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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

CHINA

FROM 21 TO 28 OCTOBER 2013

IN ORDER TO ASSESS THE CONTROL SYSTEMS IN PLACE TO CONTROL  
MICROBIOLOGICAL CONTAMINATION IN SOFT FRUIT INTENDED FOR EXPORT TO  
THE EUROPEAN UNION

## ***Executive Summary***

*This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in China from 21 to 28 October 2013.*

*The objective of the audit was to assess the systems in place to control microbiological contamination in soft fruit intended for export to the European Union (EU).*

*This audit was included in the FVO 2013 audit programme due to the volume of exports of these commodities to the EU combined with the number of notifications in the Rapid Alert System for Food and Feed (RASFF). Strawberries from China have been listed since 1 January 2013 under Regulation (EC) No. 669/2009 with a control frequency for Noroviruses (NoV) and Hepatitis A Virus (HAV) of 5%. Since then, two RASFF notifications concerning NoV in strawberries, originating from China, were issued.*

*The Chinese Competent Authorities (CA) have put in place official controls on the production and processing of soft fruit. The official control system is based on an adequate legal framework and includes documented control procedures, the obligation for food operators to register and to implement Good Hygiene Practice (GHP) and Hazard Analysis and Critical Control Points principles (HACCP).*

*However, in some cases the evaluation of the HACCP based procedures was not sufficiently thorough to allow for an assessment of compliance with national requirements in the context of equivalence as set out in Article 5 of Regulation (EC) No 852/2004. No processor considered viruses as a hazard in soft fruit in the risk assessments for the HACCP plans.*

*In 2013, strawberries intended for export to the EU were sampled and analysed for NoV with a frequency of about 50% in Shandong province and about 20% in Liaoning province.*

*The effectiveness of the system is undermined by the sampling and testing procedures applied by the officially designated laboratories for NoV/HAV analyses. The procedures do not allow for the analysis of soft fruits with the sensitivity considered necessary and could not provide sufficient guarantees that exported consignments are in line with EU food safety requirements.*

*The report contains recommendations to the CA of China aimed at addressing the identified shortcomings.*

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**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

<b>Abbreviation</b>	<b>Explanation</b>
AQSIQ	General Administration of Quality Supervision, Inspection and Quarantine
CCA(s)	Central Competent Authority(ies)
CA(s)	Competent Authority(ies)
CAC/GL	Codex Alimentarius Commission/Guideline
CEFAS	Centre for Environment, Fisheries & Aquaculture Science of the United Kingdom
CFPQS	Centre for Farm Produce Quality & Safety
CIQ	Entry-Exit Inspection and Quarantine Bureau
CNAS	China National Accreditation Service for Conformity Assessment
CNCA	Certification and Accreditation Administration of the People's Republic of China
CODEX	Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization
CCP(s)	Critical Control Points(s)
EC	European Commission
EU	European Union
EURL	European Union Reference Laboratory
EUROSTAT	Statistical Office of the European Union
FBO(s)	Food Business Operator(s)
FVO	Food and Veterinary Office

GAP	Good Agricultural Practices
GHP	Good Hygiene Practice
HACCP	Hazard Analysis Critical Control Points
HAV	Hepatitis A Virus
ISO	International Organisation for Standardisation
LIMS	Laboratory Information Management System
MS(s)	Member State(s)
NHFPC	National Health and Family Planning Commission
NoV	Noroviruses
PCR	Polymerase Chain Reaction
PPP(s)	Plant Protection Product(s)
RASFF	Rapid Alert System for Food and Feed
RNA	Ribonucleic Acid
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
SOPs	Standard Operating Procedures
TC(s)	Third Country(ies)

## 1 INTRODUCTION

The audit took place in China from 21 to 28 October 2013 in order to assess controls on microbiological contamination in soft fruit intended for export to the European Union (EU). The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one national expert from a 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 a representative from the Central Competent Authority (CCA) the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

An opening meeting was held on 14 October 2013 with the CCA, and the EU Delegation to China. During the meeting, the audit objectives, itinerary, and the standard reporting procedures were confirmed.

## 2 OBJECTIVES

The objective of the audit was to evaluate official controls in relation to the production and processing of soft fruit intended for export to the EU within the framework of Regulation European Commission (EC) No 178/2002 and Regulation (EC) No 852/2004.

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

In pursuit of this objective, the following sites were visited:

**Table 1: Audit visits and meetings**

Visits/Meetings		Comments
<b>Competent Authorities</b>		
Central	2	Opening meeting was attended by AQSIQ and closing meeting by AQSIQ and Entry-Exit Inspection and Quarantine Bureau (CIQs) from Shandong and Liaoning Provinces
Regional	1	Shandong Province CIQ
	1	Liaoning Province CIQ
<b>Laboratories</b>		
Public	1	Shandong CIQ laboratory in Qingdao
	1	Liaoning CIQ laboratory in Dalian
<b>Establishments</b>		
Food processors	2	Shandong Province
	2	Liaoning Province
Farms producing strawberries	2	Shandong Province
	2	Liaoning Province

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

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 each section.

