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PROCEDURE FOR EXPORT OF RICE TO CHINA



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PROCEDURE FOR EXPORT OF RICE TO CHINA

1. PURPOSE

To establish a procedure covering sanitary and phytosanitary requirements for export of rice to China.

2. SCOPE

- i. Rice exporters registered with General Administration of Customs of the People's Republic of China. (GACC) or source rice from GACC registered facilities are permitted for exports to China.
- ii. Directorate of Plant Protection, Quarantine and Storage (DPPQS), Department of Agriculture and Farmers Welfare, Govt. of India registers the rice mills/processing units for export to China.
- iii. APEDA recognised laboratories having scope of accreditation for GMO analysis in Rice, analyzes samples from rice consignment for GMO prior to export.

3. RESPONSIBILITY

- i. The export of rice to China shall be allowed only from the rice mills/ processing units registered with DPPQS in accordance with OM F. No. 119-36/2010-POD (Vol V) dt 04.02.2016. The Standard Operating Procedures for Rice Export to China can be accessed at “Standards” section and the lists of Registered Rice Mills / Processing Units for Rice Exports and China can be accessed “Export” section under the “Guidelines” head of Plant Quarantine Management System portal of Directorate of Plant Protection, Quarantine and Storage. The weblink for the same is as follows: <https://pqms.cgg.gov.in/pqms-angular/homeGuidelines>
- ii. Merchant exporters can export Rice to China in compliance to the procedures outlined in the SOPs.
- iii. The manufacturing unit shall implement Hazard Analysis Critical Control Point (HACCP) system and shall maintain the HACCP plan and hazard analysis.
- iv. The exporters shall get the rice consignment analyzed for GMO from APEDA recognised laboratories, having scope of accreditation for GMO analysis in Rice, before shipment.
- v. The APEDA recognised laboratories, having scope of accreditation for GMO analysis in Rice, shall draw samples from the GACC registered facilities, analyse for defined GMO genes and issue Certificate of Analysis.
- vi. The exporter shall then obtain Registration-cum-Allocation Certificate (RCAC) for Basmati Rice or non-Basmati rice, as the case may be, issued by APEDA upon registration of export contacts. The detailed requirements and procedure for applying for RCAC are outlined in the trade notices issued by APEDA time-to time.

4. DEFINITIONS

- a) **Unit:** A unit is a rice manufacturing or rice processing unit having valid GACC registration.

- b) **Lot:** A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc.
- c) **Primary sample/incremental sample:** One or more units taken from one position in a lot.

Notes:

- i. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot.
- ii. The number of units required for a primary sample should be determined by the minimum size and number of laboratory samples required.
- iii. Where more than one primary sample is taken from a lot, each should contribute an approximately similar proportion to the bulk sample.
- iv. Units may be allocated randomly to replicate laboratory samples at the time of collecting the primary sample(s), in cases where the units are of medium or large size and mixing the bulk sample would not make the laboratory sample(s) more representative, or where the units could be damaged by mixing.
- v. Where primary samples are taken at intervals during loading or unloading of a lot, the sampling 'position' is a point in time.
- vi. Units should not be cut or broken to produce the primary sample(s), except where subdivision of units is specified specifically.

- d) **Bulk sample/Aggregate sample:** The combined and well-mixed aggregate of the primary samples taken from a lot.

Notes:

- i. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample.
- ii. Where separate laboratory samples are prepared during collection of the primary sample(s), the bulk sample is the conceptual sum of the laboratory samples, at the time of taking the samples from the lot.

- e) **Laboratory sample:** The sample sent to, or received by, the laboratory. A representative quantity of material removed from the bulk sample.

Notes:

- i. The laboratory sample may be the whole or a part of the bulk sample.
- ii. Replicate of laboratory samples may be prepared.
- iii. Laboratory: An APEDA recognised laboratory for analysis of GMO in rice.

