NATIONAL CERTIFICATION SYSTEM FOR TISSUE CULTURE RAISED PLANTS (NCS-TCP)

Department of Biotechnology

Ministry of Science & Technology

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Chapter 1:

Definitions & Terms

Accreditation Panel (AP)	A team of technical experts with knowledge about audit techniques and criteria for accreditation of laboratory facilities for virus diagnosis/genetic fidelity testing of tissue cultures of plants and recognition/ renewal of recognition of Tissue Culture Production Facilities (TCPFs).
NCS-TCP Management Cell	An official unit responsible for assisting DBT in implementation of NCS-TCP in country. NMC is also responsible for assisting Tissue Culture Certification Agency (TCCA) in Accreditation of Test Laboratory for virus diagnosis/genetic fidelity testing of tissue culture raised plants and recognition of Tissue Culture Production Facilities (TCPFs).
Accredited Test Laboratory (ATL)	An institute/organization granted accreditation by TCCA i.e. Department of Biotechnology (DBT), Govt. of India for virus diagnosis/genetic fidelity testing of tissue culture raised plants.
Appeal Panel	A group of experts nominated by the DBT to review the decision taken by the NMC/ Accredited Test Laboratory.
Appellate Authority	An administrative Department/Ministry to consider the appeal in decision taken by the NMC or Accredited Test Laboratory.
Applicant Entity	Institute/organization seeking accreditation/recognition.
Controlled Document	Documents formally identified, which are registered, maintained and their change, as well as, their implementation is regulated i.e. as Standard Operating Procedures (SOPs).
Controlled Record	Record that requires to be kept and maintained for future reference in an audit and/or for traceability of a result.

Corrective Action	Any action taken to correct the deficiency/deviation from the requirements of this standard
Document	Standards, Procedures, work instructions, references, specifications or regulatory material for the administration of the system.
Initial Audit (Assessment)	'In situ' evaluation of the applicant entity for accreditation to verify if the accreditation criteria have been implemented.
NCS-TCP	National Certification System for Tissue Culture Raised Plants established under Section 8 of the Seeds Act 1966 by Department of Biotechnology, Govt. of India
Non-conformity	Any observed deficiency/deviation from the requirements of this standard
Periodical Audit (Surveillance Audit)	Periodical evaluation of Accredited Test Laboratories/ Recognized Tissue Culture Production Facilities to verify the accreditation /recognition criteria are being followed.
Quality Manual	A written document by the applicant, in which their quality parameters are described.
Recognized Tissue Culture Production Facility	A Tissue Culture Production Facility recognized by the Department of Biotechnology (DBT), Govt. of India for quality production of tissue culture plants
Record	An authenticated document (electronic or print), product or sample statement, which confirms that a procedure (or part of the procedure) has been carried out.

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Referral Laboratory (RL)	An official laboratory for the performance of confirmatory tests in the event of dispute of test results
Reinstatement	An action taken for restoring the (business) activities of an entity for which accreditation was granted.
Reinstatement Audit	A scheduled audit that was carried out for reinstatement of accredited entity following a period of suspension.
Renewal/Revalidation	An extension of validity of accreditation /recognition granted to an entity.
Standard Operating Procedures (SOPs)	Standard Operating Procedures (SOPs) are sets of written instructions that document the routine or repetitive activity followed by an organization. The development and use of SOPs are an integral part of a successful quality system as it provides individuals with the information to perform a job properly.
Standard Protocol	A standardized/validated test procedure established either nationally/internationally.
Suspension	An action taken for temporary with holding of activities of entity for which accreditation was granted.
Tissue Culture Certification Agency (TCCA)	Department of Biotechnology (DBT), Govt. of India is the TCCA authorized under Section 8 of the Seeds Act 1966 for certification of tissue culture plants up to laboratory level.
Work Instruction	Document that identifies the procedures to perform a task or activity.

Chapter 2:

About NCS-TCP

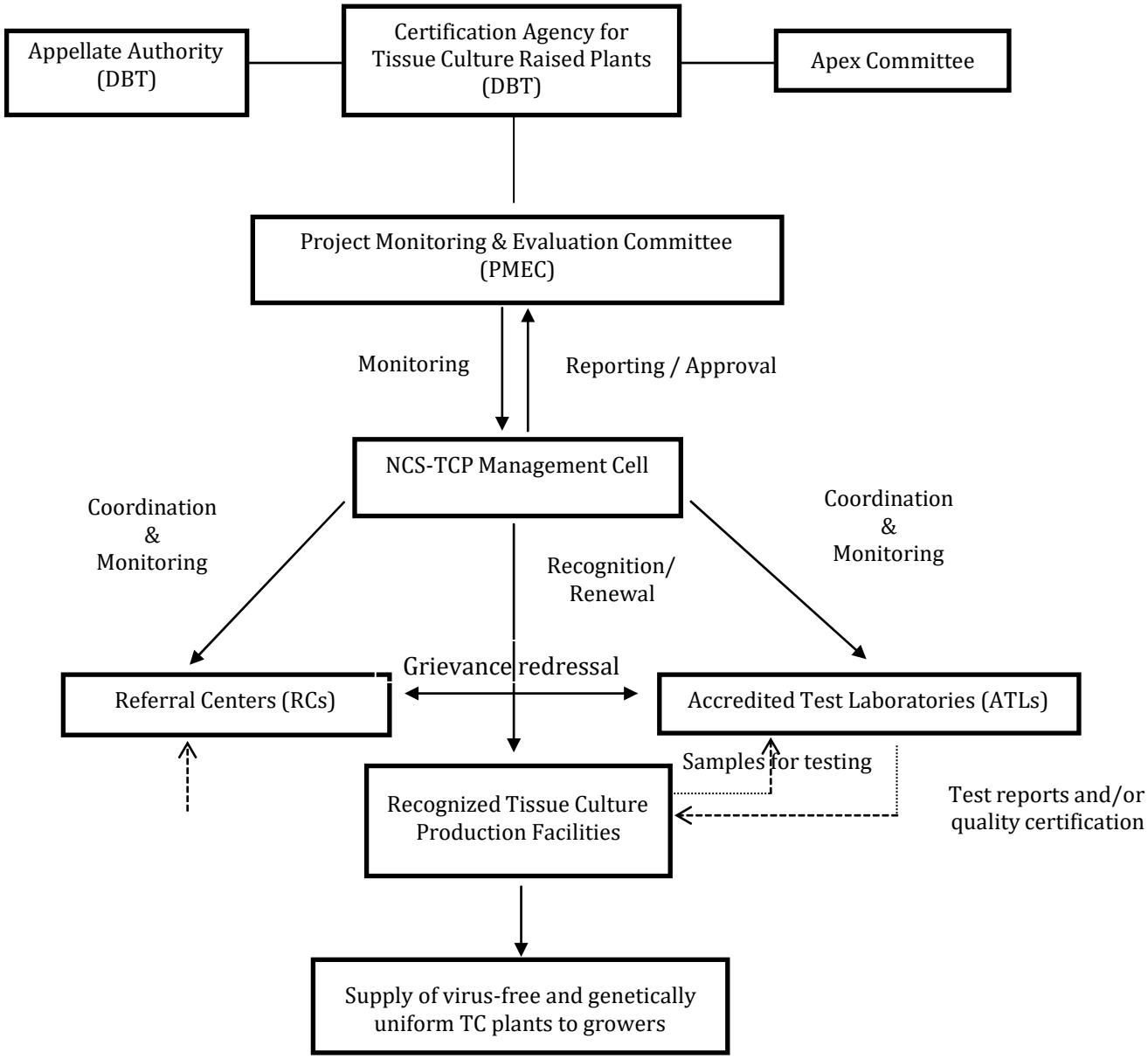
1. Introduction and background of NCS-TCP

Plant Tissue Culture Technology offers great promise for the production of quality planting material on account of disease free and true to type plants produced through micropropagation techniques. The need for a certification programme for the tissue culture plants is imperative since inadvertent micropropagation of virus infected plants will not only result in its poor performance, but also in undesirable spread of viruses wherever such plants are grown. Also, failure to use prescribed standard protocols will result in variations in the plants produced. The most deleterious variants in tissue culture raised plants are those that effect yield, genetic fidelity/uniformity and carry infection of viruses, and other fastidious pathogens, which are difficult to diagnose. This is an area of great concern, and requires a well-structured system be put in place to provide support to the tissue culture industry for the commercialization of virus free and high quality planting material.

Ministry of Agriculture has vide Gazette of India Notification dated 10th March 2006 notified that *"In exercise of the powers conferred under section 8 of the seeds Act, 1966 (54 of 1966), the Central Government hereby authorizes Department of Biotechnology, Ministry of Science and Technology, Government of India to act as Certification Agency for the purpose for certification of the tissue culture-raised propagules up to laboratory level and to regulate its genetic fidelity as prescribed by them".*

Accordingly, the National Certification System for Tissue Culture Raised Plants (NCS-TCP) has been developed for the first time, not only in the Country but also globally, where currently no such organized structure exists for certification of Tissue Culture planting material.

Structure of NCS-TCP



2. Role and Responsibility

i. Tissue Culture Certification Agency (TCCA)

The Tissue Culture Certification Agency (DBT) is responsible for implementing the National Certification System for Tissue Culture raised Plants (NCS-TCP) in the Country. A **NCS-TCP Management Cell (NMC)** has been setup for assisting DBT in Accreditation of Test Laboratories for testing of Virus and Genetic Fidelity/ Uniformity and also Recognition of Tissue Culture Production Facilities, based on the established guidelines and criteria. **Referral Laboratories** have been identified for carrying out confirmatory tests, if required, and also for developing standard protocols, validating protocol and diagnostic reagents, maintenance of referral material, training of technical personal working at accredited test laboratories (ATLs), providing diagnostic reagents to ATLs etc. The Certification Agency is overall responsible for developing standard tests, production protocols/guidelines and manuals.

ii. NCS-TCP Management Cell (NMC):

The National Institute of Plant Genome Research (NIPGR) is an autonomous institution aided by the Department of Biotechnology, Government of India. This Institute has already placed India among the major contributors to plant genomics. The NCS-TCP Management Cell (NMC) at NIPGR, New Delhi is responsible for coordinating the accreditation of test laboratories for virus diagnosis and genetic fidelity/ uniformity testing of tissue culture raised plants and recognition of TCPFs and its timely renewal. NIPGR is also responsible for advisory services to DBT for new initiatives, updating of SOPs, guidelines, management of information etc.

Accreditation Panel (AP):

The NCS-TCP Management Cell maintains a panel of experts to undertake assessment of test laboratories for virus diagnosis and genetic fidelity/ uniformity testing for Accreditation and/or periodical auditing of accredited facilities for granting renewal/revalidation/ reinstatement. The Accreditation Panel also makes an assessment of the tissue culture production facilities. The panel comprises experts specialized in plant tissue culture/plant biotechnology/plant virology/plant bacteriology/ molecular biology / phytosanitary. The Accreditation Panel submitsits assessment report based on established criteria/guidelines to the NMC for grant of Accreditation/Recognition. The criteria for Accreditation of test laboratory for Virus diagnosis and Genetic fidelity/ uniformity testing and for Recognition of tissue culture

iii. production facilities are at chapter 4 and 5 respectively. The NMC should ensure that the essential criteria are met with prior to assessment of facility for accreditation/ Recognition through application/ self assessment report.

<u>Referral Laboratory (RL):</u>

The DBT has designated **Referral laboratory (ies)** for virus diagnosis/genetic fidelity testing of tissue cultures plants.

- Referral Center for Virus Diagnosis – Indian Agriculture Research Institute (IARI), New Delhi
- Referral Centers for Genetic Fidelity/ Uniformity – National Research Center on Plant Biotechnology (NRCPB), New Delhi

The Referral Laboratory is responsible for carrying out confirmatory tests in the event of dispute or nonconformity of test results, developing standard protocols, validating protocol and diagnostic reagents, maintenance of referral material, training of technical personal working at accredited test laboratories (ATLs), providing diagnostic reagents to ATLs. <u>The Referral Laboratory will not involve in routine Virus diagnosis/Genetic fidelity/ uniformity testing of tissue culture raised plants</u>, however as per the decision of the DBT, the Referral Laboratories will undertake random testing of samples at different Test Laboratories.

iv. <u>Accredited Test Laboratories (ATLs)</u>:

Test laboratories are accredited entities, responsible for testing the Tissue Culture material for Virus diagnosis and Genetic fidelity/ uniformity, for the purpose of certification. The Test laboratory prepares a Test Report based on tests conducted in conformity with the standards/protocols/guidelines. Based on the Test Report, each Accredited Test Laboratory (ATLs) is authorized to issue the Certificate of Quality for the Tissue Culture Plant (CQ-TCP) along with certification label on behalf of the Tissue Culture Certification Agency. ATLs are responsible for maintaining/ procuring all diagnostic kits, primer, probes etc required for routine testing. **Each ATL would perform both tests-for virus diagnosis and true-to-type.**

v. <u>Recognized Tissue Culture Production Facility</u>:

Commercial Tissue Culture Production Facility with minimum production capacity of 0.5 million plants per annum may get Recognition based on their compliance with NCS-TCP guidelines which is assessed by the Accreditation Panel. All the activities of tissue culture

production facility including hardening facility needs to be operational at the time of comprehensive assessment by the AP. Comprehensive assessment report prepared by AP includes observation on infrastructure, technical/scientific expertise and package of practices. Recognized Tissue Culture Production Facilities are eligible to get there planting material certified from Accredited Test Laboratory. Recognized Tissue Culture Production Facility should adopt Standard Operating Procedure (SOP) and maintain all relevant records. Recognition of Tissue Culture Production Facility is granted for a period of **TWO YEARS** thereafter it would be re-assessed for "Renewal of Recognition".

vi. Appellate Authority (AA):

*An **Appellate Authority** under the Chairpersonship of Secretary, DBT established to review the decision taken with regard to Accreditation of Test laboratories, Recognition of Tissue Culture production facilities and also for Certification of tissue culture material. The Nodal Officer designated by the Tissue Culture Certification Agency will act as Member Secretary. The members represented in the appellate panel will include:*

- Chairman - Secretary/Additional Secretary, DBT or his nominee
- Not less than two Co-opted non-officio experts in the area of Virus Indexing and Genetic fidelity/ uniformity Testing and or expertise in the field concerned
- Representative from Ministry of Agriculture, Govt. of India
- Nodal Officer designated by the Certification Agency of NCS-TCP would act as Member Secretary

The detailed guidelines for redressal of grievances under NCS-TCP are given in **Chapter 13**

3. Modalities of Implementation

a. Accreditation of Laboratories and Recognition of Tissue Culture Production Facility:

The Applicant will register its application with the NCS-TCP Management Cell (NIPGR) (*NCS-TCP Form 1* for Accreditation of Test Laboratories & *NCS-TCP From 2* for Recognition of Tissue Culture Production Facilities on the webportal) *Tissue Culture Production Facilities should apply only through the online web portal*. Presently only public sector laboratories, universities, Government funded institute, would be considered for Accreditation as Test Laboratories. For Recognition of Tissue Culture Production Facility, all laboratories in the public sector/private

sector/NGOs are eligible to apply. The facility would apply of recognition by filling the form, completing self-assesment report and submitting the requisite fee as indicated through the online portal. **(The details information on how to fill self assessment report is available at NCS-TCP website)**. The NMC will examine the application and Self Assessment Report, subsequently only the complete application will be registered. The duly filled self assessment report received by NMC at NIPGR would be first scrutinized by NMC in order to examine their conformity with NCS-TCP guidelines. Site visit of Accreditation Panel would be organized when the applicant fulfils all mandatory parameters. Even if one mandatory parameter is not fulfilled then NMC will inform the applicant to conform to the same. If the company doesn't complete the requirements within the stipulated time period, the facility would not be considered for site visit.On receipt of compliance with NCS-TCP guidelines by the company, the Accreditation Panel will be requested for site visit. NMC will ensure compliance with mandatory criteria prior to the organization of site visit. During the time of site visit if the company does not comply with even one of the mandatory (marked as *) parameters. In such case company would be debarred for one to two years based on recommendation of PMEC for applying for recognition under NCS-TCP. The nature of false statement would be considered and recommended by the concerned authority of NCS-TCP.

Self assessment as per the prescribed format would also be done prior to site visit for "Renewal of Recognition". The procedure for processing of application for renewal will be same as mentioned above. The criteria for Accreditation of Test Laboratories and Recognition of tissue culture production facilities are provided at chapter 4 and chapter 5 respectively. Based on the report of the Accreditation Panel and the subsequent approval of concerned authority of NCS- TCP the Certificate of Recognition/ Accreditation is issued. Accreditation and Recognition is issued for a period of **Two years** .Thereafter it is re-assessed for renewal.

Chapter 3:

Procedure for Accreditation of Test Laboratory for virus diagnosis and genetic fidelity/ uniformity testing of tissue culture raised plants and Recognition of Tissue Culture Production Facility

3.1. Scope & purpose

This standard provides guidance on requirements and procedures for Accreditation of Test Laboratory for virus diagnosis and genetic fidelity/ uniformity testing of tissue culture raised plants and Recognition of Tissue Culture production facility. The purpose of this standard is to facilitate production of quality planting material through virus diagnosis and genetic fidelity/ uniformity testing. The scope of NCS-TCP certification of tissue culture raised plant is limited to freedom from viruses and uniformity within the batch in line with the notification under the Seeds Act. The responsibility of maintaining true to type should be of the company.

3.2. Accreditation of Test Laboratories and Recognition of Tissue Culture Production Facilities

3.2.1. Application:

An application for Accreditation of Test Laboratory for virus indexing /genetic fidelity/ uniformity testing of tissue culture plants and for Recognition of facilities for production of Tissue Cultureplants will be made to NMC in form prescribed (*NCS-TCP Form-1* and *NCS-TCP Form-2* respectively) along with the requisite fee (There is no fee required for Accreditation of Test Laboratories). For Recognition of Tissue Culture Production Facility, all laboratories in the Public Sector/Private Sector/NGOs with minimum production capacity of 0.5 million plants per annum are eligible to apply. The Applications received by the NMC will be entered in an appropriate register. The Tissue Culture Production Facility is required to submit form through the online web portal and send a copy of recognition form along with "Self Assessment Report" and other attachments. The date of receipt of application should be the date of receipt of complete application along with self assessment report.

The NMC will examine the application and "Self Assessment Report", subsequently only the complete application will be registered. The duly filled self assessment report and application received by NMC at NIPGR would be first scrutinized by NMC in order to examine their conformity with NCS-TCP

guidelines. Site visit of Accreditation Panel would be organized when the applicant fulfils all mandatory parameters. Even if one mandatory parameter is not fulfilled then NMC will inform the applicant to conform to the same. If the company doesn't complete the requirements within the stipulated time period, the facility would not be considered for site visit. On receipt of compliance report with NCS-TCP guidelines by the company, the Accreditation Panel will be requested for site visit. NMC will ensure compliance with mandatory criteria prior to the organization of site visit. During the time of site visit if the company does not comply with even one of the mandatory (marked as *) parameters. If it is observed during site visit that company has furnished false information to mandatory parameter(s) in self assessment report. The nature of false statements should be considered by concerned authority of NCS-TCP in order to debar TCPF for applying for recognition under NCS-TCP for one to two years. The procedure for processing of application for renewal will be same as mentioned above.

3.2.2. Technical Assessment/Periodical Audit:

The NMC will nominate an **Accredited Panel** of 2-3 experts from the list of panel of experts maintained. The Accreditation Panel (AP) will evaluate the applicant for overall competence and feasibility following the established procedure. The NMC will contact the applicant entity to organize an 'on site' evaluation.

If the company shows inability to host site visit for very long (i.e. denying to host the site visit again and again) time and such application will be closed and company will be requested to reapply when they complied with all requirements listed in self assessment form.

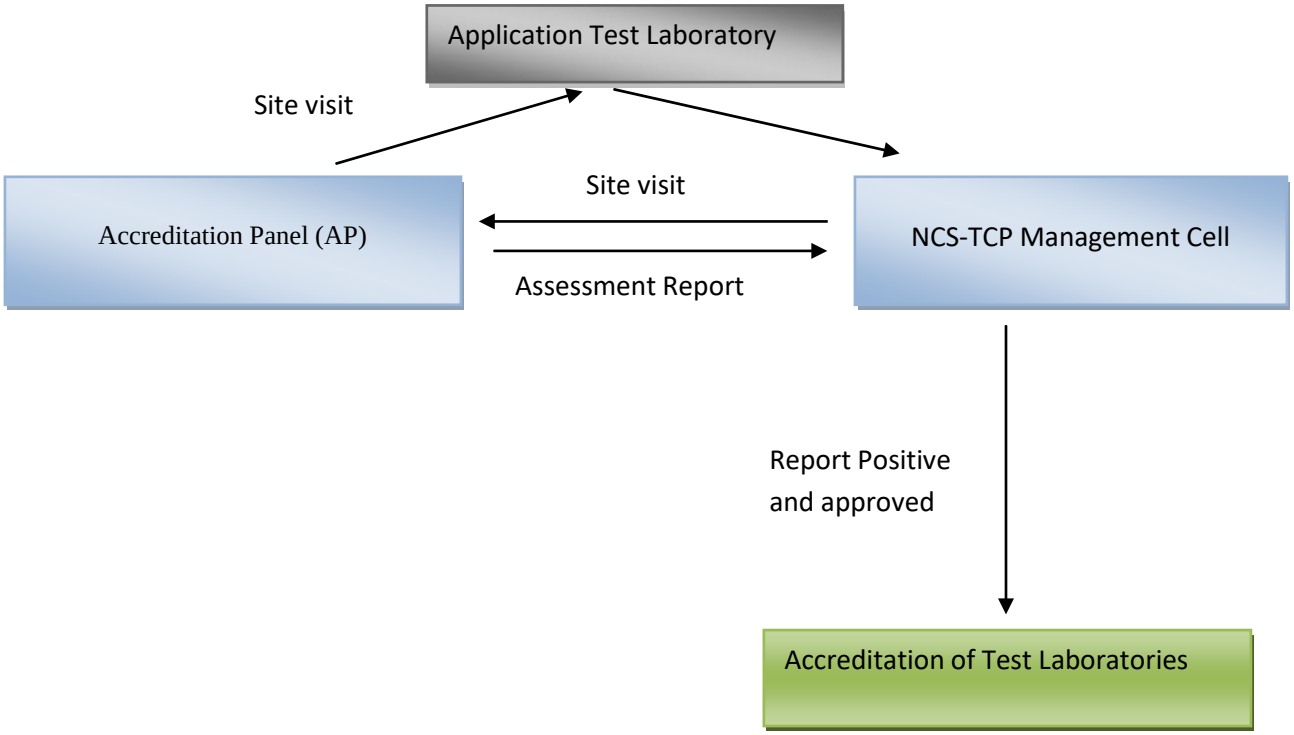
The AP will prepare a comprehensive Assessment Report based on the criteria established for accreditation of test laboratory for virus diagnosis and genetic fidelity/ uniformity testing of tissue cultures of plants/ recognition of tissue culture production facilities for production of quality planting material. The AP will conduct detailed assessment of test laboratory/tissue culture production facility. Such assessment will include opening meeting with management authority to explain the objective and methodology of assessment. The AP will interact with technical personnel to judge the technical competency and skills, review the records, procedures and documents. At the end, AP will prepare an assessment report, covering observation on non-conformities. The AP will also advise corrective actions. The AP will provide the non- conformity report (if any) to the

applicant during the closing meeting, and will submit a copy of detailed assessment report to the NMC. **The basis of recommendation to be made by AP is listed at part 3 of Assessment report present at Chapter 14**. Based on the report of the AP, and subsequent approval of concerned authority of NCS-TCP, the NMC will issue the Accreditation/Recognition Certificates. If the Accreditation Panel (AP) has suggested some corrective actions, expert (preferably from the last site visit) will verify the implementation and efficacy of corrective actions through either documentation or "on site" verification. In case of non-conformities observed during the verification visit the applicant would be required to reapply for Recognition. Scope of verification shall cover the area of entire operation and not limiting to the nonconformities observed in the previous visit. The expert will prepare the report on corrective and will submit final report to NMC

