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 Directorate-General for Health and Food Safety in Myanmar from 21 February to 1 March 2018.

The objectives of the audit were to assess the official control systems related to production and processing of seeds for human consumption (in particular, mung beans for sprouting) intended for EU export, to evaluate procedures in place for the certification for imports into the EU of seeds for the production of sprouts and to follow-up the recommendations of the previous audit on the topic carried out in 2014.

Myanmar was selected for the current audit due to a large outbreak in the EU connected with the consumption of sprouted seeds and the volume of imports from Myanmar.

The competent authority has made significant progress in implementing and improving the control system for mung beans for sprouting intended for EU export since the previous audit. Official food safety controls on primary production, collection and processing of seeds for human consumption are in place. The competent authorities of Myanmar are aware of the requirements of EU legislation on sprouts and seeds for sprouting. Hygiene practices in the processing facilities, at collectors and farms visited by the audit team were generally in line with the relevant EU requirements. The competent authority has addressed two out of three relevant recommendations of the 2014 report.

The system of official food safety controls currently in place can largely ensure that the seeds for human consumption (in particular, seeds for sprouting) were produced under conditions which meet the EU’s general hygiene provisions for primary production and therefore the competent authority is able to certify conformity with these requirements.

The report contains one recommendation to Myanmar to address the shortcomings identified.
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Annex 1 – Legal References
Annex 2 – Standards
ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
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<tbody>
<tr>
<td>CA</td>
<td>Competent Authority</td>
</tr>
<tr>
<td>CODEX</td>
<td>Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization</td>
</tr>
<tr>
<td>DG Health and Food Safety</td>
<td>Directorate-General for Health and Food Safety</td>
</tr>
<tr>
<td>DOA</td>
<td>Department of Agriculture</td>
</tr>
<tr>
<td>EFSA</td>
<td>European Food Safety Authority</td>
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<tr>
<td>FBO</td>
<td>Food Business Operator</td>
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<tr>
<td>GAP</td>
<td>Good Agricultural Practices</td>
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<td>GHP</td>
<td>Good Hygiene Practice</td>
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<td>GMP</td>
<td>Good Manufacturing Principles</td>
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<tr>
<td>HACCP</td>
<td>Hazard Analysis and Critical Control Points</td>
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<tr>
<td>ISO</td>
<td>International Organisation for Standardization</td>
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<tr>
<td>MITS</td>
<td>Myanmar Inspection and Testing Services</td>
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<tr>
<td>MOALI</td>
<td>Ministry of Agriculture, Livestock and Irrigation</td>
</tr>
<tr>
<td>MOC</td>
<td>Ministry of Commerce</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
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<tr>
<td>PPD</td>
<td>Plant Protection Division in the Department of Agriculture of MOALI</td>
</tr>
<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
</tr>
<tr>
<td>STEC</td>
<td>Shiga Toxin-Producing <em>Escherichia Coli</em></td>
</tr>
<tr>
<td>TDP</td>
<td>EU Funded Trade Development Programme</td>
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</table>
1 INTRODUCTION

This audit took place in Myanmar from 21 February to 1 March 2018. The audit team comprised two auditors from the Directorate-General for Health and Food Safety (DG Health and Food Safety).

The audit was undertaken as part of DG Health and Food Safety’s annual audit programme. The audit team was accompanied throughout the audit by representatives of the Competent Authority (CA) the Plant Protection Division (PPD) of the Department of Agriculture (DOA) under the Ministry of Agriculture, Livestock and Irrigation (MOALI).

The opening meeting was held on 21 February 2018 with the CA and the Ministry of Commerce (MOC). During the meeting, the objectives of the audit, itinerary and the standard reporting procedures were confirmed.

2 OBJECTIVES AND SCOPE

The objectives of the audit were to:

- To assess the official control systems in place for exporting seeds for sprouting to the European Union (EU).
- Follow-up the recommendations of audit DG(SANCO) 2014-7169.

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

Table 1: Audit visits and meetings

<table>
<thead>
<tr>
<th>Meetings/visits</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent authorities</td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>3</td>
</tr>
<tr>
<td>Processors /Exporters/Farms</td>
<td></td>
</tr>
<tr>
<td>Processors/Exporters</td>
<td>4</td>
</tr>
<tr>
<td>Collector of seeds for sprouting</td>
<td>2</td>
</tr>
<tr>
<td>Farms producing seeds for sprouting</td>
<td>2</td>
</tr>
</tbody>
</table>
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 non-EU countries may verify compliance or equivalence of non-EU country legislation and systems with EU feed and food law. These controls shall have particular regard to the assurances which the non-EU country 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 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 outbreak of STEC in May 2011 in the EU. The EFSA report can be found at: [http://www.efsa.europa.eu/en/efsajournal/pub/2424](http://www.efsa.europa.eu/en/efsajournal/pub/2424).