### **4 BACKGROUND**

#### **Norovirus and Hepatitis A Virus**

Article 50 of Regulation (EC) No 178/2002 requires that information on foodstuffs and feedingstuffs found to have public health implications is disseminated as notifications through the Rapid Alert System for Food and Feed (RASFF) to all MSs and to the exporting country. The finding of Noroviruses (NoV) is usually related to a food borne outbreak after consumption of contaminated foodstuffs. In 2012, there was an outbreak reported by Germany. The outbreak led to more than 11 000 people, most of them schoolchildren, falling ill as a result of acute gastroenteritis in Berlin, Brandenburg, Thuringia, Saxony and Saxony-Anhalt. This outbreak was linked to a batch of deep-frozen strawberries originating from China (Shandong province).

From 2006, up until the time of the audit there were five RASFF notifications concerning NoV in soft fruit from China, three related to strawberries and two related to raspberries. One notification concerned Hepatitis A Virus (HAV) in frozen strawberries. Strawberries from China have been listed since 1 January 2013 under Regulation (EC) No. 669/2009 with a control frequency for NoV and HAV of 5%. Since then, two RASFF notifications concerning NoV in strawberries, originating from China, were published.

**Table 2: Imports of frozen soft fruit (tonnes) from China 2011 and 2012, data from the Statistical Office of the European Union (Eurostat)**

Imports (tonnes)	2011	2012
Frozen strawberries (CN 081110)	65737	118795
Other frozen soft fruit (CN 081120)	4152	9384

**Table 3: Production and processing of strawberries and other soft fruit (data from Chinese CA)**

Year	Cultivated area (in hectare)	Number of		
		Producers	Processors	Exporters
2011	9759,8	510	183	283
2012	9195,6	416	195	349

The main growing areas of soft fruit intended for export to the EU are located in Shandong and Liaoning provinces.

The CIQ of Shandong informed the audit team that in 2013 exports from this province accounted for 15 046 tonnes of frozen strawberries and no other soft fruit was exported to the EU. The CIQ of Liaoning informed the audit team that in 2013, exports from Liaoning accounted for 10 490 tonnes of frozen strawberries, 3 003 tonnes of frozen raspberries and 24,7 tonnes of frozen blueberries.

The Shandong and Liaoning CIQs stated that they exported to about 16 MSs. Eurostat data indicates the import of frozen soft fruit from the whole of China to 24 MSs.

Due to the high volume of soft fruit exported to the EU and the number of RASFF notifications concerning NoV and HAV in soft fruit, originating from China, the FVO undertook this audit to China.

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 RELEVANT 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.

Article 10 of Regulation (EC) No 852/2004 requires that imported food meet the hygiene requirements as laid down in Articles 3 to 6 of this Regulation.

#### **Findings**

China's national legislation is as follows:

- Food Safety Law of June 2009 and Regulations for the Implementation of Food Safety Law establishing national food standards, the setting up of the National Food Safety Commission, the food recall procedure, the requirement of food processors to keep extensive records, stipulating food safety risk surveillance and assessment and making FBOs liable for food safety violations;
- Administrative Provisions for the Registration of Food Processing Enterprises for Export, were adopted by Decree No 142 in July 2011, with effect from 1 October 2011 and the deadline for implementation is the end of 2013. These provisions will replace the current Administrative Provisions on Sanitary Registration and Enrolment of Food Processing Enterprises for Export, adopted by AQSIQ Order No 20 of 2002. The audit team was informed that under these new provisions, the food processing enterprises for export shall establish and maintain food safety control systems focusing on hazard analysis and preventive control measures;
- Special Rules on Strengthening the Supervision and Management of the Safety of Food and Other Products were promulgated by the State Council and took effect on 26 July 2007. According to the Special Rules, food processors/exporters must ensure that exported foodstuffs meet the standards set by the importing countries. Furthermore, the Special Rules set out the enforcement powers and responsibilities of the CAs, and the sanctions they could impose.
- Administrative Measures for Inspection and Quarantine of Exported Fruits
- Provisions on Registration of Production Bases (farms) of Raw Materials of Exported Food

Specific notices related to strawberries are:

- The Administrative Measures concerning the publication of "Inspection and quarantine control standards for frozen strawberries intended for export" (Quality Inspection Notice (2013) no 226). A registration system for farming operators and producers of frozen strawberries intended for export has been set up in accordance with this notice;
- "2013 risk monitoring and control plan for the import and export of agricultural food products and feed" (National Quality Inspection Notice (2013) no 78) lays down, for example, sampling procedures for micro-organisms by AQSIQ. The audit team was informed that the risk control plan also applies to all frozen soft fruits for export;
- "Warning report relating to the need to improve quarantine inspections for frozen strawberries" (Quality Inspection Notice (2012) no 221);
- "Inspection procedure for exported frozen strawberries" (SN/T1046-2002).

## **Conclusions**

Chinese legislation provides the legal framework for the system of official control of soft fruit exported to the EU to comply with requirements at least equivalent to those as set out in Articles 3 and 6 of Regulation (EC) No 853/2004 on food hygiene.

## 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 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

Under the Food Safety Law of 2009, the State Council established the National Food Safety Commission (in February 2010) which co-ordinates and supervises the CAs responsible for food safety. AQSIQ's Animal and Plant Quarantine Department is the main CA for this audit.