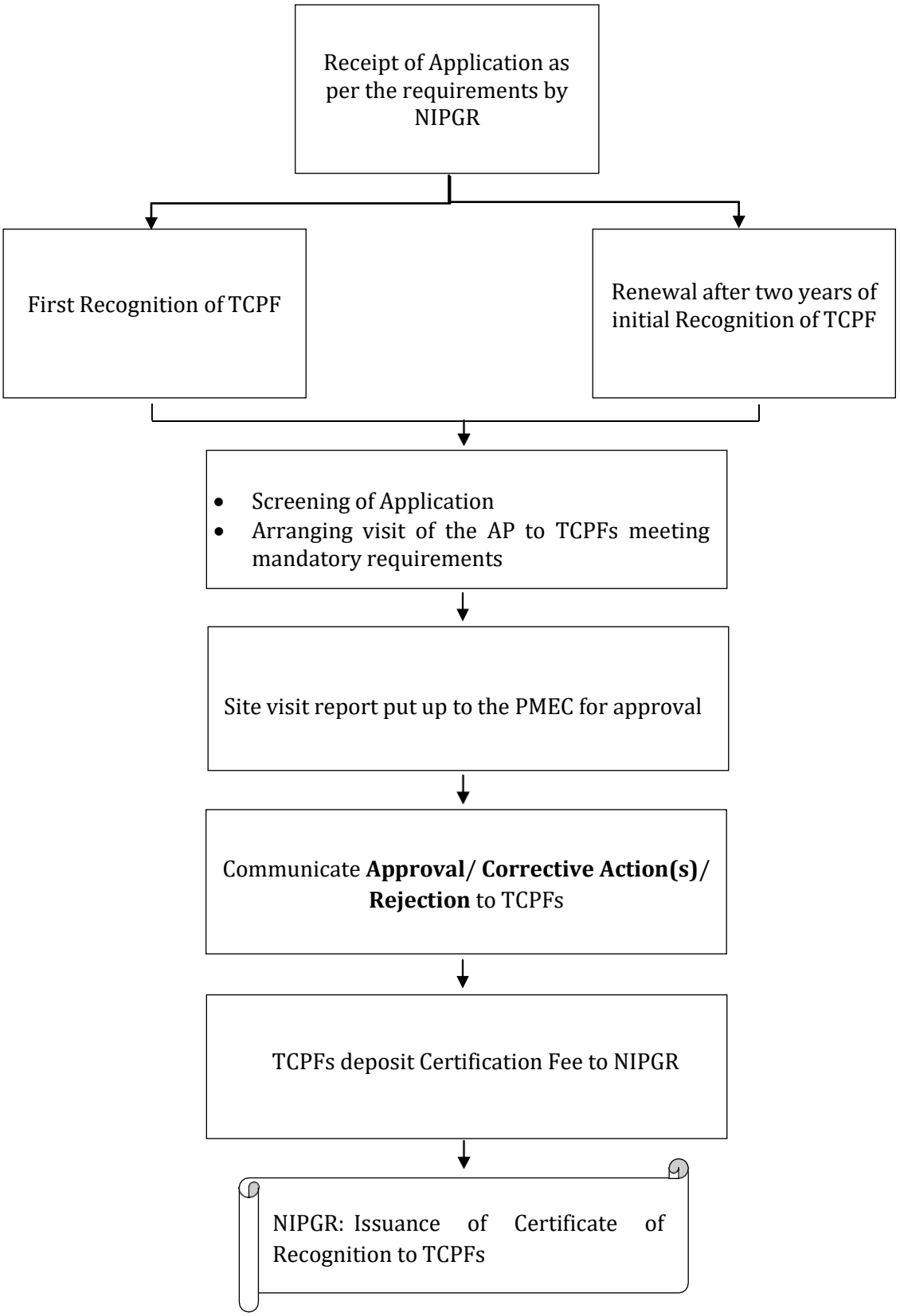
Scope of Recognition of Tissue Culture Production Facility includes entire operation covering laboratory, primary/secondary hardening and nursery. However, in case of units exclusively dealing with contract production for export and which are not distributing plants/*in vitro* cultures within the country, the Certificate of Recognition could be given for the laboratory level production only, which shall be clearly indicated in the Certificate of Recognition. The certificate will not be valid for distribution of plants in domestic market.

3.2.3. Process Flow and Time Frame for Recognition/Accreditation:

***Process for Accreditation*:**



Process of Recognition of Tissue Culture Production Facilities (TCPFs)



The NMC would adhere to the following time frame for site visit of Accreditation Panel for Accreditation/ Recognition:

Accreditation to Test Laboratory: 30 working days from the time of complete application from TLs. In case of non-conformities verification visit would be organized within 30 working days day after formal communication from TLs of their corrective actions.

Recognition/ Renewal of Recognition of TCPFs: 30 working days from the time of complete application from TCPFs. In case of non-conformities verification visit would be organized within 30 working days day after formal communication from TCPFs of their corrective actions and receipt of verification visit fee.

3.3. Renewal of Recognition under NCS-TCP

(i) The renewal request form (NCS-TCP Form – 2A) would be available **4 months** prior to the date of expiry of the "Certificate of Recognition".

(ii) Companies need to complete the "renewal request form" (*NCS-TCP Form- 2A*) and submit the form online along with registration fee of Rs.500/- (Rupees five hundred only) through the online web portal at least **2 months** prior to the date of expiry of the certificate. If the forms are submitted late, NMC will not be responsible for any delay in the renewal of Recognition.

(iii) If the complete "renewal request form" (*NCS-TCP Form- 2A*) is not received **1 month** prior to the expiry of their "Certificate of Recognition" the company will be asked apply for fresh Recognition in *NCS-TCP Form-2*.

3.4. Recognition of multiple hardening centers of recognized Tissue Culture Production Units

It has been observed that many large tissue culture companies have more than one hardening centers. Some companies have more than 10-15 hardening centers in different states which are difficult to evaluate and certify during one site visit. At present as a part of the Certificate of Recognition issued to the production facilities, recognition is being given to the main hardening units in close proximity of the lab after thorough assessment of compliance. However, to ensure the distribution of quality planting material it is necessary that all the hardening centers should be in conformity with guidelines under NCS-TCP. In such cases sublevel Accreditation Panel

consisting of Scientists may audit nearby hardening centers and submit their reports to the NMC.

3.5. Training Needs

The NMC will identify training needs for technical personnel of Accredited Test Laboratory engaged in virus diagnosis and genetic fidelity/ uniformity testing of tissue culture plants and co-ordinate with respective Referral Laboratory to organize the training programme

Chapter 4:

Criteria for Accreditation of Test Laboratory for Virus Indexing/Genetic Fidelity/ Uniformity Testing of Tissue Culture Raised Plants

4.1. Minimum Eligibility Criteria:

(1) Public Sector, Govt. funded Institute/University having adequate capacities in both virology and molecular biology, which is not engaged in commercial tissue culture activity

(2) Laboratory should be headed by trained virologist with experience in moleculardiagnostics / molecular biologist working on molecular marker related technologies

(3) Laboratory should have at least one trained Scientist and one Technical Assistant having expertise in the area of virology/molecular markers and have experience with regard to the latest techniques/tools to be adopted for the test procedures.

4.2. Assessment Criteria for Accreditation of Test Laboratories (TLs):

The Criteria for assessment fall under following categories:

(i) Availability of qualified and trained "Human Resources"

(ii) Dedicated functional laboratory

(iii) Glasshouse/Green House Facility (Insect-proof glasshouse/green house facility for conducting biological test)

(iv) Availability of dedicated space, minimum infrastructure and equipment listed below:

<u>General Equipments:</u>

- Common laboratory glassware and instruments
- Digital top pan/analytical balance
- pH meter
- Distilled and sterile//millipore water
- Gas burners
- Autoclave

- Laminar flow hoods
- Incubation chambers
- Freezer (-20^{o} C)
- Refrigerator 4^{o} C
- Vortex mixer
- Micropippettes

Specific Equipments

- DNA extraction equipment
- DNA probes
- Tissue grinder
- Centrifuge / Microcentrifuge
- PCR
- Horizontal Gel Electrophoresis
- Gel documentation unit
- Equipments for DNA fingerprinting

Reagents

- Dignostic reagents
- cDNA probes
- Polyclonal / monoclonal anti-bodies for diagnostic for commonly occurring Viruses
- Primers

(v) Applicable test methods as per prescribed norms

(vi) ISO-17025 Certification is preferred

Chapter 5

Criteria for Recognition of Tissue Culture Production Facilities under National Certification System for Tissue Culture Raised Plants (NCS-TCP)

5.1. Minimum Eligibility Criteria for Registration of Application:

The minimum requirements to apply for Recognition of Tissue Culture Production Facility under NCS-TCP are as follow:

1. Total annual production capacity needs to be more than or equal to 0.5 million plants.

2. Clearly demarcated areas for Washing room, Media preparation room, **Media storage, Inoculation, Growth room, Plant transfer area** and Acclimatization **(Primary and Secondary hardening area)**.

3. Special entry to clean area consisting of Media store room(s), Inoculation room(s) and Growth room(s)

4. All the activities of tissue culture production facility (including hardening facility) needs to be operational during the time of application.

5. All the recognized tissue culture production facility should get their tissue culture raised plant certified from ATLs. It may be noted that plants produced by the recognized tissue culture production facilities should be certified from ATLs prior to supply to end user. Recognized TCPFs not complying the above requirement will not be considered for renewal of recognition under NCS-TCP.

During assessment of application and self assessment, if the applicant is found to be complied with the above criteria they would be considered as eligible for applying under NCS-TCP for Recognition and their application would be considered for further processing.

5.2. Assessment Criteria for Recognition of Tissue Culture Production Facility:

Other than above parameters following area wise operations and quality requirements are also need to be complied prior to the site visit of Accreditation Panel. Parameters highlighted as bold and * marked are mandatory. All mandatory requirements are need to be complied with in order to get the recommendation for Recognition. Site visit would only be organized if applicant makes statements for compliance with all mandatory parameters. These mandatory and non- mandatory requirements are listed in the form of questionnaire in self assessment report. Applicant must ensure compliance with all the parameters to ensure the effective site visit.

5.3. Questionnaire for Self Assessment:

(To submit these questionnaires please refer and use the Form of Self Assessment available at Chapter 14)

Do you have special entry to the clean area consisting of following three areas*:

- **Media store room(s)***
- **Inoculation room(s)***
- **Growth room(s)***
- **Transfer/Grading area***
- **Greenhouse(s)/ Poly-house(s)***
  - Do you have a separate misting facilities
  - Do you have fire fighting system and emergency exit at your facility
  - Power backup (% needs met by electricity generation)
  - Do you have provision for restricted entry to tissue culture production facility and within different of facility?

<u>Area wise operations and quality requirements:</u>

1. **Mother plant and Explant material:**

   Are you following listed procedures?

   1.1. Do you have clearly defined criteria (species wise) for the selection of elite plants

   1.2. Do you keep proper records (such as unique code no. and passport data of the mother plant)

   1.3. Are you sending the stock cultures/ mother plant tissue for virus testing for all the known viruses?*

   1.4. Are you importing/procuring stock cultures from different sources If yes! Give the details of testing (institute, test result etc.)

   Note: Few applicant companies don't establish cultures for mass multiplication. Such companies import starter/ stock culture or procure starter/ stock culture from company within the country. The above applicant company (seeking recognition/renewal of recognition under NCS-TCP) also needs to test the starter material/ stock culture prior to its large scale multiplication in addition to test conducted by its supplier. Companies importing cultures for only mass multiplication under buy back arrangement are also required to test stock cultures for all known viruses under NCS-TCP.

2. **Washing and drying:**
   2.1. Do you have dedicated washing room?*

   2.2. **Is washing room well connected with the media preparation room for transfer of washed vessel*** (Connected through pass box or a closed corridor)

   2.3. Is washing done mechanically/manually?

   2.4. Do you have availability of running tap water?

2.5. Do you have separate basins for keeping glassware at different stages of washing?
2.6. Do you have provision for separate dipping of jars from the hardening area/infected cultures?
2.7. Whether washing is done in close or open area
2.8. Is cleanliness being maintained
2.9. Is drying of glass wares done in ovens or at room Temperature

3. Discard of used agar:

3.1. Do you autoclave the contaminated culture/media
If no, please specify the procedure of decontamination

3.2. Do you keep records of decontamination/autoclaving of infected cultures
3.3. Do you treat used agar at site
-Procedure being followed

-Discard at Pit which is to be used as nutrient for bio-fertilizer

3.4. Do you keep records of material being discarded

4. Media Preparation:

4.1. **Do you have all the basic equipments*** (including electronic weighing balance, pH meter, conductivity meter, microwave oven, de-ionizer/distillation unit/RO water facility, autoclave etc.)
4.2. Do you suitable water purification system such as RO/distillation units
4.3. Equipment details:
-Autoclave (Number Single door/Double door)

4.4. Calibration of all analytical and measuring equipments
4.5. Are you keeping proper records for:
-Stock solution preparation

-Media preparation

-Autoclave cycle

-Calibration of equipments

4.6. Do you label the individual jar/tray
4.7. Do you use the AR/tissue culture grade chemicals
4.8. Do you have suitable mechanism for transfer of media into media storage room immediate after the autoclaving without entering into the other area
4.9. Do you give emphasis on efficiency of the operators engaged in media preparation (volume, number of jars, wastage etc.)

5. **Media storage:**
   - 5.1. **Are you maintaining class 100,000 sterility level?*** Mention the installed facility (pressure module/AHU/ HVAC).
   - 5.2. Do you maintain particle count data in support of sterility class 100,000
   - 5.3. Do you monitor the airborne microbe through microbial plating? If so, its frequency
   - 5.4. Adequate space for media storage (to store the media for at least 3 days)
   - 5.5. Do you have provision of UV lights in the room
   - 5.6. Range of number of days (Minimum 3-4 days) for which media is stored prior to inoculation
   - 5.7. Do you keep records routine screening of media for any contamination
   - 5.8. Do you have plastic paint/water proof emulsion on the wall
   - 5.9. Do you fumigate the room periodically with the sterilant

6. **Inoculation:**
   - 6.1. **Are you maintaining class 100,000 sterility level?*** Mention the installed facility (pressure module/AHU/ HVAC)
   - 6.2. Do you maintain particle count data in support of sterility class 100,000
   - 6.3. Do you monitor the airborne microbe through microbial plating? If so, its frequency.
   - 6.4. Are you following the maintenance schedule for laminar air-flow cabinets
     -Cleaning of pre-filters

     -Checking air flow

     -Checking efficiency of HEPA filters by exposing plates
   - 6.5. Do you have plastic paint/water proof emulsion on the wall
   - 6.6. Do you fumigate the room periodically with the sterilant
   - 6.7. Do you use glass bead sterilizer for sterilization of forceps/scalpel
   - 6.8. Record keeping for:
     -Efficiency of operators (through monitoring number of jars handled, multiplication rate, contamination losses, rooting percentage and general health of the culture etc.)

     -Calculating multiplication fold at the end of each passage

     -Contaminated cultures

     -Particle count data for maintaining class 100,000

7. **Incubation: Growth room related activities**
   - 7.1. **Are you maintaining class 100,000 sterility level?*** Mention the installed facility (pressure module/AHU/ HVAC)
   - 7.2. Do you maintain particle count data in support of sterility class 100,000
   - 7.3. Do you monitor the airborne microbe through microbial plating? If so, its frequency.

7.4. Is the temperature in the growth room uniform
7.5. Do you fumigate the room periodically with the sterilant
7.6. Record keeping for:
-Contamination

-Continuous temperature recording device

-Light intensity/duration

7.7. Do you make production schedules based on the protocol efficiency
7.8. Do you have plastic paint/water proof emulsion on the walls

8. Power back up:

8.1. Do you have power backup arrangement If so what percentage would be covered by power back in case of power failure

9. Transfer of plantlets from lab to hardening facility:

9.1. Do you have dedicated transfer area*

9.2. Do you have arrangement of washing of plantlets to remove culture medium
9.3. Are plants graded? If so do you have organized grading system such as working table with pictorial map of the handled plant species

10. Hardening: Mist chamber, Green house/Polyhouse

10.1. Do you have double door to entry*

10.2. **Do you have facilities for controlling***:
-Temperature

-Humidity

-Light intensity and duration

10.3. Do you monitor plants for their growth or any other feature
10.4. Do you keep record of dead plants
10.5. Do you maintain record of any treatments given to the plants (fertilizer applications; sprays etc)
10.6. Do you have sticky yellow traps for insect pest monitoring
10.7. Do you label individual hardening trays convening the details of number of plants, date of transfer, batch number etc.
10.8. Do you use potable water/good quality water for watering of plantlets. Please specify the TDS level
10.9. Do you avoid excessive watering and water-logging
10.10. Do you have raised bed to avoid contact of roots with ground soil

11. Nursery and sales/ dispatch of plants for planting

11.1. Double door to check infection*

11.2. **Availability of net house*** (To provide partial shade and prevent insect entry). If so, its mesh size.

11.3. Availability of reliable clean water source

11.4. Do you monitor plants for their growth or any other feature

11.5. Do you keep record of dead plants

11.6. Do you maintain record of any treatments given to the plants (fertilizer applications; sprays etc)

11.7. Do you have sticky yellow traps for insect pest monitoring

11.8. Do you label individual batch convening the details of number of plants, date of transfer, batch number and batch size etc.

11.9. Do you avoid excessive watering and water-logging with drainage system

11.10. Do you undertake regular weeding and remove dead plants

11.11. Do you maintain records to trace back the history of plants

Quality Management Aspects:

12. Virus indexing of TC raised plants (advisable during first application)

Are you routinely getting following done:

12.1. Virus indexing of tissue culture raised plants. If yes, give details of the laboratory where this testing is done.

13. Genetic Fidelity testing

13.1. Are you restricting number of multiplication cycles

13.2. Are you strictly monitoring the procedures while transferring plantlets from:
-Growth room to transfer area

-Greenhouse to shade area

-At the time of dispatch

13.3. Are you getting the genetic fidelity testing done through molecular markers (advisable)

13.4. Do you preserve leaf samples preserved for future reference and genetic fidelity studies (advisable)

14. Overall technical management

14.1. Competent technical supervision and effective monitoring of entire production process:
Indicate management/operational structure & their qualification. Please also specify their role & responsibilities

14.2. Do you have separate in-charge/supervisor for at least lab facilities and hardening facilities

14.3. Do you provide training to the supervisor/operators If so, internal training or external training

15. Overall Quality of Plants

15.1. Do you ensure that plants are fully hardened and transplantable size at the time of dispatch

15.2. In case of ex-agar plants, it is ensured that plantlets should be appropriate size to ensure their survival during transport/transplantation in greenhouse/nursery

15.3. Do you provide handout to the farmers along with plants covering the package of practices for cultivation of particular species

15.4. Do you have mechanism for receiving and addressing the feedback/complaints from farmers

5.4. Basis of Recommendation for Recognition

(1) Recommended for Recognition: As the company complies with all the mandatory parameters (marked as *) along with other parameters listed in the assessment form.

(2) Not Recommended for Recognition and suggested to reapply: If the company does not comply with even one of the mandatory parameter (marked as *).

(3) To be considered for Recognition on completion of corrective action (s): As the company complies with all the mandatory parameters (marked as *) except non mandatory parameters, company would be advised to complete the corrective actions within one month in order to be considered for recognition under NCS-TCP.

5.5. Basis of Recommendation for Renewal of Recognition

(1) **Recommended for Renwal of Recognition:** As the company complies with all the mandatory (marked as *) requirements along with other parameters listed in the assessment form.

(2) **Not Recommended for Renewal and suggested to reapply:** As the company does not comply with even one of the mandatory (marked as *) parameters.

(3) **To be considered for Renewal of Recognition on completion of corrective action (s):** As the company fulfils the mandatory parameters (marked as*) but, however, does not conform to non mandatory parameters, company would be advised to complete the corrective actions within one month in order to be considered for renewal of recognition under NCS-TCP.

Chapter 6:

Guidelines for Recognition of Hardening Center(s) of Recognized Tissue Culture Production Facilities

6.1. Background:

It has been observed that many tissue culture production facilities (with production capacity of more than 3.0 million plants per annum) have more than one hardening center(s) in different locations. Some companies have even more than 10 hardening centers in various locations which are difficult to evaluate and recognize during site visit to the main production facility. At present as a part of the "Certificate of Recognition" issued to the tissue culture production facilities, recognition is only given to the main hardening unit(s) which is in close proximity of the tissue culture lab. However, to ensure the distribution of quality planting material and enable certification of tissue culture raised plants, it is necessary that all the hardening centers of the recognized tissue culture production facilities used for the distribution of plants within the country should be in conformity with the NCS-TCP guidelines. In such cases, Recognition of multiple hardening center(s) of recognized tissue culture production facility is essential for the distribution of virus free and genetically true to type/ uniform tissue culture raised plants. Recognition of multiple hardening center(s) would also be helpful for the companies to get tissue culture raised plants certified from the nearest ATLs.

6.2. Eligibility criteria for recognition and or renewal of hardening centre(s):

i. Only hardening centre(s) of the Recognized Tissue Culture Production Facility are only eligible to apply for recognition of their multiple hardening center(s) located at various parts within the country under NCS-TCP.

ii. Each hardening centre seeking recognition should have the basic infrastructure facilities such as poly house/green house with misting arrangements for primary hardening of tissue culture plantlets and also shade net facilities for secondary hardening or nursery. The applicant multiple hardening center(s) located at various locations should harden the plants received from only recognized facility.

iii. Each hardening centre seeking recognition under NCS-TCP should have minimum hardening capacity of 0.5 million plants per annum

iv. Each hardening centre of recognized tissue culture production facility will be treated as extended facility of recognized units and hence should comply with standard operating procedures established under NCS-TCP with respect to management of hardening centre and subject to assessment for recognition/renewal.

v. Each hardening centre should apply separately for seeking recognition under NCS-TCP, through the recognized tissue culture production facility.