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 levels.

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 laid down in Regulation (EC) No 852/2004. Appropriate certification requirements are therefore laid down for such commodities imported into the EU.

In view of the large 2011 outbreak and the volume of imports from Myanmar, DG Health and Food Safety decided to undertake an audit to Myanmar in order to assess the control systems in place to control microbiological contamination in seeds for human consumption (in particular seeds for sprouting) intended for export to the EU.
Table 2: Imports of seeds for sprouting from Myanmar to the EU (data from CA)

<table>
<thead>
<tr>
<th>Year</th>
<th>Export to EU (in tons)</th>
<th>Main regions and cultivated areas (in hectares)</th>
<th>Number of Producers</th>
<th>Processors Exporters (Yangon) to EU</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yangon</td>
<td>Bago</td>
<td>Yangon</td>
</tr>
<tr>
<td>2015</td>
<td>7,755</td>
<td>25,484.66</td>
<td>29,549.72</td>
<td>5,708</td>
</tr>
<tr>
<td>2016</td>
<td>7,163</td>
<td>30,037.77</td>
<td>31,500.02</td>
<td>7,099</td>
</tr>
<tr>
<td>2017</td>
<td>11,014</td>
<td>21,982.67</td>
<td>31,153.92</td>
<td>5,509</td>
</tr>
</tbody>
</table>

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 non-EU country.

Findings

1. At the time of the previous audit Myanmar had no food safety requirements applicable to producers of seeds for sprouting to be exported to the EU (in line with the requirements of Annex I to Regulation (EC) No 852/2004). No legislation existed for official controls at primary production for either foods of animal or of non-animal origin.

2. Since the last audit new legislation has been brought into force to fill this gap. In particular Directive No. 75/2016 was issued on 5 September 2016, defining PPD as the CA in charge of issuing the EU certificate “Certificate for the Import of Sprouts or Seeds Intended for the Production of Sprouts” as laid down in Regulation (EU) No 211/2013. The directive also sets out the requirement for inspections along the supply chain (primary producers, collectors and processors/exporters) to verify the implementation of EU regulations, directives and decisions, regarding exports of seeds intended for sprouting to the EU Member States. This directive is issued under the provisions of Article 27 (a) of Chapter VIII of the Plant Pest Quarantine Law 1993.

Conclusion on National Legislation

3. Significant progress has been made since the last audit. The legal requirements in national legislation meet EU requirements and cover official controls along the supply chain of seeds for sprouting to be exported to the EU.
5.2 COMPETENT AUTHORITIES

Legal requirements

Articles 46(1)(b) and (c) of Regulation (EC) No 882/2004 stipulate that EU controls shall have, *inter alia*, particular regard to the organisation of the CAs in the non-EU country, 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

4. On 29 January 2015 PPD under the umbrella of DOA was designated as the CA via a Memorandum of Understanding (MOU) signed between the DOA of MOAI (since renamed to MOALI)) and the Department of Trade Promotion of MOC. Directive No. 75/2016 identifies PPD as the CA responsible for issuing the EU certificate for the import into the EU of seeds intended for sprouting required under Regulation (EU) No 211/2013.

5. As per the above mentioned MOU, PPD is responsible for food inspections at farmer and collector level and MOC's then "Research Development and Technical Extension Division" now called the Information Technology and Quality Management Division is responsible for inspections at processors level. The latter body has delegated the responsibility of inspection to the Myanmar Inspection and Testing Services (MITS) via an agreement signed on 13/02/2015.

6. MITS is an autonomous semi-government organisation under the MOC with competency to conduct inspections at processor levels. MITS is International Organisation for Standardization (ISO) 9001 certified and is in process of implementing ISO 17020.

7. For official control of exports of beans intended for sprouting PPD has at central level sixteen staff (three are full time working in this area) and at regional level nine inspectors in the Yangon region and nine more in the Bago region responsible for seeds for sprouting. If required, additional resources can be made available from other divisions within MOALI.

