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FINAL REPORT OF AN AUDIT  
CARRIED OUT IN  
INDIA  
FROM 09 DECEMBER 2014 TO 17 DECEMBER 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

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

## ***Executive Summary***

*This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in India from 9 to 17 December 2014. The objectives of the audit were to evaluate the control systems in place to control microbiological contamination in seeds for human consumption (in particular Salmonella contamination of sesame seeds as well as seeds for sprouting e.g mung beans and other seeds for sprouting) intended for export to the European Union (EU) in the framework of Regulations (EC) No 178/2002 and No 852/2004. The evaluation of procedures in place for certification for imports into the EU of seeds for the production of sprouts as required by Regulation (EU) No 211/2013 was also assessed.*

*This FVO audit to India on the microbiological controls of sesame seeds was undertaken as part of the 2014 FVO audit programme due to the number of Rapid Alert System for Food and Feed (RASFF) notifications linked to this issue.*

*There is no requirement for exporters of sesame seeds to the EU to be registered with the Shellac and Forest Products Export Promotion Council (SHEFEXIL), the competent authority responsible for sesame seeds. A number of exporters who were mentioned in RASFF notifications were not members of SHEFEXIL and could not be followed up by SHEFEXIL.*

*A number of consignments that were tested and found to be Salmonella and E. coli free prior to shipment from India were found to be Salmonella positive in the EU.*

*Overall, there are a number of significant gaps in existence which cannot assure that sesame seeds exported to the EU are safe. The CA responsible for sesame seeds, SHEFEXIL, does not carry out any controls on growers, processors or exporters of sesame seed. In addition, there is a failure to follow up RASFF notifications relating to sesame seeds in India. This is mainly due to a lack of co-ordination between the Ministry of Commerce and Industry which is the national contact point for RASFF in India and SHEFEXIL, which is responsible for following up on RASFF notifications relating to sesame seeds. Laboratories visited were capable of undertaking the relevant testing for Salmonella detection. However, the approach to sampling of consignments for microbiological testing prior to export could not ensure statistical representativeness.*

*The Agricultural and Processed Food Products Export Development Authority (APEDA) confirmed that they are the CA for sprouted seeds and seeds for sprouting. APEDA is aware of the certification requirements for imports into the EU of sprouts and seeds intended for the production of sprouts as required by Regulation (EU) No 211/2013. APEDA has received no requests from exporters for such certification to date, thus no certificates have been issued.*

*The report contains recommendations to India to address the shortcomings identified.*

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## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
APEDA	Agricultural and Processed Food Products Export Development Authority
CA(s)	Competent Authority(ies)
CCA	Central Competent Authority
CODEX	Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization
EFSA	European Food Safety Authority
EU	European Union
FBO(s)	Food Business Operator(s)
FNAO	Food of Non Animal Origin
FOSFA	Federation of Oil Seeds and Fats Association
FVO	Food and Veterinary Office
HACCP	Hazard Analysis and Critical Control Points
ISO	International Organisation for Standardization
IS	Indian Standard
MoCI	Ministry of Commerce and Industry
MS(s)	Member State(s)
NABL	National Accreditation Board for Laboratories
PT(s)	Proficiency Test(s)
RASFF	Rapid Alert System for Food and Feed
SHEFEXIL	The Shellac and Forest Products Export Promotion Council
SOP	Standard Operating Procedure
STEC	Shiga Toxin-Producing <i>Escherichia Coli</i>
TC(s)	Third Country(ies)

## **1 INTRODUCTION**

This audit took place in India from 9 to 17 December 2014 to assess the official control systems in place to control microbiological contamination in seeds for human consumption (in particular, *Salmonella* contamination of sesame seeds as well as seeds for sprouting eg. mung beans and other seeds for sprouting) intended for export to the European Union (EU). The FVO audit team comprised two auditors 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 FVO audit team was accompanied throughout the audit by representatives of the Central Competent Authority (CCA).

The opening meeting was held on 9 December 2014 with the CCA for exports of sesame seeds, the Ministry of Commerce and Industry (MoCI) and the Shellac and Forest Products Export Promotion Council (SHEFEXIL) as well as the Agricultural and Processed Food Products Export Development Authority (APEDA), the Competent Authority (CA) responsible for the certification of sprouted seeds and seeds for sprouting. During the meeting, the objectives of the audit, itinerary and the standard reporting procedures were confirmed.

