Health and Family Planning Commission is responsible for risk assessment and the formulation of standards relating to food safety.

The MOA is responsible for the administration of the supervision of primary production of FNAO.

China's Food and Drug Administration is responsible for the supervision of domestic food production, distribution and consumption.

AQSIQ and, in particular, its Import and Export Food Safety Bureau and Department of Animal and Plant Quarantine Supervision are responsible for the supervision of safety of food and agricultural products for export.

In both Provinces visited, the provincial level of CIQs is responsible for the registration of “farm basis”¹ and processing facilities/exporters of seeds for sprouting. The registered facilities are then entered into the database kept by the AQSIQ. The local offices in both Provinces visited by the audit team are responsible for issuing the export certificate for seeds for sprouting.

The local CAs of the MOA are responsible for the official safety control on agricultural food products, including seeds for human consumption and seeds for sprouting for domestic consumption.

Since August 2014, the local CIQs in Inner Mongolia are in charge of inspections of farms and processors/exporters dealing with mung beans for sprouting intended to be exported to the EU.

AQSIQ provides training on Good Agricultural Practices (GAP) to provincial staff. This knowledge is then transmitted via a cascade procedure to local staff, who in turn are responsible for the training of processors/exporters and farmers. In September 2013 local staff received training on the processing of seeds for sprouting, traceability and microbiological investigation of seeds for sprouting.

Specific training was provided to the CIQ inspectors on the production and processing of seeds for

¹A “farm basis” in the context of this report is a group of contracted farms that are merged to one or several big fields that are managed in a uniform manner.

sprouting to be exported to the EU in early July 2014. On 25 July a specific training on legal requirements for the exports of seeds for sprouting to the EU was provided to AQSIQ and CIQs by DG SANCO. AQSIQ informed the audit team that additional training is planned for 2015.

Conclusions

The CAs are designated and their responsibilities are defined in national legislation. The CAs have the authority to enforce the applicable legislation.

Local CIQs are in charge of official control on producers of mung beans for sprouting and exporters. Staff received training including on food safety requirements for the production of seeds for sprouting to be exported to the EU.

5.3 OFFICIAL CONTROLS

Legal requirements

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

Requirements contained in part II of the model health certificate for the import of seeds for sprouting established in the Annex to Regulation (EC) No 211/2013.

Articles 3,4 and 6 of Regulation (EC) No 852/2004 in connection with its Article 10.

The Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003, Rev. 2010) provides in Annex II recommended practices to prevent contamination of seeds from key risks such as water, animals, workers and manure.

Codex Alimentarius General principles of food hygiene (CAC/RCP 1-1969).

Findings

The CCA declared during the opening meeting that there are at present no applications from exporters to export seeds for sprouting other than mung beans. However, in case such applications are received the same control system will be applied also for other seeds. The CCA explained that the new control system was developed and implemented explicitly for seeds for sprouting.

The CIQ's inspectors met by the team stated that seed processing/exporting facilities are controlled at least once a year. This information was confirmed in all facilities visited.

The provincial CIQ together with the local CIQ in Inner Mongolia had conducted in August 2014 inspections for the registration of the farms and exporters dealing with mung beans intended to be exported to the EU. Three specialised inspectors were selected for the future inspections of farms and exporters of seeds for sprouting.

5.3.1 Documented Control Procedures

The inspections in seed processing facilities are carried out in accordance with General Working

Procedures for the Inspection and Quarantine of Export Plants and Plant-Derived Food Volume.

Forms and checklists for the registration and approval of “farm basis” and processors/exporters are available and in use.

New checklists for the farm and company inspections based on AQSIQ Directive 114/2014 were developed by AQSIQ after the training provided by DG SANCO and will be published in the coming weeks.

5.3.2 Registration of Food Business Operators

The CIQs, in accordance with the AQSIQ Circular on Strengthening the Administration of the Registration of Plant Product Exporting Enterprises (GuoZhiJian Dong Han [2008] No. 106), implement the registration of food processing plants for export and require FBOs to implement the additional requirements for the assessment of production and processing enterprises of seeds for sprouting intended for export to the EU.