8. MITS has seven inspectors (plus two team leaders) for inspecting exporter facilities processing seeds intended for sprouting.

9. Inspectors of PPD and MITS received specific training on hygiene requirements and microbiological risk reduction along the production chain of seeds for sprouting. For example inspectors of PPD, responsible for inspecting farmers, are trained in Good Agricultural Practices (GAP). These inspectors have attended a series of nine workshops on performance of official controls and on GAP.

10. The MOU specifies the schedule of inspections at each level. The responsibility of inspectors to record his/her findings by completing a checklist is also defined in the MOU. MITS sends the verified inspection reports to PPD. Based on inspection findings at each level i.e. farmer and collector, the exporter is approved for export of beans for sprouting to the EU on an annual basis.
11. PPD is a structured organisation with clear responsibilities established for various personnel involved in the activities of inspection.

12. The audit team was informed that, based on the experience of the past two years, PPD plans to improve, update and document these responsibilities along with competencies required for personnel involved in the various activities of inspection. PPD is developing an "Action Plan 2020" for improving inspection procedures with focus on independence, impartiality and competency. The goal of PPD is to implement a fully documented inspection system in line with requirements of CODEX CAC/GL 20, CAC/GL 26 and ISO 17020 by 2020.

13. Under the "Action Plan 2020", a series of hands-on workshops and trainings for inspectors and personnel involved in other activities of inspection have been identified.

### Conclusion on Competent Authorities

14. The CA has a structure, organisation, powers, staff, documented control procedures and resources available for an official control system covering the production chain of mung beans for sprouting to be exported to the EU. These should allow the CA to enforce adequate guarantees as regards compliance with the relevant EU requirements.

### 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 (EU) 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

##### Training Activities to Reduce Microbiological Risks

15. Before the previous audit mung bean farmers, collectors and processors were not aware of best practices to control microbiological contamination. Although GAP were partly in place, hygiene practices were absent at farm level. Conditions of collectors’ warehouses
were also not fully in line with good storage practices. Only one processing plant had a certified Hazard Analysis and Critical Control Points (HACCP) system in place.

16. Since 2015, 6,215 farmers received training on GAP and all collectors and processors/exporters were trained in Good Manufacturing Principles (GMP) and Good Hygiene Practice (GHP) by DOA and via various international projects including the EU funded Trade Development Programme (TDP). The Extension Division of the DOA also provides training on GAP to the farmers. Processors are additionally being trained by international programmes such as TDP. However, the CA informed the audit team that by end-2018 around 45% of the 5,558 farmers registered for exporting to the EU will have received training on GAP and GHP.

17. That is a considerable improvement regarding the situation in 2017, where only 10% of the farmers exporting to the EU in 2017 had received the training organised by DOA.

18. DOA has developed Myanmar GAP documentation for 15 crops (including green mung beans for sprouting). The documentation is in local language, to improve the understanding at farm level. Under the TDP an easy to understand guideline is at the final stage of development. The guideline is based on the European Sprouted Seeds Association guideline.

19. The audit team was informed that DOA will continue training farmers and collectors

5.3.1 System of Official Controls of Green Mung Beans for Sprouting

20. The control system of green mung beans for sprouting intended for EU export consists of systematic official controls along the production chain. Official controls are performed at the level of farms, collectors and processor/exporters. Farms and collectors must be registered and processor/exporters must additionally be approved by the CA for EU exports.

5.3.2 Organisation of Official Controls

Supervisory Committee for Exports of Seeds for Sprouting to the EU

21. After the previous audit in 2014 the MOALI has introduced a Supervisory Committee for exports of seeds for sprouting to the EU. The Committee consists of representatives of the CA and CAs as well as exporters and relevant divisions of DOA such as Extension Division and Seed Division. Committee meetings take place 3-5 times a year, if needed the frequency could be higher. The Committee decides on future measures to be implemented such as contract farming or the obligation for exporters to finance the training of farmers on GAP etc. Several records of these meetings were presented to the audit team.

Planning of Official Controls

22. Based on the decisions of the Supervisory Committee, PPD has focused on the transition from traditional inspection to modern inspection methodologies. Three checklists for inspections were developed as well as procedures for planning inspections, recording the findings on the checklists, applying for certification of export consignments and for
issuing of the export certificates as required by Regulation (EU) No 211/2013. The procedures are based on Regulation (EC) No 882/2004 and are implemented. The CA provided the audit team with the three comprehensive checklists that are based on the EU approved guideline of the European Sprouts Association and the first detailed planning for the inspections of producers of seeds for sprouting in 2018. Before 2018 such inspections were performed at farms selected by the exporters.