## **2 OBJECTIVES**

The objectives of the audit were to evaluate:

- 1) the official control systems in place related to the production and processing of seeds for human consumption (in particular *Salmonella* contamination of sesame seeds and seeds for sprouting) intended for export to the EU in the framework of Regulation (EC) No 853/2004 and Regulation (EU) No 211/2013
- 2) procedures in place for the certification for imports into the EU of seeds for the production of sprouts required by Regulation (EU) No 211/2013

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 and the export certification procedure.

**Table 1: Audit visits and meetings**

Meetings/visits	Comments	
<b>Competent authorities</b>		
Central	2	Opening meeting, closing meeting and an information meeting were attended by representatives from the MoCI, SHEFEXIL and APEDA, producers and processors and representatives from laboratories.
<b>Laboratories</b>		
Private	3	Three private laboratories were visited.
<b>Processors /Exporters/Mandis</b>		
Processors/Packers/Exporters	5	Five Processors / exporters were visted
Mandis (auction areas)	2	Two mandis were visited.

### **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, after 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.

There is a requirement for certification of imports into the EU of sprouts and seeds intended for the production of sprouts as described in Commission Regulation (EU) No 211/2013. The FVO audit team reviewed the provisions in India for implementation of this requirement.

Since 1st October 2014 sesame seeds from India have been included in the list of products subject to an increased level (20%) of official controls to be carried out on imports of feed and food of non-animal origin (FNAO) at the points of entry in line with Regulation (EC) No 669/2009 due to *Salmonella* contamination. Between the period 01/10/2014 until 06/01/2015 there were 14 notifications on the Rapid Alert System for Food and Feed (RASFF) system related to sesame seeds from India being contaminated with *Salmonella*.

**Table 2 Exports of sesame seeds from India to the EU (SHEFEXIL)**

<b>Year</b>	<b>Imports of sesame seeds in tonnes</b>
2011-2012	65273.60
2012-2013	63723.83
2013-2014	71569.20

**Table 3 Exports of alfalfa seeds from India to the EU (APEDA)**

<b>Year</b>	<b>Imports of alfalfa seeds in tonnes</b>
2012-2013	22
2013-2014	1494.25
2014-2015	32 (to October 2014)

**Table 4 Exports of mung beans from India to the EU (APEDA)**

<b>Year</b>	<b>Imports of mung beans in tonnes</b>
2013	178
2012	248
2011	659

## **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**

- 1 The relevant national legislation is the Food Safety and Standards (Contaminants, Toxins and Residues) Regulation 2011, issued by the Food Safety and Standards Authority of India.

#### **Conclusions on National Legislation**

- 2 The relevant national legislation is in place.

### **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**

- 3 The CAs responsible for the control systems in place to control microbiological contamination in sesame seeds for human consumption intended for export to the EU are the MoCI and SHEFEXIL.
- 4 The MoCI is divided into two main departments, the Department of Industrial Policy & Promotion and the Department of Commerce. The latter is responsible within the scope of this mission and is charged with promoting foreign trade, coordination of

commercial activities, policy and providing financial incentives. The mandate of the Department of Commerce is regulation, development and promotion of India's international trade and commerce through formulation of appropriate international trade & commercial policy and implementation of the various provisions thereof.

- 5 SHEFEXIL (formerly known as the Shellac Export Promotion Council) is an export promotion body sponsored by the MoCI. Its primary role is the promotion of a range of commodities for which it is responsible, including Shellac, Guar Gum, Sesame seeds, Medicinal Plants etc. It has been working in partnership with the industry since 1957 as the catalysing agency for the long-term development and export promotion of shellac and lac-based products. The objective of the Council is to realise the full export potential of India's non timber forest produce as well as commodities such as guar gum and sesame seeds and through collective action to create a global brand.
- 6 Although SHEFEXIL is the CA for all issues relating to sesame seeds, it has no powers to oblige exporters of sesame seeds to be registered by SHEFEXIL. In addition, SHEFEXIL informed the FVO audit team that it does not undertake any official controls at facilities processing sesame seeds.
- 7 APEDA confirmed that they are the CA for sprouted seeds and seeds for sprouting. APEDA is aware of the certification requirements for imports into the EU of sprouts and seeds intended for the production of sprouts as required by Regulation (EU) No 211/2013. APEDA has received no requests from exporters for such certification to date. In the case of exports of alfalfa seeds from India, APEDA confirmed that these exports were registered as forage, but agreed that such seeds could also be used for sprouting in the EU.

