EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

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FINAL REPORT OF AN AUDIT

CARRIED OUT OF

INDIA

FROM 03 TO 27 MARCH 2023

IN ORDER TO

ASSESS THE CONTROL SYSTEM IN PLACE TO CONTROL AFLATOXIN CONTAMINATION IN PEANUTS INTENDED FOR EXPORT TO THE EUROPEAN UNION

Executive Summary

This report describes the outcome of an audit of India carried out by the Directorate-General for Health and Food Safety from 03 to 27 March 2023.

The objective of the audit was to assess if the systems in place to control aflatoxin contamination in peanuts intended for export to the European Union (EU) comply with, or are in line with Article 10 of Regulation (EC) No 852/2004 of the European Parliament and of the Council and are adequate to ensure that the produce concerned is within the specified contaminant limits laid down in Commission Regulation (EC) No 1881/2006 and complies with Regulation (EU) 2019/1793 regarding sampling and testing requirements for export consignments.

Overall, India has the necessary legal and organisational framework for implementing the official controls of peanuts. The competent authorities provide written instructions, guidelines, and procedures to staff on the implementation of the controls, which are carried out at operators handling peanuts post-harvest. Moreover, visits at establishments and visual checks of consignments take place for every consignment of peanuts intended for export to the EU, once the results of the official samples are available and below the legal maximum residue levels for aflatoxins. Laboratories approved for aflatoxin analysis of peanuts are accredited and performing well.

The food business operators, as well as the actors involved in the production and marketing sector, continue to promote the implementation of good agricultural and manufacturing practices for the prevention and reduction of aflatoxin contamination of peanuts at farm and post-harvest level.

However, the official controls at primary producers are not designed to verify and monitor if and to what extent they indeed implement good agricultural practices to prevent the formation of aflatoxins or their compliance with the relevant EU requirements. In addition, the reporting on official controls, including of the effectiveness of the Hazard Analysis and Critical Control Points plans (and related own checks) implemented by the processors, is poor. Therefore, the central competent authorities are prevented from adequately monitoring the quality of the official controls carried out to ensure compliance with Annex I and II of Regulation (EC) No 852/2004.

In recent years there has been an increase in the number of notifications in the Rapid Alert System for Food and Feed for peanuts coming from India. Although this may be related to the increased number of consignments sampled at EU ports, it should be noted that a small number of operators account for most of the rejections. Even if the competent authority does follow up the notifications, there is no clear evidence that the operators involved in notifications implement effective corrective actions.

While the control system can guarantee that peanut consignments at the time of export to the EU comply with the EU requirements regarding sampling and analysis of aflatoxins and ensure that the limits laid down in Regulation (EC) No 1881/2006 are not exceeded, the system cannot fully guarantee the compliance with all the requirements listed in the model certificate of Regulation (EU) 2019/1793, which the competent authority sigs. This raises concerns about the reliability of the certification of system

The report contains recommendations to the Indian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
APEDA	Agricultural and Processed Food Products Export Development Authority
CA	Competent Authority
CN	Combined Nomenclature
Codex	Codex code of practice for the prevention and reduction of aflatoxin contamination in peanuts
DG	Directorate General
EC	European Community
EIC	Export Inspection Council
EN ISO/IEC	European Normalisation, International Organisation for Standardization and the International Electro technical Commission
EU	European Union
FBO	Food Business Operator
HACCP	Hazard Analysis Critical Control Points
IOPEPC	Indian Oilseeds and Produce Export Promotion Council
NRL	National Reference Laboratory
RASFF	Rapid Alert System for Food and Feed
TRACES	Trade Control and Expert System

1 INTRODUCTION

The audit took place from 03 to 27 March 2023 as part of the Directorate General (DG) Health and Food Safety's annual audit programme. The audit team comprised two auditors from this DG and one national expert from a Member State of the European Union (EU).

The opening meeting was held on 3 March 2023 with the two Central Competent Authorities (CAs): the Agricultural and Processing Food Products Export Development Authority (APEDA) and the Export Inspection Council (EIC). Also present were representatives of the National Reference Laboratory (NRL) and the Indian Oilseeds and Produce Export Promotion Council (IOPEPC). At this meeting, the audit team confirmed the objectives of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.

Representatives from the Central CAs accompanied the team during the audit.

2 OBJECTIVES AND SCOPE

The objective of the audit was to evaluate whether official control systems in place to control aflatoxin contamination in peanuts intended for export to the EU:

1. comply with, or are in line with Article 10 of Regulation (EC) No 852/2004 of the European Parliament and of the Council and are adequate to ensure that the produce concerned is within the specified contaminant limits laid down in Commission Regulation (EC) No 1881/2006.
2. comply with Regulation (EU) 2019/1793 regarding sampling and testing requirements for export consignments.

In terms of scope, the audit reviewed the controls in place for the primary production, the handling and export of peanuts, including the national legislation in place, the organisation of the CAs involved and their controls and enforcement capabilities.