AQSIQ is responsible for the quarantine inspection, registration and supervisory management of soft fruit producers, processors and exporters. AQSIQ designates the CIQ in each region to carry out the quarantine and management tasks relating to soft fruit. The CIQs are responsible for the formulation of standards, guides, Standard Operating Procedures (SOPs), instructions on Good Agricultural Practices (GAP), management and supervision on the soft fruit plantation and harvest processes, monitoring of water for irrigation and atmospheric conditions in the plantation areas. The Certification and Accreditation Administration of the People's Republic of China (CNCA) is in charge of the administration of the sanitary registration (filing) of processing companies, formulating rules on sanitation and providing guidance for certification. The CNCA authorises the CIQs to carry out the day-to-day work on the registration of food processors. Provincial CIQs provide registration data to the CNCA. The audit team was informed by the CAs that annual monitoring of microbial contamination in soft fruit intended for export, as required by AQSIQ, is carried out by the CIQs.

The audit team visited two provincial CIQs. The Shandong CIQ has 23 local CIQ branches and 19 representative offices, from which 13 CIQ branches with about 70 staff are involved in the inspection of soft fruit including testing soft fruit intended for export. The Liaoning CIQ has 16 local CIQ branches, of which 3 branches with about 150 staff are involved in the inspection of soft fruit and testing soft fruit intended for export.

The provincial CIQs visited undertake measures for the prevention of microbial contamination of soft fruit. They provide technical guidance and training for processors and growers.

The Food Safety Law gives the CAs the legal powers to have access to premises and documentation, and to take samples at food establishments. The audit team noted that inspectors could access premises and all documentation necessary for the purposes of checking compliance with food hygiene requirements.

AQSIQ and CIQs apply a cascade training approach. For example, in April 2013, specific training on microbial contamination was organised by AQSIQ in Shandong. CIQ officials from Liaoning participated in this training and afterwards provided training to inspectors and processors in Liaoning.

CIQ inspectors participate in training courses provided by CNCA once a year. The audit team noted that all inspectors met had a good knowledge of most food hygiene requirements and they were able

to assess compliance with these requirements in a satisfactory manner. However, some deficiencies regarding the knowledge of the inspectors in terms of the management of potential contamination of soft fruit with viruses were observed.

The Centre for Farm Produce Quality & Safety (CFPQS) is responsible for carrying out risk assessments relating to the food safety of agricultural products and providing guidance relating to technical trade measures. CFPQS drafts national standards relating to agricultural products and their production. CFPQS is also responsible for safety controls relating to agricultural products and the production and dissemination of related information.

The Food Safety Standards and Supervisory Assessment directorate which is part of the National Health and Family Planning Commission (NHFPC) is responsible for drafting food safety standards; carrying out food safety tests and evaluating and communicating the findings; participating in the drafting of testing methods approved by qualified food safety testing organisations.

#### *Customs authorities*

The Customs administration of the People's Republic of China is responsible for the customs clearance of soft fruit consignments for export to the EU.

### **Conclusions**

The CAs in charge of official controls on soft fruit have been designated, have the necessary legal powers to carry out their attributed tasks effectively and have access to qualified staff. However, some weaknesses regarding the knowledge of inspectors in the area of hygiene management of viruses were detected.

## **5.3 OFFICIAL CONTROLS**

### **Legal requirements**

Articles 46(1)(e) and (b) of Regulation (EC) No 882/2004 stipulate 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.

The Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003, Rev. 2010) provides in Annex II 'Fresh Produce' recommended practices to prevent food handlers from contaminating food with viruses, in particular, NoV, due to poor personal hygiene.

Codex Alimentarius Guidelines (CAC/GL) on the application of the general principles of food hygiene on the control of viruses in food (CAC/GL 79-2012) provides guidance to the primary producers on how to prevent/minimise the presence of viruses in food and to the CAs on a framework for the control of viruses in food with a view to protecting the health of consumers and ensuring fair practices in the food trade.

## Findings

### 5.3.1 *Registration of Establishments*

A registration system for farming operations and processors of frozen soft fruit intended for export has been set up in accordance with the notification concerning the publication of the "Inspection and quarantine control standards for frozen strawberries intended for export" (Quality Inspection Notice (2013) no 226). Processors and farmers need to apply to the CIQ in charge for registration. After an on-the-spot inspection by the CIQ, registration is granted. The registration is valid for three years for farmers and for four years for processors.

The audit team was informed that in Shandong province there are 149 processors and 231 farms registered for strawberries. The register is published on the internet. In Liaoning province, 35 out of 50 registered farms and 29 out of 41 registered processors of soft fruit are involved in exports to the EU. The audit team confirmed that all FBOs visited were registered by CIQs.

### 5.3.2 *Documented Control Procedures*

AQSIQ and CIQs have developed several procedures, checklists and guidelines for the performance of official food controls, including:

A Manual of Procedures for conducting official controls of food establishments involved in soft fruit production and processing. This manual includes: a) relevant legislation, b) procedures for inspection of cold stores for fruit, c) procedures for official controls of food safety systems based on Good Hygiene Practice (GHP), GAP and Hazard Analysis Critical Control Points (HACCP) principles, d) checklists for evaluation of food hygiene requirements, HACCP plans, traceability systems and produce recall, e) template for inspection reports.