6.3. Application Procedure for Recognition of Hardening Centre:

i. Each recognized tissue culture production facility will submit separate applications for Recognition of Hardening Center(s) under NCS-TCP (*NCS-TCP Form-3*) in respect of each of multiple hardening centres located in various parts of the country using the online portal.

ii. Each applicant should also submit the duly filled and signed "self assessment form" in respect of each hardening centre at the time of application to ensure the mandatory requirements stated there under are complied with. Also a suitable lay out plan of hardening centre indicating clearly the poly house/green house area (primary) and shade net area (secondary) and any other essential facilities.

iii. Prescribed registration fee of Rs. 500/- for recognition should be paid using the webportal..

iv. If the application is complete in all respects and the applicant complies with all mandatory requirements, a site visit to applicant hardening centre by a member of accreditation panel will be organized to assess the hardening centre facilities to ensure compliance with mandatory requirements for recognition under NCS-TCP.

v. The site visit of one member of accreditation panel is organized when the applicant complies with all mandatory requirements.

vi. The applicant will be required to pay prescribed fee of Rs. 1500/- using the webportal towards inspection and report preparation at the time of scheduling the site visit.

vii. The assessment report along with recommendations of accreditation expert will be examined by the Project Management Evaluation Committee constituted under the NCS-TCP, which will take final decision in the matter

viii. If any non-conformity is observed with the mandatory parameters in the "Self Assessment Report", the applicant would be requested to take corrective action(s) for the same. On receipt of compliance report from the applicant, the expert member of Accreditation Panel will be requested for the verification either through documentation or "on site" verification, which will cover the area of entire operationof hardening center(s) and not limiting to the nonconformities observed in the previous visit.

ix. In case of no corrective actions are implemented as verified during the verification process, the application will be treated as cancelled and the applicant would be required to reapply for recognition of hardening center(s) of recognized tissue culture production facility.

x. If the applicant meets all the mandatory requirements prescribed in the self assessment form, as verified by the accreditation panel expert and finally approved by the PMEC, a Certificate of Recognition will be granted in prescribed format to the applicant hardening center of Recognized Tissue Culture Production Facility". The certificate of recognition granted will be valid for a period of t**wo years** subject to the validity period of recognition of main tissue culture production facility. In case of validity of recognition of main tissue culture production facility expires earlier, the validity of recognition of hardening centre will be deemed to expire.

xi. Each applicant will be required to pay a fee of Rs.2000/- using the webportal towards "processing and certification" at the time of issue of certificate of recognition.

6.4. Application Procedure Renewal of Recognized Hardening Centre:

i. The applicant will submit the NCS-TCP Form- 3A for renewal of Recognition of Hardening Center(s) to the NCS-TCP Management Cell along with registration renewal fee of Rs.250/- (Rupees two hundred and fifty only) using the webportal at least 2 months prior to the date of expiry of the certificate of recognition.

ii. The rest of procedure for renewal of recognition of hardening centre will be same as the application procedure for recognition.

Formats for Application, Self Assessment Report/ Assessment criteria for Recognition of hardening centers of recognized tissue culture production facilities are at **Chapter 14**.

Chapter 7:

Certification of Tissue Culture Raised Plants

7.1. Testing of Mother Plant Tissue/Stock Culture

Virus indexing of stock culture could be done from ATL or any other reputed organization but certification of tissue culture raised plant testing of material for freedom from virus would be only done by ATLs under NCS-TCP for recognized TCPFs

Prior to the certification of tissue culture raised plant "Mother Plant Tissue/Stock Culture(s)" need to be indexed for all known virus listed under NCS-TCP. For virus indexing of Plant Tissue/Stock Culture(s) recognized companies must submit the 'Intimation Form for Virus Indexed of Mother Plant/Stock Culture(s)' to the nearest ATL using the online web-portal. (Non-recognized companies may submit "Intimation form for Virus Indexing of Plant Tissue/Stock Culture(s)" (Annexure-1A) available at the NCS-TCP Website (https://dbtncstcp.nic.in/Application-Form) along with self-addressed envelope. The above request should reach the ATL 2 weeks before the sample is (are) being sent. The ATL will examine the intimation form and if found complete in all respect it will intimate the applicant, regarding requirements for sending the samples. Guidelines for dispatch of material, sample size, quantity of sample, fee etc. will be provided. Subsequently after the receipt of acknowledgement from ATL the companies need to submit the prescribed fee.

(Further details are available at Standard Operating Procedures (SOPs) for TCPFs and ATLs). An **Annexure-1A, Annexure-2A and other Forms** might be downloaded from NCS-TCP web site.

Note: ATLs should accept samples from companies only in the prescribed format

7.2. Process Flow and Relevant Formats for Testing of Mother Plant Tissue/Stock Culture

Intimation form **(Annexure 1A)** will be received from TC companies for Virus Indexing of Plant Tissue/ Stock Culture(s) preferably at least two weeks before the sample(s) received. ATL will acknowledge the intimation and inform the company regarding fee to be submitted for testing

↓

Sample(s) will be received along with application **(Annexure 2A)** covering detailed information of the samples to be tested and requisite fee. Each sample will be assigned unique 21 digits sample registration number by ATLs

↓

The samples would be forwarded by in- charge ATL to technical person with a **job card (Annexure 3A)**

↓

The laboratory technician (Virology) after testing will prepare a **test report** and submit to Scientist concerned to verify and sign the test report (**Annexure 4A**)

↓

In case of dispute, the concerned ATL will forward the second sub-sample to referral laboratory (**Annexure 5A**)

↓

The ATL will maintain the whole record in **master register for stock cultures (Annexure 6A**)

7.3. Testing of Mother Plants/Stock Culture

Testing of "mother plants/stock cultures" for freedom from viruses as required by NCS-TCP

1. All mother plants/stock cultures must be indexed for all the viruses affecting the plant species listed in NCS-TCP website.

(a) Ideally individual mother plants/stock cultures should be tested.

(b) If the number of mother plants/stock culture is large, the samples from batches consisting of a maximum of **10 mother plants/stock cultures** may be pooled for testing.

In such cases –

(i) The tissue culture unit must maintain proper record of individual mother plants/stock cultures of each batch, so that individual mother plants/stock cultures or smaller batches could be tested, in cases where the pooled samples are found positive for infection, so that only the cultures from infected mother plant/stock culture are discarded.

(ii) If testing is not done as envisaged in 1(b)(i), all the cultures generated from the infected mother plants/stock cultures will have to be discarded.

2. Virus testing can be done ATLS or any Govt. Institute or University having facilities and expertise for virus testing.

Note: Few applicant companies don't establish cultures for mass multiplication. Such companies import starter/ stock culture or procure starter/ stock culture from company within the country. The above applicant company (seeking recognition/renewal of recognition under NCS- TCP) also needs to test the starter material/ stock culture prior to its large scale multiplication in addition to test conducted by its supplier. In case companies importing cultures for only mass multiplication under buy back arrangement are also required to test stock cultures for all known viruses under NCS-TCP.

7.4. Certification of Tissue Culture Raised Plants:

Only Recognized Tissue Culture Production Facilities will be eligible to register for certification of plant tissue culture raised material. ATL would not accept the sample of tissue culture raised plants for certification if the mother plant/stock culture has not been indexed for respective batch of TC plants.

The Tissue Culture Production Facility will register its application for Certification of Tissue Culture material with the nearest **ATL** through filling **"Intimation form for (Virus/ genetic fidelity) Testing for Batch Certification of Tissue Culture Raised Plants" using online webportal**(**Annexure-1B**). The above request should reach the ATL 2 weeks before the sample is (are) being sent. The **ATL** will examine the **Annexure-1B** and if found complete in all respect it will intimate the applicant (in two working days), regarding requirements requisite fee for the testing.

The fees for batch certification of tissue culture raised plant should be paid online and the sample would be dispatched. Print of Send sample screen i.e. **"Application for (Virus/ genetic fidelity) Testing for Batch Certification of Tissue Culture Raised Plants (Annexure-2B)"** will be deposited at the ATL with the samples (The details are at SOP for TCPUs and ATLs). An **Annexure-1B** and **Annexure-2B** might be downloaded from NCS-TCP web site.

The **ATLs,** will arrange for site inspection, receipt of samples, testing etc as per prescribed format. On receipt of requisite fee ATL personal should visit the hardening facilities of recognized tissue culture production facilities for collecting samples for batch certification. The cost of the visit might be borne by the ATL under travel head.

7.5. Certificate of Quality and Certification Label:

The ATL will generate the Test Report within the prescribed time frame and based on the test report the Certificate of quality will be issued as per prescribed norms. On preparation of Certificate of Quality, NMC would issue 10 number of certification labels (Sample label is at Chapter 14) duly signed and stamped for affixing on the packages of consignment of tissue culture plants as prescribed under certification standards established by the Department of Biotechnology in accordance with provisions of Seeds Act, 1966. Additional label will be provided by NMC to TCPFs only on written request from company without any charges.

Duly signed/stamped certification labels will be dispatched by NMC to the Tissue Culture Production Facility after issuance of certificate of quality of tissue culture raised plants for affixing on the packages/accompanying with dispatched planting material. (The details of fee to be charged by the ATL from companies are at Chapter 10).

7.6. Guidelines for Issuance of Certificate of Quality and Certification Label:

"Certificate of Quality" and "Certification Labels" are to be issued if samples of tissue culture raised plants have been tested for both freedom from viruses and true to typeness / Genetic uniformity testing. However, genetic fidelity/ uniformity testing may not be required in some plant species. In such cases, only "Certificate of Quality" may be issued without "Certification Label" clearly stating that this certificate is only for Quality with respect to freedom for viruses. It may be noted that tissue culture raised plants should be tested for all the known viruses affecting the plant species being tested, as listed in the Standard Operating Procedures (SOPs) for the purpose of issuance of certificate. The "Certificate of Quality" should clearly mention the nature of testing conducted. Whenever "Certification Label" is issued both type of testing (i.e. virus indexing and genetic fidelity/ uniformity testing) has to be conducted and samples are found virus free and true to type/ genetically uniform.

Note: Tolerance level of genetically true to typeness/ uniformity need to be zero percent for all the tissue culture multiplied crops in order to issue the "Certificate of Quality"

7.7. Process Flow and Relevant Formats for Testing and Certification of Tissue Culture Raised Plants

Intimation form **(Annexure 1B)** will be received from TC companies for testing and certification of tissue culture raised plants preferably at least two weeks before the sample(s) received. ATL will acknowledge this intimation and inform the company regarding fee to be submitted for testing. *Application for certification of tissue culture plants would be accepted only from the recognized tissue culture facility and only in the case when the batch of tissue culture plants has been produced from indexed stock cultures/mother plant***.**

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Samples will be received along with application **(Annexure 2B)** covering detailed information such as batch number/batch size and requisite fee. Each batch of plants will be assigned unique **42 digits** batch registration number by ATL

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The samples will be forwarded by the In-charge, Division of ATLs to the respective lab technician/research assistant with a job card **(Annexure 3B)**

↓

The laboratory technician (Virology/Molecular Biology) after testing will prepare a **test report** and submit to concerned scientist to verify and sign the test report (**Annexure 4B**)

↓

Director/ HoD of ATL will issue a "**Certificate of Quality"** based on test report (Virus indexing and/or genetic fidelity) to the concerned TCPF (**Annexure 5B**)

↓

NMC will issue required number of **certification labels** to the company only if the samples are free from known viruses and/or true to type along with "Certificate of Quality" issue by ATL (**Annexure 6B**)

↓

If the test report is positive for virus or not found true to type, the Director/ HoD of ATL will issue a **certificate of disapproval/Tissue Culture Plants Not Approved for Certification** to the concerned TCPF (**Annexure 7B**)

↓

In case of dispute, the concerned ATL will forward the sub-sample to referral laboratory (**Annexure 8B**)

↓

The ATL will maintain the whole record in **master register** for testing and certification of **tissue culture raised plant (Annexure 9B**)

7.8. Standards for Production of Tissue Culture Material:

Standards/Guidelines for production of Tissue Culture material are currently being prepared for different crops as per requirements, by DBT in consultation with scientists/institutes, working in the area. The Accredited Test Laboratories will issue the certificates only if Tissue Culture material is produced in conformity with these notified guidelines. The Guidelines for potato have already been notified by Ministry of Agriculture. Guidelines have been approved for other crops like Banana, Sugarcane, Apple, Citrus, Vanilla and Black pepper. These guidelines are given at **Chapter 8**

Chapter 8:

Standard Guidelines/Parameters for Production of Tissue Culture Raised Plants

Potato, Banana, Sugarcane, Apple, Citrus,

Black Pepper, Vanilla and Bamboo

8.1. Potato – Tissue Culture - Raised Minituber - (Ptcmt) Standards For Certification

I. Application and Amplification of General Seed Standards for PTCMT

a. The General Seed Standards are basic and, together with the following specific standards constitute the standards for approval of PTCMT. As the name implies, these standards are applicable to tissue culture raised mini tubers multipliedunder laboratory and greenhouse conditions as laid here.

b. The General Standards are amplified as follows to apply specifically to the PTCMT:

1. Eligibility requirements for PTCMT production:

The PTCMT to be eligible for production shall be from a source meeting the following standards for laboratory and greenhouse facilities.

i. Laboratory and greenhouse facilities used for production of plantlets/microtubers or minitubers shall be maintained free of potato pests or vectors of potato pathogens. Failure to keep such pests under control may cause rejection of all lots maintained in the facility. All potting or growth media shall be sterile. Water to be used in a laboratory or greenhouse operation should be free from impurities.

ii. Hygienic conditions shall be strictly observed during micro propagation, potting, planting, irrigating, movement and use of equipment and other laboratory and greenhouse practices to guard against the spread of diseases or pests in the facilities used for seed multiplication.

iii. All micro propagation and greenhouse facilities must be approved, as per the standard/guidelines. These facilities must have a changing area between the double doors.

iv. The greenhouse (protected environment) must be "insect proof" and be equipped with a double-door entrance, provision for footwear disinfection prior to entering the protected environment and insect proof ventilation screening on intakes and exhaust openings. The persons entering the protected environment should use Wellington boots (Plastic boots) and change lab-coat in the changing area to reduce the chances of inadvertent introduction of vector insects clinging to clothes.

v. The material being initiated for producing PTCMT must be of Registered/Notified variety and confirmed identity. It must be duly documented with respect to origin.

vi. The plants of a potato varieties being initiated for tissue culture should be tested in an *accredited* laboratory *for freedom from the* following:

PVA, PVS, PVM, PVY, PVX, PLRV, PALCV, PSTVd and endophytic or epiphytic bacteria and fungi. Tests must be carried on a minimum of ten plantlets of each variety selected at random. For virus testing ELISA or an equivalent method should be used, for viroid RT-PCR should be used, and for fungi and bacteria light microscopy and culturing on media should be used.

2. Sources of seed:

i. The facility should use recognized aseptic initiation and propagation procedures (i.e. follow procedures and use equipment, which will maintain sterile conditionsas per standard tissue culture morns).

ii. The initiating facility must maintain following information on each variety for review and audit by the competent authority once in a year: variety identification, date of initiation, origin and testing results from accredited laboratory.

iii. Tests must be carried out on a minimum of ten plantlets, selected at random, for each variety by an accredited laboratory. No plant should contain PVA, PVS, PVM, PVY, PVX, PLRV, PALCV, PSTVd and other endophytic or epiphytic bacteria and fungi.

iv. Valid pathogen testing results are required prior to the initiation of micro tubes production cycle or planting of test tube plantlets in the greenhouse.

v. PTCMT shall be produced and multiplied from approved source *in vitro* plants or microtubers, as per the prescribed procedure.

vi. PTCMT may be used as breeder seed for further production certified classes of seed as prescribed in the Indian Minimum Seed Certification Standards.

vii. Concerned laboratory should issue a certificate to the effect that the PTCMT has been produced with the standards as prescribed under their supervision.

II. Greenhouse/Controlled Environment Requirements

1. All micropropagation and greenhouse facilities must meet the standards given above under eligibility requirements.

2. The soil used for PTCMT production should not be infested with pathogen and pests of potato, particularly the following:

- Wart *(Synchytrium endobioticum* (Schilb.) Perc.) and or cyst forming nematodes;
- Brown rot *(Pseudomonas solanacearum (E.F.* Sm.) E.F. Sm.) or non-cyst forming nematodes within the previous three years;
- Common scab *(Streptomyces scabies* (Thaxt.) Waks. & Henrici).

III. Inspection of Greenhouse/Controlled Environment facility used for production of PTCMT

1. The grower must notify the Competent Authority of his production plans well in advance of the planting.

2. The crop must be grown from approved basic source *in vitro* plants or micro tubers, which were produced, in an aseptic environment.

3. A minimum of three inspections shall be made as follows:

i. The first inspection shall be made 35 days and 45 days after planting for plains and hills respectively to verify growing conditions, extent of disease infectionand off types and also to confirm isolation requirement of one meter between different varieties as to avoid mechanical admixture;

ii. The second inspections shall be made at 60-65 days after planting to verify off types, disease infection if any and pathogen testing, on a representative sample, comprising of *1% of the plants with a minimum of 5 and a maximum of 25 plants* sampled *for each* variety:

iii. The third inspection shall be made immediately after haulms cutting/ destruction in order to verify that haulms have been cut/destroyed by the

prescribed date and proper manner.

iv. Effective sanitation practices including insect and disease monitoring and prevention must be adhered to.

v. Basic Stock can be planted in commercially available medium, which has not been recycled. If nursery beds are used, the substrate should be properly sterilized before planting.

vi. The greenhouse must be free from all potato and solanaceous plant debris before planting.

vii. No field-produced seed potatoes (including pathogen tested clonal selections), non-seed potatoes, nor any other solanaceous species of plants can be grown in the protected environment while used to produce Basic Stock.

viii. Varieties must be separated by appropriate partitioning of greenhouse to prevent varietal mixture.

ix. If testing performed by an accredited laboratory reveals the presence of banned virus (es), fungus or bacteria all the crops in the protected environment will be ineligible for multiplication and the entire material will be destroyed.

x. In the eventuality of detection of insect (particularly aphids, thrips and white flies) vectors (for which yellow sticky traps should be put at least at three places in a greenhouse) by competent Authority, the grower must provide post harvest test results to this authority. A representative sample, representing each variety grown in the protected environment must be post harvest tested and if the results are negative for PVA, PVS, PVM, PVY, PVX, PLRV and PALCV, the crop will be assigned basic stock status or otherwise rejected.

IV. Field Standards

A. Field Standards of PTCMT at greenhouse

a. *General requirements*

1. Isolation: Minimum 1 meter between the different varieties grown in greenhouse so as to avoid mechanical admixture.
2. All micropropagation and greenhouse facilities must be notified (approved) by DAC, as per the standards given above under eligibility requirements.

b. Specific requirements

Factor	**Maximum permissible limits**
* Offtypes	0.05%
**Plants showing symptoms of	
- Mild mosaic	0.05%
- Servere mosaic, leaf roll, yellows and apical leaf curl	0.05%
** Plants infected by brown rot (syn. Bacterial wilt) (Ralstonia solamacearum)	nil

*Maximum permitted before dehaulming

** Maximum permitted at final inspection, though the diseases mentioned above are not expected to be present in tissue culture raised plants but it essential to maintain a good crop hygiene.

c. Seed Standards for PTCMT

Factor	Standards for PTCMT
Weight of mini tuber (minimum)	1.0gm
Germination/sprouting (minimum)	90%
Varietal Purity (minimum)	99%
Pure seed	98%
Virus	0.01%

B. Field standards for Foundation Crops and Certified Crop raised out of Potato-Tissue Culture raised Mini Tuber PTCMT1 shall be same as prescribed for conventional method.

[1] in vitro multiplication for custom production of an imported variety or a non-notified variety can be taken up by the industry exclusively for export purposes. Such varieties, however, should be introduced following the approved guidelines of Government of India.

Seed Certification Standards for Potato Tissue Culture raised Minitubers (PTCMT)

I. Application and Amplification of General Seed Certification Standards

a. The General Seed Certification Standards are basic and, together with the following specific standards constitute the standards for certification of seed potato.

b. Classification of seed potato on the basis of area of Production:

There shall be two types of seed potatoes, namely the Hills and Plains - grown and shall be designated as Hill Seed (HS) and Plains Seed (PS) respectively. Hill Seed (HS) shall be grown in the high hills generally 2500 meters above the mean sea levelor in situations declared technically suitable for seed production. Plains Seed (PS) shall be grown in such areas where aphid infestation is low during the crop growing season and which are technically suitable for seed production.

II. Land Requirements

A crop of seed potato shall not be eligible for certification if grown on land infested with:

a. Wart *(Synchytrium endobioticum (Schilb.)* Perc. And or cyst forming nematodes;

b. Brown rot *(Pseudomonas solanacearum* (E.F_ Sm.). E.F. Sm. Or non-cyst forming nematodes within the previous three years;

c. Common scab *(Streptomyces scabies* (Thaxt.) Waks. & Henrici).

III. Field Inspection

A minimum of four inspections shall be made as follows:

1. The first inspection shall be made about 45 days after planting the PTCMT in the hills and about 35 days after planting the PTCMT in the plains to verify isolation, offtypes and the extent of disease infection with specific reference to mild and severe mosaics, leaf roll, yellows, brown rot and other relevant factors;

2. The second inspection shall be made about 60-65 days after planting the PTCMT for early varieties and about 70-75 days after planting the PTCMT for late varieties or at appropriate growth stage depending on the crop duration of the variety concerned to check isolation, offtypes and extent of disease infection with specific reference to

mild and severe mosaics, leaf roll, yellows, brown rot and other relevant factors;

3. The third inspection shall be made immediately after haulms cutting/destruction in order to verify that haulms have been cut/destroyed by the prescribed date and in proper manner;

4. The fourth inspection shall be made about 10 days after haulms cutting/destruction and before harvesting in order to verify that no re-growth of haulms has taken place.

IV. Field Standards

A. General Requirements

1. Isolation

The fields of seed potato shall be isolated from the contaminants shown in column 1 of the Table below by the distances specified in columns 2, 3 and 4 of the said Table.

Contaminants	Minimum distance (meters)		
	Foundation		Certified
	Stage l	Stage- II	
1.	2.	3.	4.
Fields of other varieties	5	5	5
Fields of the same variety not conforming to varietal purity requirements for certification	5	5	5

B. Specific requirements

		Maximum permissible limits		
Factor	Stage	Foundation		Certified
		Stage-I	Stage-II	
1.	2.	3.	4.	5.
Off types	I & II Inspection	0.050%	0.050%	0.10%
Plants showing symptoms of: - Mild mosaic	1 & II Inspection	1.0%	2.0%	3.0%
-Severe mosaic, leaf roll and yellows	I & 11 Inspection	0.50%	0.750%	1.0%
*Total Virus	-	1.0%	2.0%	3.0%
**Plants infected by brown rot (Syn. Bacterial wilt) *(Pseudomonas solanacearum (E.F.* Sm.) E.F. Sm.)	I & II Inspection	None	None	3 plants per hectare
***Re-growth of plants after destruction of haulms	IV Inspection	0.50%	0.50%	0.50%

*Of the two inspections, the higher virus percentage will be considered for the purpose of the specified limits of tolerance.

**The presence of brown rot infected plants within the specified limits of tolerance shall be permitted in the areas known to be infected with this disease. In case of plants suspected to be infected with brown rot, the neighboring plants, one on either side should also be rogued along with tubers

***Standards for re-growth after destruction of haulms shall be met at fourth inspection to be conducted about 10 days after haulms cutting.

Note: 1. All off types and diseased plants should be rouged out along with the tubers and destroyed.

2. Gaps in the seed plot should not be more than 10.0%.

3. Haulms must be destroyed as close to the ground as possible before the date specified by the Certification Agency. Failure to destroy haulms in time shall render the crop liable for rejection.