Processors/exporters of seeds for sprouting intended to be exported to the EU must be approved by the regional CIQ. After the enterprise has sent an application to the CIQ, an on-the-spot inspection takes place and facilities are assessed under the criteria equivalent to Annex I to Regulation (EC) No 852/2004. The processors/exporters are required to implement procedures based on the Hazard Analysis and Critical Control Points (HACCP) principles. However, implementation of HACCP is not obligatory under current Chinese legislation.

In Inner Mongolia, one processor/exporter of seeds for sprouting to the EU was approved at the time of the audit by the CA to export seeds for sprouting to the EU. In Liaoning, currently five processors/exporters of mung beans for sprouting were approved by the CA following the same procedure. The audit team checked the related documentation (applications and inspection reports) of the six companies and found it comprehensive. The audit team was informed by the CCA that another five exporters are approved in Jilin Province for exporting mung beans for sprouting to the EU.

“Farm basis” producing seeds for sprouting intended to be exported to the EU must have contracts with the exporting companies and must be registered and approved by CIQs based on the Administrative Regulation for Filing of Plantations for export of Food Raw Materials (AQSIQ Announcement 56/2012). One precondition for the approval of a “farm basis” is a minimum size of the individual fields for growing mung beans. The audit team was informed that, in Inner Mongolia, the minimum size is 20 ha and in Liaoning Province 5 ha per field. After the exporting enterprise has sent an application for approval of the “farm basis” to the CIQ, an on-the-spot inspection takes place and field operations (pre- and post-harvest) are assessed under the criteria equivalent to Annex I to Regulation (EC) No 852/2004 for fulfilling the requirements of Regulation (EC) No 211/2013. Recommendation No. 1 of the last audit report, *ensure that all farms where seeds for sprouting for export to the EU are produced are under official food safety controls, to ensure that produce exported to the EU meets the requirements of Article 3 of Regulation (EU) No 211/2013*, was therefore fully addressed.

5.3.3 Cultivation

The main mung bean production areas in China include Jilin, Heilongjiang, Henan, Shanxi and Inner Mongolia Provinces. The main types are shiny mung beans, golden mung beans and dull

mung beans.

The representatives of the Chinese CAs explained to the audit team that for the production of seeds for sprouting intended to be exported to the EU a low risk supply chain was implemented. The chain consists of growing the mung beans on large scale fields by approved farms, preferably harvesting with combines, filling of the beans directly after harvest into bags and transport of the produce directly after harvest to the protected areas at the approved exporter's facilities. In this way there is no or very limited risk for microbial contamination of the produce. AQSIQ has developed and published a specific Directive for GAP and Good Hygiene Practices (GHP) covering hygiene aspects for the whole production chain of seeds for sprouting (AQSIQ Directive Nr. 114/2014).

In Inner Mongolia the audit team visited three fields for growing mung beans. The fields are located remotely in a large scale industrial farming environment with field sizes between 20 and 150 ha. The first field visited belonged to a grower that is not registered with AQSIQ and the beans were not intended to be exported to the EU. The field had a size of 25 ha and harvest was in full swing. The workers had cut the bushes with mung beans and deposited the bushes on heaps on the field for drying. Afterwards the produce would be transported to a threshing place for threshing.

The second field belonged to the exporting company and had a size of 20 ha. Threshing was already finished and the traces of mechanised threshing with a combine were to be observed on the field. The farmer explained that the threshed beans were directly filled from the combine into bags that are instantly transported to the company for storage and cleaning. The third field belonged also to the company and had a size of 90 ha. The field was also already harvested like the previous field. The audit team considered the risk for microbial contamination of the mung beans produced on the fields visited to be low.

The processors/exporters visited by the audit team in Liaoning Province explained to the audit team that their "farm basis" are located in Northern China and would be ready for harvest in the coming two weeks. The mung beans are grown on fields with a minimum size of 5 ha. Harvest will be done with combines and the produce will be transported to the exporters facilities directly after harvest. Liaoning CIQ stated to the audit team that inspections would be carried out at the "farm basis" shortly before or during harvest to check the compliance with the requirements of Regulation (EC) No 211/2013.