Checklists for auditing of production basis for registration and routine inspections were also used as a template for the reports. In all the establishments visited there was a uniform inspection approach, in line with the instructions as set out by AQSIQ and CIQ.

In both provinces the checklists for processors were identical. They contained, for example, details of hygiene procedures like personal hygiene and protection of the premises against intake of microbial contaminated material.

However, the checklists for farms regarding hygiene checks were more detailed in Liaoning. In Liaoning the routine inspection checklists for farms also contained detailed checks of the health status of staff, the use of gloves, disinfection of hands, temporary toilets and transport containers. The audit team was informed that checklists exist in Liaoning province since 2008.

### 5.3.3 *Official Controls*

CIQ inspectors audit farms and processors for registration and carry out routine inspections several times a year depending on the number of consignments intended for export. CIQ inspectors verify compliance with requirements for food hygiene at primary production stage and at processors. The audit team checked several audit reports on farms and processors in Shandong and Liaoning provinces. The reports were comprehensive and follow-up of any identified deficiencies was

performed and documented. During routine inspections of farms in Liaoning, the FVO team noted that inspectors perform a detailed check and report on the health status of staff, the use of gloves during harvest, disinfection of hands, availability of temporary toilets and the use of hygienic transport containers. However, the audit team was informed that such checks are not recorded in detail in Shandong.

The audit team was informed that producers' own safety checks are the primary means of safety control and that routine quarantine controls are only an auxiliary measure. In addition, pre-export sampling should be carried out for key export items. The usual frequency of sample taking at processors is determined by the number of consignments exported and varies from 1-2% for companies with more than 300 consignments and could go up to 5% for companies with less than 100 consignments.

From September 2012 up until March 2013, strawberries intended for export to the EU were sampled and analysed for NoV with a frequency of 100%. From March 2013 onwards, the control frequency varied between about 50% in Shandong and about 20% in Liaoning.

Before exporting any frozen strawberries, the consignor or the agent must contact the local inspection and quarantine authority to arrange an inspection. In Shandong about 50% of consignments exported to the EU in 2013 were tested for NoV, HAV and Salmonella with negative results. However, in Liaoning province in 2013, only 61 out of 390 exported consignments of strawberries to the EU were tested for NoV with negative results. Of the 126 consignments of raspberries and 5 consignments of blueberries exported from Liaoning to the EU no tests were performed.

#### *5.3.4 Visits to Farms*

The audit team visited two farms growing strawberries intended for export to the EU in Shandong province and two farms in Liaoning province. All farms belonged to the processors.

The farm managers of the farms visited used tailor-made GAP guidelines for the production of strawberries. The managers stated that the guidelines were developed based on information provided by CIQs. One processor visited stated that his farms had been inspected and certified up until 2010 by a private GAP scheme. He discontinued this practice because of the high costs involved.

The farm managers met were aware of the appropriate preventive measures that can be taken to manage microbial contamination of strawberries and the circumstances in which they should be employed. They applied GAP, such as the use of recommended mineral fertilisers and registered Plant Protection Products (PPPs), and the application of adequate irrigation systems where necessary. One of the farms visited had a drip irrigation system in place and the other one had a system that produces fog like fine drops of water. During the visits, interviews were held with the CIQ inspectors to confirm the content of the inspection reports presented and to explain the format and objectives of their inspections.

The CIQ inspectors met demonstrated good knowledge. They were able to check that farmers were aware of the measures that should be in place to prevent microbial contamination of strawberries and that PPPs and fertilisers had been correctly used.

In Liaoning province, the routine inspections of farms also includes checks of the health status of staff, the use of gloves, disinfection of hands, temporary toilets and cleanliness of transport containers. The manager of one of the farms visited in Liaoning stated that during the harvest

season mobile toilets are rented from the environmental protection bureau. The managers of the second farm showed the audit team that the company owned their own mobile toilets. The farm managers in Liaoning stated that workers are trained in hygiene measures before harvest. These training courses are considered to be good practice.

At the farms visited in Shandong the managers stated that during harvest the workers use the toilets and hand washing facilities in the office buildings which are not in close proximity to the fields as required by the Codex Alimentarius Code for fresh fruits and vegetables (CAC/RCP 53-2003) chapter 3.2.3.

### 5.3.5 Visits to Processors

In Shandong province the audit team visited three processors and in Liaoning province two processors, all of whom exported strawberries to the EU. The hygiene standards in the establishments visited was high and are in line with requirements which are equivalent to those as set out in Annex II of Regulation (EC) No 852/2004.

All processors visited had put in place a personal hygiene policy that included the need for personnel to undergo health screening, to receive training in food hygiene and to be supervised.

The CIQ inspectors met used checklists as a guide during their inspections. Their controls covered all relevant Chinese food hygiene requirements, including the implementation of HACCP based procedures and traceability systems. The implementation of food safety procedures based on HACCP principles is not a legal requirement for FBOs in China.

