Standard Operating Procedure for GMO Sampling and Testing



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INTRODUCTION



The Organic Cotton Accelerator's (OCA) Farm Programme is a brand-driven sourcing and capacity-building programme with the aim of building integrity and prosperity at the farmer level. The Programme is OCA's primary market transformation tool for strengthening and growing the organic cotton sector. This harmonised industry approach is paired with a stream of investment capital to the farm-level (that includes direct brand-to-farm linkages) to build a resilient and transparent supply of organic cotton. A shared set of common guidelines and global indicators are used to measure and report on progress and impact.

Working as an additional layer on top of the national and international organic cotton standards OCA's Farm Programme Monitoring and Evaluation (M&E) system provides additional transparency and insight into inputs, activities, outputs at earliest stages of the supply chain. Through its M&E system, OCA provides additional insight into genetically modified organism (GMO) contamination at seed, farm and gin level. This information provides Farm Programme stakeholders with a comprehensive overview, alert and action system if GMO is detected, enabling Farm Programme stakeholders to make informed decisions with regards to their supply chain sourcing decisions.

Organic is a claim that genetically modified organisms (GMOs) are not deliberately or knowingly used and that organic producers take far-reaching steps to avoid GMO contamination along the organic cotton value chain,¹ from seed producers to farmers, to spinners, to brands/retailers. To manage this, it is essential that organic cotton stakeholders can test the cotton for any GMO presence or contamination at different Critical Control Points (CCPs) in the supply chain. They can do so alongside taking preventative measures such as the use of tall and dense border crops to minimise the risks of cross pollination.

For OCA's Farm Programme to achieve its goals of building integrity and prosperity at the farmer level, testing the cotton in different levels is vital. The purpose of this Standard Operating Procedure (SOP) is to guide OCA's Third-Party Agencies (TPA)s and Implementation Partners (IP)s on how to sample and test for the potential presence of GM cotton from seed to farm, to gin, in each Farm Project. A streamlined GMO sampling process should be followed across OCA Farm Projects, so that comparable and consistent GMO testing results can be obtained in the Farm Programme.

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TERMS AND DEFINITIONS



DEFINITIONS

TERMS AND

Agricultural and Processed Food Products Export Development Authority (APEDA): The Indian government department responsible for the implementation of accreditation of the Certification bodies under the National Programme for Organic Production (NPOP for organic exports).

Brands/Retailers: The OCA partner Brands/Retailers actively involved in the Farm Programme

Critical Control Points (CCPs): Steps in the production process where preventative measures can be applied to reduce or remove a hazard, in this case contamination by genetically modified cotton.

Genetically Modified Organism (GMO): Genetically Modified Organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Farmers: Organic (certified/in-conversion) farmers that are part of the groups and organisations from which the IP sources their cotton.

Internal Control Systems (ICS): An organised group of farmers/producers who intend to produce organic products/engage in organic processes in accordance with the National Standards of Organic Production.²

Implementing Partner (IP): Value chain players that are part of the Farm Programme. They are contacted by Brands/Retailers and manage source organic cotton from organic farmer programmes/ groups growing cotton. IPs can cover one or more (integrated) steps in the supply chain, e.g. cooperative, ginners, spinners, weavers, garment makers.

Monitoring & Evaluation (M&E): The process of collecting data and conducting analysis to understand the extent to which a programme or intervention has (or has not) met its original goals.

National Programme for Organic Production (NPOP): Provides standards for organic production, systems, criteria and procedure for the accreditation of Certification Bodies within India and the regulation of import and export of organic products from the country.

Organic Agriculture: Organic Agriculture is a production system that sustains the health of soils, ecosystems, and people. It relies on ecological processes, biodiversity and cycles adapted to local conditions, rather than the use of inputs with adverse effects. Organic Agriculture combines tradition, innovation, and science to benefit the shared environment and promote fair relationships and good quality of life for all involved.³

Organic Cotton Accelerator (OCA): A multi-stakeholder organisation dedicated to unleashing the potential of organic cotton for people and planet.

Standard Operating Procedure (SOP): A set of step-by-step instructions complied into a single document in order to provide guidance when carrying out a particular routine or task.

Third-Party Agency (TPA): Third-party entities that conduct data collection and validation activities.

^{2.} Based upon the definition used by APEDA (APEDA, Organic Contents, Chapter 5, Guidelines for certifications of grower groups (http://apeda.gov.in/ apedawebsite/organic_contents/Chapter_5.pdf)

^{3.} Based upon the definition used by IFOAM (https://www.ifoam.bio/why-organic/organic-landmarks/definition-organic)

OVERVIEW OF THE KEY PROCESSES AND PROCEDURES



1. Roles and Responsibilities

A series of GMO tests are made compulsory under this SOP. These GMO tests must be performed as per the ISO IWA32:2019 qPCR test protocol at accredited laboratories. OCA's GMO sampling is performed by the IPs and TPAs in different stages during the season. In this way, the truthfulness of the GMO test results is ensured. The IP cooperates in this process, pays for the GMO lab tests (unless specified otherwise in the Farmer Commitment Agreement, the other option being to channel the GMO testing costs via OCA) and reports to OCA on extra preventative measures taken within the Farm Programme.