5.3.4 Processing and Storage

In Liaoning Province, the audit team visited two approved processors/exporters of seeds for sprouting.

The first processor/exporter visited, is prepared to export approximately 200 tonnes of mung beans for sprouting to the EU. The company has a "farm basis" of about 10000 ha in Heilongjiang. He contracted approximately 35 farmers on 400 ha for producing mung beans for sprouting to be exported to the EU. The processor provides farmers with advice on cultivation on the basis of written guidelines. The processor stated that the mung beans intended to be exported to the EU are transported to the processing plant in Dalian directly after harvest and that beans in need of drying after harvest are not considered for export to the EU.

The company has a designated store for produce to be exported to the EU. The processing includes machine cleaning, sorting and packing. The processor was inspected regularly by the CIQ and no non-compliances were recorded by the CA. The processor had a HACCP plan in place. A

traceability exercise was not possible as the store was empty. The audit team assessed that the facility visited was in compliance with requirements of Codex Alimentarius General Principles of Food Hygiene (CAC/RCP 1-1969) and the FBO was aware of risks associated with its activities.

The second processor/exporter visited had also been visited during the previous audit. In 2012 he exported to the EU approximately 1,000 tonnes of mung beans, 4,000 tonnes of soya beans, 300 tonnes of red beans and 25 tonnes of alfalfa seeds for sprouting. In March each year the processor contracts approximately 45 farmers in Inner Mongolia. The producers are provided with written information on mung bean production by the company. The processor stated that the mung beans intended to be exported to the EU are transported to the processing plant in Dalian directly after harvest. The produce is sorted, cleaned and packed by machines in a protected area. The company has a designated storing place for produce to be exported to the EU. Since the introduction of the new Chinese legislation, the company has not exported seeds for sprouting to the EU. The processor has a HACCP system in place and is able to trace internally produce back to the “farm basis”. The audit team assessed that the facility visited was in compliance with the requirements of Codex Alimentarius General Principles of Food Hygiene (CAC/RCP 1-1969). The shortcomings regarding the storage facilities which had been identified in the previous FVO visit had been rectified. No seeds for sprouting are stored outside and a pest monitoring and control programme was implemented. The CA confirmed that other FBOs had implemented pest control systems. Therefore, recommendation No. 2 of the last audit report, *ensure that the storage conditions and the prevention of pests entering processing and storage facilities for seeds for sprouting comply with the requirements set out in the CODEX Code of Practice CAC/RCP 1-1969 – General Principles of Food Hygiene section 6.3.2.*, was addressed. The FBO was aware of the risks associated with its activities.

In Inner Mongolia Province one processor/exporter is approved by CIQ for exporting seeds for sprouting to the EU. The audit team visited this company which handles produce from approximately 6000 ha every year. The company previously exported annually approximately 1,000 tonnes of mung beans to Europe. The processor did not export any batch of seeds for sprouting to the EU since July 2013. However, he is newly approved under the provisions of AQSIIQ directive 2012/52 for export of mung beans to Europe. The audit team examined the comprehensive inspection report for the registration produced by the local CIQ inspectors.

The FBO had implemented a HACCP based food safety control system. The FBO was able to trace back produce at the store for export produce back to the “farm basis”. The facility visited had a designated area for produce to be exported to the EU and was in compliance with requirements of Codex Alimentarius General Principles of Food Hygiene (CAC/RCP 1-1969).

At the local CIQ office, the audit team examined the inspections reports of the company from 2013 (3 inspections) and 2014 (4 inspections). The reports indicated that proper hygiene checks were conducted and recommendations were systematically followed-up. The local CIQ inspector stated that he inspected over a longer time the agricultural production of the company in relation to other commodities and no deficiencies in terms of hygiene were detected. The representative of AQSIIQ confirmed that the farming land related to the company operations was inspected several times in 2013 and 2014.

The FBO produces mung beans to be exported to the EU on 2000 ha own agricultural land that is divided in about 60 plots. The exporter co-operates additionally with 7 contracted growers (800 ha).