All processors visited had HACCP systems in place containing three Critical Control Points (CCPs) relevant to bacterial hazards. The CCPs had critical limits indicated and corrective measures to be applied. However, hazard analysis conducted by the FBOs did not consider the likely occurrence of viruses in soft fruits and the severity of their adverse health effects. No control measures to prevent, eliminate or reduce viral contamination of soft fruit were described in the FBO's HACCP plans. The measures were based on strict hygiene rules for production and personal hygiene.

At the processor visited in Shandong the audit team observed that during production of frozen strawberries, the fruits were washed in sodium hypochlorite solution (NaClO) of a concentration from 50 to 100 ppm for 120 seconds. However, a second processor uses the same concentration of NaClO but applies 30 seconds. In both facilities, the NaClO concentration is controlled as a CCP in the HACCP system.

According to point 6.1.2. of Codex Alimentarius CAC/GL 79-2012 (Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food) efficient inactivation of the relevant viruses requires a concentration of 1000 ppm free chlorine and 5 min exposure time.

The NaClO concentration and contact time applied by these processors do not allow inactivation of NoV and HAV. However, Coliform and *Escherichia coli* which are used as hygiene indicator organisms will be affected by this concentration of NaClO; therefore the testing of finished products in this fashion will mimic better hygienic conditions and cannot be used for risk assessment of viral contaminations.

The first processor visited in Shandong province exported approximately 2 900 tonnes of frozen strawberries and approximately 100 tonnes of blackberries and blueberries to the EU in 2012.

Since 2005, the company has a certified HACCP system in place and has been certified by a private post farm gate scheme since 2009. The company was inspected by the CIQ three times last year.

The company sources the majority of it's produce from their own farms. Approximately half of the

produce is grown in greenhouses and the rest in open fields. One out of six production bases is owned by around 35 contract farmers. The company provides support regarding implementation of GAP to the external growers in the form of advice and written instruction. The GAP instructions were developed with the support of the local CIQ and contain requirements regarding PPP use. However, hygiene requirements in relation to personal hygiene and field toilets are not part of the GAP instructions. The audit team was informed by the company that hygiene requirements are imparted orally.

The second processor visited in Shandong province exported approximately 120 tonnes of frozen strawberries to the EU in 2012. The company was suspended from exporting to the EU in 2013 as a result of its involvement in a RASFF notification concerning NoV.

The company has a certified HACCP system in place. However, the HACCP plan did not include in the list, hazards related to viruses. All CCPs were relevant to eliminate bacterial contamination. The company was inspected by the CIQ four times last year and the CIQ inspectors did not note that an assessment of viral hazard was not included in the hazard assessment.

The company sources all produce from contract farms that grow strawberries in open fields. The company provides support regarding GAP to external growers in the form of advice and written instruction. The GAP instructions were developed with the support of the local CIQ and contain requirements regarding PPP use. Hygiene requirements, with regard to personal hygiene etc. are imparted orally. The contracted farms are located around 100 km away from the farm. The produce is transported directly after harvest to the processor. The audit team checked the trays for transport and found them to be in line with hygiene requirements.

The third processor visited in Shandong province exported approximately 600 tonnes of frozen strawberries to the EU in 2012.

Since 2003 the company has a certified HACCP system in place and has been certified by a private post farm gate scheme since 2007. However, the HACCP plan did not include hazards related to viruses in the list. All CCPs were relevant to eliminate bacterial contamination. The company sources the produce from their own farms and the strawberries were produced in open fields.

The first processor visited in Liaoning province exported approximately 2 000 tonnes of frozen strawberries and 1 000 tonnes of raspberries to the EU in 2012.

Since 2005 the company has a certified HACCP system in place. However, the HACCP plan did not include hazards related to viruses on the list. All CCPs were relevant to eliminate bacterial contamination. The company was inspected by the CIQ four times in 2012. The company sources its produce from their own farms and strawberries were produced in open fields.

The second processor visited in Liaoning province exported approximately 20 tonnes of frozen strawberries to the EU in 2012.

Since 2003 the company has a certified HACCP system in place. However, the HACCP plan did not include hazards related to viruses on the list. All CCPs were relevant to eliminate bacterial contamination. The company was inspected by the CIQ four times in 2012 and CIQ inspectors did not note this.

The company sources produce from its own farms and strawberries were produced in open fields.

### *5.3.6 Non-Conforming Products*

The Food Safety Law of June 2009 and Regulations for the Implementation of Food Safety Law establish the food recall procedures.

According to AQSIQ's (National Quality Inspection Notice (2013) no 78) producers should establish appropriate control systems and corrective measures in response to food safety incidents (recall system).

However, no non-compliant products had been detected by the CAs at the time of the audit.

## **Conclusions**

Official controls are carried out according to documented procedures, including registration for food establishments. However, differences between the provinces visited were observed regarding checklists on hygiene requirements for farm operations. At the farms visited in Shandong the hygienic and sanitary facilities are not in close proximity to the fields as required by the Codex Alimentarius Code for fresh fruits and vegetables (CAC/RCP 53-2003) chapter 3.2.3.