#### **Conclusions on Competent Authorities**

- 8 The relevant CAs in the context of this audit have been designated. At the time of the audit, neither SHEFEXIL nor APEDA were undertaking any official control activities in their respective areas of responsibility.

### **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**

### *5.3.1 Organisation of official controls*

- 9 There are no official controls undertaken by any public or private organisation for sesame seeds or seeds for sprouting, neither for the Indian market nor for export from India.

### *5.3.2 Registration of Food Business Operators*

- 10 There is a mandatory requirement for all exporters to register with the Directorate General for Foreign Trade to obtain an Export, Import Code Number. This code is used for customs and excise purposes and it is impossible to export any product (food and non-food) from India without such a code. However, this system of registration and code is not used for traceability or for any food safety purposes. No other registration of processing establishments is in place.

### *5.3.3 Cultivation Good Agricultural Practice*

- 11 Sesame Seed crop is a wild, hardy and arid crop. It is grown in Gujarat, Rajasthan, Andhra Pradesh and Karnataka. The crop duration extends from three to five months depending on the crop variety. There are about three varieties i.e., Black, Brown & White coloured crops. All the varieties are used for extraction of oil whereas the white variety is used in the Confectionery Industry. This audit is focussed on the white variety, which can be hulled or natural. The FVO audit team was informed that there are approximately 1.5 million subsistence farmers producing sesame seeds in India. The CA confirmed that there is no traceability of sesame seed to the farm level.
- 12 The matured crop is harvested before the pods burst and stacked in the fields for drying. The dried stacks are thrashed in the same field and raw seeds are separated by winnowing. All these activities are conducted manually.

- 13 Farmers bring their sesame seed crop to the mandi, which is a Government controlled auction of agricultural produce. The FVO audit team visited two mandis and noted that the seeds were displayed out of doors on the ground. Consequently, up to the point of purchase of the seeds by the processor at the mandi, there can be no guarantee of the hygienic state of the sesame seeds. There is no microbiological testing undertaken before processing. Lots in the mandis are selected by preliminary testing for moisture and visual aspects.
- 14 In one processor for natural sesame seed, the FVO audit team observed the fumigation with Aluminium Phosphide of natural sesame seed in hemp bags. The FBO explained that this practice is not routinely done but only carried out when pests are observed.

#### 5.3.4 Processing and Storage

- 15 There are two main categories of white sesame seeds exported to the EU, these are natural sesame seed and hulled sesame seed. After purchasing the sesame seed at the mandi, the seeds are processed as follows: Both natural and hulled sesame seeds are cleaned and graded. The hulled seeds are immersed in hot water with 0.3% sodium hydroxide. The temperatures for this heating step varied from processor to processor, but temperatures provided to the FVO audit team varied between 55, 90 and 100 degrees centigrade. This step blanches the seed. The seeds are then washed twice using cold water, to remove the chemicals and the husks. This is followed by a drying process where the seeds are shaken in a ‘hopper’ apparatus in a hot air chamber with temperatures ranging from 120 - 150 degrees centigrade for 10-30 minutes. An optical sorting step is used to remove the undesirable coloured seeds. Following this, packing is undertaken which may involve manual intervention. Due to the washing step of the hulled seeds, the risk of *Salmonella* contamination is increased. However, the subsequent heating step should overcome this risk. Nevertheless, potential problems such as insufficient heat or cross contamination in the processing site can give rise to microbial contamination. The FVO audit team noted that the lines for hulled and natural sesame seeds can be used in common. The FVO audit team was informed that not all processors have implemented a hazard analysis and critical control point (HACCP) plan.
- 16 The FVO audit team undertook five site visits to processors and exporters of sesame seeds. The FVO audit team was informed that all the consignments for export to the EU were required to be sampled, tested and be *Salmonella* and *E. coli* free prior to shipment. Two site visits involved establishments that had been subject to a *Salmonella* related RASFF alert and two other establishments were involved in RASFFs relating to unacceptable organoleptic characteristics of sesame seeds. One company had not been the subject of a RASFF to date. The FVO audit team was informed that sesame seeds were also imported from several African countries for processing in India and these could also be exported to the EU. According to exporters met, no *Salmonella* or *E.coli* positives had been detected in their

consignments prior to exportation. In the event of *Salmonella* or *E coli* being detected in consignments, the FVO audit team was informed by the exporters that an investigation would not be undertaken by the FBOs to find out the source of the contamination.