5.3.5 *Non- Conforming Products*

The CA informed the audit team that no non-compliant official samples of the seeds for sprouting were recorded by the CAs up to the time of the audit.

Conclusions

The CAs of China explained that at the time of the audit there were no applications from exporters to export seeds for sprouting other than mung beans.

The Chinese CAs have implemented a system for registration and approval of exporters and farm operations dealing with the production and export operations for mung beans for sprouting intended to be exported to the EU. At the time of the audit eleven exporters for mung beans for sprouting were approved by the Chinese CAs for exporting to the EU.

Recommendation No. 1 related to official controls and recommendation No. 2 related to storage conditions and pest control made in the last audit report were fully addressed.

There is a comprehensive system in place to control producers and exporters of seeds for sprouting intended to be exported to the EU from the point of view of food hygiene. There is a CA designated to ensure that those establishments comply with the requirements equal to Article 4 of Regulation (EC) No 852/2004 in conjunction with Article 10 and Annex I of the same Regulation.

There is specific information on GAP available for growers of seeds for sprouting.

Traceability of the products was ensured as required by Section IX product information and consumer awareness of the Codex Alimentarius Code of Practice CAC/RCP1-1969- General Principles of Food Hygiene.

At the processors/exporters visited, Good Manufacturing Principles (GMP) established in the Codex Alimentarius Code of Practice CAC/RCP1-1969- General principles of food hygiene were followed.

5.4 METHOD OF SAMPLING

Legal Requirements

The Codex General Guidelines on sampling (CAC/GL 50-2004) provides fair and valid sampling procedures to be used when food is being tested for compliance with Codex commodity standards.

Regulation (EU) No 211/2013 amended by Regulation (EU) No 704/2014.

Findings

AQSIQ published on 19/08/2014 Directive Nr. 114 about controls of seeds intended to export to Europe for sprouting purposes. Part two of the Directive defines the Chinese sampling standard for seeds intended to be exported to Europe for sprouting purposes. Chapter three lays down the batch size, Chapter four the number of samples to be taken and Chapter five the sampling procedure for microbiological testing of seeds intended to be exported to Europe for sprouting purposes. The practical application of the new sampling procedure was shown to the audit team in a laboratory

report concerning the investigation of mung beans in the CIQ laboratory in Dalian. The analysis was carried out using five sub-samples (5 kg) of a batch as laboratory samples, investigated separately.

Recommendation No. 4 of the previous audit, *ensure that sampling procedures for microbiological analysis of seeds for sprouting intended for export to the EU, in particular the representativeness of the laboratory sample, meet requirements at least equivalent to those laid down by CODEX Alimentarius General Guidelines on sampling CAC/GL 50-2004 chapters 2.1.2. and 2.3.3.*, was therefore addressed.

Conclusions

The new sampling procedure in place is considered to be comprehensive and recommendation No. 4 of the previous audit was fully addressed.

5.5 LABORATORY SERVICES

Legal requirements

Article 46(1)(d) of Regulation (EC) No 882/2004 stipulates that EU controls shall have, *inter alia*, particular regard to the resources, including diagnostic facilities, available to CAs in the performance of official controls.

Points 41 and 42 of CODEX Guidelines CAC/GL 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.

Findings

General Organisation

The laboratory services for testing seeds for sprouting are comprised of official and private laboratories. The official laboratories operate as technical centres for the local CIQ. The official microbiological laboratories are ranked on three levels: on the first level the regular laboratories, followed by the regional key laboratories and on the third level, the national key laboratories. Method development and implementation of international standards into the national system is done by the key laboratories. The official microbiological laboratories also provide services for local CIQs and FBOs. The audit team visited the national key laboratory in the Liaoning Province, the CIQ laboratory in Dalian.