The performance of official controls in relation to hygiene requirements which are largely equivalent to those as laid down by Regulation (EC) No 852/2004, are satisfactory. However, in some cases the evaluation of HACCP based procedures was not considered thorough enough to assess compliance with national requirements as equivalent to those set out in Article 5 of Regulation (EC) No 852/2004. No processor considered viruses to be a hazard in soft fruit in the risk assessments for the HACCP plans. No CCPs were of relevance to prevent viral hazards.

Compliance with the requirements for traceability was satisfactory.

## **5.4 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.

### **Findings**

The points of export of strawberries and other soft fruit to the EU are Shandong, Liaoning, Hebei, Heilongjiang and Jiangsu provinces.

Exporters must submit a notification to CIQ prior to export. CIQ staff are then required to perform either a documentary check or a documentary and physical check of the consignment. Based on the results of these controls, two certificates are issued which should accompany the consignment – a phytosanitary certificate and a certificate of origin. In addition, CIQ staff are required to issue a Customs Declaration. This document is required for the customs clearance for export. Physical pre-export controls at FBOs' premises are performed with the following frequency: at processors that export less than 100 consignments per year, 5% of the consignments should be sampled for microbial contamination, at processors that export 100 – 300 consignments per year 3 to 5% of the consignments should be sampled and at processors with more than 300 consignments per year 1 to 3% of the consignments should be sampled. This is the frequency of controls for exports of soft fruit in general.

However, since January 2013, in order to strengthen pre-export controls for strawberries in China, and in response to increased EU import controls for strawberries from China (Annex I to Regulation (EC) No 669/2009), the frequency of pre-export controls by CIQs had been increased.

## **Conclusions**

There are comprehensive export procedures in place. However, the effectiveness of the system is undermined by the sampling (see section 5.5) and testing procedures (see section 5.6) applied and could not provide sufficient guarantees that the exported consignments are in line with EU food safety requirements.

### **5.5 METHOD OF SAMPLING**

#### **Findings**

The sampling protocol in place uses a strategy based on document SN/T1046-2002 (Inspection procedure for exported frozen strawberries). This protocol does not consider the heterogeneous distribution of a viral contamination in the lot under investigation; stratified sampling is not applied. A sampling document showing a clear trace of the sample to the lot under investigation is not available. At present, traceability of the lot is spread over several documents issued during the sampling process.

The sample size of frozen strawberries for the laboratory is 2 kg according to the information provided by the local CIQ in Feng Cheng (Liaoning Province), and the technical centre of Shandong CIQ, whereas a 3 kg sample size was regarded as a correct sample size by the laboratory of the technical centre in Dalian.

Strawberry sampling in the field follows the standard SFB/T0159-1013, according to which 5 sub samples of 1 kg each need to be taken from different places in the field. The laboratory sample is a composite sample of a mixture of sub samples.

To date, no internationally agreed sampling protocol addressing the heterogeneous distribution of viral contamination in frozen soft fruits has been published. The CA considers it necessary to develop a sampling protocol for soft fruits. This could be accomplished on a scientific basis by experts from the parties involved.

## **Conclusions**

The sampling procedures as applied are not considered representative of the consignment nor of the lot. However, to date, no internationally agreed sampling protocol addressing the heterogeneous distribution of a viral contamination in frozen soft fruits has been published.

### **5.6 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 lay down that inspection services should utilize laboratories that are evaluated and/or accredited under officially recognised programmes to ensure that adequate quality controls are in place to provide for the reliability of test results. In accordance with the Guidelines of CODEX CAC/GL 27-1997, point 3, the laboratories should comply with International Organisation for Standardisation (ISO) 17025.

According to point 9 of the introduction into Codex Alimentarius CAC/GL 79-2012 (Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food) test results are subject to variability depending on the food product, the distribution of a virus within the food matrix and the presence of Polymerase Chain Reaction (PCR) inhibitors.

## **Findings**

### *General*

The laboratory services for testing viral contamination in soft fruit are provided by official laboratories. The official laboratories belong to the local CIQ as technical centres. These laboratories work relatively independently with regard to the methods applied. A national reference laboratory for viral contamination of food has not yet been nominated. Method development and implementation of international standards within the national system is done by key laboratories. Some lack of knowledge exchange between the laboratories is evident. Positive NoV control material is not available to ensure full method validation.

In Shandong province, five laboratories are responsible for carrying out tests for NoV and HAV in frozen soft fruits. In Liaoning province the tests are carried out by two laboratories. There were no reported positive findings of NoV or HAV in either of the laboratories.

### *CIQ Laboratory in Qingdao*

The laboratory responsible for testing soft fruit for viral contaminations is the Food and Agricultural Products Testing Agency and is part of the technical centre of Shandong CIQ. The laboratory is accredited by the national Chinese accreditation bodies CNCA and China National Accreditation Service for Conformity Assessment (CNAS). According to the information provided, the scope of accreditation does not comprise the detection of NoV and HAV in soft fruit. The laboratory visited organised and participated in a proficiency test for the detection of HAV in frozen soft fruit along with the five laboratories responsible for virological analysis of soft fruits in Shandong province.

The laboratory is properly equipped and adequately staffed. The personnel responsible had visited the European Union Reference Laboratory (EURL) for monitoring bacteriological and viral contamination of bivalve molluscs in May 2013.