V. Seed Standards

A. Specification in respect of size and weight of seed material for Foundation Stage-1, Foundation Stage-II and Certified class shall be as under:

Size	Mean length and two widths at the middle of tuber	Corresponding weight
a. Hill Seed (HS) Seed size Large size	30mm-60mm above 60 mm	25-150 gm above 150 gm
b. Plains Seed (PS) Seed Size Large size	30 mm - 55 mm above 55 mm	25-125gm above 125 gm

Note:

1. The size of tuber will be decided either on the basis of mean of two widths of a tuber at the middle and that of length or on the basis of corresponding weight of tuber.
2. In a seed lot, tubers not conforming to specific size of seed shall not exceed more than 5.0% (by number).
3. (a) The seed material shall be reasonably clean, healthy, firm and shall conform to the characteristics of the variety. The tubers not conforming to the varietal characteristics shall not exceed 0.050% and 0.10% (by number) for Foundationand Certified seed classes respectively.

   (b) Cut, bruised, unshapy, cracked tubers or those damaged by insects, slugs or worms shall not exceed more than 1.0% (by weight).

   (c) Greenish pigmentation on tubers will not be a disqualification for certification.

B. Maximum tolerance limit of tubers showing visible symptoms caused by the diseases mentioned below will be as follows!

Diseases	Maximum permissible limits		
	Foundation		Certified
	Stage-I	Stage-II	
1.	2.	3.	4.
Late blight *(Phytophthora* infestations (Mont.) de Bary), dry rot *(Fusarium caeruleum* (Lib.) Sacc.) or Charcoal rot *(Macrophomina phaseoli* (Tassi) G. Goidanich).	1.0% (by number)	1.0% (by number)	1.0% (by number)
Wet rot *(Scierotium rolfsii)* Sacc.)	None	None	None
* Common scab *(Streptomyces* scabies (Thaxt) Waks. & Henrici)	3.0% (by number)	3.0% (by number)	3.0% (by number)
** Black scur *(Rhizoctonia solani* Kuehn.)	5.0% (by number)	5.0% (by number)	5.0% (by number)
*** Total diseases	5.0% (by number)	5.0% (by number)	5.0% (by number)

* Even if a single tuber infected with common scab is detected in a seed lot, the entire seedlot shall be treated with approved fungicide before seed lot is declared fit for certification. Seed lots having infected tubers more than the prescribed limits will not becertified even after treatment.

**(a) A tuber carrying 10.0% or above scurfed surface will be considered as one infected unit.

(b) Seed lots having black scurf infection more than the prescribed limits could be certified after treatment with approved chemical/fungicide.

For all diseases, the higher disease percentage will be considered for the purpose of the specified limits of tolerance.

8.2. Banana- Tissue Culture – (BTC) - Standards

I. Applications and Amplification of General seed Standards for BTC

a. The General Seed Certification Standards are basic and, together with the following specific standards constitute the standards for approval of BTC. As the name implies, these standards are applicable to tissue culture multiplied under laboratory and greenhouse conditions as laid here.

b. The General Standards are amplified as follows to apply specifically to the BTC.

1. Eligibility requirements for BTC production:

i. All micropropagation and greenhouse facilities must be approved as per standards/ guidelines set by the competent authority. These must have a changing area between double doors.

ii. Laboratory and greenhouse facilities used for production of plantlets shall be maintained free of pests or vectors of banana pathogens. Failure to keep such pests under control may cause rejection of all lots maintained in the facility. All potting or growth media shall be sterile. Water sources used in the laboratory or greenhouseoperation shall be treated or otherwise rendered free of all possible pathogens by the applicant.

iii. Hygienic conditions shall be strictly observed during micropropagation, potting,planting, irrigating, movement and use of equipment and other laboratory and greenhouse practices to guard against the spread of diseases or pests in the facilities used for banana plant multiplication.

iv. The greenhouse (protected environment) must be "insect proof" and be equipped with a double-door entrance, provision for footwear disinfection prior to entering the protected environment and insect proof ventilation screening on intakes and exhaust openings. The persons entering the protected environment should use Wellington boots (plastic boots) and change lab-coat in the changing area to reduce the chances of inadvertent introduction of vector insects clinging to clothes

v. The material being initiated must be of a notified variety and confirmed identity. It must be duly documented with respect to origin.

vi. All samples of banana varieties being initiated should be tested in an accredited laboratory and be free of viruses (Banana Bunchy Top Virus, Cucumber Mosaic Virus, Banana Bract Mosaic Virus, Banana Streak Virus) and other endophytic or epiphytic bacteria and fungi.

vii. The basic material for sub-multiplication need to be obtained afresh from the nodal organization as soon as the maximum permitted number of passages (as confirmed by DNA fingerprinting) of shoot multiplication with old cultures has been completed.

viii. On application for inspection, the mother cultures as developed above are eligible for certification. The micropropagation facility to be inspected must have been approved by the competent Authority. All stocks must have a valid variety identification and disease testing report at any time during multiplication process.

In vitro multiplication of an imported variety or a non-notified variety can be taken up by the industry exclusively for export purposes. Such varieties, however, should be introduced following the approved guidelines of Government of India.

2. Source of Seed:

i. The facility should use recognized aseptic initiation and propagation procedures (i.e. follow procedures and use equipment, which will maintain sterile conditions as per standard tissue culture norms).
ii. The initiating facility must maintain following information on each variety for review and audit by the competent authority at least once in a year: variety identification, date of initiation, origin and testing results from accredited laboratory.
iii. Tests must be carried out on a minimum of 0.1% (at least ten) plantlets for each variety by an accredited laboratory. Such tests will be valid so long as cultures of that particular batch are under production (subject to a maximum of 8 passages). No plant should contain (Banana Bunchy Top Virus, Cucumber Mosaic Virus, Banana Bract Mosaic Virus, Banana Streak Virus) and other endophytic or epiphytic bacteria and fungi.
iv. Valid pathogen testing results are required at the2nd/3rd subculture stage prior to the bulking up of the cultures.
v. The guidelines for production of tissue culture plant is at Appendix-I

Minimum Quality Standards for growing of plants inside greenhouses/polyhouses

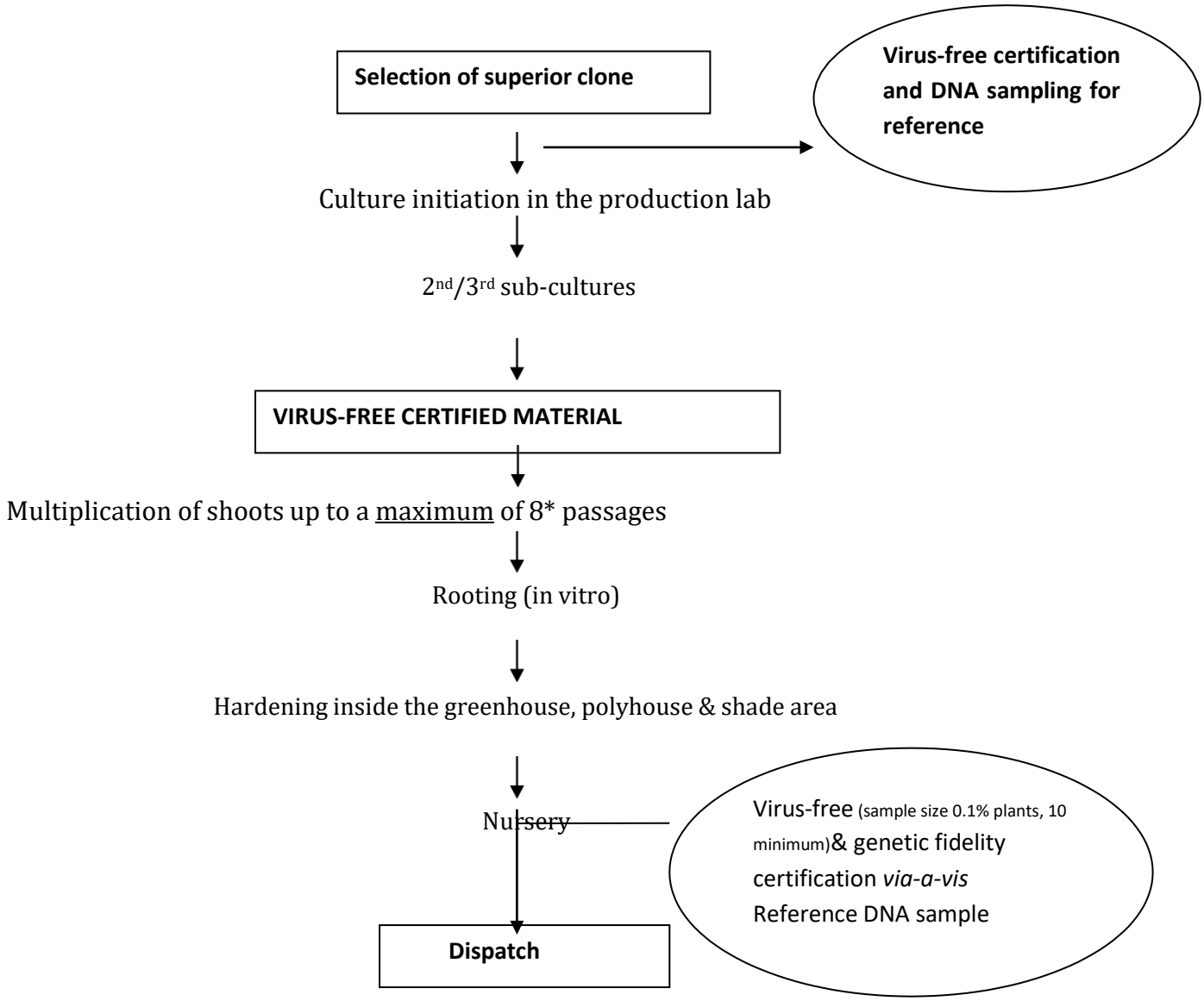
The following requirements must be met for production of plantlets:

i. Effective sanitation practices including insect and disease monitoring and prevention must be adhered to.
ii. No field-produced banana plants can be grown in the protected environment (greenhouse/polyhouse) along with tissue cultured plants.
iii. Varieties must be separated by physical barriers (such as proper tagging), which will prevent varietal mixture.
iv. Before dispatch to the farmers, the tissue-cultured plants growing in the nursery should be tested for the absence of the viruses (Banana Bunchy Top Virus, Cucumber Mosaic Virus, Banana Bract Mosaic Virus, Banana Streak Virus) and clonal uniformity. For establishing clonal fidelity, the sample size should be 0.1% of the batch size with a minimum of 10 plants.

v. If testing performed by an accredited laboratory reveals the presence of banned viruses, fungus or bacteria the tissue-cultured plants should not be dispatched from the premises of the production lab and the entire material should be destroyed.
vi. The concerned laboratory/agency producing the tissue culture raised material should issue a certificate to the effect that BTC have been produced as per guidelines.
vii. The agency producing BTC will follow the labelling procedures as given at Appendix-A

Appendix-I

Procedures and standard parameters for production of Banana by tissue culture



* *There is a difference of opinion among researchers and production labs on the number of passages that could be regarded as "safe" for shoot multiplication in banana with respect to clonal uniformity of plants. In tissue culture it is well known that lesser the number of subcultures, lower will be the chances of somaclonal variation. However, it must also be realized that if the number of passages are far too small then the entire production process becomes economically unviable. Therefore, efforts should be made to optimise the shoot multiplication process and extend the number of passages only till the clonal uniformity of the progenies is maintained. This could be achieved through a) strict monitoring of shoot multiplication process ensuring that adventitious shoots are not multiplied and*
b) confirming the clonal fidelity of tissue cultured plants using molecular markers in different passages. However, in banana under no circumstances shoots should be subcultured for more than 8 passages

8.3. Sugarcane- Tissue Culture – (STC)- Standards

I. Applications and Amplification of General seed Standards for STC

a. The General Seed Certification Standards are basic and, together with the following specific standards constitute the standards for approval of STC. As the name implies, these standards are applicable to tissue culture multiplied under laboratory and greenhouse conditions as laid here.

b. The General Standards are amplified as follows to apply specifically to the STC.

1. Eligibility requirements for STC production:

i. All micropropagation and greenhouse facilities must be approved as per standards/ guidelines set by the competent authority. These must have a changing area between double doors.

ii. Laboratory and greenhouse facilities used for production of plantlets shall be maintained free of pests or vectors of sugarcane pathogens. Failure to keep such pests under control may cause rejection of all lots maintained in the facility. All potting or growth media shall be sterile. Water sources used in the laboratory or greenhouseoperation shall be treated or otherwise rendered free of all possible pathogens by the applicant.

iii. Hygienic conditions shall be strictly observed during micropropagation, potting,planting, irrigating, movement and use of equipment and other laboratory and greenhouse practices to guard against the spread of diseases or pests in the facilities used for banana plant multiplication.

iv. The greenhouse (protected environment) must be "insect proof" and be equipped with a double-door entrance, provision for footwear disinfection prior to entering the protected environment and insect proof ventilation screening on intakes and exhaust openings. The persons entering the protected environment should use Wellington boots (plastic boots) and change lab-coat in the changing area to reduce the chances of inadvertent introduction of vector insects clinging to clothes

v. The material being initiated must be of a notified variety and confirmed identity. It must be duly documented with respect to origin.

vi. All samples of sugarcane varieties being initiated should be tested in an accredited laboratory and should be free of viruses (Sugarcane mosaic virus, Badnavirus, yellow leaf and Luteovirus) and other endophytic or epiphytic bacteria and fungi.

vii. The basic material for sub-multiplication need to be obtained a fresh from the nodal organization as soon as the maximum permitted number of passages (as confirmed by DNA fingerprinting) of shoot multiplication with old cultures has been completed.

viii. On application for inspection, the mother cultures as developed above are eligible for certification. The micropropagation facility to be inspected must have been approved by the competent Authority. All stocks must have a valid variety identification and disease testing report at any time during multiplication process.

In vitro multiplication of an imported variety or a non-notified variety can be taken up by the industry exclusively for export purposes. Such varieties, however, should be introduced following the approved guidelines of Government of India.

2. Source of Seed:

i. The facility should use recognized aseptic initiation and propagation procedures (i.e. follow procedures and use equipment, which will maintain sterile conditions as per standard tissue culture norms).

ii. The initiating facility must maintain following information on each variety for review and audit by the competent authority at least once in a year: variety identification, date of initiation, origin and testing results from accredited laboratory.

iii. Tests must be carried out on a minimum of 0.1% (minimum ten) plantlets for each variety by an accredited laboratory. Such tests will be valid as long as cultures of that particular batch are under production. No plant should contain (Sugarcane mosaic virus, Badnavirus, yellow leaf and Luteovirus) and other endophytic or epiphytic bacteria and fungi (Testing for Redrot, Smut and grassy shoot should also be included)

iv. Valid pathogen testing results are required at the2nd/3rd subculture stage prior to the bulking up of the cultures.

v. The guidelines for production of tissue culture plant is at Appendix-I

Minimum Quality Standards for growing of plants inside greenhouses/polyhouses

The following requirements must be met for production of plantlets:

i. Effective sanitation practices including insect and disease monitoring and prevention must be adhered to.

ii. No field-produced sugarcane plants can be grown in the protected environment (greenhouse/polyhouse) along with tissue cultured plants.

iii. Varieties must be separated by physical barriers (such as proper tagging), which will prevent varietal mixture.

iv. Before dispatch to the farmers, the tissue–cultured plants growing in the nursery should be tested for the absence of the viruses (Sugarcane mosaic virus, Badnavirus, yellow leaf and Luteovirus) and clonal uniformity. For establishing clonal fidelity, the sample size should be 0.1% of the batch size with a minimum of 10 plants per batch. Genetic variation up to 0.01% of the representative sampling may be permitted. Beyond this limit plants have to be discarded.

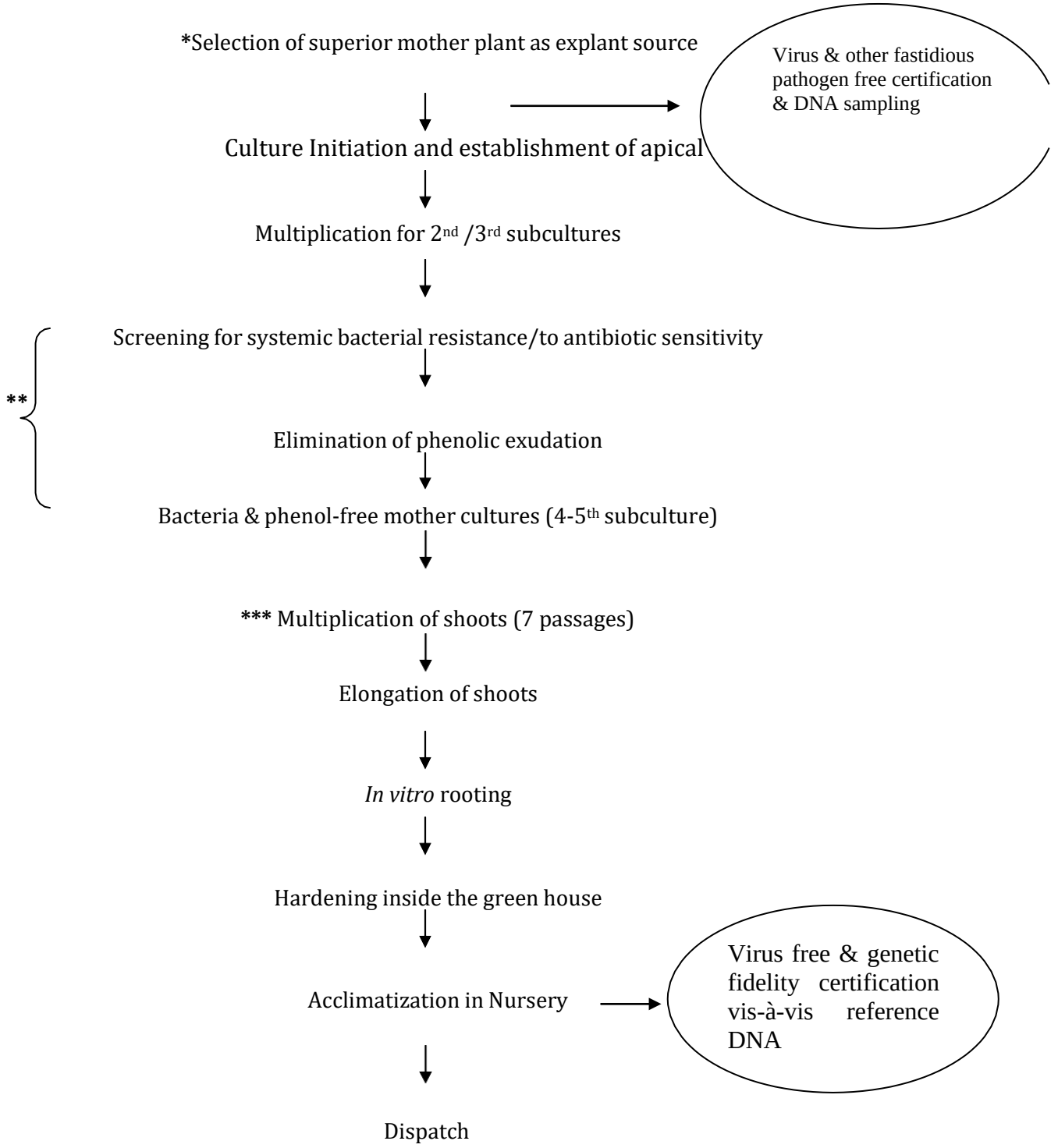
v. If testing performed by an accredited laboratory reveals the presence of banned viruses, fungus or bacteria the tissue-cultured plants should not be dispatched from the premises of the production lab and the entire material should be destroyed.

vi. The concerned laboratory/agency producing the tissue culture raised material should issue a certificate to the effect that STC have been produced as per guidelines

vii. The agency producing STC will follow the labelling procedures as given at Appendix-A

Appendix-I

Procedure and standard parameters for production of Sugarcane by tissue culture



* *Plants should be of superior quality in terms of growth, disease / pest resistance, drought tolerance, high yield (fresh weight), sugar content etc. The explant should be healthy and free from microbial infections, smut and, grassy shoot. One set of mother plants must be maintained in the insect proof glass house as reference sample.*

** *Since sugarcane tissue culture is frequently confronted with endogenous bacterial contamination and phenolic exudation, these should be eliminated using appropriate method.*

*** *In sugarcane the number of passages can be up to 7 for subculture of shoots.*

8.4. Apple- Tissue Culture – (ATC)- Standards

I. Applications and Amplification of General seed Standards for ATC

a. The General Seed Certification Standards are basic and, together with the following specific standards constitute the standards for approval of ATC. As the name implies, these standards are applicable to tissue culture multiplied under laboratory and greenhouse conditions as laid here.

b. The General Standards are amplified as follows to apply specifically to the ATC.

1. Eligibility requirements for ATC production:

i. All micropropagation and greenhouse facilities must be approved as per standards/ guidelines set by the competent authority. These must have a changing area between double doors.

ii. Laboratory and greenhouse facilities used for production of plantlets shall be maintained free of pests or vectors of apple pathogens. Failure to keep such pests under control may cause rejection of all lots maintained in the facility. All potting or growth media shall be sterile. Water sources used in the laboratory or greenhouse operation shall be treated or otherwise rendered free of all possible pathogens by the applicant.

iii. Hygienic conditions shall be strictly observed during micropropagation, potting,planting, irrigating, movement and use of equipment and other laboratory and greenhouse practices to guard against the spread of diseases or pests in the facilities used for banana plant multiplication.

iv. The greenhouse (protected environment) must be "insect proof" and be equipped with a double-door entrance, provision for footwear disinfection prior to entering the protected environment and insect proof ventilation screening on intakes and exhaust openings. The persons entering the protected environment should use Wellington boots (plastic boots) and change lab-coat in the changing area to reduce the chances of inadvertent introduction of vector insects clinging to clothes

v. The material being initiated must be of a notified variety and confirmed identity. It must be duly documented with respect to origin.

vi. All samples of apple varieties being initiated should be tested in an accredited laboratory and be free of viruses such as apple mosaic virus, apple chlorotic leaf spot virus, and other endophytic or epiphytic bacteria and fungi.

vii. The basic material for sub-multiplication need to be obtained afresh from the nodal organization as soon as the maximum permitted number of passages (as confirmed by DNA fingerprinting) of shoot multiplication with old cultures has been completed.

viii. On application for inspection, the mother cultures as developed above are eligible for certification. The micropropagation facility to be inspected must have been approved by the competent Authority. All stocks must have a valid variety identification and disease testing report at any time during multiplication process.

In vitro multiplication of an imported variety or a non-notified variety can be taken up by the industry exclusively for export purposes. Such varieties, however, should be introduced following the approved guidelines of Government of India.