CIQ Laboratory in Dalian

The laboratory is accredited according to the International Organisation for Standardisation (ISO) 17025:2005 as an analytical laboratory for microbiological and molecular tests of food and food products by two National Chinese accreditation bodies and also by the South Korean accreditation organization. There is also an accreditation for providing proficiency tests (PTs). The accreditation is granted under a fixed scope regarding matrices and methods. There is a quality management system in place comprising, *inter alia*, external and internal audits, participation in national and international PTs including the detection of common food borne pathogens like *Salmonella spp.* and *Listeria monocytogenes*.

The laboratory staff includes, inter alia, two researchers, 10 technicians and six assistant researchers. The laboratory is adequately equipped and staffed for the whole range of microbiological analysis including the detection of food borne pathogens in seeds for sprouting. The laboratory layout and sample handling is appropriate to prevent cross contamination leading potentially to false positive results. The equipment for identification of bacterial strains (e. g. MALDI-TOF mass spectrometry) guarantees a high quality level for microbiological investigation. The laboratory is also well equipped and organized for molecular analysis, especially real-time-PCR.

Detection of Shiga Toxin-producing *Escherichia coli*

For the detection of STEC, CEN ISO/TS 13136:2012 was implemented in the laboratory, the verification was finalized and summarized in a verification report provided to the audit team. Since 2014 the detection of STEC according to the CEN ISO/TS 13136:2012 is also part of the accreditation. Therefore recommendation No. 6 of the previous report, *it should be ensured that the laboratory method used for the STEC analysis is accredited as required by CODEX Alimentarius Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems Section 6*, was fully addressed.

In 2014 the laboratory organized a national proficiency test for the detection of food borne pathogens, including STEC and *Salmonella spp.* as target organisms, the matrix used for the PT was artificially contaminated mung beans.

The laboratory took part in 2014 in a PT provided by an international service provider for the detection of *Salmonella spp.* in vegetable salad. The result was satisfactory.

Sample investigation

In the sample registration area the status of the incoming samples is checked, every sample is registered in the laboratory resources planning system and labelled with a bar-code. This system allows the tracing throughout the analytical process and is also part of the test report. At present mung beans for sprouting are not exported to the EU, therefore an example of a test report for the analysis of mung beans used for other purposes was provided to the audit team. The analysis was carried out using five sub-samples (5 kg). Every sub-sample was analysed for the presence of STEC, *Salmonella spp.*, *Listeria monocytogenes* and *Staphylococcus aureus*.

The test report provided to the audit team for testing of mung beans was designed according to CODEX Alimentarius General Guidelines on sampling (CAC/GL 50-2004) section 2.3.7 in connection with section 2.3.3. In the report the official sample was clearly to identify. Therefore recommendation No. 5 of the previous report, *it should be ensured that the official sample used for the decision for export to the EU is clearly identified in line with CODEX Alimentarius General Guidelines on sampling (CAC/GL 50-2004) section 2.3.7 in connection with section 2.3.3.*, was fully addressed.

Conclusions

The CIQ Laboratory in Dalian is adequately equipped and staffed for the whole range of microbiological analysis and also for molecular investigations.

The recommendations of the last FVO audit report relating to the identification of samples (No. 5) and the accreditation of a method (No. 6) were both fully addressed.

5.6 CERTIFICATION PROCEDURES FOR EXPORTING TO THE EU

Legal Requirements

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

Article 3 of Regulation (EU) No 211/2013.

Findings

The main points of export are in Liaoning Province, Jilin Province and Inner Mongolia. The ports for export are Dalian Port and Tianjin Port.

In both Provinces visited, the procedure for approved exporters of mung beans for sprouting is to request the local CIQ to issue a certificate for export, based on Regulation (EU) No 211/2013. The certificate for export is issued by local CIQ staff on the basis of inspections carried out in the processing/exporting facilities and “farm basis”, which covers requirements equivalent to those set down in Annex I to Regulation 852/2004. The new procedure in place requires control activities of the local CIQs concerning the hygienic production of seeds for sprouting.

On the basis of the certificate for export, the local CIQ issues an additional document for customs clearance. Customs clear the consignment on the basis of this document.

AQSIQ and the regional CIQs visited informed the audit team that no sprouts are exported from China to the EU at present. However, in Inner Mongolia the exporter is ready for export and in Liaoning Province the final inspections prior to harvest and during harvest were to be conducted during the two weeks following the FVO audit in order to fulfil the requirements of Regulation (EU) No 211/2013.