The laboratory organisation follows the forward flow principle; cross contamination was prevented by separation of the different working areas. A Laboratory Information Management System (LIMS) allows for the simple registration of incoming samples and traceability of incoming samples throughout the analytical process.

There is a written SOP in place for testing NoV and HAV in frozen soft fruit based on ISO/TS

15216-2:2012. However, the analytical process is not monitored by the application of a process control as required. The audit team was informed that a process control based on the Mengo virus will be introduced in the future, as soon as the Mengo virus is multiplied by cell culture.

The laboratory assesses the method performance characteristics quantitatively by regular application of spiked samples of frozen strawberries using the HAV vaccine.

The size of incoming samples varies between 2 and 4 kg. Each sample was analysed in one test portion of 25 g throughout the whole process, resulting in one real-time reverse transcription-polymerase chain reaction (RT-PCR) result. A commercial kit based on silica columns applicable for total ribonucleic acid (RNA) was used for RNA extraction after virus extraction. A specific extraction kit for viral RNA is not in use. For real-time RT-PCR, a pre-manufactured commercial primer-probe system is used. Specific information about the sequence of the primer and probe sequences in this kit was not available. The sensitivity of the commercial system is 50 RNA copies according to the manufacturer's information. This is not considered to be sensitive enough for soft fruits.

#### *CIQ Laboratory in Dalian*

The laboratory is accredited according to ISO 17025:2005 as an analytical laboratory by the national Chinese accreditation bodies - CNCA and CNAS. The analysis of NoV and HAV has been in the scope of accreditation since July 2013. The written SOP follows the published procedure in line with the soft fruit protocol from the EURL for monitoring bacteriological and viral contamination of bivalve molluscs based on the Centre for Environment, Fisheries & Aquaculture Science of the United Kingdom (CEFAS) website, dated 23 November 2012. The written procedure, as presented in the Dalian technical centre does allow the application of other systems for RNA extraction and real-time RT-PCR. However, validation data indicating the method performance characteristics could not be provided. The accreditation by CNAS of the method for the analysis of soft fruits for NoV and HAV without verification of the validation data to be presented is not considered appropriate. The validation tests which were carried out consisted of two negative samples of frozen strawberries. Artificially contaminated positive samples were not used for method validation because of the lack of adequate positive control material.

The laboratory is adequately staffed in terms of the number of staff. It became evident during the audit that the staff members require more training in food virological methods.

Laboratory layout and sample handling is appropriate to prevent cross-contamination leading to false positive results. It is planned that the maintenance of the facilities and equipment will be improved in the future.

The LIMS allows the unambiguous registration of the incoming samples and tracing throughout the analytical process. However, the temperature of incoming samples is not registered in the LIMS.

The laboratory has a test method in place to test for HAV and NoV in soft fruits. This method follows the principles of ISO/TS 15216:2013 published online as "Protocol - Qualitative detection of NoV in soft fruit", issue No. 2, Date 23.11.2012:1-14, by the EURL for monitoring bacteriological and viral contamination of bivalve molluscs. However, information about the existence of ISO/TS 15216-2:2012 was not available. Deviations from the protocol of virus extraction, deviations in the application of the oligonucleotides and the RT-real-time PCR protocol were noticed by the audit team. The use of a portion of less than 50% of the virus extract for

downstream RNA extraction procedures reduces the sensitivity significantly; this could lead to false negative results. A process control, being mandatory according to ISO/TS 15216-2:2012, was not applied.

Instead of using primers and probes as laid down in the method description, a commercial kit system was used for molecular testing. The relevant sequence information of oligonucleotides in this kit was unavailable. Validation data of these deviations, especially with respect to their influence on method sensitivity, could not be presented. A process control which monitors the complete testing process is not carried out. This leads to insufficient information about the overall efficiency of the analysis. Instead of using a process control, an internal amplification control submitted together with the commercial kit system was used. This is not considered as being equivalent to a process control according to ISO/TS 15216-2:2012.

## **Conclusions**

At present there is no general system of NoV analysis in place for soft fruit being exported to the EU. The testing procedures as applied do not allow for the analysis of soft fruit with the sensitivity considered necessary.

The accreditation system of CNAS did not detect in the case of the visited laboratories inconsistencies between written procedures and actual analysis. Laboratory accreditation without full method validation like that observed in one of the laboratories is not in line with the requirements as specified in point 5.4.5 of ISO 17025:2005.

The analytical system in place could not provide a sufficient guarantee that exported consignments are in line with EU food safety requirements.

## **5.7 RESPONSE TO RASFF NOTIFICATIONS**

### **Legal requirements**

Point 6 of Codex Guidelines CAC/GL 25-1997 requires the exchange of information between countries on rejections of imported food. In particular, the food control authorities in the exporting country should undertake the necessary investigations 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 any available information on the outcome of the necessary investigation. If needed, bilateral discussions should take place.

### **Findings**

The RASFF notifications are received by the AQSIQ. The audit team was informed that not all RASFF notifications related to NoV in 2013 in strawberries had been received by AQSIQ.