2. Source of Seed:

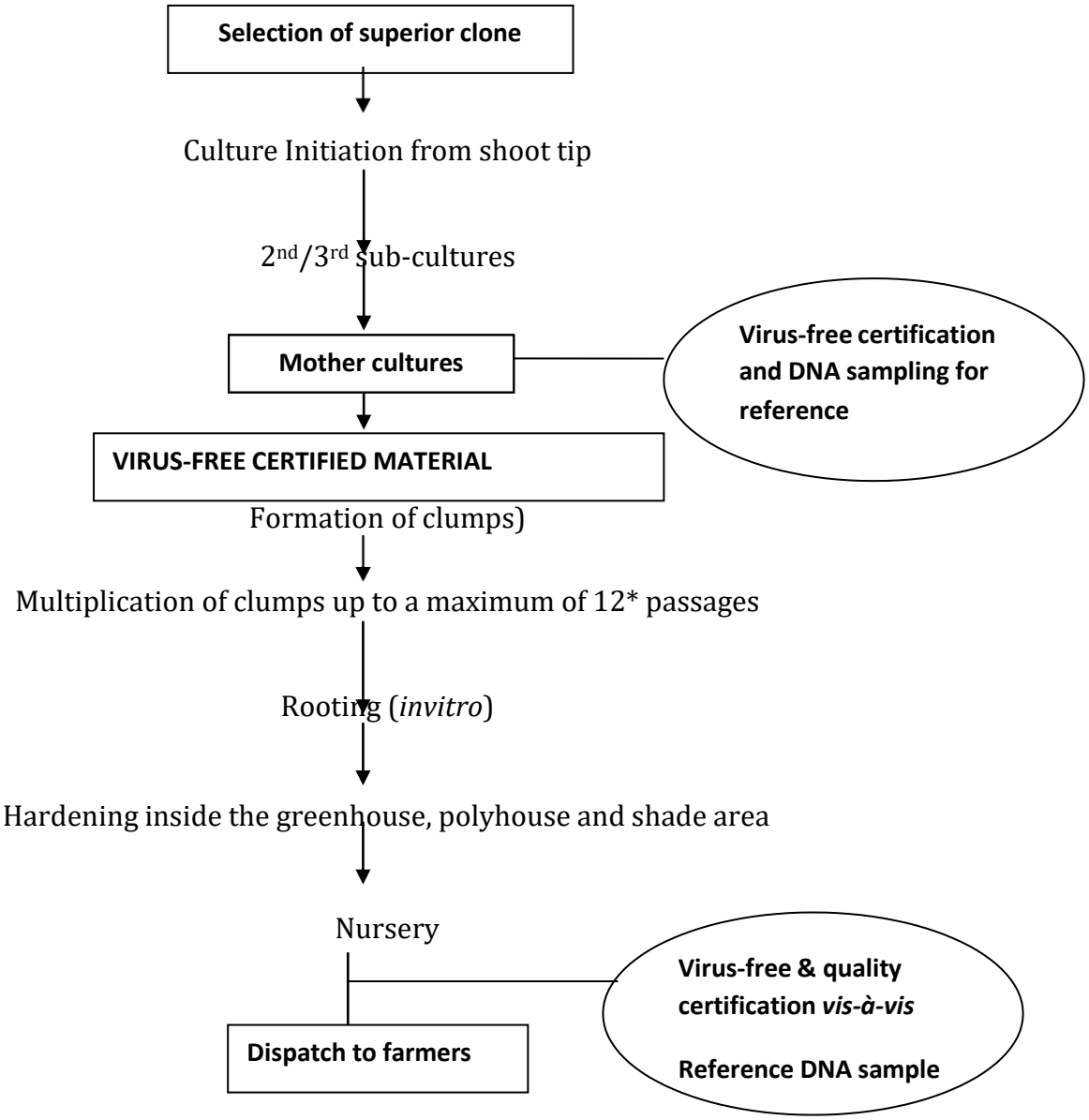
i. The facility should use recognized aseptic initiation and propagation procedures (i.e. follow procedures and use equipment, which will maintain sterile conditions as per standard tissue culture norms).
ii. The initiating facility must maintain following information on each variety for review and audit by the competent authority at least once in a year: variety identification, date of initiation, origin and testing results from accredited laboratory.
iii. Tests must be carried out on a minimum of 0.1% (at least ten) plantlets for each variety by an accredited laboratory. Such tests will be valid so long as cultures of that particular batch are under production (subject to a maximum of 12 passages). No plant should contain viruses such as apple mosaic virus, apple chlorotic leaf spot virus, and other endophytic or epiphytic bacteria and fungi.
iv. Valid pathogen testing results are required at the2nd/3rd subculture stage prior to the bulking up of the cultures.
v. The guidelines for production of tissue culture plant is at Appendix-I

Minimum Quality Standards for growing of plants inside greenhouses/polyhouses

The following requirements must be met for production of plantlets:

i. Effective sanitation practices including insect and disease monitoring and prevention must be adhered to.
ii. No field-produced apple plants can be grown in the protected environment (greenhouse/polyhouse) along with tissue cultured plants.
iii. Varieties must be separated by physical barriers (such as proper tagging), which will prevent varietal mixture.
iv. Before dispatch to the farmers, the tissue-cultured plants growing in the nursery should be tested for the absence of the viruses such as apple mosaic virus, apple chlorotic leaf spot virus, and clonal uniformity. For establishing clonal fidelity, the sample size should be 0.1% of the batch size with a minimum of 10 plants.
v. If testing performed by an accredited laboratory reveals the presence of banned viruses, fungus or bacteria the tissue-cultured plants should not be dispatched from the premises of the production lab and the entire material should be destroyed.
vi. The concerned laboratory/agency producing the tissue culture raised material should issue a certificate to the effect that ATC have been produced as per guidelines
vii. The agency producing ATC will follow the labelling procedures as given at Appendix-A

Procedures and standard parameters for production of Apple by tissue culture



***In tissue culture it is well known that lesser the number of subcultures, lower will be the chances of somaclonal variation. However, it must also be realized that if the number of passages are far too small then the entire production process becomes economically unviable. Therefore, efforts should be made to optimise the shoot multiplication process and extend the number of passages only till the clonal uniformity of the progenies is maintained. This could be achieved through a) strict monitoring of shoot multiplication process ensuring that adventitious shoots are not multiplied and b) confirmingthe clonal fidelity of tissue cultured plants using molecular markers in different passages. Apple shoots have been sub-cultured upto12 passages without any loss of clonal fidelity. There is a possibility that the clonal fidelity of the tissue-cultured plants is maintained even beyond 12 passages.*

8.5. Citrus- Tissue Culture – (CTC) - Standards

I. Applications and Amplification of General seed Standards for CTC

i. The General Seed Certification Standards are basic and, together with the following specific standards constitute the standards for approval of CTC. As the name implies, these standards are applicable to tissue culture multiplied under laboratory and greenhouse conditions as laid here.

ii. The General Standards are amplified as follows to apply specifically to the CTC.

1. Eligibility requirements for CTC production:

i. All micropropagation and greenhouse facilities must be approved as per standards/ guidelines set by the competent authority. These must have a changing area between double doors.

ii. Laboratory and greenhouse facilities used for production of plantlets shall be maintained free of pests or vectors of citrus pathogens. Failure to keep such pests under control may cause rejection of all lots maintained in the facility. All potting or growth media shall be sterile. Water sources used in the laboratory or greenhouse operation shall be treated or otherwise rendered free of all possible pathogens by the applicant.

iii. Hygienic conditions shall be strictly observed during micropropagation, potting, planting, irrigating, movement and use of equipment and other laboratory and greenhouse practices to guard against the spread of diseases or pests in the facilities used for banana plant multiplication.

iv. The greenhouse (protected environment) must be "insect proof" and be equipped with a double-door entrance, provision for footwear disinfection prior to entering the protected environment and insect proof ventilation screening on intakes and exhaust openings. The persons entering the protected environment should use Wellington boots (plastic boots) and change lab-coat in the changing area to reduce the chances of inadvertent introduction of vector insects clinging to clothes

v. The material being initiated must be of a notified variety and confirmed identity. It must be duly documented with respect to origin.

vi. All samples of citrus varieties being initiated should be tested in an accredited laboratory and be free of viruses such as Indian Citrus Ringspot Virus (ICRSV), Tristeza Virus (CTV) and Citrus Yellow Mosaic Virus (CYMV) and other endophytic or epiphytic bacteria and fungi.

vii. The basic material for sub-multiplication need to be obtained afresh from the nodal organization as soon as the maximum permitted number of passages (as confirmed by DNA fingerprinting) of shoot multiplication with old cultures has been completed.

viii. On application for inspection, the mother cultures as developed above are eligible for certification. The micropropagation facility to be inspected must have been approved by the competent Authority. All stocks must have a valid variety identification and disease testing report at any time during multiplication process.

In vitro multiplication of an imported variety or a non-notified variety can be taken up by the industry exclusively for export purposes. Such varieties, however, should be introduced following the approved guidelines of Government of India.

2. Source of Seed:

i. The facility should use recognized aseptic initiation and propagation procedures (i.e. follow procedures and use equipment, which will maintain sterile conditions as per standard tissue culture norms).
ii. The initiating facility must maintain following information on each variety for review and audit by the competent authority at least once in a year: variety identification, date of initiation, origin and testing results from accredited laboratory.
iii. Tests must be carried out on a minimum of 0.1% (at least ten) plantlets for each variety by an accredited laboratory. Such tests will be valid so long as cultures of that particular batch are under production (subject to a maximum of 12 passages). No plant should contain viruses such as Indian Citrus Ringspot Virus (ICRSV), Tristeza Virus (CTV) and Citrus Yellow Mosaic Virus (CYMV), and other endophytic or epiphytic bacteria and fungi.
iv. Valid pathogen testing results are required at the2nd/3rd subculture stage prior to the bulking up of the cultures.
v. The guidelines for production of tissue culture plant is at Appendix-I

Minimum Quality Standards for growing of plants inside greenhouses/polyhouses

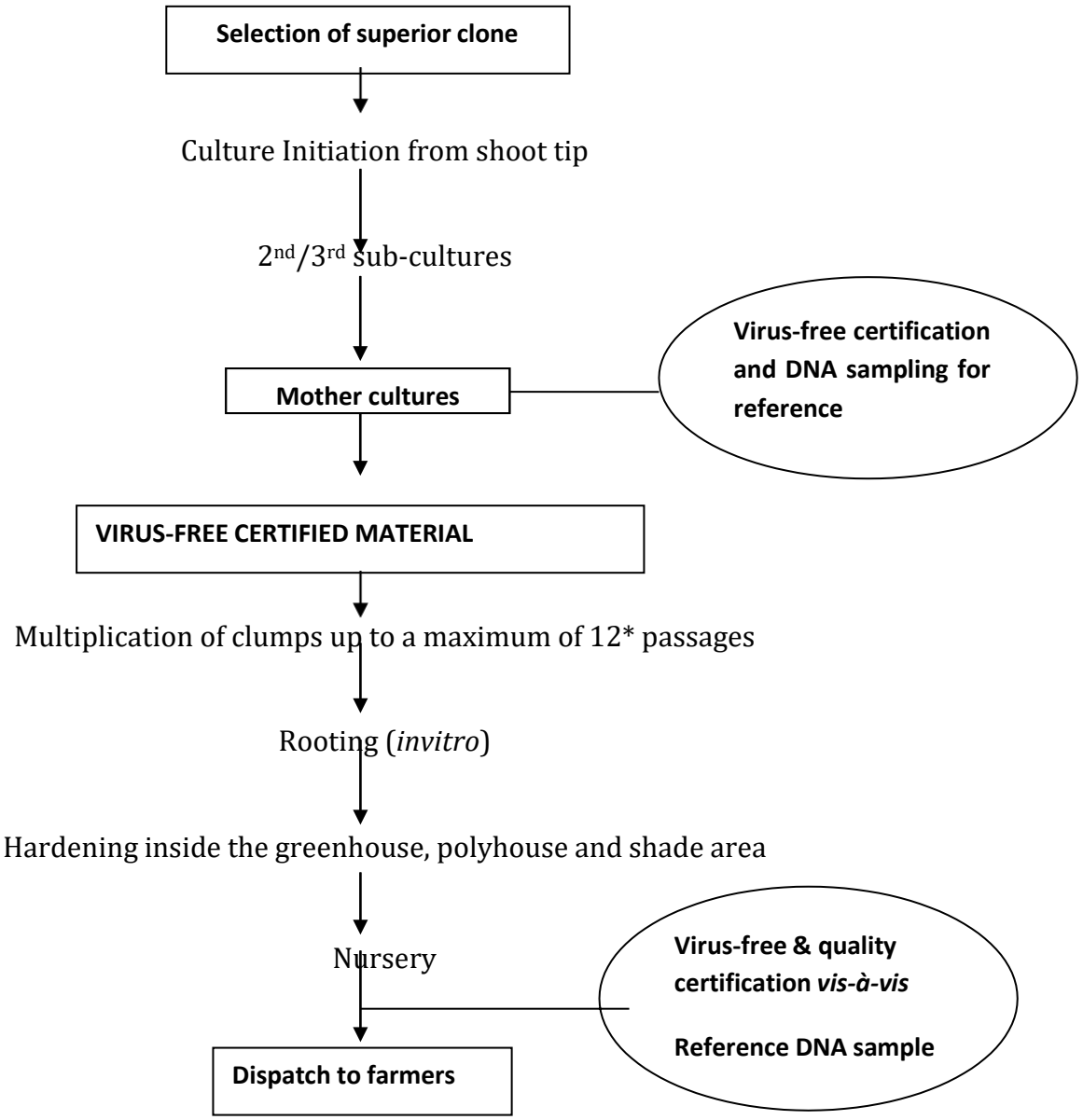
The following requirements must be met for production of plantlets:

i. Effective sanitation practices including insect and disease monitoring and prevention must be adhered to.
ii. No field-produced citrus plants can be grown in the protected environment (greenhouse/polyhouse) along with tissue cultured plants.
iii. Varieties must be separated by physical barriers (such as proper tagging), which will prevent varietal mixture.
iv. Before dispatch to the farmers, the tissue-cultured plants growing in the nursery should be tested for the absence of the viruses such as Indian citrus ringspot virus (ICRSV), Tristeza virus (CTV) and Citrus Yellow Mosaic Virus (CYMV) and clonal uniformity. For establishing clonal fidelity, the sample size should be 0.1% of the batch size with a minimum of 10 plants.

v. If testing performed by an accredited laboratory reveals the presence of banned viruses, fungus or bacteria the tissue-cultured plants should not be dispatched from the premises of the production lab and the entire material should be destroyed.
vi. The concerned laboratory/agency producing the tissue culture raised material should issue a certificate to the effect that CTC have been produced as per guidelines
vii. The agency producing CTC will follow the labelling procedures as given at Appendix-A

Appendix-I

Procedures and standard parameters for production of citrus by tissue culture



**In tissue culture it is well known that lesser the number of subcultures, lower will be the chances of somaclonal variation. However, it must also be realized that if the number of passages are far too small then the entire production process becomes economically unviable. Therefore, efforts should be made to optimise the shoot multiplication process and extend the number of passages only till the clonal uniformity of the progenies is maintained. This could be achieved through a) strict monitoring of shoot multiplication process ensuring that adventitious shoots are not multiplied and b) confirming the clonal fidelity of tissue cultured plants using molecular markers in different passages. Citrus shoots have been sub-cultured upto12 passages without any loss of clonal fidelity. There is a possibility that the clonal fidelity of the tissue-cultured plants is maintained even beyond 12 passages*

8.6. Black Pepper- Tissue Culture – (BPTC)- Standards

I. Applications and Amplification of General seed Standards for BPTC

i. The General Seed Certification Standards are basic and, together with the following specific standards constitute the standards for approval of BTC. As the name implies, these standards are applicable to tissue culture multiplied under laboratory and greenhouse conditions as laid here.

ii. The General Standards are amplified as follows to apply specifically to the BPTC.

1. Eligibility requirements for BPTC production:

i. All micropropagation and greenhouse facilities must be approved as per standards/ guidelines set by the competent authority. These must have a changing area between double doors.
ii. Laboratory and greenhouse facilities used for production of plantlets shall be maintained free of pests or vectors of banana pathogens. Failure to keep such pests under control may cause rejection of all lots maintained in the facility. All potting or growth media shall be sterile. Water sources used in the laboratory or greenhouseoperation shall be treated or otherwise rendered free of all possible pathogens by the applicant.
iii. Hygienic conditions shall be strictly observed during micropropagation, potting,planting, irrigating, movement and use of equipment and other laboratory and greenhouse practices to guard against the spread of diseases or pests in the facilities used for banana plant multiplication.
iv. The greenhouse (protected environment) must be "insect proof" and be equipped with a double-door entrance, provision for footwear disinfection prior to entering the protected environment and insect proof ventilation screening on intakes and exhaust openings. The persons entering the protected environment should use Wellington boots (plastic boots) and change lab-coat in the changing area to reduce the chances of inadvertent introduction of vector insects clinging to clothes
v. The material being initiated must be of a notified variety and confirmed identity. It must be duly documented with respect to origin.
vi. All samples of black pepper varieties being initiated should be tested in an accredited laboratory and should be free of viruses (CMV, badnavirus phytoplasm) and other endophytic or epiphytic bacteria and fungi
vii. The basic material for sub-multiplication need to be obtained afresh from the nodal organization as soon as the maximum permitted number of passages (as confirmed by DNA fingerprinting) of shoot multiplication with old cultures has been completed.
viii. On application for inspection, the mother cultures as developed above are eligible for certification. The micropropagation facility to be inspected must have been approved by

the competent Authority. All stocks must have a valid variety identification and disease testing report at any time during multiplication process.

In vitro multiplication of an imported variety or a non-notified variety can be taken up by the industry exclusively for export purposes. Such varieties, however, should be introduced following the approved guidelines of Government of India.

2. Source of Seed:

i. The facility should use recognized aseptic initiation and propagation procedures (i.e. follow procedures and use equipment, which will maintain sterile conditions as per standard tissue culture norms).
ii. The initiating facility must maintain following information on each variety for review and audit by the competent authority at least once in a year: variety identification, date of initiation, origin and testing results from accredited laboratory.
iii. Tests must be carried out on a minimum of 0.1% (minimum ten) plantlets for each variety by an accredited laboratory. Such tests will be valid as long as cultures of that particular batch are under production. No plant should contain (CMV and Badnavirus) and other endophytic or epiphytic bacteria and fungi.
iv. Valid pathogen testing results are required at the2nd/3rd subculture stage prior to the bulking up of the cultures.
v. The guidelines for production of tissue culture plant is at Appendix-I

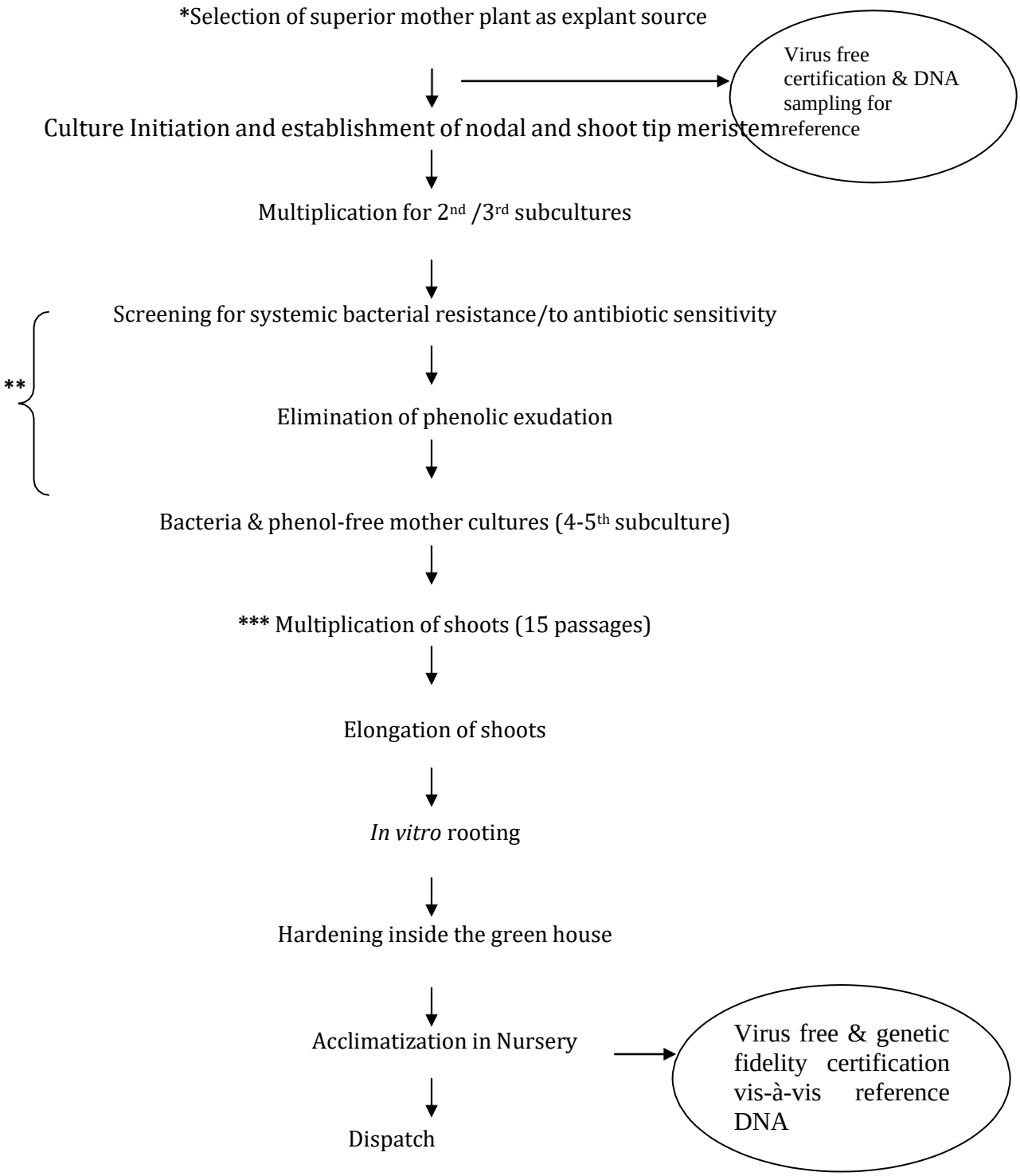
Minimum Quality Standards for growing of plants inside greenhouses/polyhouses

The following requirements must be met for production of plantlets:

i. Effective sanitation practices including insect and disease monitoring and prevention must be adhered to.
ii. No field-produced black pepper plants can be grown in the protected environment (greenhouse/polyhouse) along with tissue cultured plants.
iii. Varieties must be separated by physical barriers (such as proper tagging), which will prevent varietal mixture.
iv. Before dispatch to the farmers, the tissue–cultured plants growing in the nursery should be tested for the absence of the viruses (CMV, Badnavirus) and clonal uniformity. For establishing clonal fidelity, the sample size should be 0.1% of the batch size with a minimum of 10 plants.
v. If testing performed by an accredited laboratory reveals the presence of banned viruses, fungus or bacteria the tissue-cultured plants should not be dispatched from the premises of the production lab and the entire material should be destroyed.
vi. The concerned laboratory/agency producing the tissue culture raised material should issue a certificate to the effect that BPTC have been produced as per guidelines
vii. The agency producing BPTC will follow the labelling procedures as given at Appendix-A

Appendix-I

Procedure and standard parameters for production of Black Pepper by tissue culture



* *Plants should be of superior quality in terms of growth, disease / pest resistance, drought tolerance, constant bearing (confirmed for at least three consecutive years), high yield (fresh and dry weight),*

oil and oleoresin content etc. The explant should be healthy and free from microbial infections. One set of mother plants must be maintained in the glass house as reference sample.