5. RESPONSIBILITY OF EXPORTERS:

1. Exports of rice consignments to China shall be undertaken only by the exporters holding a valid GACC registration for their processing unit or sourced from rice processing units holding valid GACC registration.
2. Manufacture and Manufacture cum Merchant Exporter intending to export rice to China may register on the GACC website through the browser-based CIFER system, accessible at <https://cifer.singlewindow.cn> [<https://cifer.singlewindow.cn>]

3. The exporters shall obtain Phytosanitary Certificate issued by Directorate of Plant Protection, Quarantine & Storage (DPPQS) prior to export.
4. Export consignments of rice shall be allowed to be shipped to China only after testing by laboratories recognized by APEDA having scope of accreditation for GMO analysis in Rice. The list of laboratories recognized for GMO analysis in rice is available on APEDA website under icon “Quality”.
5. The exporter shall apply to recognized laboratories for drawl and testing of samples for GMO analysis. The format for application is at Annexure-I.
6. After sampling, the lot shall not be shifted/relocated by the processing unit/exporter to another location.
7. On conformity of the sample, the exporter shall submit the Certificate of Analysis to APEDA Head Office, New Delhi, along with the application for Registration-cum –Allocation-Certificate (RCAC) which shall be issued prior to export.

6. RESPONSIBILITY OF LABORATORIES:

1. Based on the application submitted by the exporter, the laboratory shall designate an authorized representative for drawing sample. The sampler shall draw samples from the manufacturing facility registered under GACC for GMO testing.
2. The sampler shall draw sample from a specified percentage of the lot selected on a random basis as per the prescribed procedure and homogenizes it to make a composite sample. The laboratory official drawing the sample shall sign Part – II of the Annexure-I and shall dispatch along with the sample. The laboratory shall maintain record of the same.
3. The laboratory shall conduct the testing of sample for GMO as per standard procedure.
4. The laboratory shall issue the Certificate of Analysis to the exporter/processing unit within 5 days of the drawl of the sample on the letter head of the recognized laboratory. The format for issuance of Certificate of Analysis is at **Annexure II**.
5. After the analysis, the laboratory shall retain remnant sample for 90 days and reference sample for a period of 120 days.
6. The Laboratories shall on a Quarterly basis share summary statement of the GMO tests carried out by them for rice, in the format as may be prescribed by APEDA.

7. CRITERIA FOR RECOGNITION OF LABORATORIES:

1. Laboratories for carrying out GMO analysis shall maintain a valid ISO/IEC 17025 accreditation for the applicable commodity matrix i.e. Rice and target genetic elements from NABL. The accreditation shall be covered under the integrated assessment of NABL and recognized within the scope approved by APEDA or EIC. The scope of accreditation shall contain the following GMO elements:
 - CaMV 35S Promoter (pCaM35S)
 - NOS terminator (tNOS)
 - CryIA(b) gene
 - CryIA(c) gene
 - Bar gene
2. The laboratory shall follow the below standard procedure for analysis of GMO with LoD of 0.1%.

8. GENERAL REQUIREMENTS OF SAMPLING:

1. Sample should be drawn only by the trained authorized personnel of laboratory.
2. Samplers should obtain sufficient quantity of the sample to ensure the laboratories will have adequate amounts for processing and reanalysis if necessary (Table 1).
3. If collecting from multiple containers as specified by the procedure to obtain the suggested amounts of the sample, samplers should confirm the products being sampled are from the same lot only.
4. The minimum number of primary/incremental samples to be taken from a lot is determined from Table 1.

Table 1. Minimum number of primary samples to be taken from a lot

Category	Minimum number of primary samples to be taken from lot
Products, packaged or in bulk, which can be assumed to be well mixed or homogenous	Minimum 3 primary samples should be taken.
Products, packaged or in bulk, which may not be well mixed or homogenous Either	
Weight of lot(kg)	
< 50	03
50 – 500	05
> 500	10
Number of cartons, can or container in the lot	Minimum number of cartons, can or container in the lot to be covered
1 – 25	01
26 – 100	05
>100	10

5. Each primary sample should be taken from a randomly chosen position in the lot, as far as practicable. The primary samples must consist of sufficient material to provide the laboratory sample(s) required from the lot.
6. The primary samples should be combined and mixed well, if practicable, to form the bulk sample.
7. In case, where units may be damaged (and thus residues may be affected) by the processes of mixing or sub-division of the bulk sample, or where large units cannot be mixed to produce a more uniform residue distribution, the units should be allocated randomly to replicate laboratory samples at the time of taking the primary samples. In this case, the result to be used should be the mean of valid results obtained from the laboratory samples analyzed.