23. Inspection planning currently takes account of the number of farms in a particular village, the size of the farms and/or the accessibility of the plots cultivated, it does not take into account risks involved. A risk-based planning is intended to be implemented in 2019/2020. The current plan is based on lists provided by the exporters and covers 5,558 producers of mung beans involved in the EU export trade and has a target of 189 inspections for 2018.

Table 3: Inspection planning 2018

<table>
<thead>
<tr>
<th>Stakeholder in value chain (number)</th>
<th>Inspection frequency</th>
<th>Inspection conducted by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processor/Exporter (7)</td>
<td>100% -200%</td>
<td>MITS</td>
</tr>
<tr>
<td>Collector (12)</td>
<td>100%</td>
<td>PPD</td>
</tr>
<tr>
<td>Farmer (5558)</td>
<td>3% to 5% of farmers per company</td>
<td>PPD</td>
</tr>
</tbody>
</table>

24. At present all exporters (located in the Yangon region) procure seeds for sprouting for EU export from two regions – Yangon and Bago. Each region is divided into townships. Collectors from both regions source seeds from farmers located in various villages within each township.

5.3.3 Registration of Food Business Operators

25. The Union of Myanmar requires all stakeholders in the production chain to be registered. The CA stated that all farmers, collectors and processors/exporters of green mung beans for EU export were registered at the time of the audit.

   a. Farmers must register with the Department of Agricultural Land Management and Statistics of MOALI.
   b. Collectors must register with the local government under the Ministry of Industry, while the
   c. Processors/exporters must register with the local government (e.g. Yangon City Development Committee).
   d. Processors need also to be registered by the MOC, Ministry of Planning and Finance (Directorate of Investment and Company Registration) and the Ministry of Industry (Directorate of Industrial Supervision and Inspection).
   e. Exporters need to be approved and registered for EU export of green mung beans for sprouting after an inspection of the premises by MITS, the approval needs to be renewed every year.
26. The main production areas in Myanmar for mung beans intended for export to the EU are about 50 km south of Yangon in the Yangon region and 100 km north east in the Bago region (see Table 2 above). The CA stated that the main production of seeds for sprouting for EU export was switched to Yangon region due to a request from EU buyers for a specific variety that is mainly produced in Yangon region. The audit team visited two townships in the Yangon region.

27. The frequency of official controls is 3-5% of farms registered with exporters. In 2017 PPD conducted 251 inspections at farm level in Yangon and Bago regions. Deficiencies noted and leading to a recommendation covered training of workers (119 reports), cleaning of threshing machines (22 reports), toilets and washing facilities (30 reports) and the use of tarpaulins post-harvest (17 reports).

28. Of the 47 reports covering the Bago region one report a deficiency was noted in only one report (access of animals to the field). The CA stated that they assume that the approach of the inspection team in Bago region is different and non-compliances are not recorded accordingly. Corrective actions (training and an up-dated checklist) are planned to be implemented in the following weeks.

29. The audit team together with the representatives of the CA evaluated 53 of these inspection reports of farms producing seeds. Deficiencies leading to a recommendation were noted in most farms visited. Problems covered areas such as training of workers (43 reports), cleaning of threshing machines (15 reports), toilets and washing facilities (11 reports) and the absence of tarpaulins for post-harvest use were recorded in three reports.

30. The audit team also reviewed a sample of 2018 reports (47) based on an up-dated checklist that allows inspectors to provide more comments and to reduce the need of judgements regrading non-compliances by the reduction from of a four-level judgement (compliant, minor, major, serious) to a two-level judgement (compliant, non-compliant). The inspectors that used the new checklist reported that it was easier to use.

31. The audit team visited two mung bean farmers in two different townships in Yangon region. One farm of 30 acres was subject to an official control (inspection) by PPD. The other farm of 150 acres was checked in the frame of a non-compliant EU lot investigation (see paragraphs 47 and 48 below) by the exporter and the EU buyer. Both farmers were aware of EU requirements for seeds for sprouting and all measures for the reduction of microbiological risks such as field toilets, hand washing facilities, use of tarpaulins during drying were in place at the time of the visit.