Summary of Requirements

The table below provides an overview of the stages of GM sampling and testing, and responsible parties. Bear in mind that all the tests, except for S1-IP, are mandatory. S1-IP and S3-IP (pink boxes) indicate that the sampling is done by the IPs themselves whereas S2-TPA, F-TPA and G-TPA (yellow boxes) indicate the sampling under the oversight of the TPAs.



2. Overall Process for GMO Sampling and Testing

Getting started:

- 1. The IP agrees to a set of conditions with OCA and its partnering brands/retailers, laid out in the Farmer Commitment Agreement for each individual Farm Project the IP facilitates. This includes:
 - a. The modalities of payment of the GMO test typically paid by the Implementation Partner or OCA depending on the choice of the partnering brand
 - b. The laboratory chosen to carry out the GMO test to be selected from the list of laboratories that meet OCA's requirements. See Annex 2
 - c. A contingency plan to be followed if GMO presence is found in the project throughout the season. The contingency plan should include the corrective actions recommended under this SOP, complemented by the requirements from the IP or the brand specified in the Farmer Commitment Agreement (FCA).
- 2. A TPA is assigned to the Farm Project by OCA
- 3. The TPA carries out or conducts a risk assessment at farm project level to define their 'risk profile' as per OCA's scoring matrix. A total number of GMO tests (to be sent to laboratories) is defined proportionally to the risk level of the project.
- 4. The TPA recommends a stage-wise plan for GMO sampling, testing and reporting as per this SOP, the risk assessment outcomes and the seed procurement plan of the Implementation Partner. The Implementation Partner finalises its budget for GMO testing, including both laboratory and Bt-strip test costs.
- 5. GMO sampling, testing and reporting is carried out at seed level at different stages. See tests S1-IP, S2-TPA, S3-IP.
- 6. GMO sampling, testing and reporting is carried out at farm level typically 100 to 130 days after planting. See test F-TPA.
- 7. GMO sampling, testing and reporting is carried out at gin level typically 180 to 200 days after planting. See test G-TPA.
- 8. GMO contamination is reported via the following means:
 - 8.1 Mid-season general performance reporting: Progress Update Report (PUR) is produced by OCA several times during the season which provides an update on GM presence – if any detected
 - 8.2 **End of season general performance reporting:** The overall GM presence (if any) can be found in Farm Project External Validation Report
 - 8.3 End of season feedback loop: Performance Improvement Report (PIR) is provided by TPAs after the season ends created to establish continuous improvement.

3. Calculating the total number of Mandatory Laboratory GMO Tests per Farm Project

Total number of samples

The total number of samples to be sent for laboratory testing can be calculated as follows.

OCA Formula to calculate the total number of samples for laboratory testing

Number of samples to be sent for laboratory testing

risk factor * $\sqrt{(0,92)}$ number of Metric Tons of lint committed under the Farm project)

This formula has been extracted from IFOAM's requirements for external inspection of organic farm groups⁴ and converted into volumes of metric tons of lint committed under an OCA Farm Project, using agronomic yield data from OCA's Farm Programme between 2018 and 2021.

Evaluation of the risk factor to be used in the formula above

The risk factors are drawn from a risk assessment that is carried out by the TPA prior to the season.

This risk assessment process is under development by OCA. Until it is finalised, all Implementation Partners will be assigned a Medium Risk Factor for the season 2022/23.

Risk factor to be used in the formula		
Low risk factor	1	
Medium risk factor	1,2	
High risk factor	1,4	

Example:

Number of samples to be sent for laboratory testing = risk factor * $\sqrt{(0,92)}$ number of Metric Tons of lint committed under the Farm project)

45 samples to be sent for laboratory testing = $1,2 * \sqrt{(0,92*1500)}$

4. Distribution of Samples across Different Stages

Sampling stages

Samples are drawn by OCA's TPAs in different proportions at critical stages throughout the organic cotton farming system, i.e., at seed, farmer, and gin level. These CCPs have been identified to enable segregation and isolation of any contaminated produce before it is passed on to the next actor in the supply chain, when product ownership changes.