There is a documented procedure in place for RASFF follow-up by the CAs. AQSIQ forwards all RASFF notifications concerning China's exported soft fruit to provincial CIQs, which are responsible for follow-up. The local CIQ requires the processor to prepare an investigation report and after that inspects the processor. Meanwhile, any export activities are suspended. The local CIQ provides the investigation report to the provincial CIQ and after reviewing it, the CIQ sends information for follow-up activities to AQSIQ.

In general, companies involved in a RASFF notification are suspended from EU export during the investigation and until such time as corrective measures are taken and the local CIQ have verified their implementation.

Provincial and local CIQs provided evidence of follow-up to RASFF notifications.

In response to RASFF notifications, there was evidence of the measures applied by the CIQ visited: strict pre-export inspection, increased frequency of laboratory analysis and health certification of consignments intended for export to the EU, regular supervision of processors, strict measures to deal with non-compliant consignments and imposing enforcement measures on RASFF notified products.

## **Conclusions**

There are administrative structures and clear procedures in place for the follow-up of RASFF notifications within AQSIQ. Adequate investigations were carried out in the companies notified via the RASFF.

### **6 OVERALL CONCLUSIONS**

The Chinese CA have put in place official controls on the production and processing of soft fruit. The official control system is based on an adequate legal framework and includes documented control procedures, the obligation for food operators to register and to implement GHP and HACCP principles.

However, in some cases the evaluation of the HACCP based procedures was not sufficiently thorough to allow for an assessment of compliance with national requirements in the context of equivalence as set out in Article 5 of Regulation (EC) No 852/2004. No processor considered viruses as a hazard in soft fruit in the risk assessments for the HACCP plans.

In 2013, strawberries intended for exported to the EU were sampled and analysed for NoV with a frequency of about 50% in Shandong province and about 20% in Liaoning province.

The effectiveness of the system is undermined by the sampling and testing procedures applied by the officially designated laboratories for NoV/HAV analyses. The procedures do not allow for the analysis of soft fruits with the sensitivity considered necessary and could not provide sufficient guarantees that exported consignments are in line with EU food safety requirements.

### **7 CLOSING MEETING**

A closing meeting was held on 28 October 2013 with representatives from the CCA. The audit team presented the main findings and preliminary conclusions of the audit. The CAs made initial comments and provided some additional information.

### **8 RECOMMENDATIONS**

The CAs are invited to provide, within 25 working days of receipt of this report, details (including completion deadlines 'action plan') of actions taken and planned to address the recommendations set out below.

Nº.	Recommendation
1.	Ensure that soft fruit intended for export to the EU comply with the relevant requirements of food law, as laid down in Article 11 of Regulation (EC) No 178/2002, or their equivalents, and do not contain noroviruses and/or Hepatitis A viruses.
2.	Ensure that the evaluation of the HACCP based procedures to assess compliance with national requirements is equivalent to those as set out in Article 5 of Regulation (EC) No 852/2004 in particular to ensure that all hazards are assessed including viral hazards.
3.	Ensure that sanitary facilities for personal hygiene are in close proximity to the fields in all provinces as required by Codex Alimentarius Code for fresh fruits and vegetables (CAC/RCP 53-2003) chapter 3.2.3.
4.	Ensure that laboratories performing official analysis for noroviruses and Hepatitis A viruses in strawberries to be exported to the EU use methods of analysis which have been validated according to the principles as laid down by the Codex Alimentarius Commission, to ensure that adequate quality controls are in place to provide for the reliability of test results (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997).
5.	Ensure the use of the ISO technical specification for analytical method for determination of noroviruses in food when testing soft fruit intended for export to the EU.

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

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2013-6682](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6682)

## 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. 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. 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. 2076/2005	OJ L 338, 22.12.2005, p. 83-88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 669/2009	OJ L 194, 25.7.2009, p. 11-21	Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC

**ANNEX 2 - STANDARDS**

<b>Reference number</b>	<b>Full title</b>	<b>Publication details</b>
CAC/GL 25-1997	Guidelines for the exchange of information between countries on rejections of imported food (CAC/GL 25-1997).	<a href="http://www.codexalimentarius.net/web/standard_list.jsp">http://www.codexalimentarius.net/web/standard_list.jsp</a>
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).	<a href="http://www.codexalimentarius.net/web/standard_list.jsp">http://www.codexalimentarius.net/web/standard_list.jsp</a>
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).	<a href="http://www.codexalimentarius.net/web/standard_list.jsp">http://www.codexalimentarius.net/web/standard_list.jsp</a>
CAC/GL 50 -2004	General Guidelines on Sampling (CAC/GL 50 -2004).	<a href="http://www.codexalimentarius.net/web/standard_list.jsp">http://www.codexalimentarius.net/web/standard_list.jsp</a>
CAC/RCP 53-2003	Code of hygienic practice for fresh fruits and vegetables (CAC/RCP 53-2003).	<a href="http://www.codexalimentarius.net/web/standard_list.jsp">http://www.codexalimentarius.net/web/standard_list.jsp</a>
CAC/RCP 1-1969	General principles of food hygiene (CAC/RCP 1-1969).	<a href="http://www.codexalimentarius.net/web/standard_list.jsp">http://www.codexalimentarius.net/web/standard_list.jsp</a>