8.1 Preparation of the laboratory sample

1. Where the bulk sample is larger than is required for a laboratory sample, it should be divided to provide a representative portion. A sampling technique, quartering shall be used to prepare the minimum size required for laboratory samples i.e 1kg.
2. Samples should be random and an upper limit should be placed on a sample size.

8.2 Packaging and transmission of the laboratory sample

1. The laboratory sample must be placed in a clean, inert container which provides secure protection from contamination, damage and leakage.
2. The container should be sealed, securely labeled and the sampling record must be attached.
3. Each sample should be identified by the following minimum information:
 - i. Name & Address of exporter(city/state/zip/country).
 - ii. Sampling location (Unit name & address)
 - iii. Sample identification, including commodity information, variety, brand name and lot number (if applicable), or other identification.
 - iv. Date of sampling
 - v. Sampler's name and signature
4. The sample must be delivered to the laboratory as soon as practicable (Max. within 48 hours)

9. METHODOLOGY AND REQUIREMENTS FOR GMO ANALYSIS BY LABORATORIES

9.1 Analytical Standards

1. GMO analysis shall be conducted using PCR-based methods, preferably Real-Time PCR, in accordance with internationally recognized standards, including:
 - ISO 21571 – DNA Extraction
 - ISO 21569 – Qualitative PCR Detection
 - ISO 21570 – Quantitative PCR Detection
 - ISO 24276 – General Requirements and Method Validation
2. Laboratories may also adopt validated methods published in the EU-JRC Compendium of Reference Methods for GMO Analysis.

9.2 Sample Preparation

1. Representative sampling procedures shall be followed to ensure that the test sample accurately reflects the bulk consignment.
2. Samples shall be properly homogenized prior to analysis to ensure uniform distribution of analytes and to minimize the risk of cross-contamination.

9.3 DNA Extraction and Quality Assessment

1. DNA shall be extracted using validated methods suitable for the specific food, feed, seed, or agricultural matrix under examination.
2. Extracted DNA shall be evaluated for:

- Concentration
 - Purity
 - Integrity
 - Absence of PCR inhibitors
3. Only DNA meeting established quality criteria shall be used for PCR analysis.

9.4 Screening for GMO Markers

1. Initial GMO screening shall be performed using validated qualitative PCR assays targeting commonly occurring GMO genetic elements, including:
 - CaMV 35S Promoter (P-35S)
 - NOS Terminator (tNOS)
2. Additional screening markers may be included to improve detection coverage and efficiency, such as:
 - BAR gene
 - Cry1Ab gene
 - Cry1Ac gene
 - Other validated GMO-specific genetic elements, as applicable.

9.5 Qualitative GMO Detection

1. Qualitative PCR assays shall be used to detect GMO-specific sequences, including:
 - Promoter sequences
 - Terminator sequences
 - Construct-specific sequences
 - Event-specific sequences
2. Detection shall be performed using validated methods demonstrating adequate specificity, sensitivity, and robustness.

9.6 Quantitative GMO Analysis

1. Where quantification is required, Real-Time PCR methods shall be employed.
2. GMO content shall be determined relative to an appropriate species-specific reference gene using validated quantitative PCR procedures.