Sampling stage	Proportion of total samples to be taken for lab tests	Example for a Farm Project of 45 total GMO samples
 Seed Level (S2-TPA): Sampling of Purchased seed bags after reception by Implementing Partners and prior to distribution to farmers This test can be done once by the IP across all its OCA Farm Projects See Seed-level sampling for more information 	 Dependent upon seed procurement plan: 1 composite sample per unique seed lot* per seed variety per Implementation Partner across all its OCA Farm Projects. Note: The composite number of samples reported is artificially capped at 40% of the total sample size. The total number of seed samples taken for S2-TPA can then be subtracted from the total number of samples for each OCA Farm Project once the project FCAs are signed. 	 If an IP procures 10 seed lots for all its Farm Projects: 10 composite samples are taken for S2-TPA testing. Remaining samples to be taken after seed sampling is completed: 35 (=45-10)
 Farmer Level (F-TPA): Sampling of Seed cotton on the field before harvest Seed cotton at farmer storage post-harvest, depending on what is available at the time of the TPA visit 	70% of remaining samples after seed sampling	25 of the remaining samples will be used in farmer level (F-TPA)
 Gin Level (G-TPA): Sampling of Storage heaps of seed cotton, Baled lint cotton at the ginner, depending on what is available at the time of the TPA visit 	30% of remaining samples after seed sampling	10 of the remaining samples will be used in gin level (G-TPA)

*A seed lot (as per ISTA) is a batch of seed produced by a (commercial) seed producer / supplier, identified with a unique number that is mandatory on seed packaging. The germination rate and purity of this seed lot has been previously assessed and recorded by the seed producer / supplier before distribution.

5. GMO Test Methods

ISO IWA 32:2019 qPCR test at laboratories

Among the several methods of GMO testing, qualitative Real-Time Polymerase Chain Reaction (qPCR) testing is considered the best technological option to perform a general screening for GMO detection. qPCR (Polymerase Chain Reaction) testing methods can detect the presence of a transgenic DNA sequences in a plant cell's genome. They must be performed by a qualified laboratory. qPCR testing is the most sensitive testing method as it commonly has a limit of detection of 0.01%. Please note that the only conclusion that can be drawn from qualitative qPCR tests is the fact that a sample 'contains GM-elements' or 'does not contain GM elements' involved in GM cotton events (no quantitative percentage can be deducted).

The ISO IWA 32:2019 protocol must be used by the laboratory for testing the samples from the Farm Project. The International Organization for Standardization (ISO)

International Workshop Agreement (IWA) 32 protocol on screening of Genetically Modified Organisms (GMOs) in cotton and textiles. This protocol ensures the screening of genes (GM-elements) that are involved in all known GM cotton events, across all four commercial cotton species (G.hirsutum, G.barbadense, G.arboreum, G.herbaceum). The protocol can be purchased <u>here</u> on the ISO website.

Strip tests in-house

Strip testing (Lateral Flow strip) methods are immunological GMO testing methods, able to detect transgenic proteins. They can be done in-house. The limit of detection above which GMO presence can be detected by a Strip testing method ranges between 0.1 and 1%, which is less than qPCR methods but still make it a powerful decision tool to screen and monitor the presence of GMOs, identify risks, and verify corrective actions daily. They are especially useful to check that no contamination has occurred during seed distribution, and later, on the farmer's field to check that the farmer has only planted GM-free seed (including for gap filling). OCA recommends the use of Bt-Strip tests that can screen at least for the **Cry1Ac** delta-endotoxin / protein.

Advice on the procurement and use of Bt-strip tests can be found in Annex 1.

6. Selecting and Interacting with Laboratories for qPCR Tests⁵

It is strongly recommended that only one lab is used by the Farm Project for qPCR analysis at all stages to maintain consistency of results, i.e., the laboratory chosen in the Farmer Commitment Agreement. When completing the 'Additional Services Covered By OCA' section of the FCA as 'Payment for Laboratory GMO qPCR testing via OCA', OCA will designate the lab for the IP.

Laboratory selection criteria for qPCR tests

When carrying out qualitative GMO testing in cotton and greige cotton products as per the ISO IWA 32:2019, OCA requires IPs to work with laboratories who:

- have successfully passed the proficiency test for qualitative cotton screening according to ISO IWA 32:2019 organised in 2021 by Organic Cotton Accelerator in collaboration with the Global Organic Textile Standard and Textile Exchange, and with the technical support of Wageningen Food Safety Research
- hold a valid ISO/IEC 17025:2017 accreditation by a local laboratory accreditation body (e.g., NABL in India) for GM cotton screening as per the ISO IWA 32:2019. This standard verifies its competence, impartiality, and consistent operation.
- are recognised by organic standard setting organisations (e.g., APEDA in India) for sampling and analysing GMOs in organic cotton products

The list of laboratories that meet OCA's requirements for GMO testing is available in Annex 2.