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

Table 1: Audit visits and meetings

Sites visited	Number	Comments
Competent Authorities		
Central	2	APEDA (3 days) and EIC (1 day)
Laboratories		
Central	3	Two private APEDA approved laboratories and the NRL for aflatoxins
Producers		
Farmers	2	Peanut farmers in Gujarat State

Sites visited	Number	Comments
Processors/Exporters		
Peanut processing units	3	Operators located in Gujarat State

3 LEGAL BASIS AND STANDARD

3.1 Legal Basis

The audit was carried out under the general provisions of EU legislation, in particular Article 120 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

Full legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

DG Health and Food Safety carries out audits to the main exporting non-EU countries to evaluate official control systems in place for preventing mycotoxins contamination in foodstuffs. The reports on these audits are available on the European Commission's website at: http://ec.europa.eu/food/audits-analysis/audit_reports/

Two previous audits concerning aflatoxins in peanuts took place in India in 2009 and 2013 (DG (SANCO) 2009/8148 and 2013/6683). The reports contained recommendations addressed to the CAs.

The main shortcomings of the 2013 audit were related to the laboratory method validation and sampling and official controls of primary production and processing activities. Action plans were received, which were considered satisfactory to address these recommendations.

According to Article 44(1) of Regulation (EU) 2017/625, EU Member States shall carry out checks of foodstuffs imported into the EU. When risks to public health are detected during these checks, information is disseminated as alerts or notifications through the Rapid Alert System for Food and Feed (RASFF) to all Member States and to the exporting country. This audit was planned against the background of continuing RASFF notifications in recent years for aflatoxins in peanuts imported from India, see tables 2 and 3 below.

Table 2: EU imports and RASFF notifications for Indian peanuts in the period 2019-2022*

Products Combined Nomenclature [1] (CN) Codes (tonnes)	**2019**	**2020**	**2021**	**2022**
Groundnuts (peanuts) in shell CN code 1202 41 00	8	191	286	50
Groundnuts (peanuts) shelled, CN code 1202 42 00	50	11 062	4 828	8 006
Peanut butter	129	11 687	3 033	3 591
Groundnuts (peanuts, otherwise preserved, prepared processed, see table 3 below)		169	45	81
RASFF Notifications for Aflatoxins contamination		26	15	39

**Source: Indian CAs, TRACES (Trade Control and Expert System) and RASFF databases.*

Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 imposes special conditions on the import of certain feed and food from certain third countries due to risk of contamination by aflatoxins.

Currently, each consignment of peanuts originating in or consigned from India must be accompanied by a health certificate issued by the CA following the model official certificate of Annex IV to the same Regulation (hereinafter referred to as the official health certificate) and by the results of official sampling and analysis verifying compliance with EU requirements regarding maximum levels of aflatoxins stipulated in Regulation (EC) No 1881/2006. The sampling and analysis shall be performed in accordance with Regulation (EC) No 401/2006.

[1] Regulation (EEC) NO 2658/87 established a goods nomenclature to meet, at one and the same time, the requirements of the Common Customs Tariff, the external trade statistics of the Union, and other Union policies concerning the importation or exportation of goods.

Regulation (EU) 2019/1793 also sets a minimum level of controls that EU Member States must perform upon import, see table 3 below.

Table 3: Product categories subject to reinforced controls.

Food	CN[2] Codes	Minimum frequency of physical and identity checks at import
Groundnuts (peanuts) in shell	1202 41 00	50%
Groundnuts (peanuts), shelled	1202 42 00	
Peanut butter	2008 11 10	
Groundnuts (peanuts) otherwise prepared or preserved, including mixtures	2008 11 91 2008 11 96 2008 11 98 Ex 2008 19 12 (40) Ex 2008 19 19 (50) Ex 2008 19 92 (40) Ex 2008 19 95 (40) Ex 2008 19 99 (50)	
Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00	
Groundnut flours and meals	Ex 1208 90 00 (20)	
Groundnut paste	Ex 2007 10 10 (80) Ex 2007 10 99 (50) Ex 2007 99 39 (07;08)	

[2] "Combined Nomenclature" of goods following Commission Implementing Regulation (EU) 2008/1602. The TARIC subdivision is indicated in brackets where only certain products under any CN category are required to be examined.

5 FINDINGS AND CONCLUSIONS

5.1 Relevant National Legislation

Legal requirements

Article 120(2)(a) of Regulation (EU) 2017/625.

Articles 7, 10 and 11 of Regulation (EU) 2019/1793

Article 10 of Regulation (EC) No 852/2004.

Regulation (EC) No 1881/2006.

Regulation (EC) No 401/2006.

Findings

1. The national legal acts and CA provisions relevant for this audit were the following:
    - The Government of India, Ministry of Commerce and Industry, Department of Commerce with Notification No. 28 (RE-2012)/2009-2014 dated 3rd January, 2013 conferred powers to APEDA and made export of peanuts subject to registration with APEDA and to a controlled aflatoxin level certificate issued by a laboratory.
    - The Export (Quality Control and Inspection) Act, 1963 is the relevant national legislation for the control of mycotoxins in peanuts. EIC was established in 1964 under section 3 of this act and the export inspection agencies were established in 1965 under section 7.
    - Furthermore, the APEDA regulation of 5 July 2021 on export of peanut and peanut products provides provisions for control of aflatoxins.
    - APEDA also has criteria for structural and hygiene conditions for establishments registered for export of peanuts to the EU.
2. The audit team reviewed the above-mentioned pieces of legislation and noted that they overall contain requirements equivalent to those in the relevant EU regulations. However, the hygiene criteria are not fully in line or do not cover all provisions of Annex I and II of Regulation (EC) No 852/2004.