- 17 None of the processors / exporters visited undertook comprehensive environmental sampling and testing for microbial contamination during the production process.
- 18 The first processor had been the subject of a RASFF notification related to *Salmonella* contamination in 2012. This RASFF was not communicated to the FBO until November 2014 by SHEFEXIL. It was reported by the importer in the EU to the FBO who then organised for the return of the consignment which was later used for feed. The FBO stated that this was the only RASFF they had been involved in and they considered the cause of the problem to be due to allowing another processor to export on their behalf. This FBO processed natural and hulled sesame seeds in separate lines without any physical separation of the two lines. A HACCP plan and third party certification was in place.
- 19 The second site visit to a processor / exporter which was involved in a RASFF notification in 2011, which was not directly concerned with *Salmonella* contamination. The consignment was destroyed in the EU. Although the FBO stated this was the only occasion to have had a RASFF, it became apparent during the site visit that *Salmonella* contamination had been reported from Greece in 2010. This consignment was returned to India and subjected to steam sterilisation and sold on the domestic market. No corresponding notification could be detected in the RASFF system. This FBO processed both hulled and natural sesame seeds and the two processes were housed in separate areas of the processing plant. This FBO had implemented a HACCP plan.
- 20 The third processor / exporter was associated with a RASFF notification which occurred in early 2014. He had not been informed of the RASFF by the Indian authorities until November 2014. The RASFF was linked to a consumer complaint relating to the organoleptic properties of the product. The FBO processed natural and hulled sesame seeds and the two processes were housed in separate buildings. A HACCP plan and third party certification was in place.
- 21 The fourth exporter was the subject of a RASFF notification relating to *Salmonella* contamination in 2014. The exporter stated that the contamination arose due to the consignment being blocked in a Greek port for three months during the Summer. The delay in presenting the consignment for sampling was due to financial issues. The consignment was returned to India. This FBO processes natural sesame seed and buys in hulled sesame seeds which he subsequently sorts in the same equipment where the natural sesame seed is processed. A HACCP plan was in place in this site however,

HACCP plans were not implemented in the establishments from whom he purchased his hulled sesame seeds.

- 22 The fifth company had no RASFF notification to date. This company processes natural sesame seeds and hulled seeds which have been hulled elsewhere. The same line is used for both hulled and natural sesame seeds.

#### 5.3.5 Non- Conforming Products

- 23 The consignments of sesame seed found to be non-compliant at the point of entry to the EU are normally shipped back to India. Some of the exporters met stated that frequently they are not informed of the reason for the non-compliance.

#### Conclusions on Official Controls

- 24 Sesame seeds are produced by numerous subsistence farmers. There is no system of traceability in place from growers of sesame seeds to the point of sale at the mandis. There is no registration of FBOs involved in processing and exporting sesame seeds for food safety purposes. Some of the processors / exporters visited were involved in RASFF notifications, however, SHEFEXIL had not been involved in any follow-up of these. All processors/exporters met, stated that no *Salmonella* or *E.coli* positives were detected in consignments prior to export. The processors met had HACCP plans in place.

### 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.

#### Findings

- 25 If present, the distribution of *Salmonella* is not homogenous in any consignment of sesame seed or other foodstuff. In general, sampling of sesame seeds prior to export is undertaken at the processing establishments. For each lot which could be up to 38 tonnes, an intermediate sample of approximately five kilograms is obtained from which five samples of 500g are produced and sealed. Two samples are sent to the laboratory and the rest retained by the FBO. A range of, quality, physicochemical and microbiological analyses are carried out. A single analysis for *Salmonella* and *E. coli* is carried out. This is not in line with section 3.2 of the CODEX General Guidelines on sampling CAC/GL 50-2004 which requires at least five samples to be analysed.

- 26 The sampling of the consignments are normally undertaken by sampling technicians employed by accredited laboratories chosen by the processors / exporters to sample and test consignments prior to shipment.
- 27 In the pre audit questionnaire it was stated that the sampling procedure is in accordance with the provisions of EU Commission's Directive 2002/63/EC of 11th July, 2002 which deals with pesticides.
- 28 The inspection and sampling procedures are always carried out by a third party which frequently offers laboratory testing services as well to the processors / exporters. The FVO audit team reviewed the procedures at the two companies most frequently used by the exporters visited and noted that they were certified by an external body for this activity. The FVO audit team reviewed the standard operating procedure (SOP) for sampling (at the first and second laboratory visited). In one case sampling was undertaken according to the procedure described by the Federation of Oil Seeds and Fats Association (FOSFA), which is an international official method of sampling. However it is not specifically focussed on microbiology and the intended use of this sampling method may be aimed at parameters with a more homogenous distribution. In the FOSFA SOP it was stated that 2% of bags were to be selected randomly. The inspection reports completed by the sampling technicians, were reviewed by the FVO audit team, illustrated the percentage of bags sampled. These ranged from 3% to 10%.
- 29 The FVO audit team observed a demonstration of a sampling procedure at an exporter of sesame seeds to the EU. There were contradictory descriptions between the sampling technician and the exporter of what normally happens. This demonstration was not in line with the company sampling SOP.