32. Recommendation No 1 of the previous audit “Ensure that all farms where seeds for sprouting for export to the EU are produced are under official food safety controls, to ensure that produce exported to the EU meets the requirements in the certificate laid down in Regulation (EU) No 211/2013” can be considered as fully addressed.
5.3.5 Official Controls at Collectors

33. The frequency of official controls is at least once a year for collectors connected with exporters. In 2017 PPD conducted 10 inspections at collector level.

34. The audit team visited two collectors of seeds for sprouting which are based in the same townships as the growers. The collectors buy mung beans from the farmers and store them in their facilities. They grade the incoming bags either high quality or low quality. Both collectors visited had received training on good hygiene practices and EU requirements.

35. One of the collectors was traced as supplier of raw material resulting in a non-compliant lot at the EU importer (see paragraphs 47 and 48). Both collectors were subject to official inspections, the audit team checked the inspection reports that indicated no non-compliances. For confirmation purposes the audit team assessed the facilities visited and found they were, in general, in compliance with the requirements of Annex II of Regulation (EU) No 852/2004 and Codex Alimentarius General principles of food hygiene (CAC/RCP 1-1969). However, in both storage rooms the audit team spotted that some nets for protection against birds had holes and that there were other small openings in the walls, ceilings, and entrance that could potentially provide access for rodents. The inspectors had not noted these defects and the collectors stated that they would rectify them as soon as possible.

36. Recommendation No 2 of the previous audit to “Ensure that the storage conditions and the prevention of pests entering processing and storage facilities for seeds for sprouting meet the requirements set out in particular in Annex I and Annex II, Chapters I. 2. (c), II. 1. (d) and IX. 4. of Regulation (EC) No 852/2004 and the CODEX Code of Practice CAC/RCP 1-1969 – General principles of food hygiene section 6.3.2.” is partly addressed.

5.3.6 Official Controls at Processors/Exporters

37. The CA informed the audit team that in 2017 the processors/exporters had been inspected once or twice as regards food hygiene by MITS.

38. For the season 2018 seven processors/exporters were inspected for the export of seeds for sprouting to the EU.

39. Processors/exporters are encouraged to implement HACCP based systems which require developing own-check systems (internal verification/audit) and monitoring suppliers along the supply chain from where hazards could be introduced. Six processors/exporters now have HACCP systems in place and the seventh is in the process of installing one. At the last audit only one exporter had a HACCP system.

40. The audit team visited four processors/exporters of seeds for sprouting in the Yangon region. At the request of customers the processors carry out microbiological testing of seeds for sprouting (*Salmonella, E. coli*). The managers of the four FBOs informed the audit team that no non-compliant samples had been found during these importers requested tests.
41. The four processors/exporters visited, exported last year approximately 8,000 tons of mung beans for sprouting to the EU. The FBOs bought the produce from one to two collectors.

42. The audit team reviewed all the inspection reports done by MITS (2014-2018) at the processors visited. All reports/checklists were thoroughly filled out and showed a small number of deficiencies in particular in 2015 and 2016. Corrective actions promised by the exporters and signed on the reports had been implemented. The MITS inspectors were asked by the audit team to perform during the visits demonstration exercises of parts of official controls for validating the performance in conducting traceability checks (also with a non-compliant lot identified during testing in the EU see paragraphs 47 and 48), in assessing analytical reports and HACCP plans.

43. MITS inspectors showed, during their demonstration exercises, good knowledge regarding traceability and weaknesses/deficiencies in evaluating analytical reports and assessing the FBOs' HACCP plans.

44. The processors were able to fully trace the produce back to the collectors and to producers. Traceability of the seeds intended for sprouting is based on the exporter name, container number and date of shipment. The container number can be traced to the exporter that dispatched the container. The container number can be traced through the processing to the collector supplying the seeds for sprouting. The exporter maintains the records of incoming material along with the name of the collector, date of receipt and truck number. The collector is able to trace the beans to the farmers with details on quantity and date of receipt. This traceability is verified during inspection at all levels – farmer, collector and exporter.

45. Plausibility checks were not performed by exporters or inspectors. Plausibility checks of the audit team regarding delivered quantity of mung beans of farmers in relation of acreage under production did not always fully result in matches, in two cases the quantity delivered seemed to be too high for the area under production. The FBO involved promised to analyse and sort out the issues.