Conclusions on Legal requirements

3. The legal framework in India establishes the basis for the performance of official controls all along the chain of production and handling of peanuts for export to the EU. However, the APEDA hygiene criteria for registration of establishments are not fully equivalent to the requirements of Annex II to Regulation (EC) No 852/2004.

5.2 Competent Authorities

Legal requirements

Articles 120(2)(b) and (c) of Regulation (EU) 2017/625.

Findings

4. The two main CAs for the purpose of this audit at national and regional levels are APEDA and EIC. APEDA is a body under the Ministry of Commerce and Industry (Government of India) and was established by an Act of the Indian Parliament in 1986. It is funded by the Ministry of Commerce and Industry and was established for export promotion of scheduled agricultural commodities and processed foods including peanuts and peanut products. APEDA has its headquarters in New Delhi and five regional offices. APEDA has developed a procedure for a national system for export of peanuts and peanut products from India to eliminate various toxins.

5. The responsibilities of APEDA among others are to monitor the functioning of the NRL and APEDA approved laboratories, register Food Business Operators (FBOs) for export and issue the certificates of export. This certificate is a national requirement and a prerequisite for getting the EU health certificate. APEDA is also the national contact point for the EU RASFF and is responsible for the follow-up of the RASFF notifications related to peanuts and peanuts products exported to the EU.

6. The Central CA for issuance of the EU health certificates (as in Regulation (EU)2019/1793) for peanuts and peanut products, is EIC. Export Inspection Agencies - Delhi, Mumbai, Kolkata, Chennai & Kochi and their sub-offices have responsibilities for issuance of such health certificates at regional or local level. EIC is a statutory body operating under the Department of Commerce of the Ministry of Commerce and Industry.

7. The NRL for aflatoxins supervises the performance of the APEDA approved laboratories for aflatoxins analysis for export to the EU. This involves, supervision of the sampling carried out by such laboratories as well as technical support for developing methods, method validation and the organisation of proficiency testing.

8. The Customs Authorities under the Ministry of Finance are responsible for the application of the Customs Act 1962. The audit team visited the customs office in Jamnagar and verified that EIC had circulated a letter dated 29/10/2013 informing all Commissioners of Customs that consignments of peanut and peanut products for export to the EU should be accompanied by a health certificate issued by EIC.

Training

9. APEDA informed the audit team that officials undergo theoretical and practical training to issue the certificate of export and to provide general knowledge of food safety issue in food processing establishments.

10. The NRL provided evidence that training had been provided to staff in APEDA approved laboratories in relation to sampling of peanuts and peanut products intended for export to the EU. Training is also provided by the NRL to technical staff for analytical methods for aflatoxins.

Conclusions on Competent Authorities

11. The responsibilities of the various CAs are clearly defined and staff met were knowledgeable.

5.3 Organisation and prioritisation of official controls

Legal Requirements

Article 120(2)(e) (g) and (h) of Regulation (EU) 2017/625.

Regulation (EC) No 1881/2006.

Article 10 of Regulation (EC) No 852/2004.

Findings

12. The main peanut-growing areas are in the north-west of the country, and these were selected to visit during this audit. Registration is not compulsory for peanut farmers and APEDA did not provide figures on the number of farmers producing peanuts intended for export to the EU.

13. The audit team was informed by APEDA that the State agricultural extension services or IOPEPC may visit farmers to promote good agricultural practices. They also distribute brochures including measures recommended in the Codex Code of Practices CAC/RCP 55-2004 to avoid or reduce the formation of aflatoxins in peanuts. However, there was no evidence that the purpose of these visits is to verify the implementation of good practices by farmers, which would establish their compliance with requirements of Part B of Annex I to Regulation (EC) No 852/2004. The farmers stated that no inspection reports are provided by the extension service and only oral feedback is provided during the visits.

14. Personnel of the peanut exporters may also visit farmers in order to verify the implementation of good agricultural practices in accordance with the guides they provide to them.

15. In the APEDA procedure for export of peanuts to the EU and in the APEDA criteria for registration of establishments it is stated that it is the obligation of the FBOs to verify that suppliers of raw material apply good agricultural practices and other measures provided in the Codex Code of Practices CAC/RCP 55-2004 for prevention and reduction of aflatoxin contamination in peanuts.

16. FBOs must be registered for export to the EU. This includes establishments with processing, integrated peanut processing, peanut shelling, peanut grading and peanut storage, hereafter called “peanut units”. APEDA has a set of criteria FBOs must comply

with in order to be registered. A physical inspection is carried out to ensure compliance. The registration is valid for two years after which the registration must be renewed. A physical inspection is also required for the renewal.

17. However, the audit team was informed that peanut units doing shelling or/and sorting which are not exporting directly but providing raw material to EU registered peanut units do not need to be registered. Thus, these peanut units are not under control to ensure they are producing in line with Regulation (EC) No 852/2004.

18. In order to ensure that the registered peanut units work in accordance with the criteria set up by APEDA unannounced inspections must be carried out annually at 10% of them. However, the audit team could not get evidence of such inspections. The CA stated that these unannounced inspections were discontinued during the Covid-19 pandemic and had not yet resumed. APEDA may carry out additional physical inspections at FBOs involved in RASFF notifications. However, APEDA does not have any risk assessment or any planning to establish the frequency of inspections or to focus inspections on high-risk peanut units.