#### **Conclusions on Method of Sampling**

- 30 Sampling procedures are not standardised and may differ between different sampling services. The sampling procedures observed by the FVO audit team and described in SOPs cannot guarantee that samples sent for microbiological analysis are representative of the whole consignment.

## **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

- 31 The FVO audit team visited three private laboratories accredited for microbiology in food by the Indian Accreditation body, the National Accreditation Board for Laboratories (NABL). The NABL formally audits laboratories every two years which is complimented by a desk top audit every year. All laboratories were adequately staffed, well equipped and participated in proficiency tests (PTs) for *Salmonella* with satisfactory results.
- 32 The FVO audit team was informed that all consignments of sesame seeds destined for the EU are tested for *Salmonella* and *E. coli* prior to shipment and can only be exported if found negative for these two microorganisms. The CA does not have a comprehensive list of laboratories which offer this service in India. During the audit, at least seven laboratories were identified through reports provided by exporters. Of the three laboratories visited during this audit, the first had approximately 1,000 samples of sesame seed, and the second laboratory had 1,500 samples of sesame seed on average over the past three years. The third laboratory had only recently commenced testing sesame seed samples. The percentage of samples related to exports to the EU from the total is not known as this information is not obtained by the laboratories.
- 33 The first laboratory informed the FVO audit team that they had approximately 5% positive for *Salmonella* amongst sesame seed samples. The second laboratory stated that three *Salmonella* positive samples of sesame seeds had been detected this year. In the event of a positive *Salmonella* result in the EU, none of the exporters met by the FVO audit team are known to have alerted the laboratory which undertook the initial testing to try and establish the cause of such a discrepancy. The testing for *Salmonella* is mainly undertaken in India according to the Indian Standard (IS) 5887: Part 3:1999 and in the EU it is generally carried out according to the International Organisation for Standardization (ISO) 6579:2002. The two methods have not been shown to be equivalent.
- 34 The first laboratory was accredited for *Salmonella* detection methods, ISO 6579:2002, a polymerase chain reaction method, in addition to the IS. The most recent accreditation report was reviewed and was satisfactory. The laboratory tests approximately 1,000 samples for microbiological parameters of sesame seed per year. These samples come mainly from 10 major exporters of sesame seed. The microbiological parameters always include *Salmonella* and *E. coli*. In the second laboratory visited both the Indian and the ISO standard were in the scope of the accreditation. This laboratory uses the Indian method unless a client specifies that they require the ISO 6579:2002. Most of the laboratory reports seen by the FVO audit team had used the Indian method IS 5887: Part 3: 1999. The FVO audit team was informed that about one third of the microbiological samples analysed were of sesame seed. In 2014 three *Salmonella* positive results were detected. The third

laboratory visited is not accredited for ISO 6579:2002. The laboratory currently uses the Indian method.

- 35 Some consignments that have been sampled, tested and found to have no contamination with *Salmonella* and *E.coli* prior to shipment from India are found to be *Salmonella* positive in the EU.

#### **Conclusions on Laboratory Services**

- 36 The laboratories visited are accredited, adequately staffed and equipped. The equivalence between the two methods used for detection of *Salmonella* had not been established, however the satisfactory results from participation in PTs by the laboratories visited, indicates that the methods being used are adequate.

### **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**

- 37 There is no certification procedure as required by Regulation (EU) No 211/2013 in place for the export of seeds for sprouting to the EU as there is currently no demand from exporters for such certification.
- 38 Although there is no EU requirement to certify sesame seeds for human consumption, the exporters met stated that, prior to shipment to the EU, all consignments had to undergo microbial analysis for *Salmonella* and *E.coli* in India. Once the laboratory results are received and are considered to be satisfactory the batches are loaded on to a container at the premises of the processor and / or exporter in the presence of the sampling technician from the laboratory who witnesses the loading of the container with the relevant batches that have been tested and found to be satisfactory. All consignments found to be *Salmonella* positive in the EU, had previously been tested and found to be *Salmonella* free in India.