** *Since black pepper tissue culture is frequently confronted with endogenous bacterial contamination and phenolic exudation, these should be eliminated using appropriate method.*

*** *In black pepper the number of passages can be up to 15 for subculture of shoots.*

8.7. Vanilla- Tissue Culture – (VTC)- Standards

I. Applications and Amplification of General seed Standards for VTC

i. The General Seed Certification Standards are basic and, together with the following specific standards constitute the standards for approval of VTC. As the name implies, these standards are applicable to tissue culture multiplied under laboratory and greenhouse conditions as laid here.

ii. The General Standards are amplified as follows to apply specifically to the VTC.

1. Eligibility requirements for VTC production:

i. All micropropagation and greenhouse facilities must be approved as per standards/ guidelines set by the competent authority. These must have a changing area between double doors.
ii. Laboratory and greenhouse facilities used for production of plantlets shall be maintained free of pests or vectors of vanilla pathogens. Failure to keep such pests under control may cause rejection of all lots maintained in the facility. All potting or growth media shall be sterile. Water sources used in the laboratory or greenhouseoperation shall be treated or otherwise rendered free of all possible pathogens by the applicant.
iii. Hygienic conditions shall be strictly observed during micropropagation, potting,planting, irrigating, movement and use of equipment and other laboratory and greenhouse practices to guard against the spread of diseases or pests in the facilities used for banana plant multiplication.
iv. The greenhouse (protected environment) must be "insect proof" and be equipped with a double-door entrance, provision for footwear disinfection prior to entering the protected environment and insect proof ventilation screening on intakes and exhaust openings. The persons entering the protected environment should use Wellington boots (plastic boots) and change lab-coat in the changing area to reduce the chances of inadvertent introduction of vector insects clinging to clothes.
v. The material being initiated must be of a notified variety and confirmed identity. It must be duly documented with respect to origin.
vi. All cultures of vanilla varieties being initiated should be tested in an accredited laboratory and be free of viruses such as Vanilla mosaic potyvirus, Vanilla necrosis potyvirus, Cymbidium mosaic potexvirus, Odontoglossum ring spot tobamovirus,uncharacterized potyvirus/ rhabdovirus and other endophytic or epiphytic bacteria and fungi.
vii. The basic material for sub-multiplication need to be obtained afresh from the nodal organization as soon as the maximum permitted number of passages (as confirmed by DNA fingerprinting) of shoot multiplication with old cultures has been completed.

viii. On application for inspection, the mother cultures as developed above are eligible for certification. The micropropagation facility to be inspected must have been approved by the competent Authority. All stocks must have a valid variety identification and disease testing report at any time during multiplication process.

In vitro multiplication of an imported variety or a non-notified variety can be taken up by the industry exclusively for export purposes. Such varieties, however, should be introduced following the approved guidelines of Government of India.

2. Source of Seed:

i. The facility should use recognized aseptic initiation and propagation procedures (i.e. follow procedures and use equipment, which will maintain sterile conditions as per standard tissue culture norms).
ii. The initiating facility must maintain following information on each variety for review and audit by the competent authority at least once in a year: variety identification, date of initiation, origin and testing results from accredited laboratory.
iii. Tests must be carried out on a minimum of 0.1% (at least ten) plantlets for each variety by an accredited laboratory. Such tests will be valid so long as cultures of that particular batch are under production (subject to a maximum of 15 passages). No plant should contain pathogens such as Vanilla mosaic potyvirus, Vanilla necrosis potyvirus, Cymbidium mosaic potexvirus, Odontoglossum ring spot tobamovirus, uncharacterized potyvirus/ rhabdovirus and other endophytic or epiphytic bacteria and fungi.
iv. Valid pathogen testing results are required at the2nd/3rd subculture stage prior to the bulking up of the cultures.
v. The guidelines for production of tissue culture plant is at Appendix-I

Minimum Quality Standards for growing of plants inside greenhouses/polyhouses

The following requirements must be met for production of plantlets:

i. Effective sanitation practices including insect and disease monitoring and prevention must be adhered to.
ii. No field-produced vanilla plants can be grown in the protected environment (greenhouse/polyhouse) along with tissue cultured plants.
iii. Varieties must be separated by physical barriers (such as proper tagging), which will prevent varietal mixture.
iv. Before dispatch to the farmers, the tissue-cultured plants growing in the nursery should be tested for the absence of the viruses such as Vanilla mosaic potyvirus, Vanilla necrosis potyvirus, Cymbidium mosaic potexvirus, Odontoglossum ring spot tobamovirus and uncharacterized potyvirus/ rhabdovirus) and clonal uniformity. For establishing clonal fidelity, the sample size should be 0.1% of the batch size with a minimum of 10 plants.

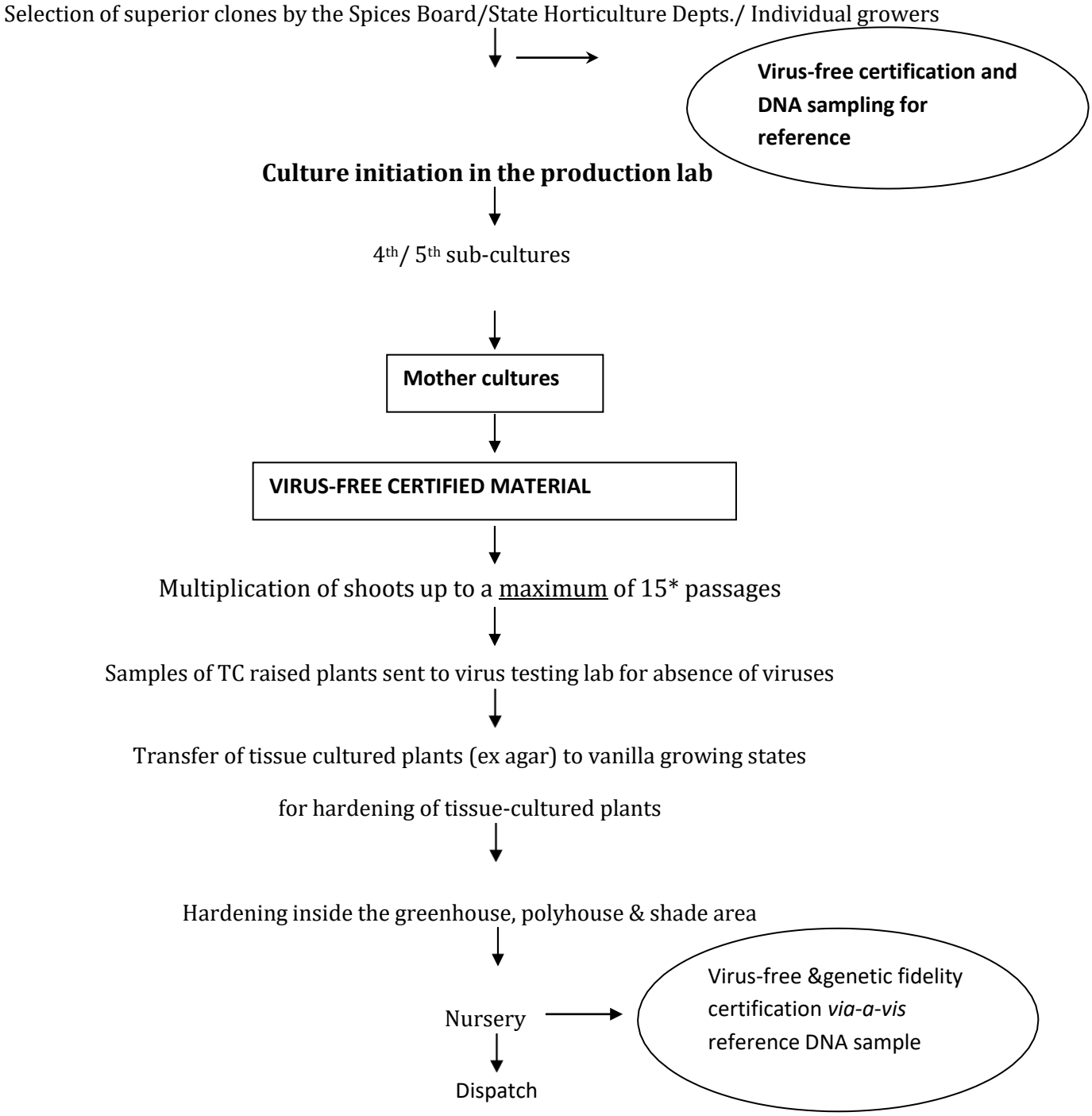
v. If testing performed by an accredited laboratory reveals the presence of banned viruses, fungus or bacteria the tissue-cultured plants should not be dispatched from the premises of the production lab and the entire material should be destroyed.

vi. The concerned laboratory/agency producing the tissue culture raised material should issue a certificate to the effect that VTC have been produced as per guidelines

vii. The agency producing VTC will follow the labelling procedures as given at Appendix-A

Appendix-I

Procedures and standard parameters for production of Vanilla by tissue culture



** In tissue culture, it is well known that lesser the number of subcultures, lower will be the chances of somaclonal variation. However, it must also be realized that if the number of passages are far too small then the entire*

production process becomes economically unviable. Therefore, efforts should be made to optimize the shoot multiplication process and extend the number of passages only till the clonal uniformity of the progenies is maintained. This could be achieved through a) strict monitoring of shoot multiplication process ensuring that adventitious shoots are not multiplied and b) confirming the clonal fidelity of tissue cultured plants using molecular markers in different passages. It has been seen in vanilla using molecular markers that clonal fidelity is maintained even up to 24th passage. However, to be on the safer side, the shoot multiplication process should not be carried out beyond 15 passages.

8.8. Bamboo- Tissue Culture – (BaTC) - Standards

I. Applications and Amplification of General seed Standards for BaTC

i. The General Seed Certification Standards are basic and, together with the following specific standards constitute the standards for approval of BaTC. As the name implies, these standards are applicable to tissue culture multiplied under laboratory and greenhouse conditions as laid here.

ii. The General Standards are amplified as follows to apply specifically to the BaTC.

1. Eligibility requirements for BaTC production:

i. All micropropagation and greenhouse facilities must be approved as per standards/ guidelines set by the competent authority. These must have a changing area between double doors.
ii. Laboratory and greenhouse facilities used for production of plantlets shall be maintained free of pests or vectors of bamboo pathogens. Failure to keep such pests under control may cause rejection of all lots maintained in the facility. All potting or growth media shall be sterile. Water sources used in the laboratory or greenhouseoperation shall be treated or otherwise rendered free of all possible pathogens by the applicant.
iii. Hygienic conditions shall be strictly observed during micropropagation, potting,planting, irrigating, movement and use of equipment and other laboratory and greenhouse practices to guard against the spread of diseases or pests in the facilities used for banana plant multiplication.
iv. The greenhouse (protected environment) must be "insect proof" and be equipped with a double-door entrance, provision for footwear disinfection prior to entering the protected environment and insect proof ventilation screening on intakes and exhaust openings. The persons entering the protected environment should use Wellington boots (plastic boots) and change lab-coat in the changing area to reduce the chances of inadvertent introduction of vector insects clinging to clothes
v. The material being initiated must be of a notified variety and confirmed identity. It must be duly documented with respect to origin.
vi. All samples of bamboo varieties being initiated should be tested in an accredited laboratory and be free of endophytic or epiphytic bacteria and fungi.
vii. The basic material for sub-multiplication need to be obtained afresh from the nodal organization as soon as the maximum permitted number of passages (as confirmed by DNA fingerprinting) of shoot multiplication with old cultures has been completed.
viii. On application for inspection, the mother cultures as developed above are eligible for certification. The micropropagation facility to be inspected must have been approved by the competent Authority. All stocks must have a valid variety identification and disease testing report at any time during multiplication process.

In vitro multiplication of an imported variety or a non-notified variety can be taken up by the industry exclusively for export purposes. Such varieties, however, should be introduced following the approved guidelines of Government of India.

2. Source of Seed:

i. The facility should use recognized aseptic initiation and propagation procedures (i.e. follow procedures and use equipment, which will maintain sterile conditions as per standard tissue culture norms).
ii. The initiating facility must maintain following information on each variety for review and audit by the competent authority at least once in a year: variety identification, date of initiation, origin and testing results from accredited laboratory.
iii. Tests must be carried out on a minimum of 0.1% (at least ten) plantlets for each variety by an accredited laboratory. Such tests will be valid so long as cultures of that particular batch are under production (subject to a maximum of 15 passages). No plant should contain endophytic or epiphytic bacteria and fungi. Generally, viral infection is not seen in bamboos. However, there are reports that suggest infection by Bamboo Mosaic Virus (BaMV) at the nursery stage in India.
iv. Valid pathogen testing results are required at the2nd/3rd subculture stage prior to the bulking up of the cultures.

Minimum Quality Standards for growing of plants inside greenhouses/polyhouses

The following requirements must be met for production of plantlets:

i. Effective sanitation practices including insect and disease monitoring and prevention must be adhered to.
ii. No field-produced bamboo plants can be grown in the protected environment (greenhouse/polyhouse) along with tissue cultured plants.
iii. Varieties must be separated by physical barriers (such as proper tagging), which will prevent varietal mixture.
iv. Before dispatch to the farmers, the tissue-cultured plants growing in the nursery should be tested for clonal uniformity. For establishing clonal fidelity, the sample size should be 0.1% of the batch size with a minimum of 10 plants.
v. If testing performed by an accredited laboratory reveals the presence of banned viruses, fungus or bacteria the tissue-cultured plants should not be dispatched from the premises of the production lab and the entire material should be destroyed.
vi. The concerned laboratory/agency producing the tissue culture raised material should issue a certificate to the effect that BaTC have been produced as per guidelines
vii. The agency producing BaTC will follow the labelling procedures as given at Appendix-A

Nursery Development

The plants to be used for field trials would be supplied either in poythene bags or bare-rooted (to save the transportation cost). In both cases the plants should be kept in the nursery till they have recovered from the transportation shock. While the plants in polythene bags may be kept directly in the nursery, the bare-rooted plants should be transferred to the polybags prior to their transfer to the nursery. The plants should be kept in the nursery for a minimum period of **10 days**. However, many a times the plants supplied are not of planting height. In such a situation it would be necessary to prolong the stay of plants in the nursery (till the plants are at least **18 inches** in height) before their transfer to the planting site in an open field.

Requirements of a bamboo nursery (holding area)

- The nursery site should be on level ground and well drained
- It should be as close as possible to the plantation site
- It should have all necessary facilities for irrigation of plants
- The site should be protected from animals

Managing a bamboo nursery

- In the nursery the plants of different species should be kept in separate beds to avoid any mixing. If there are more then one genotype for each species, then it would be desirable to keep the plants genotype-wise.
- The approximate size of the nursery bed could be (8-10 m x 1-1.5 m)
- As much as possible, the beds should be prepared where there is some protection (shade of a tree/thatch) for the plants from direct sunlight
- The beds should be leveled so that there is no accumulation of water
- Each bed should be properly labeled so that there is no mixing of plants
- In the nursery the plants should be irrigated periodically, and care should be taken that they remain free of diseases
- Only healthy plants of uniform size (approximately) should be used for field trials, particularly experimental trials

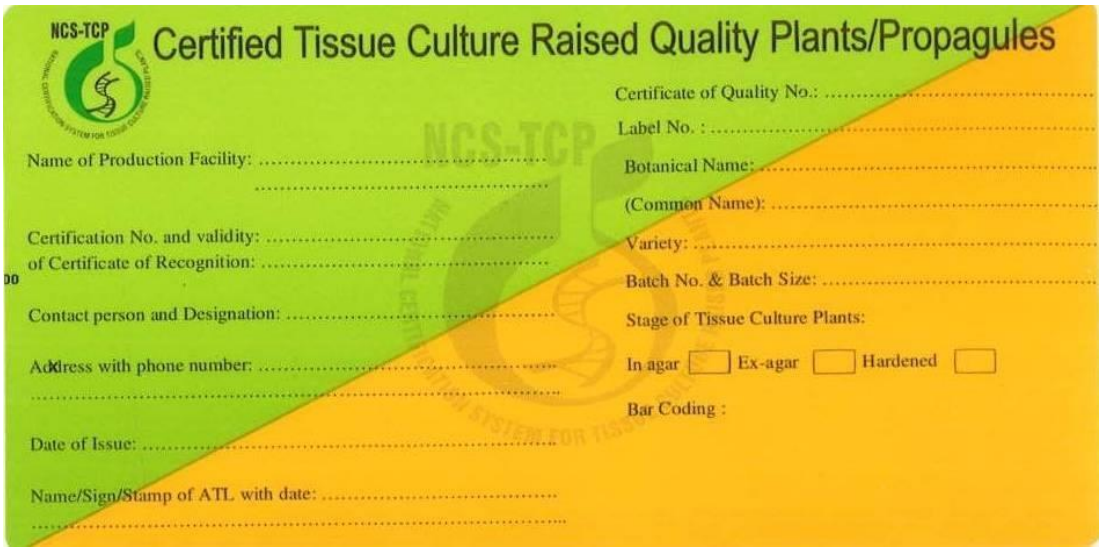
Attributes of primary and secondary hardened tissue cultured bamboo plants

S. No.	Trait	Primary hardened tissue cultured plant	Secondary hardened tissue cultured plant
1.	Minimum height of the shoot	5 inches	18 inches
2.	Minimum number of shoots	> 3	> 4
3.	Minimum number of leaves per shoot	> 4	> 8
4.	Root system	Well developed	Well developed
5.	Rhizomes	Small rhizomes in the initial stages of development	Proper rhizomes
6.	Minimum age of the plant	1 month	> 3 months

Appendix-A

Labeling of Tissue Culture Raised Plants/Propagules

1. Tissue culture plants/propagules shall be supplied in containers. A paper-lined label of 12cm x 6 cm containing following information shall be affixed on the container
2. Certified Tissue Culture Raised Quality Plants/Propagules



'The container should also have printed on it the kind, variety and name of Institution'

3. The label shall be rubber stamped with signature, name and designation of the concerned Agency. Colour of the label shall be diagonally yellow No. 356 (IS 5-1978) and opaline green (IS No. 275)
4. Tissue culture raised plant producing Agency shall maintain the account of labels printed and issued

Chapter 9:

Operational Guidelines for Accredited Test Laboratories (ATLs)

Operational Guidelines

For

Accredited Test Laboratories (ATLs)

National Certification System for Tissue Culture Raised Plants (NCS-TCP)

1. Scope:

This document provides operational guidelines for Accredited Test Laboratories (ATLs) for virus indexing & genetic fidelity/uniformity testing and certification of tissue culture raised plants.

2. Mandate:

Certify the tissue culture raised plants as per the specified guidelines and procedure laid down under NCS-TCP. ATLs will accept samples for certification only under NCS-TCP.

3. Vision to become the self sustaining testing centre:

ATL will function as a separate "Service Providers" with financial autonomy to receive all income received through fees, which will be deposited in the centralized account of NCS-TCP.

4. Fee Structure:

The prescribed fee to be charged by Accredited Test Laboratories (ATLs) is as follows. ATLs would charge this fee until further revision

(i) For genetic fidelity: Rs 1500.00 per 10 samples of same species

(ii) For virus indexing: A minimum fee of Rs 1000.00, for 10 samples of the same species for a maximum of 5 viruses. (Tests for additional viruses will be charged @ Rs 100.00 per virus)

5. Timelines:

For virus indexing and/or genetic fidelity testing of tissue culture raised plants following time-lines would be followed by Accredited Test Laboratories (ATLs):

STEPS	PROCEDURE	TIME FRAME
1	Receipt of the sample/Recording sample details, storage and planning for conducting test	Day 1
2	Conducting virus and quality test	Day 2-3
3	Preparation of test report/ Review of procedure and report generation	Day 4
4	Repeat the tests if needed and prepare second test report/ Dispatch of test report and certificate to the company/applicant	Day 5-6
	Total	**6 working days**

Note: The date of receipt of samples by ATLs should be the date on which samples are received in good condition

6. Responsibilities:

- **Project Coordinator:** The Project Coordinator of Accredited Test Laboratory is responsible for overall management of Accredited Test Laboratory and would duly sign the certificate of quality for tissue culture raised plants. The Director may entrust this responsibility through proper written delegation of power to senior official of the institute.

- **Scientist (Virology):** The In-charge, Virus Indexing Division of ATL or a senior scientist (virology) designated by him through written delegation of powers will be responsible for generating test report for virus testing and maintenance of all records related to virus indexing of tissue culture plants

- **Scientist (Molecular Biology):** The In-charge, Genetic Fidelity Division of ATLs or a senior scientist (Molecular Biology) designated by him through written delegation of powers will be responsible for generating test report for genetic fidelity/ uniformity testing and maintenance of all records related to genetic fidelity testing of tissue culture raised plants

7. Procedural compliance

- Registration of application, sampling, storage & handling of samples and reporting would be done in line with the SOPs for ATLs
- ATLs would follow the protocols and standard formats of reporting provided in the Standard Operating Procedures (SOPs). SOPs are subject to timely revisions and revised section would be circulated to ATLs by NMC of DBT
- In order to use the uniform set of primers/ diagnostic reagents by all ATL for testing genetic fidelity the diagnostic reagents will be provided by referral laboratories under NCS-TCP.
- ATLs would forward master report and a copy of test reports & certificates to the NMC every month.
- Annual meeting of ATLs will be held to review the progress and to revise the SOPs based on experience of ATLs.

8. Testing of stock cultures and certification of tissue culture raised plants:

- *ATLs will entertain applications only from recognized tissue culture production facility for the purpose of issuance of Certificate of Quality under NCS-TCP.* However, they may receive and entertain applications for testing of stock cultures from any plant tissue culture production facility whether recognized under NCS-TCP/non recognized.
- ATL would not accept the sample of tissue culture raised plants for certification if the mother plant/stock culture has not been indexed for respective batch of TC plants.

- ATLs must ensure receipt of complete information in the application for stock culture testing as well as certification of tissue culture raised plants such as batch number and batch size.
- If the test report issued for tissue culture raised plants indicates the plants are free from viruses and true to type/ uniform, the certificates and labels are also to be generated accordingly and issued. However, genetic fidelity/ uniformity testing may not be required in some plant species. In such cases only, "Certificate of Quality" may be issued without "Certification labels" clearly stating that this certificate is only for Quality with respect to freedom for viruses. It may be noted that "Certificate of Quality" should clearly mention the nature of testing conducted.
- ATLs would follow the approved fee structure under NCS-TCP for recognized as well as non recognized tissue culture production facilities.
- ATLs would follow the approved fee structure under NCS-TCP for recognized tissue culture production facility. However fee charged for the virus indexing from non recognized tissue culture production facilities can be as per the institute norms.
- Samples are to be tested for all viruses listed in SOPs/NCS-TCP website.

9. Issuance of labels:

- Duly signed/stamped certification labels will be provided by the Accredited Test Laboratory (ATL) to the Tissue Culture Production Facility at the time of issue of certificate of quality of tissue culture raised plants for affixing on the packages. It is to be noted that "Certification Label" are to be issued if samples of tissue culture raised plants have been tested for both freedom from viruses and true to typeness/ genetic uniformity.
- Colour of the label shall be diagonally yellow No. 356 (IS 5-1978) and opaline green (IS No. 275).
- NMC will issue at least 10 labels per Certificate of Quality and additional labels would be issued as per the requirement of the company.

10. Actions to be taken in the case of samples found to be virus infected/ genetically variants

- If the test results for the viruses are positive and or the results of genetic fidelity/ uniformity testing exceeded the tolerance limits, Head, Accredited Test Laboratory will issue a report "Tissue Culture Plants Not Approved for Certification".