19. The audit team was provided with evidence that for registration and renewal of registration, physical inspections were carried out. At the time of this audit, 103 peanut units were registered with APEDA for export to the EU.

Conclusions on organisation and prioritisation of official controls

20. Although there are advisory visits to promote good agricultural practices at farms, they are not designed to verify the implementation of these practices or the compliance of farmers with the relevant EU requirements for export.

21. The planning and execution of controls for registration of FBOs involved in the post-harvest handling of peanuts for export to the EU is adequate. However, the controls after registration are not carried out as planned and peanuts units not exporting directly to the EU are not registered.

5.4 Controls on Production and Post-harvest handling

Legal Requirements

Article 120(2)(e) (g) and (h) of Regulation (EU) 2017/625.

Regulation (EC) No 1881/2006.

Article 10 of Regulation (EC) No 852/2004.

Regulation (EC) No 401/2006.

Findings

Pre-harvest activities

22. The audit team visited two small-scale farms providing peanuts to a large-scale FBO exporter to the EU. In these farms peanuts are harvested and dried in the sun for 7 to 15

days. A machine is available for threshing the peanuts, once dried. The farmers informed the audit team that their peanut crops had been sprayed with a fungicide. A crop rotation system was in place. Between the two peanut harvests, chilli or other vegetables were cultivated. The land was fertilised using mineral fertilisers.

23. The audit team noted that the two farmers visited were supplying peanuts to a registered FBO. They stated that they had received training and instructions from the processing unit on how to handle peanut crops. The representative of the FBO reported that their supplier farms followed good agricultural practices and some practices included those recommended by the Codex, such as soil testing before planting, crop rotation, choice of peanut variety, timely irrigation prior to harvesting, use of fungicides and appropriate harvesting and drying times.

Post-harvest activities

24. The audit team visited three peanut units exporting in-shell and shelled peanuts. All were involved in several EU RASFF notifications in recent years. During the visits and the following consultation of previous inspection reports, the audit team was able to confirm that the official controls cover the APEDA requirements for registration related to food safety.

25. The inspection reports produced by the APEDA inspectors consist of a checklist covering mainly structural requirements for peanut units to be registered such as the condition of ceilings, walls, floors and windows. Other inspection reports produced by a committee formed by APEDA officials and an official from the State Agricultural Services showed that these inspectors verified the same information provided by the FBO for registration which is mainly related to the mentioned structural requirements.

26. The reports lack the information necessary for concluding whether the establishments operate with good hygiene conditions and apply Hazard Analysis and Critical Control Points (HACCP) plans. There is no written evidence that HAACP plans are verified, that measures are in place to mitigate the level of aflatoxins in peanuts or that specific factors that would influence the conditions for mould growth and aflatoxin production have been assessed. Therefore, it cannot be concluded that the registered peanut units comply with the requirements of Annex II of Regulation 852/2004.

27. APEDA representatives stated that the inspections carried out include the verification of food hygiene requirements and the implementation of HACCP. However, no evidence of this (such as checklists used during the previous years and inspection reports) was provided to the audit team and the checklist used did not contain references to HACCP plans or other hygiene requirements related to aflatoxins.

28. The audit team reviewed the HACCP plan of a FBO and noted certain discrepancies between what was done in practice and what was stated in the plan (aflatoxin threshold for raw material, control of farmers, suppliers not registered, storage temperature). These points had not been detected by the joint inspection committee during the inspections carried out for the renewal of the FBO approval.

29. Nevertheless, the three establishments visited were overall in compliance with the structural and hygiene requirements contained in the APEDA criteria and in Annex II of EU Regulation (EC) No 852/2004.

30. The three FBOs had in place HACCP plans describing the presence of aflatoxins as a hazard and providing measures to avoid or mitigate the growth of mould and the development of aflatoxins in peanuts. There are checks of the levels of aflatoxins and moisture in raw material, intermediate products as wells as in final products. The audit team reviewed the analysis results of the FBO own checks carried out at all stages of production. In one case, the operator was not able to provide the HACCP plan to the audit team.

31. All establishments visited had electronic sorting devices to eliminate kernels potentially contaminated with aflatoxins and manual sorting. Only one of the establishments visited had a cold store for peanuts. The two other establishments stored the peanuts at ambient temperature. In the record reviewed by the audit team, this storage was short-term and the temperature range from 20°C to 30°C. But the audit team was informed that such storage could also be long-term. The Codex Code of Practices CAC/RCP 55-2004 advises to store peanuts below 10°C to keep the level of aflatoxin under control. Most FBOs did not have the capacity to do this.

32. The audit team examined the reception of raw material at the FBOs and noted that a significant number of lots was rejected due to the high level of aflatoxins detected upon reception. This may indicate that farmers or peanut units providing raw material to exporting peanut units are not applying adequate measures to minimise or mitigate the presence of aflatoxin in their products at primary production level, in storage or in shelling units.