46. The audit team assessed three of the four facilities visited and found they were, in general, in line with the requirements of Annex II of Regulation (EC) No 852/2004 and of Codex Alimentarius General Principles of food hygiene (CAC/RCP 1-1969). However, in two cases the audit team spotted holes in the entrance door nets and door seals that could potentially provide access for rodents; this is not in compliance with the requirements set out in section 6.3.2. of the same standard. Only some of these deficiencies were spotted by the inspectors during the audit team visits.

47. The audit team checked the follow-up actions of the exporter of a lot that was considered by an EU importer as microbiologically contaminated (after a microbiological analysis). The CA was not aware about this case.

48. The FBO stated that they made together with a representative of the EU importer a root cause analysis along the chain, checking possible sources during harvest, transport and storage. One of the collectors and one of the farmers were traced as suppliers of the raw
material resulting in the non-compliant lot. As the most probable source for microbiological contamination of the lot they identified that the farmer did not always use tarpaulins for drying the beans after harvest due to a shortage of tarpaulins. As corrective action the collector provided afterwards 100 tarpaulins and 250 mobile handwashing containers to some of his 1,076 farmers supplying produce for EU export.

5.3.7 Non-Conforming Products and Deficiencies Detected During Inspections

49. Testing for microbiological contamination is not legally required for beans for sprouting intended for EU export and was not performed. Non-compliant products were not identified and therefore no enforcement actions occurred.

50. Deficiencies identified during the inspections are shared with the farmer/collector/processor (subject of the inspection) with a written recommendation of the inspectors and a written statement of the FBO inspected agreeing to take corrective actions (documented in the checklist). At the time of the audit there was no system in place for automatic follow-up on the implementation of corrective actions. However, the audit team checked the inspection reports and noted that non-compliances did not reappear in consecutive inspection reports.

51. The CA informed the audit team that under the TDP, PPD plans to improve the risk based planning of inspections (findings of the previous inspection) using statistical tools. Procedures for systematic follow-up activities are planned to be implemented. This new inspection plan will be implemented in the next season in 2019.

Conclusions on Official controls

52. There is an official control system in place covering farmers, collectors and exporters of mung beans for sprouting intended for EU export.

53. As a result, the CA can largely guarantee that farmers, collectors and exporters involved in exports of seeds for sprouting to the EU comply with the requirements of Article 4 of Regulation (EC) No 852/2004 in conjunction with Article 10 and Annex I of the same Regulation.

54. The measures for the prevention of pests entering processing and storage facilities for seeds for sprouting did not always meet the requirements set out in particular in Annex I and Annex II, Chapters I. 2. (c), II. 1. (d) and IX. 4. of Regulation (EC) No 852/2004 and the CODEX Code of Practice CAC/RCP 1-1969 – General principles of food hygiene section 6.3.2.”.
5.4 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

55. There is no legal requirement for official sampling and testing of the microbiological parameters of seeds for sprouting to be exported to the EU. Sampling and testing is not performed by Myanmar for seeds for sprouting prior to EU export.

56. Recommendation No 4 of the previous audit “Ensure that sampling procedures for microbiological analysis of seeds for sprouting intended for export to the EU, in particular, the representativeness of the laboratory sample, meet requirements at least equivalent to those laid down by CODEX Alimentarius General Guidelines on sampling CAC/GL 50-2004 chapters 2.1.2. and 2.3.3.” was obsolete as official sampling and analysis is not performed.

57. However, at the request of customers the processors carry out microbiological testing of seeds for sprouting (Salmonella spp., E. coli). These tests are conducted in external laboratories. The test reports from the external laboratories are available on request.

Conclusion on Sampling

58. Official sampling of consignments of seeds for sprouting intended for EU export for the detection of Salmonella spp. and E. coli is not performed.

5.5 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 non-EU country can give regarding compliance with, or equivalence to, EU legislation.

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

Findings

The procedure for export certification is as follows:

59. Once a consignment is ready for export, the exporter or his agent applies for the phytosanitary certificate and the EU’s Certificate for the Import of Sprouts or Seeds Intended for the Production of Sprouts at PPD. Before export, the PPD, upon reception
of all the necessary documentation, carries out an on-site inspection of the consignment intended for export at the premises of the exporter. On condition that the result of the official control is in compliance with the requirements of the Plant Pest Quarantine Law and importing countries’ relevant requirements it issues a phytosanitary certificate.

60. If the exporter is officially approved for export of beans for sprouting to the EU, PPD issues the certificate for seeds intended for the production of sprouts. The certificates include the details of the exporter, the importer, container number, number of bags etc. as required by Regulation (EU) No 211/2013.