Instructions for laboratories:

- The laboratories should be instructed to follow the ISO IWA 32:2019 protocol when screening for the presence of GM cotton in Farm project samples
- The IP should confirm the shipping address with the lab by email prior to sample shipping

Handling test reports from laboratories:

- The IP should share a standing instruction with the labs to keep OCA in copy when sharing test results
- In case that is not possible, the IP should share all GMO testing result reports with the TPA and OCA on a timely basis, within one week of receipt of the results

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Overview on the detection, interpretation and reporting on the presence of unauthorised genetically modified materials - Guidance document from the European Network of GMO Laboratories (ENGL), European Commission - Joint Research Centre - Institute for Health and Consumer Protection, 2011

SEED-LEVEL SAMPLING (S)



1. GMO Testing Processes

GMO testing prior to seed purchase (S1-IP)

Even though this stage is **not mandatory**, OCA strongly encourages that the IP always tests its seed lots to be procured prior to purchase, at the seed supplier, to secure the quality and reliability of the purchased lots. Potential risks of GMO contamination in seed level stage include unreliable purity of seed lots and mixing of seeds during seed packaging.

- **Sampler:** The sampling can be managed preferably by the IP, or alternatively by the seed supplier itself. See Sampling Methodology below.
- **Test method:** a qPCR lab test (as per ISO IWA 32:2019) should preferably be carried out at one of the laboratories recommended by OCA. Alternatively, a Bt-strip test can be used in cases of time pressure.
- **Reporting:** All GMO test results should be reported by the IP to OCA as per the reporting guidelines.

The test reports will inform OCA's Seed Assurance programme where OCA provides seed producers with capacity building support to monitor and prevent GMO presence along their seed supply chain as per expert guidelines. The more contamination detected in the seed lots from the seed supplier, the more OCA will extend its effort to support them. Read more about OCA's Seed Assurance Programme here.

- Corrective actions in case of contamination detected in S1-IP:
 - The IP must reject the seed lots that tested positive and instead buy the missing seed quantities from other lots which have not tested positive for GMO presence
 - If there is unavailability of uncontaminated seed for the project, the IP must inform OCA

When the presence of GMOs is detected in seed lots / bags prior to purchase, the following corrective actions are recommended by OCA:

- If there is time available, the project partner can re-test the seed lot / bag by breaking it down into several sub-samples to assess the extent of the contamination
- The IP must reject the seed bags and lots testing positive and buy seeds from reserve lots which have not tested positive for GMO presence
- If there is unavailability of seed for the project, the IP must inform OCA

GMO testing after seed purchase (S2-TPA)

OCA will send its TPA to sample the seed lots procured by the IP after purchase and prior to seed distribution to farmers. This stage is **mandatory** to ensure action is taken in a timely manner to eliminate GMO presence from an OCA Farm Project from the start.

- Sampler: The sampling will be managed and sent to the laboratory by the TPA.
- **Test method:** a qPCR lab test (as per ISO IWA 32:2019) must be carried out at the laboratory chosen in the Farm Commitment Agreement.

- **Required from the IP:** At least four to five weeks prior to seed distribution to farmers, once seeds have been procured, the Farm Programme Project must inform OCA to initiate third-party sampling of the selected lots for lab qPCR testing. The IP's seed procurement plan should be made available to the TPA as soon as possible, including the name of the seed varieties procured, their seed lot numbers, the seed volumes (number of seed bags) procured as well as the tentative time of seed distribution to farmers. The IP should also help the TPA to schedule an appropriate visit time for seed sampling.
- Number of samples taken: 1 composite sample per unique seed lot per seed variety per Implementation Partner across all its OCA Farm Projects. The TPA will define the number of samples to be taken based on the seed procurement plan of the IP across all its Farm projects. All seed lots of all seed varieties procured by the IP should be sampled using the composite sampling methodology provided by OCA further below.
- **TPA-IP communication:** TPA will send a summary email to the IP with an overview of samples taken and the related sample details.
- **Reporting:** All GMO test results will be reported to OCA by the TPA as per the reporting guidelines.
- Corrective actions in case of contamination detected in S2-TPA:
 - If time allows and guarantee systems have been agreed with the seed producer, the IP can
 return the seed lots that tested positive to the seed producer and instead buy the missing
 seed quantities from other lots which have not tested positive for GMO presence. If there is
 no uncontaminated seed available for the project, the IP must inform OCA.
 - If product return is not possible and there is time available, the project partner can re-test the seed lot to assess the extent of the contamination using qPCR lab tests. Re-tests can be done by breaking the composite sample down into several sub-samples (minimum 5). Both OCA and the TPA need to be informed about the results of the re-test before a decision is made by the IP.
 - If a re-test shows contamination in many sub-samples: the lot should be rejected and clean seeds from a different seed lot should be used instead.
 - If a re-test shows that contamination is minimal, and all parties (OCA, TPA, IP) decide to take the risk to distribute the seed lot to farmers: Bt-strip tests S3-IP should be carried at ALL project farmers to whom the potentially contaminated seed lot is distributed.

GMO testing during seed distribution to farmers (S3-IP)

OCA Implementation Partners must test the purity of each seed bag in front of the farmer at the moment of seed distribution, using rapid Bt-strip tests. This stage is mandatory to eliminate GMO dissemination right from the start of the Farm Project.