33. In addition, APEDA is not targeting controls on FBOs from where a high number of consignments could not be exported to the EU. For example, in one laboratory visited, the audit team noted that ten consignments originating from the same processing unit were not exported to the EU due to the levels of aflatoxins. However, APEDA did not consider focusing on this unit by including it in an intensive inspection plan, trying to identify the sources of the contamination. As mentioned in paragraph 18 above, in general, peanut units are not classified according to risk and no frequency for visits is established other than for registration or its renewal.

34. The audit team noted in one establishment that the shelling peanut units providing raw material were not registered. As mentioned in paragraph 17 above, such registration is not required. This could increase the risk of the presence of aflatoxin in peanuts supplied from such units as they are not under APEDA control.

35. The NRL has all the data related to the consignments that could not be exported to the EU due to high levels of aflatoxin detected in the pre-export checks. This data demonstrates that the percentage of containers rejected for export in 2023 was quite high. For example, it was almost 22% in one APEDA approved laboratory visited.

Conclusions on Official Controls on Production and processing

36. Growers visited were aware of good agricultural practices recommended by the Codex to prevent aflatoxin contamination at farm level and they implemented them. However, no official controls are in place to verify that such practices are implemented in general and that they are effective to ensure compliance with the relevant EU requirements.

37. FBOs handling peanuts for export have in place measures to avoid or mitigate the presence of aflatoxins in peanuts and are subject to official controls. However, these controls cannot guarantee that establishments handling peanuts for export are fully in compliance with the EU requirements.

5.5 Procedure for Exporting to the EU

Legal requirements

Article 120(2)(h) of Regulation (EU) 2017/625.

Regulation (EU) 2019/1793

Findings

38. Certification of peanuts for export to the EU takes place with close co-operation between APEDA, EIC, the APEDA approved laboratories and the NRL. Every consignment of peanuts for export must be subjected to visual and identity checks following the successful outcome of official samples taken for aflatoxins analysis.

39. The export procedure for peanuts to the EU has been streamlined through the use of the IT tool Peanut.net, which was developed by APEDA for exporters of peanuts from India. It became available years ago but is now compulsory for the application for and issuance of certificates of export.

40. The peanut.net system is a modular system whereby the exporter only has access to the fields that are relevant to export data and the laboratory can only access the section relevant to sampling and laboratory results. The same applies for APEDA officials who issue the certificates.

41. When the exporter decides to send a consignment of peanuts to the EU, he is obliged to encode the consignment quantity in Peanut.net. The exporter may select the laboratory to do the sampling and the analysis from a dropdown list. Only APEDA approved laboratories are available.

42. The consignment is inspected and sampled by the designated laboratory personnel who deliver the sample to the laboratory. Samples are taken at the exporter's premises from processed consignments labelled for export. The inspectors must verify that the products are well packaged and have the appropriate labels with information that matches that which was submitted in the application for export. The consignments are sealed and put on hold pending the laboratory results. The laboratory puts the analytical results into the Peanut.net.

43. When the laboratory results become available to the exporter, he then decides on the destination of the consignment and applies for a certificate of export. The Peanut.net is encoded to prevent the issuance of the APEDA export certificate if the laboratory results are outside the legal limits for aflatoxin for the requested destination. The staff of APEDA in the regional office verify the analytical results and if everything is in order, the certificate of export is issued stating that the peanut unit is registered, and the aflatoxin levels are in line with the EU requirements. The audit team reviewed a number of reports and noted that they included the reference to the lot sampled and the results of the analysis.

44. Once the FBOs get the APEDA certificate of export, they apply to EIC for the health certificate required by Regulation (EU) 2019/1793.

45. The documents to be presented with the application are: statement by the FBO that the consignment of peanuts has been produced in line with Regulation (EC) No 852/2004, APEDA certificate of export, packing list, invoices, etc. If all documents are in order, EIC issues the heath certificate.

46. While EIC has supporting documents to sign the part II 2.1 of the health certificate regarding sampling and analysis of aflatoxins they do not have clear evidence from any supporting document to sign the health information in point 1.1 related to the primary production and processing requirements of Annex I and II of Regulation (EC) no 852/2004. As a consequence of this, EIC issues official certificates for peanut consignments produced and handled by operators who do not or may not comply with all the necessary conditions.

47. The next step is to alert the designated laboratory personnel to return to the premises to release the sealed lot and witness the stuffing of the container with the appropriate peanut lot numbers. Each bag of the lot is sealed and serially numbered. Once this process is complete, the laboratory personnel issues a stuffing certificate through Peanut.net.

48. Finally, the consignment reaches the customs office where the customs officials can release the consignment for export to the EU on condition that it is accompanied by the health certificate, which is duly signed by EIC designated staff, the certificate of export, the stuffing certificate and the laboratory report.

Conclusion on Procedure for Exporting to the EU

49. There is a comprehensive procedure for export of peanuts to the EU and it is implemented well with good cooperation between the various CAs. It guarantees the integrity of the consignments and that they have been analysed for aflatoxins by accredited laboratories.

50. However, the health certificate is issued by EIC without adequate evidence that the consignments of peanuts destined for export have been produced in line with Annex I (primary production) and Annex II of Regulation 852/2004. In addition, the control system in place by APEDA also cannot guarantee that all hygiene requirements are complied with.

5.6 Method of Sampling Consignments

Legal requirements

Regulation (EC) No 401/2006.