9.7 Quality Assurance and Quality Control

1. Laboratories shall operate under an ISO/IEC 17025-compliant quality management system.
2. Quality assurance measures shall include:
 - i.** Method validation and verification
 - ii.** Personnel competency assessment
 - iii.** Equipment calibration and maintenance
 - iv.** Contamination prevention and control measures
3. Each analytical batch shall include, as appropriate:
 - i.** Certified Reference Materials (CRMs)
 - ii.** Positive controls
 - iii.** Negative controls
 - iv.** Extraction blanks

v. Internal amplification controls

9.8 Method Verification and Determination of LOD

1. Laboratories shall verify the performance of adopted methods under their own operating conditions.
2. Verification shall demonstrate that the claimed Limit of Detection (LOD) can be consistently achieved.
3. This shall be established using Certified Reference Materials containing known GMO mass fractions, preferably at or near the target detection level.
4. Verification studies should include replicate analyses of low-level GMO reference materials (e.g., 0.1% GMO content or lower) to confirm expected detection probability and assay performance.

9.9 Interpretation and Reporting of Results

1. Test results shall be interpreted in accordance with the validated performance characteristics of the method, including:
 - i. Limit of Detection (LOD)
 - ii. Limit of Quantification (LOQ), where applicable
2. A result shall be reported as “Detected” only when the amplification criteria established during method validation are fulfilled and all quality control parameters are acceptable.
3. Results below the validated LOD shall be reported as “Not Detected at or Above the Method LOD”.
4. Such results shall not be interpreted as confirmation of the complete absence of GMO material.
5. Test reports shall clearly indicate the method used, target genetic elements analyzed, LOD/LOQ values, and the basis for result interpretation.

10. RECORD KEEPING AND TRACEABILITY

Laboratories shall maintain complete records of sample receipt, preparation, analysis, quality control data, calibration records, and test reports to ensure full traceability and auditability of analytical results.

11. RELATED DOCUMENTS

1. Phytosanitary Certificate by NPPO India
2. Certificate of Analysis
3. RCAC issued by APEDA

REFERENCES:

1. Standard Operating Procedures for Rice Export to China of DPPQS, India
2. EU Regulation 691/2013 of 19 July 2013 “Amending Regulation (EC) No 152/2009 as regards methods of sampling and analysis”
3. ISO 21571 on Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction

4. ISO 21569 on Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods
5. ISO 21570 Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods
6. ISO 24276 Methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions
7. EU-JRC Compendium of Reference Methods for GMO Analysis

Part-I

**APPLICATION FOR DRAWAL OF SAMPLES OF
RICE FOR LABORATORY TESTING**

TO BE FILLED BY THE APPLICANT EXPORTER:

1.	Name & Address of the exporter	
2.	APEDA RCMC No.	
3.	GACC registration No.	
4.	Name, Address and GACC registration No. of the Processing unit	
5.	Consignment details: Product Lot Nos. Number of bags/packages Quantity (MT) Date of packing Date of shipment Port of dispatch Port of destination	
6.	Grade and variety of the produce	

DECLARATION

1. It is certified that the product covered by this application is not derived from genetically modified sources.
2. It is certified that, to the best of my knowledge and belief, the above information is true and correct in all respects.

Date:

Signature of Exporter

Place:

(Name of Exporter)

PART II

**TO BE FILLED BY THE REPRESENTATIVE OF THE
AUTHORISED LABORATORY**

1. This is to certify that, I _____ have drawn this sample personally from the above mentioned rice processing unit.
2. I have sealed the consignment bearing Seal Nos. as follows :

Lot No.	Number of bags	Quantity (MT)	Date of sealing	Seal No.

3. It is certified that the sampling has been done at the finished product storage premises.
4. Address and Location of drawl of samples :

Date :
Place :

Signature :
Name of authorized :
Representative of
Nominated Laboratory
Official address

CERTIFICATE OF ANALYSIS					
Test Report No.		Issue Date		ULR No.	
Exporter Name					
Exporter Address					
Order/Reference					
Specification					
Sampling Details:					
Sample drawn by					
Sampling date					
Sampling location (Unit name, GACC registration number and address)					
Lot/Batch number					
Sample quantity					
Sample Packing					
Sample Details :					
Sample Name					
Sample Nature					
Sample Received on		Sample condition on receipt			
Start of analysis		End of Analysis			
Sr. No.	Parameters	Result	LOQ	Unit	Method
Genetically Modified Organisms					
1					
2					
3					
4					
5					
6					
Remarks					

Authorised signatory