Conclusions

The procedure for export certification of seeds for sprouting can attest that mung beans for sprouting were produced under conditions which comply with the general hygiene provisions for primary production as mentioned in Annex I, Part A of Regulation (EC) No 852/2004 and associated operations as required by Regulation (EU) No 211/2013. Approved exporters from Inner Mongolia and Liaoning Province are ready or almost ready to export mung beans for sprouting to the EU.

5.7 RESPONSE TO RASFF NOTIFICATIONS

Legal requirements

Point 6 of Codex Guidelines CAC/GL 25-1997 requires exchange of information between countries on rejections of imported food. In particular, the food control authorities in the exporting country should undertake the necessary investigation to determine the cause of any problem that has led to a rejection of the consignment. If requested, the food control authority in the exporting country should provide the authorities in the importing country with available information on the outcome of the necessary investigation. Bilateral discussions should take place as necessary.

Findings

The Import and Export Food Safety Office of the AQSIQ is responsible for receiving and responding to Rapid Alert System for Food and Feed (RASFF) notifications.

The AQSIQ receives RASFF notification, notifies relevant CIQ, which notifies subordinate inspection and quarantine agencies. The enterprises are requested to investigate relevant micro-organisms and send back investigation results to inspection and quarantine agencies. The agencies send feedback to CIQ which informs AQSIQ of the results.

At the time of the audit there was no notification concerning seeds for sprouting from China.

Conclusion

There is an adequate system in place for follow-up of the RASFF notifications.

6 OVERALL CONCLUSIONS

Significant progress was made by the Chinese Competent Authorities (CAs) since the last audit in 2013 and all six recommendations made in the report of that audit were fully addressed.

The CAs have implemented the requirements of the EU legislation on hygiene for exports of mung beans for sprouting. A new control system has been devised explicitly for seeds for sprouting for export to the EU. This is based on registration and approval of farms by regional CAs and the introduction of specific official controls of farms and processors/exporters. The processing facilities visited by the audit team followed Good Hygiene Practices. The laboratory visited was accredited and suitable for the purpose of official microbiological analysis including Shiga Toxin-Producing *Escherichia coli*.

At the time of the audit there were no export certificates being issued by the CAs of China for seeds for sprouting to be exported to the EU. However, the system of official food safety controls currently in place can assure that the mung beans for sprouting were produced under conditions which comply with the general hygiene provisions for primary production and associated operations set out in Part A of Annex I to Regulation (EC) No 852/2004 as required by Article 3 of Regulation (EU) 211/2013. The system in place enables the CAs of China to issue the required export certificates. This applies already for the 2014 harvest.

The report contains no recommendations to China.

7 CLOSING MEETING

A closing meeting was held on 22 September 2014 with representatives of the CCA, CAs, private sector representatives and the EU Delegation to China. The audit team presented the main findings and preliminary conclusions of the audit. The CAs made initial comments and provided some additional information.

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 211/2013	OJ L 68, 12.3.2013, p. 26-29	Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts

ANNEX 2 - STANDARDS

Reference	number	Full title Publication details
CAC/GL 25-1997	Guidelines for the exchange of information between countries on rejections of imported food (CAC/GL 25-1997).	http://www.codexalimentarius.org/
CAC/GL 26-1997	Guidelines on the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1997).	http://www.codexalimentarius.org/
CAC/GL 27-1997	Guidelines for the Assessment of the competence of testing laboratories involved in the import and export control of food (CAC/GL 27-1997).	http://www.codexalimentarius.org/
CAC/GL 50-2004	General Guidelines on Sampling (CAC/GL 50-2004).	http://www.codexalimentarius.org/
CAC/RCP 53-2003	Code of hygienic practice for fresh fruits and vegetables (CAC/RCP 53-2003).	http://www.codexalimentarius.org/
CAC/RCP 1-1969	General principles of food hygiene (CAC/RCP 1-1969).	http://www.codexalimentarius.org/