#### **Conclusions on Certification Procedures for Exporting to the EU.**

- 39 Due to the lack of demand from industry, APEDA has not put in place any system of certification in line with Regulation (EU) No 211/2013.

## 5.7 RESPONSE TO RASSF 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

- 40 The FVO audit team noted that there are significant problems relating to the follow up of RASFFs involving sesame seeds in India. The FVO audit team were informed that the national contact point for RASFF in India is the MoCI. Although SHEFEXIL are the designated CA responsible for receiving RASFF notifications relating to sesame seeds, there is no system in place within the MoCI to ensure that SHEFEXIL received such RASFF notifications. As a consequence, significant delays in alerting processors /FBOs involved in such RASFFs had occurred.
- 41 The FVO audit team noted that a number of RASFFs relating to *Salmonella* contamination in sesame seeds involved processors that were not known or registered with SHEFEXIL. The FVO audit team was informed that there was no way of following up such RASFFs linked with these processors.

### Conclusions on Response to RASSF Notification

- 42 The system in place for handling RASFFs related to sesame seeds is not satisfactory.

## 6 OVERALL CONCLUSIONS

Overall, there are a number of significant gaps in existence which cannot assure that sesame seeds exported to the EU are safe. The CA responsible for sesame seeds, SHEFEXIL, does not carry out any controls on growers, processors or exporters of sesame seed. In addition, there is a failure to follow up RASFF notifications relating to sesame seeds in India. This is mainly due to a lack of co-ordination between the MoCI which is the national contact point for RASFF in India and SHEFEXIL, which is responsible for following up on RASFF notifications relating to sesame seeds. Laboratories visited were capable of undertaking the relevant testing for *Salmonella* detection. However, the approach to sampling of consignments for microbiological testing prior to export could not ensure statistical representativeness.

APEDA confirmed that they are the CA for sprouted seeds and seeds for sprouting. APEDA is aware of the certification requirements for imports into the EU of sprouts and seeds

intended for the production of sprouts as required by Regulation (EU) No 211/2013. APEDA has received no requests from exporters for such certification todate.

## 7 CLOSING MEETING

A closing meeting was held on 17 December 2014 with representatives of the CCA, processors and laboratory representatives. The FVO audit team presented the main findings and preliminary conclusions of the audit. The CAs made initial comments and provided some additional information.

## 8 RECOMMENDATIONS

An action plan in response to the recommendations should be forwarded to the Commission within 25 days of receipt of the report. This action plan should clearly set out the manner and deadline by which the CAs will address each of the following recommendations.

N°.	Recommendation
1.	<p>Ensure that all establishments where sesame seeds for export to the EU are produced and processed are registered, equivalent to the requirements of Article 6 of Regulation(EC)No 852/2004 in conjunction with Article 10 of the same Regulation.</p> <p>Recommendation based on conclusion No.24</p> <p>Associated finding No 10</p>
2.	<p>Ensure that a consistent sampling methodology is implemented to ensure representative sampling for microbiological testing of sesame seeds and other commodities as outlined in the CODEX General Guidelines on sampling (CAC/GL 50-2004).</p> <p>Recommendation based on conclusion No 30</p> <p>Associated finding: No 28</p>
3.	<p>Ensure that RASFF follow-up procedures are developed and they provide for effective enforcement measures taken against all exporters involved in notifications (point 6 of CODEX Guidelines CAC/GL 25-1997).</p> <p>Recommendation based on conclusion No 42</p> <p>Associated findings: Nos 40 and 41.</p>

## ANNEX 1 – LEGAL REFERENCES

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 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. 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
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).	<a href="http://www.codexalimentarius.org">http://www.codexalimentarius.org</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.org/">http://www.codexalimentarius.org/</a>
CAC/GL 50-2004	General Guidelines on Sampling (CAC/GL 50-2004).	<a href="http://www.codexalimentarius.org/">http://www.codexalimentarius.org/</a>
CAC/RCP 53-2003	Code of hygienic practice for fresh fruits and vegetables (CAC/RCP 53-2003).	<a href="http://www.codexalimentarius.org/">http://www.codexalimentarius.org/</a>
CAC/RCP 1-1969	General principles of food hygiene (CAC/RCP 1-1969).	<a href="http://www.codexalimentarius.org/">http://www.codexalimentarius.org/</a>