- ATL will keep the record of action taken by the concerned tissue culture production facility for disposing of infected plants.

11. Logo of NCS-TCP:

- Accredited Test Laboratories would carry the prescribed logo of NCS-TCP on its certificates, stationary, written announcements.

- The logo shall be reproduced based on the master supplied to each of the Accredited Test Laboratories.

- In case of **cancellation** of the accreditation by the Certification Agency, the Accredited Test Laboratory shall immediately cease to use its stationary, certificates and other publicity material that has logo on it. The use can be restarted only after the cancellation is revoked by the Certification Agency.

- Upon **termination** of the Accreditation on account of non-renewable/ withdrawal of the accreditation, the Accredited Test Laboratory shall immediately cease to use logo in any form including use of stationary, certificates and other publicity material that has logo on it.

12. Referral Testing

- In the event of an appeal made by aggrieved tissue culture companies and receipt of intimation from Appellate Authority, Referral Centre will ask to the ATLs for sending the disputed samples within three working days.

- ATL will forward the sub-sample of disputed samples for referral testing to Advanced Centre for Plant Virology, Division of Plant Pathology, IARI, New Delhi and /or, as the case may be with the intimation to NCS-TCP Management Cell at NIPGR.

13. Technical Auditing:

- Technical auditing would be conducted annually which would compliance with the criteria on the basis of which accreditation was given to the ATLs. Compliance with Standard Operating Procedures would also be assessed based on the available records and documents.

- Unscheduled audits may also be organized at short notice the concerned Accredited Test Laboratory to ensure compliance with the standard operating procedures as and when required.

- ATLs are expected to develop the system for its own internal auditing and inform the NCS-TCP Management Cell

14. Validity of Accreditation:

Duration of Accreditation is for two years and continuity depends on timely renewal of accreditation. Validity of the Certificate of Accreditation is subject to continuous satisfactory compliance with the standards provided under NCS-TCP

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Chapter 10:

FEE STRUCTURES UNDER NCS-TCP

10.1. Fee structure for Recognition of Tissue Culture Production Facilities

(Figures in Rs.)

	Small-scale companies **(Upto 1X10^6 plantlets/annum)**	**Medium-scale companies** **(1 to 3 million plantlets/annum)**	**Large-scale companies** **(> 3 X10^6 plantlets/annum)**
Registration fee	4000*	4000*	4000*
Inspection and report preparation	4000	12000	15000
Processing and Certification	10000	10000	10000

Period of validity of Certification is Two Years

****Registration renewal fee will be Rs. 2000.***

- Only Registration fee to be deposited at the time of Application submission,

10.2. Fee for Recognition of only hardening units:

Fee structure prescribed for recognition of hardening center(s) of Recognized Tissue Culture Production Facility under NCS-TCP.

Registration fee for Recognition	Rs. 500*
Registration fee for Renewal	Rs. 250*
Inspection and report preparation	Rs. 1500
Processing and Certification	Rs. 2000

N.B: (i) *Only Registration fee to be deposited at the time of Application submission,; and, (ii) The inspection & Report preparation fee will be payable at the time of organising site visit by Accreditation panel expert and processing and certification fee will be payable at the time of issue of certification for recognition and or/renewal as the case may be.

10.3. Fee structure for second visit of expert(s) to TCPFs for verification of corrective actions

Fee will be charged for the verification of the corrective action taken by the production unit as per the fee structure given below

Small scale Company	Rs. 2000/-
Medium scale company	Rs. 3000/-
Large scale company	Rs. 5000/-

10.4. Debaring For Applying for Recogntion under NCS-TCP

Company applied for recognition would be **DEBARRED FOR ONE TO TWO YEARS FOR APPLYING FOR RECOGNITION** under NCS-TCP, if it is observed during site visit that company had furnished false information to mandatory parameter(s) in self assessment report. The nature of false statements will be considered by PMEC prior to debarring the TCPF.

10.5. Fee to be charged by Accredited Test Laboratories for testing and certification of tissue culture raised plants

For genetic fidelity: Rs 1500.00 per 10 plants

For virus indexing: A minimum fee of Rs 1000.00 which would include testing up to 10 samples of the same plant species for a maximum of 5 viruses. (Tests for additional viruses will be charged @ Rs 100.00 per virus)

Chapter 11:

Procedure and Conditions for Use of Logo

11.1. Responsibility:

DBT is responsible to establish, implement and amend this procedure. The NCS-TCP Management Cell, Referral Laboratories, Accredited Test Laboratories are responsible to comply with the procedure.

11.2. Design of the Logo:

- The design of the logo is enclosed at appendix 'A'. The design specifies the proportions of the logo and the colour combinations in which it can be reproduced.
- The logo shall be reproduced in the colours as indicated in appendix 'A'. The size of the logo shall not normally be reduced below the size15x12mm.

11.3. Conditions for Reproduction of Logo:

- The NCS-TCP Management Cell, Referral Laboratories, Accredited Test Laboratories can reproduce the logo of NCS-TCP on its certificates, stationary, written announcements and any other requirement specified by DBT.
- The logo shall be reproduced based on the master supplied to each of the accredited Test Laboratories. Redrawn masters should not be used.

11.4. Use of Logo:

The logo shall be used in all certificates and all certified products.

- The logo shall not be displayed on vehicles except in publicity material like part of a large advertisement.
- The logo shall not be used or displayed on buildings and flags.
- The Accredited Test Laboratories (ATLs) upon suspension or withdrawal of its accreditation shall discontinue use of logo.

11.5. Contravention of the Conditions:

- In situations of contravention, the Certification Agency may withdraw the Accreditation. In case if the Accredited Test Laboratory does not take suitable action against the wrong use of the logo, the Certification Agency may suspend/withdraw the accreditation.

11.6. Action on Suspension or Termination:

- Upon the **suspension** of the accreditation by the Certification Agency, the Accredited Test Laboratory shall immediately cease to use its stationary, certificates and other publicity material that has logo on it. The use can be restarted only after the suspension is revoked by the Certification Agency.

- Upon **termination** of the Accreditation on account of non-renewable/ withdrawal of the accreditation, the Accredited Test Laboratory shall immediately cease to use logo in any form including use of stationary, certificates and other publicity material that has logo on it.

Chapter 12:

Audit criteria and audit schedule

12.1. Constitution of technical audit team:

Technical audit team will consist of at least two experts and one representative from the NCS-TCP Management Cell.

12.2. Types of technical audit:

a. Scheduled audit: Once in a year with proper intimation to the concerned entity
b. Unscheduled audits: As per the requirement at a short notice or without intimating the concerned entity

12.3. Time schedule:

a. Accredited Test Laboratories (ATLs): It would be conducted annually. First technical audit would be undertaken after the completion of training programme.
b. Tissue Culture Production Facilities (TCPFs): It would be conducted annually. First technical audit would be undertaken after 3 months of the operationalization of ATLs

12.4. Criteria:

Criteria would be similar based on which accreditation/recognition has been given to the ATLs/TCPFs respectively. Compliance with the Standard Operating Procedure would also be assessed based on the available records and documents.

Chapter 13:

Guidelines for redressal of grievances/appeal under National Certification System for Tissue Culture Raised Plants (NCS-TCP)

1. Scope:

This document provides guidelines for redressal of grievances/appeal by aggrieved person or entity under the National Certification System for Tissue Culture Raised Plants (NCS-TCP) established by the Department of Biotechnology (DBT) of Ministry of Science & Technology, Government of India.

2. Background:

Department of Biotechnology (DBT), Govt of India has been authorized under Section-8 of The Seeds Act, 1966 (Amendment published vide Gazette of India Notification No. 219 dated 10th March 2006) as Certification Agency for the certification of tissue culture raised plants to ensure they are virus-free and are true to the type (genetic uniformity/ homogeneity). For this purpose, DBT has established a National Certification System for Tissue Culture Raised Plants (NCS-TCP) to ensure distribution of quality tissue culture plants distributed to the growers or farmers. To achieve this objective, DBT has established an NCS-TCP Management Cell at NIPGR, New Delhi for assisting DBT in recognition of tissue culture production facilities and to accredit test laboratories authorize to test for viruses and true to thetype (genetic homogeneity) of the tissue culture raised plants under NCS-TCP in accordance with the guidelines developed by the Department of Biotechnology. The standard operating procedures for the recognized tissue culture production facilities and accredited test laboratories have also been developed. Further an Appellate Authority has been established under the DBT under the Chairpersonship of Secretary, Department of Bio-technology, to redress the grievances/appeal under NCS-TCP in accordance with established guidelines/standards therewith.

3. References:

I. Seeds Act, 1966, Seeds Rule, 1968and Gazette Notification issued by the S.O. No. 306(E) dated 10th March, 2006 under Section-8 of the Seeds Act, 1966.

II. Guidelines for Accreditation of Test laboratory for virus diagnosis and Genetic fidelity testing of tissue culture raised plants and Certification of Tissue Culture Production Facility, 2006, Department of Biotechnology, Ministry of Science & Technology, Govt., of India, New Delhi

III. Standard Operating Procedures for Accredited Test Laboratory, 2008, Department of Biotechnology, Ministry of Science & Technology, Govt., of India, New Delhi.

IV. Standard Operating Procedures for Tissue Culture Production Facility, 2008, Department of Biotechnology, Ministry of Science & Technology Govt., of India, NewDelhi.

V. Crop Specific Tissue Culture Standards developed by the Department of Biotechnology, Ministry of Science & Technology, New Delhi.

4. Definitions & Terms:

Certification Agency:-

Department of Biotechnology (DBT), Govt. of India has been notified vide S.O. No. 306(E) dated 10th March, 2006 under Section 8 of the Seeds Act, 1966 as Certification Agency to certify Tissue Culture Raised plants upto laboratory Level.

NCS-TCP Management Cell (NMC):-

An official unit responsible for accreditation of laboratory facilities for virus diagnosis/ genetic fidelity testing of tissue culture raised plants and recognition of tissue culture production

facilities. This responsibility has been currently assigned to NIPGR., New Delhi

Appellate Authority:-

An authority established by the Department of Biotechnology to consider the appeal in matters related to certification of tissue culture plants under NCS-TCP.

Appeal Panel:-

A group of technical experts nominated by the Department of Biotechnology, Govt of India to review the decision taken by the NCS-TCP Management Cell or Accredited Test Laboratories.

Appellant:

Any individual or entity aggrieved by the decision taken by the NCS-TCP Management Cell and/ or Accredited Test Laboratories in the matters related to certification of tissue culture plants.

Accredited Test Laboratories:

An institute or organisation accredited by Department of Biotechnology under NCS-TCP for testing and certification of tissue culture plants for domestic distribution.

Sub-standard tissue culture plants

Tissue culture plants that are not up to the standards prescribed in the NCS-TCP guidelines or tissue culture plants have not been tested/certified by Accredited Test Laboratory.

5. Constitution of an Appellate Authority:

An Appellate Authority constituted under the Chairpersonship of Secretary, Department of Biotechnology to review the decision taken with regard to certification of tissue culture plants material as per the following composition:

- Chairman - Secretary/Additional Secretary, DBT or his nominee
- Not less than two Co-opted non-officio experts in the area of Virus Indexing and Genetic fidelity Testing and or expertise in the field concerned
- Representative from Ministry of Agriculture, Govt. of India
- Nodal Officer designated by the Certification Agency of NCS-TCP would act as Member Secretary

6. Provisions for redressal of grievances of farmer(s)/growers against supply of sub-standard plants by the company recognized under NCS-TCP

(Farmer's appeal would be registered by NMC only for the recognized companiesunder NCS-TCP)

6.1 : Farmers may send written complain to the company against supply of substandard plants (plants not fulfilling the parameters as specified in tissue culture crop specific standards) with a copy to NCS-TCP Management Cell (NMC) within 15 days of the plantation. He/she may be given another 15 days relaxation on the ground of valid written reason for the delay

6.2 : Company would address the grievance of farmers and would send a satisfaction report of farmers to NMC leading to the termination the appeal.

6.3 : If the farmer is not satisfied with the response and corrective measures of company. A "Site Inspection Committee" (consisting of one expert member of accreditation panel, one expert from ATL and one subject expert from local university) would be constituted by NMC to assess the matter. They would inspect the Tissue Culture Production Facility (TCPF) to see whether the prescribed NCS-TCP guidelines are being followed. This exercise would be completed within one month.

6.4 : If the company is found to be producing TC plants with not following prescribed procedure, company would be asked by NMC to replace the plants within 30 days failing which they would refund the cost of the plants to the farmers as desired by the farmer. NMC would obtain approval of certification agency prior to above communication to the company. Company would also be asked to submit a compliance report for following prescribed TC plants production guidelines. Report should be submitted within a week.

6.5 : If it is found that the problem is due to the agro climatic conditions or due to package and practice of farmers, complain of farmer would be terminated.

6.6. The above matter would be put up for the information of Project Monitoring and Evaluation Committee (PMEC). If the company is found to be violating the prescribed norms more than once its recognition is liable to be cancelled.

7. Provisions for redressal of grievances of farmer(s)/growers against certified but suspected to be substandard plants by the company recognized under NCS-TCP

7.1. Any grower/farmer or entity receiving the supply of sub-standard quality of tissue culture plants by the recognized tissue culture production facility, in the first instance, may make a written complain within a period not exceeding 15 working days after receiving the plants to the Director/HOD of Accredited Test Laboratories (ATLs) with a copy to NMC at NIPGR along with a copy of certification label and the grounds of redressal of grievances. He/she may be given another 15 days relaxation on the ground of valid written reason for the delay

7.2. The ATL after receiving the complain will draw representative sample from the specific batch of tissue culture raised plant material supplied to the aggrieved farmer/grower or entity for testing quality of tissue culture plant material within a period not exceeding **one week**. TCPF should retain at least one sample of each batch.

7.3. Test result/report would be generated in 6 working days.

7.4. If any company is found distributing substandard tissue culture plants to farmers then in the first instance, company would be required to replace the plants with certified plants within 30 days failing which they would refund the cost of the plants to the farmers. In addition, if company repeats the distribution of sub standard quality plants to the farmers for the second time for a subsequent batch, the recognition of company is liable to be cancelled

7.5 ATL would necessarily give a copy of complain and redressal to the Certification Agency (DBT, Govt. of India) through NCS-TCP Management Cell at NIPGR.

8. Provisions for making an appeal by company against Accredited Test Laboratory (ATL)

8.1. Any person or entity affected by the decision taken by the Accredited Test Laboratory in relation to certification of tissue culture plants may make an appeal to the Appellate Authority constituted under the Chairpersonship of Secretary Department of Biotechnology within a maximum period of 15 days from the date of receipt of communication from the ATL.

8.2. The memorandum of appeal will contain a statement of facts and set out appropriate grounds of appeal against the decision of ATL which can be submitted using the online portal and a fee for ₹1000/-or as may be prescribed by the Appellate Authority.

8.3. Appeal against ATLs needs to be made directly to NMC under intimation to Appellate Authority. The NMC will direct the Referral Centre to take necessary action and also direct the concerned ATL to forward sample to Referral Centre within 7 days.

8.4. Referral Centre would test the disputed sample received from the concerned Accredited Test Laboratory and furnish the report to NMC within a period not exceeding one week under intimation to Appellate Authority.

8.5. Pending the decision of the Appellate Authority, the disputed batch of plants needs to be held in safe custody for maximum 30 days from the date of receipt of test report from the ATL at the premises of concerned company/farmers.

8.6. The Appellate Authority will review the results of referral test report and take a decision in the matter in consultation with appellate panel within a maximum period of 7 days of receipt of test report.

8.6.1 If the decision of Appellate Authority is in favour of aggrieved person(s)/company, ATL will be directed to issue a fresh “Certificate of Quality” for tissue culture plants.

8.6.2. If the decision of Appellate Authority is against the company, the communication/certificate of ATL i.e. "Tissue culture plants not approved for Certification" earlier issued to the aggrieved company would be effective.

9. Provision for making an appeal by Tissue Culture Production Facility/Institute against decision taken by Certification Agency in connection with their recognition/accreditation

9.1 An applicant/aggrieved tissue culture production facility/institute may appeal to Appellate Authority within 15 working days providing grounds of appeal. He/she may be given relaxation of another 15 days on the ground of valid reason for the delay. The address of Appellate Authority is at **annex 1**:

9.2: The Appellate Authority will receive and record the appeal

9.3 Member Secretary, Appellate Authority will organize the meeting of Appellate Authority within 15 days of receipt of appeal

9.4: NCS-TCP Management Cell would present the case history in details before the Appellate Authority along with the corresponding file

9.5: Following records pertaining to aggrieved company/institutions would be circulated to the members of appellate authority.

(i) Application for recognition/accreditation

(ii) Self assessment report and/or report for any corrective step taken prior to site visit

(iii) Assessment report of the Sub- committee of Accreditation Panel

(iv)Verification report (if verification conducted)

(v) Copy of the approved minutes of PMEC

9.6. Appellant may be invited to present the case before the Appellate Authority only if felt necessary by Appellate Authority.

9.7 Decision of Appellate Authority shall be final

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Chapter 14:

Forms to be used under NCS-TCP

Activities under the NCS-TCP can be broadly categorized into 4 areas as listed below:

1. Accreditation of Test Laboratories (TLs)

2. Recognition of Tissue Culture Production Facilities (TCPFs)

3. Testing of Mother Plant Tissue/Stock Culture and Certification of Tissue Culture Raised Plants

4. Recognition of Hardening Center(s) under NCS-TCP

NCS-TCP Form-1

Application for Accreditation of Laboratory Facilities for Virus Diagnosis and Genetic Fidelity Testing of Tissue Culture Plants

1. Applicant Entity (Institute/Organization)	
Name:	
Address:	
City:	
State:	
Tel/Fax/E-mail	
2. Laboratory-In charge Name:	
Position:	
Address:	
City	
State	Tel/Fax/ E-mail:
3. Scientific expertise available for	
Virus testing	
Genetic Fidelity Testing	
(please enclose detailed biodata)	
4. Particulars of Laboratory • University • National Laboratory • Others	
5. Laboratory Information (Space/Facilities)-(please provide details) - Laboratory & Glasshouse - Equipment available - Expertise / Staff	
6. Test Methods developed and used at the laboratory • Diagnostic probes available (list the pathogen and diagnostic probe) • Molecular markers available for determining genetic purity of different plant species (list the	

species)
7. Is it Accredited under ISO:17025 Yes/No **(if yes give details)**
Details may be provided as per essential requirement criteria

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Signature of Technical Manager/Laboratory—In Charge Signature (Authorized Entity Representative)

Head of the Institute

Public Sector, Govt. funded Institute/University having adequate capacities in both virology and molecular biology, which is not engaged in commercial tissue culture activity.

Background note for changes in NCS-TCP Form 2

- Procedure for Self Assessment by the applicant was evolved in order to have the comprehensive assessment done by applicant itself prior to onsite assessment by the expert committee and a comprehensive self assessment format was evolved.

- Application form has also been revised by including new parameters namely "Month and Year of Commencement of Production", "Production of Different Crops in Last Financial Year" and "layout of the production facility."

- It has been recommended by PMEC to merge application form and self assessmentreport as a single document in order to avoid overlapping and to make it more userfriendly.
- A Checklist for Mandatory parameter is added.
- The self-assesment form has been rearranged into 3 sections
    - A) Manadatory Parameters
    - B) Non-Mandatory Parameters
    - C) Records and Documents

Application for Recognition of Tissue Culture Production Facility

(NCS-TCP Form-2)

(Applicant should submit 3 copies of application along with all enclosures to "NCS-TCP Management Cell" at National Institute of Plant Genome Research (NIPGR), Aruna Asaf Ali Marg, New Delhi 110067)

Eligibility

1. TCPF with installed production capacity to produce 0.5 million or more tissue culture plants per annum are only eligible to apply
   Please specify Installed Production Capacity/Annum
2. Tissue culture production facility should be fully functional (including all areas of laboratory and hardening facility)

Section 1

Registration No. **Date of Registration:**

(For NIPGR office Use only)

1. Name of Tissue Culture Production Facility (TCPF):

1(a). Postal Address of the office of TCPF:

Email:

Telephone (Landline):

Mobile:

1(b). Address of Tissue Culture Production Facility, if different from 1a:

Email:

Telephone (Landline):

Mobile:

1(c). Address of Hardening Facility (if different from 1b):

Email:

Telephone (Landline):

Mobile:

2. Head of the Organization:

Name & Designation:	Ph./Mob. No:

3. Laboratory-In charge:

Name & Designation:	Ph./Mob. No.:

4. Particulars of Laboratory:

A. Public Sector *(tick appropriately)*

- National Laboratories (CSIR/ICAR etc) ☐
- State Funded Laboratories ☐
- Universities ☐

B. Private Sector *(tick appropriately)*

- Public Limited ☐
- Private Limited ☐
- Proprietorship ☐
- Partnership ☐

C. NGO

D. Others (Please specify)

5. Month and Year of Commencement of Production:

6. Plant species being multiplied at commercial level:

a.

b.

c.

7. Details of production of plants for last two years (species with approx. numbers):

Year	Species under multiplication	Plants Produced (in lakhs)	Plants sold (Domestic) (in lakhs)	Plants exported, if any (in lakhs)

8. Total number of Staff Engaged in Production activity:

9. Enclosures to the Application:

i. Acknowledgement receipt of online transfer towards fee payment.

ii. Labeled and numbered photographs showing Washing Room; Media Preparation Room(s); Media Storage Room(s); Inoculation Room(s); Growth Room(s) and Transfer/Grading Area; Locations of Pressure Module/ Air Handling Unit (AHU)/

HVAC system in Media Storage Room(s), Inoculation Room(s) & Growth Room(s); Grading area; Double door entrance in Primary and Secondary Hardening Area Hardening Areas depicting plants

iii. Layout/ Drawing of tissue culture production facility *covering lab area (entry, washing, media preparation, storage, inoculation, growth room, grading area etc.), hardening and nursery. The layout should also clearly indicate man and material movement, sterile & non-sterile zone, location of pass box, pressure module, emergency exit and double door in hardening areas*

10. Declaration

I/we hereby declare that all the information/ particulars provided in the application are true and correct to the best of my knowledge. I/we shall bear the additional cost, In the event of any discrepancies noticed during the processing of my application and or/ any deviations are observed during site visit from stated information both in application and self-assessment form. I/we further declare that I am/ we are making this application after meeting the eligibility criteria & requirements of mandatory enclosures and going through instructions/guidelines contained in Section-2 to this application.

11. Undertaking

I am/we are making this application after having understood the guidelines of National Certification System for Tissue Culture Raised Plants (NCS-TCP) framed by the Department of Biotechnology (DBT), Govt. of India, New Delhi developed on October 2006 and subsequent its amendments from time to time. The guidelines (available on the website www.dbtncstcp.nic.in) will be fully binding on the applicant.

I/we undertake if any information provided in the application is found to be incorrect, entire cost of site visit will be borne by the applicant company.

I/We also undertake that any dispute not resolved under NCS-TCP will be subject to jurisdiction of Delhi Courts.

Date:

Place:

(_____)

Signature /Name/ Designation of Authorized Person

Section-2: Checklist for Mandatory Requirements

(If any of below mentioned requirement is "No" the application will not be processed)

1. Mandatory requirements for recognition of TCPF

Tissue culture production facility should be fully functional (including all areas of laboratory and hardening facility).