- Sampler: The sampling should be managed by the IP staff in front of the farmer.
- **Test method:** Bt-strip test should be used as there is no time to externalise the testing at the moment of seed distribution to farmers. Bt-strip tests should be taken from at least 10% of the OCA project farmers, spread across different seed varieties and seed lots. Open the seed bag in front of the farmer, take a representative handful of seeds from the seed bag and follow the instructions from the strip test provider alongside the general advice provided by OCA in Annex 1.

- **Reporting:** Both Bt-strip test results and traceability records of seed distribution are required. All GMO test results should be reported by the IP to OCA as per the reporting guidelines. It is instrumental that the IP traces the seed lots from their origin to the farm, so that the seed lot can be examined as a possible root-cause in case GMOs are detected in the farmer's seed cotton later. Therefore, traceability records of seed distribution from seed provider to farmer are required by OCA. The information recorded includes seed cultivar name, seed provider name and seed lot number per farmer plot.
- Corrective actions in case of contamination detected in S3-IP:
 - If the Bt-strip test shows GMO contamination of the seed bag, the project partner must not distribute it to the farmer and must provide the farmer with a non-contaminated seed bag instead.

2. Sampling Methodology for Lab Tests

All seed lots⁶ from all seed cultivars procured by the Implementation Partner should be tested for GMO presence. The required lab samples should never be taken from a partial sub selection of cultivars and lots, so it is critical that the IP makes its seed procurement plan available to the TPA well in advance.

Two sampling methodologies are proposed for IPs and TPAs for S1-IP and S2-TPA testing, depending on whether the seed lots have already been packed into smaller seed bags or not.

Sampling methodology for retail-size seed bags (S1-IP and S2-TPA)

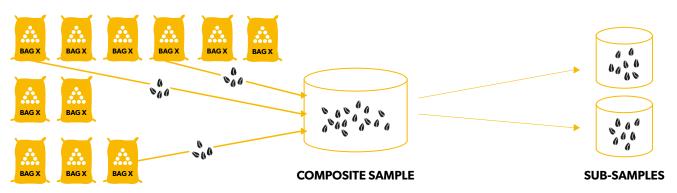
If retail size seed bags need to be sampled (either for S1-IP or S2-TPA), it is important to find the best compromise between taking a representative sample without opening too many bags (which can lead to product or quality loss, and increase the risks of mixing)

- For each seed lot: take samples from a representative number of bags or containers (e.g., 10 out of 100 bags). Care should be taken that all seed bags sampled go to OCA project farmers during seed distribution.
- Combine primary samples carefully into composite sample
- Mix well and divide by successive sample reduction procedures into homogenous subsamples as necessary to reach the number of samples required from OCA (one sub-sample required for S2-TPA) with the appropriate submitted sample size (300 g of seeds).

Please note that for each sample, 3 sub-samples must be taken:

- A sample will be sent to the laboratory (sent from the TPA office)
- A sample will be stored at the TPA office as a reserve sample for potential re-test
- A sample will be stored at the IP office for the IP's own re-testing purposes

Store the composite sample for eventual re-test at a later stage.



Submitted sample size to be sent to the laboratory : 300g of seeds minimum

Segregation:

• The 3 samples can be segregated upon collection on the spot by using envelopes or labels of different colours. e.g., Green Ranks uses white labels for the sample sent to lab, yellow for samples that stay with the IP, and green envelopes for the TPA-retained sample.

Packaging:

- Use plastic tamperproof envelopes for sampling
- Collect every sample envelope and place them in a bigger envelope for transfer to the laboratory

Labelling:

• Use printed labels or barcodes which include Farm Project details, seed lot number and seed producer.

Sampling methodology prior to seed packaging (S1-IP in special cases of early testing)

If the seed lots haven't yet been packaged in retail-size bags by the seed producer and the IP gets the opportunity to test the seed lots very early in the season, OCA recommends that the IP or seed producer carry out S1-IP sampling as per the ISTA Handbook on Seed Sampling, referenced in the Chapter 2 of the ISTA International Rules for Seed Testing. Sampling and sample reduction must be performed using appropriate techniques and equipment as per the ISTA guidelines.

The following procedure should be repeated for each seed lot of each seed cultivar:

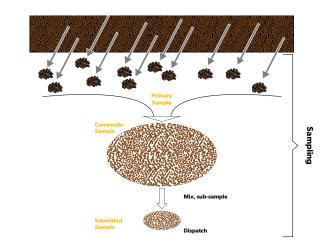
The composite sample is built from the seed lot in the following way:

- Take primary samples of appropriate and equal size from different positions of the whole seed lot, as per the rules mentioned in the ISTA guidelines
- All primary samples must be combined into a composite sample, and mixed well
- From this composite sample, sub-samples are obtained by successive sample reduction procedures until the required submitted sample size is achieved

Please note that for each sample, 3 sub-samples must be taken:

- A sample will be sent to the laboratory (sent from the TPA office)
- A sample will be stored at the TPA office as a reserve sample for potential re-test
- A sample will be stored at the IP office for the IP's own re-testing purposes

Lot



Submitted sample size to be sent to the laboratory : 300g of seeds minimum

Segregation:

• The 3 samples can be segregated upon collection on the spot by using envelopes or labels of different colours. e.g., Green Ranks uses white labels for the sample sent to lab, yellow for samples that stay with the IP, and green envelopes for the TPA-retained sample.