61. At the port, customs services verify the certificate and confirm the container and importer details. The container is permitted to be loaded only if it is accompanied with the certificates and all the required documents.

62. Recommendation No 3 of the previous audit to “Ensure that the procedure for export certification of seeds for sprouting attests that the seeds for sprouting were produced under conditions which meet the general hygiene provisions for primary production and associated operations as required by certificate laid down in Regulation (EU) No 211/2013” is fully addressed.

Conclusion on Certification Procedures for Exporting to the EU

63. There is a certification procedure for exporting to the EU in place to attest to the hygienic production for seeds for sprouting required by Regulation (EU) No 211/2013 in place for green mung bean seeds for sprouting for export to the EU.

5.6 RESPONSE TO RASFF NOTIFICATIONS

Legal requirements

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

Findings

64. At the time of the audit there were no Rapid Alert System for Food and Feed (RASFF) notifications issued concerning food of non-animal origin, including seeds for sprouting from Myanmar. The CA in charge of receiving RASFF notifications from the European Commission services related to import of beans intended for sprouting is PPD.

65. The procedure for dealing with RASFF notifications includes full investigation of the notification. This includes
a. tracing the container number to the exporter, through it to the collector and then to the farmer.
b. A root cause analysis regarding the possible cause of the notification would be conducted. Based on the traceability links of the container the previous inspection reports for the exporter, collector and the farmer will be reviewed.

66. The conclusion of the investigation will be shared with the exporter/collector/farmer requesting corrective actions to be taken for identified non-compliances, if any. The conclusions of the investigation and the non-compliances identified along with the proposed corrective actions provided by the exporter/collector/farmer will be passed, via the EU delegation in Yangon, to the RASFF team in the Commission in Brussels.

67. On completion of the proposed corrective actions by the exporter/collector/farmer, PPD will verify the effectiveness of the implementation of corrective actions before closing the non-compliances. The status of the closure of the non-compliances will also be shared with the EU via the EU delegation in Yangon.

68. The audit team was informed that as a proactive measure, PPD plans (Action Plan 2020) to test the procedure for dealing with the RASFF notification, which would include conducting a mock recall to verify traceability of seeds for sprouting from container number to farmer through the exporter and collector. Records of this traceability verification will be maintained.

Conclusion on Response to RASFF Notifications.

69. There is a CA responsible for follow-up of RASFF notifications and comprehensive procedures are in place.

6  OVERALL CONCLUSIONS

The competent authority has made significant progress in implementing and improving the control system for mung beans for sprouting intended for EU export since the previous audit. Official food safety controls on primary production, collection and processing of seeds for human consumption are in place. The competent authorities of Myanmar are aware of the requirements of EU legislation on sprouts and seeds for sprouting. Hygiene practices in the processing facilities, at collectors and farms visited by the audit team were generally in line with the relevant EU requirements. The competent authority has addressed two out of three relevant recommendations of the 2014 report.

The system of official food safety controls currently in place can largely ensure that the seeds for human consumption (in particular, seeds for sprouting) were produced under conditions which meet the EU's general hygiene provisions for primary production and therefore the competent authority is able to certify conformity with these requirements.
7 CLOSING MEETING

A closing meeting was held on 01 March 2018 with representatives of the CA, CAs, private sector representatives and the EU Delegation to Myanmar. The audit team presented the main findings and preliminary conclusions of the audit. The CAs made initial comments and provided some additional information.

8 RECOMMENDATION

An action plan in response to the recommendation 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 the following recommendation.

<table>
<thead>
<tr>
<th>No.</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>1.</td>
<td>The CA should ensure that the storage conditions and the prevention of pests entering processing and storage facilities for seeds for sprouting meet the requirements set out in particular in Annex I and Annex II, Chapters I. 2. (c), II. 1. (d) and IX. 4. of Regulation (EU) No 852/2004 and the CODEX Code of Practice CAC/RCP 1-1969 – General principles of food hygiene section 6.3.2.” is partly addressed.</td>
</tr>
<tr>
<td></td>
<td>Recommendation based on conclusion No 54</td>
</tr>
<tr>
<td></td>
<td>Associated findings No 35, 46.</td>
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</tbody>
</table>

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

## ANNEX 1 – LEGAL REFERENCES

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
<th>Title</th>
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# Annex 2 – Standards

<table>
<thead>
<tr>
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