Findings

51. As mentioned in paragraph 42 above, sampling is delegated to the APEDA approved laboratories. The audit team visited two such laboratories. The sampling services are not supervised by APEDA, but the NRL may supervise the sampling as part of the supervision of the approved laboratories.

52. The instruction for sampling, sample preparation and method of analysis during official control of mycotoxin levels in foodstuffs is included in the APEDA procedure for peanut exports. The two laboratories visited also have detailed procedures and instructions for sampling. The instructions are in line with those in Regulation (EC) No 401/2006.

53. The audit team met six sampling technicians at the establishments visited. They were provided with sampling equipment including gloves, seals and plastic bags. The technicians had been trained on sampling techniques and had the appropriate equipment to undertake sampling of peanut batches.

54. In two cases, the samplers explained to the audit team how they would proceed to take samples. It was clear that they knew the instructions and would take the samples in line with the established procedures. However, they did not weigh the incremental samples so it could not be ensured that they took similar incremental samples every time.

55. The audit team observed the sampling of one consignment of peanuts intended for export to the EU. The product was packaged and ready for export at the FBO premises. The samplers first verified the identity and details of the consignment, including the labelling of the bags and carried out a visual inspection of the product. The consignment, 26.1 tonnes in total, was packaged in 29 large jute jumbo bags containing approximately 900 kg each. Four incremental samples were taken from each bag. The points of sampling were chosen randomly by the sampling officer. A stainless-steel sampling spear was

immersed at different inclinations in each bag in order to extract material from its top, middle and bottom areas. The aggregate sample was then mixed with a scoop on a synthetic tarpaulin mat. Approximately 25 kg of the sample were taken and then split in two parts of 10kg for submission to the laboratory. Three smaller samples of approximately 1.5kg each were kept for moisture measurement or to be used as counter samples. Overall, the sampling criteria in Regulation (EC) No 401/2006 were met, but the size of the incremental samples was not in line with the procedures; different sizes of steel spears extracting varying volumes of material from each bag were used for sampling bags of the same consignment.

56. The sampling form completed after the sampling contained details on the circumstances of the sampling including, temperature, humidity, number of bags sampled, numbers of incremental samples, etc. However, the audit team reviewed several sampling forms and laboratory analysis reports and noted that full information on the details of the sampling carried out was not always available. This could prevent APEDA or the NRL from ensuring that sampling is always carried out according to the procedures.

Conclusions on Method of Sampling of Consignments

57. Sampling of consignments is mostly in line with the requirements of Regulation (EC) No 401/2006. The laboratories visited are properly equipped with the necessary sampling equipment for peanuts for aflatoxin analysis. Clear guidelines are provided to adequately carry out the sampling.

58. However, in some instances sampling was not fully carried out in line with these guidelines. Reporting of sampling lacks some information on the circumstances of the sampling.

5.7 Laboratory Services

Legal requirements

Article 120(2)(d) of Regulation (EU) 2107/625.

Article 2 of Regulation (EC) No 401/2006.

Findings

59. The audit team visited two APEDA approved laboratories and the NRL. The two approved laboratories are duly accredited to EN ISO/IEC 17025:2017 for the performance of aflatoxins analysis on peanuts and for meeting the relevant requirements of Annex II of Regulation (EC) No 401/2006 on sample preparation and analytical methods. They are subject to annual audits by the relevant accreditation body and are approved by APEDA. There is a list of 24 laboratories approved by APEDA for testing aflatoxin in peanuts.

60. Accreditation reports from the last audit carried out by the accreditation body were available. The accreditation body did not identify any non-compliance which prevented the renewal of the accreditation.

61. On receipt in the laboratories, the samples are given a unique identification code. In one case this was done manually with all details being registered in a logbook. The other laboratory has an electronic Laboratory Information Management System, into which all sample details are entered. Sample preparation is carried out in accordance with Commission Regulation (EC) No 401/2006 – for peanuts, 2 x 10kg portions are homogenised with water (1:1) in a large capacity blender and a portion of this is taken for analysis. One of the laboratories analyses mainly peanut butter and, in this case, a 6 kg sample is received and a portion of this is taken for analysis. The remainder of the samples are stored frozen for six months.

62. Samples are analysed following the Association of Official Analytical Chemists method 2005.08. They are extracted with solvent, cleaned using Immunoaffinity Columns and detection is by High Performance Liquid Chromatography with Fluorescence detection.

63. Certified Reference Materials are used for quantification. Individual standards are purchased and diluted down to make a mixed working standard. A five-point calibration curve is used in both laboratories. Certificates of Analysis were available for all standards and indicate that standards were manufactured under an ISO/IEC 1705:2017 certified quality system. Standards are prepared and stored correctly. There is no independent check on the standards.

64. All equipment used was adequately maintained and calibrated. Balances and pipettes are calibrated externally once a year and before-use checks are also carried out. The High Performance Liquid Chromatography systems undergo internal checks every six months and a standard check is run before each analysis.

65. Training records were available for analysts and showed competence in the method of analysis. Ongoing competency is assessed by participation in proficiency tests and satisfactory quality control results from routine batches.

66. The method of analysis is documented in a Standard Operating Procedure. Appropriate Quality Control is performed with every batch and both laboratories record the results. Only one laboratory maintains Quality Control charts. The procedure for performing the Quality Control checks is not documented in the Standard Operating Procedures. This would be useful to ensure consistency across batches and for continuity if personnel were to change. A procedure for dilution of samples that are outside the range of the calibration curve is not documented in the Standard Operating Procedures.