Packaging:

- Use plastic tamperproof envelopes for sampling
- Collect every sample envelope and put them in a bigger envelope to transfer to the laboratory at once

Labelling:

 Use printed labels or barcodes which includes farm project details, seed lot number and seed producer

FARM-LEVEL SAMPLING (F)



1. GMO Testing Processes

GMO testing: Farmer's field or storage (F-TPA)

One F-TPA sample can be taken either on the farmer's field, or in his storage facilities depending on what is available during the TPA visit.

OCA will send a TPA to sample the seed cotton directly at the farmers' field or at the farmer's storage, depending on what is available at the time of the TPA visit. This stage is **mandatory** to eliminate GMO dissemination. Potential risks of contamination in farm stage are gap filling at sowing, cross pollination, and mixing of batches after harvest, during storage or transport.

- **Sampler:** The sampling will be managed and sent to the laboratory by the TPA.
- **Test method:** a qPCR lab test (as per ISO IWA 32:2019) must be carried out at the laboratory chosen in the Farm Commitment Agreement.
- **Preparation required from the IP:** At least three weeks prior to the farm level sampling, the IP should share the number of farmers per Internal Control System (ICS) with the TPA via OCA, to inform the distribution of samples across farmers.
- **TPA-IP communication:** TPA will send a summary email to the IP with an overview of samples taken and the related sample details.
- **Reporting:** All GMO test results will be reported to OCA by the TPA as per the reporting guidelines.
- Corrective actions in case of contamination detected in F-TPA:
 - In partnership with the TPA, investigate and if possible confirm the source of contamination. Carry out GMO testing with other farmers who used the same seed lot to rule out the seed contamination hypothesis.
 - Carry out further GMO testing at the farmer to investigate whether the contamination is incidental and can be controlled
 - If high volume detections occur in a particular location (like a village), the project partner should discuss the issue with OCA for further decisions, after investigating the possible root causes.

2. Sampling Methodology

Selection of the farmers to be visited

The TPA must select a number of farms to be visited as per the number of samples to be taken during the F-TPA stage. Care should be taken to select project farmers that:

- Grow different seed lots from each other, to cover the entire range of seed lots procured by the IP
- Belong to different ICSs
- Are located in different villages, in way that reflects the diversity of farmers within the Farm Project
- Additionally, at least one production site shall be chosen at random.

Where possible, consecutive TPA visits should avoid duplicate sampling during subsequent years. However, if there are justified reasons, such as receipt of a substantiated and/or high-risk complaint, a production site should be visited two years in a row.

Sampling on farmers' fields

OCA recommends following the methodology from the IFOAM EU Guideline for Pesticide Residue Contamination for International Trade in Organic.

- Visually split the field into at least 10 blocks / sections avoiding 2-meter edges
- Take one handful of seed cotton per block, each constitutes a primary sample
- Combine primary samples into a composite sample by mixing well
- From this composite sample, sub-samples are obtained by successive sample reduction procedures until the required submitted sample size is achieved

Please note that for each sample, 3 sub-samples must be taken:

- A sample will be sent to the laboratory (sent from the TPA office)
- A sample will be stored at the TPA office as a reserve sample for potential re-test
- A sample will be stored at the IP office for the IP's own re-testing purposes

Sampling in farmers' storage

OCA recommends following the methodology developed by GOTS and the Organic Cotton Standard in alignment as per the ISO 1130:1975 on Textile Fibres — Some methods of sampling for testing.

Product type	Lot size available at the storage	Sampling methodology
Raw / seed cotton	< 5 kg	Random selection of about 100 tufts each about 0,3 or 0,5 g totalling between 30 and 50 g
Raw / seed cotton	> 5 kg	Consider division into equal portions and then select randomly equal number of tufts from each of about 0,3 or 0,5 g such that the total from all portions is at least 100.

Submitted sample size to be sent to the laboratory: 200g of seed cotton minimum

Segregation:

• The 3 samples can be segregated upon collection on the spot by using envelopes or labels of different colours. e.g., Green Ranks uses white labels for the sample sent to lab, yellow for samples that stay with the IP, and green envelopes for the TPA-retained sample.

