STANDARD OPERATING PROCEDURE (SOP) TO HANDLE RAPID ALERT (RASFF) AND COMPLAINT FOR APEDA SCHEDULED PRODUCTS

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STANDARD OPERATING PROCEDURE TO HANDLE THE RAPID ALERT (RASFF) AND COMPLAINT FOR APEDA SCHEDULED PRODUCTS

Background
It is essential to establish Standard Operating Procedure (SOP) to handle Rapid Alerts and complaints which includes investigating the cause of concern, verifying the remedial measures taken in order to minimize possibilities of presence of harmful micro-organisms like bacterium, insect, pest, pathogens and mycotoxins in excess of prescribed levels in APEDA scheduled products.

Applicability: This Standard Operating Procedures (SOP) applies to all APEDA scheduled products.

Procedure for dealing with RASFF and rejection

An intimation alongwith copy of the RASFF, rejection and complaints shall be disseminated by APEDA through email as well as letter to Exporters, Pack house, NPPO and to authorized laboratory. APEDA may intimate the concerned exporter and seek clarification from the exporter within next seven days. The exporter will be required to submit the following information within seven days of receipt of notice:

i) Full particulars of the consignment such as product name, quantity, batch code/grade along with self-attested copies of related documents such as Laboratory Test Report, Phytosanitary certificate for export, health certificate, etc. and also source of Raw Agricultural Commodities used for Post Harvest Handling like sorting, grading, processing, packing and export.

ii) Test reports of finished products including the pre export test report for presence of harmful micro-organisms like bacterium, insect, pest, pathogens and mycotoxins in APEDA scheduled products pertaining to the consignment.

iii) The particulars of Raw Agricultural Commodities (RAC) products procured by the exporter for Backward Linkage Traceability.

iv) Feedback regarding the reason for rapid alert or rejection.

v) Additional information, if any, relevant to the RASFF/rejection/complaint.
2. **Information from the laboratory and in-house Laboratory of pack house/processing unit, which had tested the product in question:**

   i) The laboratory will submit complete set of Test reports like chromatograph, Agrochemicals residue details of test done to APEDA

   ii) The pack house / in-house labs will submit the observations recorded by Quarantine Inspector for the issue of Phytosanitary Certificate i.e. Plant Passport (where ever applicable). The observations from Quarantine Inspector would be required for the purpose of assessment during the pack house recognition procedure of the exporter.

3. The feedback received pertaining to respective Rapid Alert (RASFF) and rejection or complaint from the concerned exporter, shall be reviewed by the Two member committee comprised of Quality division, Product division.

4. **Penal provision:** In the event of breach of these procedures by any of the stakeholders, APEDA may initiate action following action.

   4.1 **Action against exporter:**

   - **On 1st failure:** Warning to the concerned exporter.

   - **On 2nd failure:** 15 days’ temporary suspension on export of APEDA scheduled products by the concerned exporter by suspending RCMC / pack house. Labs will also be intimated of this so that no samples would be drawn from the banned exporter /pack house. APEDA will inform NPPO for stopping issuance of PSC to the said exporter.

   - **On 3rd failure:** Cancellation of Registration/ Recognition Certificate of concerned exporter/pack house/processing unit. The exporter shall not be allowed to undertake exports from any other APEDA recognized pack house(s) till he conforms to satisfactory demonstration of compliance requirements.
5. Restoration of approval:

5.1 Assessment of Root-Cause Analysis (RCA) by Inter Department Panel member (IDP)

i) APEDA will carry out a root cause analysis and send a detailed report on the proposed corrective actions and measures to prevent the recurrence of the non-compliance.

ii) The periodicity of verification by APEDA shall be on basis depending on occurrence of the RASFF and rejection.

iii) Assessment to be carried out by at least two member Inter Department Panel (IDP), consisting of one representative each from APEDA, one either from Dte. of Plant Protection Quarantine and Storage (NPPO), Faridabad/ representative/ from respective state Government from Agriculture/ Horticulture department, representative from State Agriculture University. The root-cause analysis would involve the following:

- A detailed root causes analysis by the panel (including audit of primary production facilities to ascertain the actual cause of rejection).

- IDP will verify the remedial measures so as to prevent further rejection and to collect details of the rejected consignment, in case the same has not been received.

Assessment shall include

Control measures exercised by the exporter/ pack house/ processing unit at all stages of production, Post Harvest Handling procedure and transportation, including Good Handling Practices (GHP), sanitary controls, personal hygiene control, pest control, calibration, record keeping, etc.

Source of raw materials, traceability system of the unit, testing of raw materials pre-export test reports as applicable, transportation etc.

Internal audits including primary production, training of employees.
Report may contain

- Source of produce / procurement of raw materials for the rejected consignment.
- Details of pre-export testing of the rejected consignment.
- Hygiene and sanitation procedures adopted by the exporter / pack house facility operator. Good Management Practices (GMP), control on water, personal hygiene control, pest control etc., as applicable.
- Control measures exercised by the exporter / pack house facility operator/ processing unit at all stages of production starting from primary production to prevent presence of harmful microorganisms like bacterium, insect, pest, pathogens and mycotoxins in APEDA scheduled products in excess of prescribed levels of importing country.
- Details of monitoring/supervisory visits of Quality Manager of exporter / Pack house facility operator/ Processing Unit.
- Implementation of the recommendations given, if any, based on earlier RASFF and rejection.
- Possible reasons for rejection of consignment and identified root cause with justification.
- Overall performance of the exporter/Pack house/ Processing unit during IDP visit.

In case Assessment report is found satisfactory exporter will be allowed to export further APEDA scheduled products. In case the report is unsatisfactory, exporter will not be allowed to export of APEDA scheduled products till corrective action is taken and deficiencies rectified.
### Annexure-I

**FORMAT FOR REPORTING ON THE STATUS OF A CONSIGNMENT REJECTED IN THE EUROPEAN UNION (CLAUSE 6 OF CODEX GUIDELINES CAC/GL-25/1997)**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Particulars</th>
<th>Details sought from exporter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rapid Alert No and date</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Reason of rejection of consignment</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Name of the Exporter with address &amp; contact details (Phone/Fax/e-mail)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Intimation received from EU on rejection of consignment vide RASFF No. ______ dated ________ or letter No. ________ dated ________</td>
<td>(Please provide details of shipment of this consignment along with relevant documents like Invoice, Airway Bill/ Bill of Lading, Lab Test Report and Phytosanitary Certificate)</td>
</tr>
<tr>
<td>5</td>
<td>Product(s) of shipment under the above consignment (with HS Code)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Date of Actual shipment from India</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Name &amp; Address of importer and country of imports</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Date of landing of consignment in the EU country (Please specify country)</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Details of laboratory from where prior to export testing was conducted</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Was the consignment complaint with EU norms. If yes, please provide brief details of test report no. and date and provide a copy of the test report</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>When was intimation of rejection received by the exporter and from what source.</td>
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</tr>
<tr>
<td>12</td>
<td>Action taken to retrieve the situation at exporter’s end. (details to be mentioned right from backward linkage like collection of produce to Post Harvest Handling like sorting, grading, packing and Transportation)</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Was the incident reported to APEDA. If yes, when and how (please provide copies of communication in this regard)</td>
<td></td>
</tr>
</tbody>
</table>

Seal of Firm                        Signature of the Exporter