67. Both laboratories participate in annual proficiency tests, which are organised by the NRL. Results for both laboratories for the last two years were satisfactory.

68. Both laboratories validated the method of analysis in-house. Limit of Detection and Limit of Quantification were calculated based on signal to noise ratios of 3:1 and 10:1, respectively. Linearity was assessed and all calibration curves had coefficient of determination values > 0.999, which is satisfactory. Percentage recovery of the spiked samples met criteria set down in Regulation (EC) No 401/2006. Precision parameters were only partially assessed for one of the laboratories while the values estimated for the other laboratory met the requirements.

69. Both laboratories only have validation data at the lower end of the measurement range defined in their scope of accreditation. Validating the method at higher concentrations would give precision data at the higher levels, which in turn would give more confidence in the analytical result at higher levels.

70. Test reports from a number of laboratories were examined by the audit team and mainly comply with ISO 17025 requirements, though the date of sample receipt is not on the reports. Regulation (EC) No 401/2006 requires that the analytical result is reported ± the measurement uncertainty. Acceptance or rejection of a lot or sublot is dependent on the analytical result, taking into account the correction for recovery and measurement uncertainty. There was no consistency in the estimates of measurement uncertainty quoted on reports nor on the method of reporting the measurement uncertainty.

71. The NRL was also visited. This laboratory does not have any commercial function but provides training to the testing laboratories. It is ISO 17043 accredited and organises Proficiency Tests for all APEDA registered laboratories. It carries out documentary checks on 10% of samples analysed in the laboratories. It investigates RASFF cases and analyses the control samples as well as checking all documentation regarding the initial analysis of the disputed samples. The NRL also carries out supervision of APEDA approved laboratories. The audit team noted that supervision took place as stipulated in the APEDA peanut procedure. The audit team considers it as a good practice.

Conclusions on Laboratory Services

72. The laboratories performing analyses for the official control of aflatoxin contamination in peanuts intended for export to the EU are subject to adequate accreditation and approval to ensure that they are competent. The laboratories visited overall comply with requirements of Annex II to Regulation (EC) No 401/2006 on sample preparation and methods of analysis used for the official control of mycotoxin levels in foodstuffs. However, some practices are not fully compliant with the requirements, leading to some deficiencies in the validation of methods and inconsistencies in the reporting of results.

5.8 Response to RASFF Notifications

Legal requirements

Chapter IV, section 1 of Regulation (EC) No 178/2002

Findings

73. The audit team were informed that the national contact point for RASFF notifications in India is APEDA which has also developed a procedure for their follow-up.

74. Following a notification, APEDA informs the FBO concerned and asks for explanations with possible sources of contamination. The FBO must provide documents related to the batch exported. In exceptional cases, APEDA may consider a visit on the spot. The FBO may be suspended if there are repeated RASFF notifications.

75. The audit team focused on 29 RASFF notifications in which two peanut units were involved in 2022. The audit team noted that initial correspondence with the FBOs had taken place, however, the investigations had not been completed to the point where a root cause analysis was undertaken for providing a solution to the underlying problem.

76. In the cases investigated, a physical check was not carried out due to the Covid-19 pandemic restrictions.

77. From the documentary investigation, it could be established that the FBOs involved could not provide full information related to the circumstances of the sampling, certificate of stuffing and laboratory documents regarding the sampling and analysis. APEDA decided to suspend the exports from these establishments and the operation of two laboratories involved in the sampling and analysis.

78. One establishment was suspended for one month and the other for around four months. Later on, in August when Covid-19 pandemic restrictions where partially lifted, APEDA carried out physical visits to these two establishments for investigation. Although APEDA identified a significant number of non-compliances, the suspension was revoked. APEDA could not provide concrete evidence, such as an action plan rectifying the deficiencies identified, for lifting the suspensions.

79. The audit team noted that all RASFF notifications took place within a limited time period, where many problems in shipping consignments were encountered due to the Covid-19 pandemic. APEDA provided information to the audit team which showed long periods of up to 90 days or more of time-lapse between the pre-export analysis in India and the analysis at the EU laboratory. APEDA and the FBOs involved stated that in some cases, this was because of significant delays between the arrival of the consignment at the port in the EU and the import sampling. They considered that aflatoxins levels may have increased during these long storage and transportation periods. All the consignments involved in these RASFF notifications had aflatoxin below the EU regulatory levels in the pre-export analysis in India.

80. During its visit to the NRL, the audit team was provided with evidence demonstrating that for all cases of RASFF notifications in 2020 and 2021, the sampling and analysis of the involved consignments were investigated by the NRL by requiring the corresponding private laboratories to provide records of the technical aspects of the analysis as well as details of the sampling. However, when the audit team asked for the records of the investigation and follow up of the above-mentioned 29 RASFF notifications, the NRL could not find any record to demonstrate that these cases were investigated by them.

Conclusion on Response to RASFF Notifications

81. APEDA has a procedure for the management and monitoring of RASFF notifications. However, at the time of this audit, it was not properly implemented as to provide a consistent and timely follow-up including inspections at the involved FBOs to ensure that they took corrective measures.