Packaging:

- Use plastic tamperproof envelopes for sampling
- Collect every sample envelope and put them in a bigger envelope to transfer to the laboratory at once

Labelling:

• For seed cotton: Use printed labels or barcodes which includes farm project details, details of farmer and Tracenet code

GIN-LEVEL SAMPLING (G)



1. GMO Testing Processes

GMO testing: At the Ginnery (G-TPA)

One G-TPA sample can be taken either on storage heaps of seed cotton or baled lint cotton at the ginnery, depending on what is available at the time of the TPA visit. This stage is **mandatory** to eliminate GMO dissemination. Potential risks of contamination in gin stage are mixing of batches at gin storage or during ginning, mis-identified heaps or bales and mislabelling.

- Sampler: The sampling will be managed and sent to the laboratory by the TPA.
- **Test method:** a qPCR lab test (as per ISO IWA 32:2019) must be carried out at the laboratory chosen in the Farm Commitment Agreement.
- **Preparation required from the IP:** The IP should have traceability records from farmer to gin with him at the time of the TPA visit.
- **TPA-IP communication:** TPA will send a summary email to the IP with an overview of samples taken and the related sample details.
- **Reporting:** All GMO test results will be reported to OCA by the TPA as per the reporting guidelines.
- Corrective actions in case of contamination detected in G-TPA:
 - In partnership with the TPA, create smaller heaps with a limited number of farmers and re-test each heap separately for GMO presence to be able to limit any rejections
 - Only procure from uncontaminated sources as identified from previous GMO tests and segregate cotton from unconfirmed sources. This can avoid large scale rejections, in case of positive GMO detection from the ginning heaps.

Please note that for each sample, 3 sub-samples must be taken:

- A sample will be sent to the laboratory (sent from the TPA office)
- A sample will be stored at the TPA office as a reserve sample for potential re-test
- A sample will be stored at the IP office for the IP's own re-testing purposes

2. Sampling Methodology

The total number of samples required for G-TPA should be taken across different seed cotton and lint batches using the sampling methodology below. Care should be taken that the seed cotton and lint originate from as many different farmers as possible.

Sampling of raw / seed cotton storage heaps

OCA recommends following the methodology developed by GOTS and the Organic Cotton Standard in alignment as per the *ISO* 1130:1975 on Textile Fibres — Some methods of sampling for testing.

Product type	Lot size available at the storage	Sampling methodology
Raw / seed cotton	< 5 kg	Random selection of about 100 tufts each about 0,3 or 0,5 g totalling between 30 and 50 g
Raw / seed cotton	> 5 kg	Consider division into equal portions and then select randomly equal number of tufts from each of about 0,3 or 0,5 g such that the total from all portions is at least 100.

Sampling of baled / lint cotton

OCA recommends following the methodology developed by GOTS and the Organic Cotton Standard in alignment as per the *ISO 1130:1975 on Textile Fibres — Some methods of sampling for testing*. This will allow the IP to use the OCA gin sample for its transaction certificate for verification against its Chain of Custody Standard (GOTS or OCS)

Product type	Lot size available at the storage	Sampling methodology
Cotton bale	1 bale	Going down vertically, pull tufts from all sides of the bale where each tuft is about 0,3 - 0,5g, totalling about 50 g. Avoid soiled cotton.
Cotton bales	Between 2 and 10	Select about 100 tufts from the lot covering all bales, from random locations, each tuft being about 0,3 - 0,5g and totalling about 50 g. Avoid soiled cotton.
Cotton bales	>10	Randomly select 10% of the total number of bales and proceed to draw tufts as described above.

Submitted sample size to be sent to the laboratory: 200g of seed cotton or 50g of lint minimum

Segregation:

• The 3 samples can be segregated upon collection on the spot by using envelopes or labels of different colours. e.g., Green Ranks uses white labels for the sample sent to lab, yellow for samples that stay with the IP, and green envelopes for the TPA-retained sample.

Packaging:

- Use plastic tamperproof envelopes for sampling
- Collect every sample envelope and put them in a bigger envelope to transfer to the laboratory at once

Labelling:

- For seed cotton: Use printed labels or barcodes which includes farm project details, details of farmer and Tracenet code
- For lint: Use printed labels or barcodes which includes farm project details, heap and ginning lot number

ANNEX 1 RECOMMENDATIONS ON PROCUREMENT AND USE OF BT-STRIP TESTS



Where can I buy Bt-Strip tests?

The following Bt-strip suppliers are known to OCA. Please note that OCA hasn't run any tests to verify the reliability of the different brands.

- DesiGen https://www.desigendx.com
- Envirologix https://www.envirologix.com/gmo-testing/gmo-testing-kits-protein/
- Agdia https://orders.agdia.com/gmo-trait-tests/immunostrip-tests

Which Bt-Strip tests should I buy from the provider?

- Strip tests are transgenic protein specific. Hence, they should screen relevant transgenic proteins produced by the GM cotton events known to be grown and/or approved in the country of production.⁸
- In India, the commonly available Bt strip tests in the market can detect the Cry1Ac protein (e.g., expressed by Bollgard[™] and Bollgard II[™] Cotton), the Cry2Ab protein (e.g., expressed by Bollgard II[™] Cotton), or both at the same time (for the strip tests with multiplexing capacity).
- OCA recommends the use of Bt-Strip tests that can screen at least for the Cry1Ac delta-endotoxin / protein.

How should I store my Bt-strip tests?

- These strips are moisture sensitive and at times the results cannot be conclusive if the moisture is absorbed by the kits. Poor storage conditions and high temperatures can deteriorate the quality of strip tests. Hence, strip tests should be stored under cool and dark conditions.
- Storage and handling of these kits in a controlled environment might be a challenge at the farm level but cost-effective instantaneous results are invaluable when screening for GMO contamination at critical control points.

How can I sample for Bt-strip testing?

• Please refer to the seed-level and farmer-level sampling methodologies referred in this SOP.

How should I use a Bt-strip test?

- Bt-strip testing can be done most reliably at seed stage before sowing or on fresh/young terminal leaves (as Bt protein expression is reduced during the vegetation period and in dry leaves).
- Manufacturer's guidelines need to be followed, especially regarding the proper dilution of the buffer. Users should also make sure that the strip tests are not used beyond the expiry date.

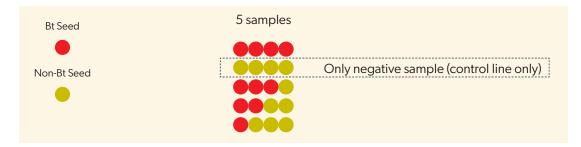


Photo: Fairtrade | Ranita Roy | Fairpicture

8. Please consult http://www.isaaa.org/gmapprovaldatabase/approvedeventsin/default.asp?CountryID=IN&Country=India

• Prior to testing with the Bt-strip kit for the first time, the quality of strip test kits can quickly be verified by testing one strip with seed of both GM and non-GM cotton cultivars.

5 total samples can be made of 10 Bt seeds and 10 non-Bt seeds in different combinations: 5:0; 3:1; 2:2; 1:3 and 0:5.



• Seed kernels should be crushed after removing the seed coat to make a homogenous sample for conducting the test as per procedure



Photo: Fairtrade | Ranita Roy | Fairpicture

Photo: Fairtrade | Ranita Roy | Fairpicture

• Put the strip in the buffer solution and interpret the strip after the time indicated by the manufacturer.





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Photo: Fairtrade | Ranita Roy | Fairpicture

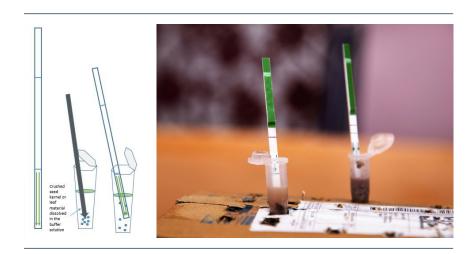


Photo: Fairtrade | Ranita Roy | Fairpicture

- Read the results:
 - If Bt proteins are present the test shows 2 lines. Even a faint line below the test line indicates Bt contamination
 - If no red control line appears on top of the strip, it indicates that the test is not working properly. Please use new strips and repeat the test

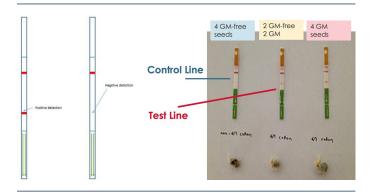


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Keep your results for record-keeping and share them with OCA



ANNEX 2 LABORATORIES THAT MEET OCA'S REQUIREMENTS FOR GMO TESTING



India

The Indian laboratories below comply with OCA's requirements as of February 2022.

1. Envirocare Labs Pvt. Ltd.

Email: <u>info@envirocare.co.in</u> Website: <u>www.envirocare.co.in</u>

2. Geo Chem Laboratories Pvt. Ltd.

Email: <u>laboratory@geochem.net.in</u> Website: <u>www.geochem.net.in</u>

3. National Collateral Management Services Ltd. (NCML)

Email: <u>raina.j@ncml.com</u> Website: <u>www.ncml.com</u>

4. NAWaL Analytical Laboratories

Email: <u>ecogreen.labs@gmail.com</u> Website: <u>www.nawallabs.in</u>

5. Reliable Analytical Laboratories Pvt. Ltd.

Email: <u>rashmi@reliablelabs.org</u> Website: <u>www.reliablelabs.org</u>

6. ProComm Laboratory NBHC Pvt. Ltd.

Email: procomm@nbhcindia.com Website: www.nbhcprocomm.com

7. TESTTEX INDIA LABORATORIES PVT.LTD.

Email: <u>labsindia@testtex.com</u> Website: <u>www.testtex.com</u>



ORGANIC COTTON ACCELERATOR

Let's unleash the potential of organic cotton, together