6 OVERALL CONCLUSIONS

Overall, India has the necessary legal and organisational framework for implementing the controls of peanuts. The CAs provide written instructions, guidelines, and procedures to staff on implementation of the controls, which are carried out at operators handling peanuts post-harvest. Moreover, visits at establishments and visual checks of consignments take place for every consignment of peanuts intended for export to the EU, once the results of the official samples are available and below the legal maximum residue levels for aflatoxins. Laboratories approved for aflatoxin analysis of peanuts are accredited and performing well.

The FBOs, as well as the actors involved in the production and marketing sector, continue to promote the implementation of good agricultural and manufacturing practices for the prevention and reduction of aflatoxin contamination of peanuts at farm and post-harvest level.

However, the official controls at primary producers are not designed to verify and monitor if and to what extent they indeed implement good agricultural practices to prevent the formation of aflatoxins or their compliance with the relevant EU requirements. In addition, the reporting on official controls, including of the effectiveness of the HACCP plans (and related own checks) implemented by the processors; is poor. Therefore, the central CAs are prevented from adequately monitoring the quality of the official controls carried out to ensure compliance with Annex I and II of Regulation (EC) No 852/2004.

In recent years there has been an increase in the number of notifications in the RASFF for peanuts coming from India. Although this may be related to the increased number of consignments sampled at EU ports, it should be noted that a small number of operators account for most of the rejections. Even if the CA does follow up the notifications, there is no clear evidence that the operators involved implement effective corrective actions.

While the control system can guarantee that peanut consignments at the time of export to the EU comply with the EU requirements regarding sampling and analysis of aflatoxins and ensure that the limits laid down in Regulation (EC) No 1881/2006 are not exceeded, the system cannot fully guarantee the compliance with all the requirements listed in the model certificate of Regulation (EU) 2019/1793 which the competent authority signs. This raises concerns about the reliability of the certification of system.

7 CLOSING MEETING

A closing meeting was held on 27 March 2023 with representatives of the two Central CAs, APEDA and EIC and other CAs concerned. At this meeting the audit team presented the preliminary findings of the audit. The CAs provided additional information/clarifications and outlined further steps to be taken to make the system of official controls in the scope of this audit more efficient.

8 RECOMMENDATIONS

No.	Recommendation
1.	To ensure that national legislation or APEDA provisions to register peanuts units for EU export cover or are equivalent to the requirements of Annex II to Regulation (EC) No 852/2004. *Recommendation is based upon conclusion No 3* *Associated finding: No 2*
2.	Continue to promote good agricultural practices and measures for preventing aflatoxin contamination and in particular to implement official controls to verify the compliance of farmers with all relevant EU requirements. This is to ensure compliance with Parts A and B of Annex I to Regulation (EC) No 852/2004. *Recommendation is based upon conclusions No 20 and 36.* *Associated findings: No 12, 13, 14, 22 and 23.*
3.	To ensure that only registered food business operators are allowed to handle and provide peanuts for export to the EU and that official controls are carried out with the established frequency of registered food business operators in line with the APEDA procedure for export of peanut to the EU. *Recommendation is based upon conclusion No 21.* *Associated findings: No 15, 16, 17 ,18, 19 and 34.*
4.	To ensure that official controls of registered food business operators guarantee that peanuts intended for export to the EU are handled, prepared, packaged and stored a in hygienic manner and in accordance with the requirements of Annex II to Regulation (EC) No 852/2004 and come from establishments implementing a programme based on HACCP principles. *Recommendation is based upon conclusion No 37.* *Associated findings: No 25, 26, 27, 28, 30, 31.*
5.	To ensure that heath certificates for export to the EU are issued only when the operators comply with the conditions stipulated in the certificate. This is to ensure compliance with the conditions set out in Annex IV to Regulation (EU) 2019/1793. *Recommendation is based upon conclusion No 50* *Associated finding: No 46.*

No.	Recommendation
6.	To ensure sampling details are properly recorded and that incremental samples are collected fully in line with Regulation (EC) 401/2006. *Recommendation is based upon conclusion No 58* *Associated findings 55 and 56.*
7.	To ensure that practices implemented by laboratories are in line with all relevant EU requirements, and in particular that: a) Adequate method validation is carried out to satisfy performance criteria specified in section 4.2 of Annex II to Regulation (EC) No 401/2006; b) That measurement uncertainty is properly calculated and reported as described in section 4.4 of Annex II to Regulation (EC) No 401/2006. *Recommendation is based upon conclusion No 72* *Associated findings: No 69 and 70.*
8.	To ensure that EU RASFF notifications are subject to adequate investigations and in particular that: a) Follow-up inspections cover all stages of production and handling of peanuts as necessary as to ascertain the root cause of the problem. b) The National Reference Laboratory carries out proper supervision of the sampling and analysis of consignments involved in RASFF notifications. c) Corrective actions are taken by the food business operators involved. *Recommendation is based upon conclusion No 81.* *Associated findings: No 75, 78 and 80.*

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2023-7865

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 2019/1793	OJ L 277, 29.10.2019, p. 89–129	Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
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. 315/93	OJ L 37, 13.2.1993, p. 1-3	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food

Reg. 2017/625	OJ L 95, 7.4.2017, p. 1–142	Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)