Mandatory requirements for TCPF:

i. Availability of following **exclusive functional areas:**

a) Washing Room (s) Yes/No

b) Media Preparation Room (s) Yes/No

c) Media Storage Room (s) maintained under positive pressure Yes/No

d) Inoculation Room (s) maintained under positive pressure Yes/No

e) Growth Room (s) maintained under positive pressure Yes/No

f) Transfer/ grading Room (s) Yes/No

g) For hardening facility, insect proof greenhouse/ poly house with double door entry fitted with humidity control Yes/No

h) For secondary hardening, insect proof Nursery/Shade house Area (s) with double door entry covered with appropriate mesh to provide partial shade Yes/No

ii. Entry to clean area should have the following arrangements: Yes/No

- facility for hand and foot washing
- air curtain, air shower, cubicles for dress changing
- dress storage before entering into sterile areas of tissue culture production facility

iii. Layout of laboratory building is planned in such a way that does not allow free movement of human and materials between sterile and non-sterile area. A layout plan for guidance is given. Yes/No

iv. Provision of well-maintained firefighting system with emergency exit, path showing fluorescent strip for guiding the emergency exit, fire alarm/ smoke alarm and fire extinguisher. Yes/No

v. Availability of uninterrupted power supply. Yes/No

vi. Availability of basic equipment (including electronic weighing balance, pH meter, conductivity meter, microwave oven, de ionizer/distillation unit/RO water facility, autoclave etc.). Yes/No

vii. Maintaining class 100,000 sterility level through pressure module/ AHU/ HVAC/any other in media storage room, inoculation room and incubation/growth room. Yes/No

viii. Pass box fitted with UV and see through glass and or/other suitable mechanism for transfer of media into media storage room immediate after autoclaving (without men entering into the other area). Yes/No

2. Recognition fee structure:

a. Application fee **Rs. 4,000/-**

b. Inspection fee:

i.	**Small scale companies (upto 1 million plantlets/annum)**	**Rs. 4,000/-**
ii.	**Medium scale companies (1 to 3 million plantlets/annum)**	**Rs. 12,000/-**
iii.	**Large scale companies (>3 million plantlets/annum)**	**Rs. 15,000/-**

c. Recognized Certificate fee **Rs. 10,000/-**

All the fee payment should be made to the following account:

Beneficiary Name	:	NIPGR-NCS-TCP
Account No.	:	40603535988
Type of account	:	Saving account
Bank	:	State Bank of India (SBI)
Branch	:	Jawaharlal Nehru University
IFSC code	:	SBIN0001624
Email	:	ncs-tcp@nipgr.ac.in

Section III

SELF ASSESSMENT REPORT FOR RECOGNITION OF TISSUE CULTURE PRODUCTION FACILITY UNDER NCS-TCP

(Part-A parameters (shaded parameters) are mandatory requirements and Part-B parameters are other requirements for consideration of application for registration. Site visit would be organized on compliance with all the mandatory requirements during self assessment.)

Section-III: Part A – Mandatory Parameters

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
A1.	Availability of following provisions in change area before entering into sterile areas of tissue culture production facility				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
	• Hand and leg washing facility				
	• Dress change cubicle				
	• Air curtain and or/Air shower facility				
A2.	Layout of laboratory building is planned to avoid crisscross movement of men and materials between sterile and non-sterile area				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
A3.	**Availability of fire fighting system at your facility (If so, are they maintained regularly)** ▪ Emergency exit				
	▪ Path marked by fluorescent strip for guiding the emergency exit				
	▪ Fire Alarm/ Smoke alarm				
	▪ Fire Extinguisher				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
A4.	Assured power supply arrangement (Indicate the nature of assured supply)				
A5.	Practice of sterilizing the garments for use in clean areas				
A6	Functional equipments (Including electronic weighing balance, pH meter, conductivity meter,				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
	microwave oven, de ionizer/distillation unit/RO water facility, autoclave etc.)				
A7	**Maintaining class 100,000 sterility level throughpressure module/ AHU/ HVAC/any other** (in case of any other, please mention the detail of nature of facility and its effectiveness).				
	• **Media storage room**				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
	• Inoculation room • Incubation/Growth room				
A8	Availability of pass box and or/other suitable mechanism for transfer of media into media storage room immediate after autoclaving without men entering into the other area? (Pass box should have see through windows and fitted with UV Light).				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
A9	Dedicated growth room/ transfer area				
A10	Primary Hardening Area: i). Mist chamber/Green house/Polyhouse ii). Insect-proof greenhouse/polyhouse with double door entry				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
	iii). Facility to maintain humidity for primary hardening area				
A11	Secondary hardening Area (Nursery Area) i). Dedicated double door entry to check insect entry				
	ii). Net house(s) covered with appropriate mesh to provide partial shade and without any openings to prevent insect entry				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
A. 12	Do you get mother plant and Explant material tested for i) Freedom from the known viruses (as listed in NCS-TCP website/SOPs)? If yes, please indicate following: • Number of stock culture intiated in last one year				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the expert committee during on-site visit If any mandatory parameter is not fulfilled, company cannot be recognized. However, experts should suggest corrective action(s)		
		Descriptive information by company (if any)	Yes	No	Remarks of expert committee (if any)
	• Number of stock culture tested in last one year • Number of batches/plants produced from tested stock				

Section-III: Part B – Other Parameters (Non-mandatory)

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	INFRASTUCTURE (B1- B7)						
B1	**Washing Area:**						
	• Is washing room connected with media preparation room for transfer of washed vessel through covered passage?						
	• Do you have availability of good quality running tap water?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	• Do you have separate basins for keeping glassware at different stages of washing?						
	• Do you have provision for separate dipping of jars from the hardening area/infected cultures?						
	• Whether washing is done in enclosed or covered area?						
B2	Do you have plastic paint/water proof emulsion on the wall?						
	i). Media storage room						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	ii). Inoculation room iii). Incubation/Growth room						
B3	**<u>Media storage Room:</u>**						
	(i) Do you have adequate space for media storage (to store the sterilized media for at least 3 days)?						
	(ii) Do you have provision of UV lights in the room?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
B4	**<u>Inoculation Room</u>**						
	(i) Do you have laminar air flow cabinets fitted with manometers for checking pressure of airflow/hepa filters/UV Germicidal lamp?						
	(ii) Do you use glass bead sterilizer for sterilization of forceps/scalpel?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	**No**	**Descriptive information by company (if any)**	**Yes**	**No**	**Remarks (if any)**
B5	**<u>Transfer of plantlets from growth room to grading room facility:</u>**						
	(i) Do you have pass box facility for transfer of culture bottles from growth room to grading/transfer area? (Pass box should have see through windows and fitted with UV Light)						
	(ii) Do you have arrangement of washing of plantlets to remove culture medium?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	**No**	**Descriptive information by company (if any)**	**Yes**	**No**	**Remarks (if any)**
	(iii) Do you have organized grading system such as working table with grading scale and or/ pictorial map to facilitate grading of tissue culture plantlets?						
B6	**<u>Primary Hardening Area:</u>** **Mist chamber/Green house/Polyhouse**			If yes, describe the arrangements			
	I) Do you have yellow sticky traps for insect pest monitoring? (at the rate of one sticky trap per 10m^2area)						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	II) Do you have facility to avoid contact of roots with ground soil?						
B7	**Secondary hardening Area (Nursery Area)**						
	(i) Do you have yellow sticky traps for insect pest monitoring? (at the rate of one sticky trap per 10m^2area)						
	(ii) Do you have facility to avoid contact of roots with ground soil?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	OPERATIONAL REQUIREMENTS (B8-B16)						
B8.	**Washing Area:**						
	(i) Is washing done mechanically/manually?						
	(ii) Is cleanliness being maintained?						
B9	**Discarding used agar:**						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	**No**	**Descriptive information by company (if any)**	**Yes**	**No**	**Remarks (if any)**
	(i) Do you autoclave the contaminated cultures? *(if no, please specify the procedure of decontamination)*						
	<u>Discard of used agar</u> - Do you treat used agarat site? (If so indicate procedure being						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	**No**	**Descriptive information by company (if any)**	**Yes**	**No**	**Remarks (if any)**
	followed)/ Discard at Pit which is to be used as nutrient for bio-fertilizer and or/ - Municipal garbage						
B10	**<u>Media Preparation:</u>** (i) Do you appropriately label the individual jar/tray?						
	(ii) Do you use the tissue culture grade chemicals?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
B11.	**Media Storage Room:**						
	(i) Do you monitor the airborne microbe through microbial plating? If so, its frequency. (ii) Do you fumigate the room periodically with the sterilant? If so indicate frequency? (iii) Range of number of days (minimum 3-4 days) for which media is stored prior to inoculation (iv) Provision of UV light						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
B12	**Inoculation Room:** (i) Do you fumigate the room periodically with the sterilant? If so indicate frequency? (ii) Do you monitor the airborne microbe through microbial plating? If so, its frequency? • Frequency of microbial plating						
	• Frequency of fumigation						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	• Maintenance schedule for laminar air flow cabinets						
	(iv). Do you fumigate the room periodically with the sterilant?						
B13.	**<u>Incubation (Growth) room:</u>**						
	(i) Do you monitor the airborne microbe through microbial plating? If so, its frequency.						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(ii) Is temperature in the growth room maintained uniform?						
	(iii)Do you fumigate the room periodically with thesterilant? If so frequency.						
B14.	**Transfer/Grading Room** Do you undertake regular grading of the plantlets according to specific criteria established for each plant species?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
B15.	**<u>Primary hardening</u> (Mist chamber/Green house/Poly house)**						
	(i) Trays properly labeled to trace back the history						
	(ii) Do you monitor plants for their growth & any other feature?						
	(iii) Do you monitor insect vector species through yellow stick cards?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(iv) Do you monitor the temp/humidity/light intensity?						
	(v) Maintaining records of: • Temperature						
	• Humidity						
	• Mortality of plants						
	• insects on yellow sticky cards						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	**No**	**Descriptive information by company (if any)**	**Yes**	**No**	**Remarks (if any)**
	(vi) Do you label individual hardening trays convening the details of numbers of plants, date of transfer, batch number etc.?						
B16.	**<u>Secondary Hardening (Nursery) Area</u>**						
	(i) Trays properly labeled for: • Tracing the batch numbers						
	• Mortality of plants						
	• Insects in yellow sticky traps						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(ii) Has the production of tissue culture raised plants reached to secondary hardening stage?						
	(iii) Do you monitor plants for their growth or any other feature?						
	(iv) Do you monitor the insect vectors by yellow stick traps?						
	(v) Do you label individual batch convening the details of number of plants, date of transfer, batch number and batch size etc.						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(vi) Do you undertake regular weeding and removal of dead plants?						
B17.	**Quality Practices** **Multiplication cycle**						
	(i) Are you restricting number of multiplication cycles?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(ii) Are you strictly monitoring the procedures while transferring plantlets from? - Growth room to transfer area - Greenhouse to shade area - At the time of dispatch						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
B18	**Overall Quality of Plants** (i) Do you ensure that plants are fully hardened and transplantable size at the time of dispatch?						
	(ii) In case of ex-agar plants, it is ensured that plantlets should be appropriate size to ensure their survival during transport/transplantation in greenhouse/nursery						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(iii) Do you provide handout to the farmers along with plants covering the package of practices for cultivation of particular species?						
OVERALL QUALITY MANAGEMENT AND CERTIFICATION							
B19.	Do you get tissue culture plants tested for following? - Virus - Genetic fidelity?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
Section-III: Part C -Reporting System/ documentation/Record							
C1	**Mother Plants** - Criteria for selection of mother plants (Species wise) - Records for selection of mother						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
C2.	plants/passport data/unique code - Records for testing of stock culture/mother plant tissue **Media Preparation** - Calibration record for measuring equipment - Records of de-contamination/dicard of used agar - Stock solution, media preparation and autoclave cycle						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
C3	**Media storage Room:** (i) Do you maintain record for monitoring of the airborne microbe through microbial plating?						
	(ii) Do you keep record of routine screening of media for any contamination?						
	(iii) Do you maintain record for fumigating the room periodically with the sterilant?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
C4	**Inoculation Room** (i) Do you maintain record for monitoring of the airborne microbe through microbial plating?						
	(ii) Do you maintain records for fumigating the room periodically with the sterilant? (iii) Do you maintain record keeping for: - Efficiency of operators						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	**No**	**Descriptive information by company (if any)**	**Yes**	**No**	**Remarks (if any)**
	(through monitoring number of jars handled, multiplication rate, contamination losses, rooting percentage and general health of the culture etc.) (iv) Calculating multiplication fold at the end of each passage						
C5.	**<u>Incubation/Growth room:</u>** (i) Do you maintain record for: - Contaminated cultures - Continuous temperature recording device - Light intensity/duration						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(ii) Do you make production schedules based on the protocol efficiency?						
C6	**Sterility Level** Do you maintain particle count data in support of sterility class 100,000? (i) Media storage room						
	(ii) Inoculation room						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(iii) Incubation/Growth room						
C7	**<u>Primary Hardening Area (</u>Mist chamber, Green house/Poly house):** (i) Do you keep record of number of plant lets transferred/dead plants-maintained batch-wise?						
	(ii) Do you maintain record of any treatments given to the plants (fertilizer applications/ insecticide/fungicidal; sprays etc)?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(iii) Do you maintain record of incidence of insect pests/diseases/vectors?						
C8	**Secondary hardening Area (Nursery):** (i) Do you keep record of number of plants transferred/dead plants maintained batch-wise?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(ii) Do you maintain record of any treatments given to the plants (fertilizer applications; insecticidal/fungicidal sprays etc)?						
	(iii) Do you maintain record of incidence of insect pests/diseases/vectors?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
C9	**Farmer's Advisory/Feed back:** (i) Do you provide printed leaflets regarding package of practices for cultivation of tissue culture raised plants?						
	(ii) Do you maintain record of farmers' feedback/data regarding field performance of tissue culture raised plants (if any)?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
C10	**Testing of Tissue Culture Raised Plants** (i) Records for testing of viruses and genetic fidelity for each batch of production (ii) Maintaining unique code/batch number till dispatch of plants						

Application for Renewal of Recognition (NCS-TCP Form 2A)

These forms will be similar to NCS-TCP Form 1 and NCS-TCP Form 2 except providing background information of Accreditation and Recognition as follows:

- Details of Certificate of Recognition

  (i) Registration No.

  (ii) Accreditation/Certification No.

  (iii) Date of issue:

  (iv) Valid up to:

Application for Renewal of Recognition of Tissue Culture Production Facility (NCS-TCP Form-2A)

(Applicant should submit 3 copies of application with all enclosures to "NCS-TCP Management Cell" at National Institute of Plant Genome Research (NIPGR), Aruna Asaf Ali Marg, New Delhi 110067)

Eligibility

1. Tissue culture production facility should be fully functional (including all areas of laboratory and hardening facility)
2. 100% batch certification of tissue culture raised plants produced at the TCPF during recognition.
3. **Pressnt Installed Production Capacity/Annum**

Section 1

1. Details of Certificate of Recognition

(i) Registration No.

(ii) Certification No.

(iii) Date of issue:

(iv) Valid up to:

1. Name of Tissue Culture Production Facility (TCPF)

1a. Postal Address of the office of TCPF:

Email:

Telephone (Landline):

Mobile:

1b), Address of Tissue Culture Production Facility, if different from 1a:

Email:

Telephone (Landline): **Mobile:**	
1c). Address of Hardening Facility (if different from 1b): **Email:** **Telephone (Landline):** **Mobile:**	
2. Head of the Organization:	
Name & Designation:	**Ph. /Mob. no:**
3. Laboratory-In charge	
Name & Designation:	**Ph./Mob. no.:**
4. **Particulars of Laboratory**	
E. Public Sector *(tick appropriately)* - National Laboratories (CSIR/ICAR etc) ☐ - State Funded Laboratories ☐ - Universities ☐	
F. Private Sector *(tick appropriately)* - Public Limited ☐ - Private Limited ☐ - Proprietorship ☐ - Partnership ☐	

G. NGO

H. Others (Please specify)

5. Month and Year of Commencement of Production

6. Plant species being multiplied at commercial level

a.

b.

c.

7. Details of production of plants for last two years (species with approx. numbers)

Year	Species under multiplication	Plants Produced (in lakhs)	Plants sold (Domestic) (in lakhs)	Plants exported, if any (in lakhs)

8. Total number of Staff Engaged in Production activity:

9. Enclosures to the Application:

iv. Acknowledgement receipt of online transfer towards fee payment.

v. Labeled and numbered photographs showing Washing Room; Media Preparation Room(s); Media Storage Room(s); Inoculation Room(s); Growth Room(s) and Transfer/Grading Area; Locations of Pressure Module/ Air Handling Unit (AHU)/ HVAC system in Media Storage Room(s), Inoculation Room(s) & Growth Room(s); Grading area; Double door entrance in Primary and Secondary Hardening Area Hardening Areas depicting plants

vi. Layout/ Drawing of tissue culture production facility *covering lab area (entry, washing, media preparation, storage, inoculation, growth room, grading area etc.), hardening and nursery. The layout should also clearly indicate man and material movement, sterile & non-sterile zone, location of pass box, pressure module,emergency exit and double door in hardening areas*

vii. Declaration regarding total production (number of plants in lakhs) and sales (number of plants in lakhs) of the last Financial Year duly certified by chartered accountant

10. Declaration:

I/we hereby declare that all the information/ particulars provided in the application are true and correct to the best of my knowledge. I/we shall bear the additional cost, In the event of any discrepancies noticed during the processing of my application and or/ any deviations are observed during site visit from stated information both in application and self-assessment form. I/we further declare that I am/ we are making this application after meeting the eligibility criteria & requirementsof mandatory enclosures and going through instructions/guidelines contained in Section-2 to this application.

11. Undertaking

I am/we are making this application after having understood the guidelines of National Certification System for Tissue Culture Raised Plants (NCS-TCP) framed by the Department of Biotechnology (DBT), Govt. of India, New Delhi developed on October 2006 and subsequent its amendments from time to time. The guidelines (available on the website www.dbtncstcp.nic.in) will be fully binding on the applicant.

I/we undertake if any information provided in the application is found to be incorrect, entire cost of site visit will be borne by the applicant company.

I/We also undertake that any dispute not resolved under NCS-TCP will be subject to jurisdiction of Delhi Courts.

Date:

Place:

( )

Signature /Name/ Designation of Authorized Person

Section-2: Mandatory Requirements

(If any of below mentioned requirement is "No" the application will not be processed)

1. Mandatory requirements for recognition of TCPF

- Tissue culture production facility should be fully functional (including all areas of laboratory and hardening facility).

- **Mother plant and Explant material**

  Are you getting 100% stock cultures/mother plants tested/indexed for freedom from all the known viruses as listed in NCS-TCP website/SOPs? Yes/No

  If yes, please indicate the following:

- Number of stock culture initiated in last two year ☐
- Number of stock culture tested in last two year ☐
- Number of batches produced from tested stock ☐

- Status of Plant Certification

  (i) Are you getting batches of plants certified from ATLs? Yes/No

  If yes:

Name of crop	**Certification done based on**	
	Virus indexing and genetic fidelity testing	**Virus indexing only**

(ii) Total plants certified since last renewal/recognition.

Total plants and batches produced and certified since last recognition			
	Produced	**Certified**	Remark, if any
Plants			
Number of Batches			

Mandatory requirements for TCPF:

i. Availability of following **exclusive functional areas**

a) Washing Room (s) Yes/No

b) Media Preparation Room (s) Yes/No

c) Media Storage Room (s) maintained under positive pressure Yes/No

d) Inoculation Room (s) maintained under positive pressure Yes /No

e) Growth Room (s) maintained under positive pressure Yes/No

f) Transfer/ grading Room (s) Yes/No

g) For hardening facility, insect proof greenhouse/ poly house with double door entry fitted with humidity control Yes/No

h) For secondary hardening, insect proof Nursery/ Shade house Area (s) with double door entry covered with appropriate mesh to provide partial shade Yes/No

ii. Entry to clean area should have the following arrangements: Yes/no

- facility for hand and foot washing,
- air curtain, air shower, cubicles for dress changing

- dress storage before entering into sterile areas of tissue culture production facility

iii. Layout of laboratory building is planned in such a way that does not allow free movement of human and materials between sterile and non-sterile area. A layout plan for guidance is given. Yes/no

iv. Provision of well-maintained firefighting system with emergency exit, path showing fluorescent strip for guiding the emergency exit, fire alarm/ smoke alarm and fire extinguisher Yes/no

v. Availability of uninterrupted power supply Yes/no

vi. Availability of basic equipment (including electronic weighing balance, pH meter, conductivity meter, microwave oven, de ionizer/distillation unit/RO water facility, autoclave etc.). Yes/no

vii. Maintaining class 100,000 sterility level through pressure module/ AHU/ HVAC/any other in media storage room, inoculation room and incubation/growth room. Yes/no

viii. Pass box fitted with UV and see through glass and or/other suitable mechanism for transfer of media into media storage room immediate after autoclaving (without men entering into the other area). Yes/no

2. Renewal of recognition fee structure:

a. Application fee **Rs. 2000/-**

b. Inspection fee:

(i) Small scale companies (upto 1 million plantlets/annum) **Rs. 5000/-**
(ii) Medium scale companies (1 to 3 million plantlets/annum) **Rs. 10,000/-**
(iii) Large scale companies (>3 million plantlets/annum) **Rs. 15,000/-**

c. Recognition Certificate fee **Rs. 10,000/-**

All the fee payment should be made to the following account:

Beneficiary Name : NIPGR-NCS-TCP
Account No. : 40603535988
Type of account : Saving account Bank
: State Bank of India
(SBI)
Branch : Jawaharlal Nehru University
IFSC code : SBIN0001624
Email : ncs-tcp@nipgr.ac.in

Section III

SELF ASSESSMENT REPORT FOR RENEWAL OF RECOGNITION FOR TISSUE CULTURE PRODUCTION FACILITY UNDER NCS-TCP

(Part-A parameters (Shaded) are mandatory requirements and Part-B parameters are other requirements for consideration of application for registration. Site visit would be organized on compliance with all the mandatory requirements during self assessment.)

Section-III: Part A – Mandatory Parameters

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the experts committee during site visit		
		Descriptive information by company (if any)	Yes	No	Remarks (if any)
A1.	Availability of following provisions in change area before entering into sterile areas of tissue culture production facility				
	Hand and leg washing facility				
	Dress change cubicle				
	Air curtain and or/Air shower facility				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the experts committee during site visit		
		Descriptive information by company (if any)	Yes	No	Remarks (if any)
A2.	Layout of laboratory building is planned to avoid crisscross movement of men and materials between sterile and non-sterile area				
A3.	Availability of fire fighting system at your facility (If so, are they maintained regularly)				
	▪ Emergency exit				
	▪ Path marked by fluorescent strip for guiding the emergency exit				
	▪ Fire Alarm/ Smoke alarm				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the experts committee during site visit		
		Descriptive information by company (if any)	Yes	No	Remarks (if any)
	▪ **Fire Extinguisher**				
A4.	**Assured power supply arrangement** **(Indicate the nature of assured supply)**				
A5.	**Practice of sterilizing the garments for use in clean areas** **(Describe the arrangements)**				
A6.	**<u>Equipment and Sterile facility:</u>** (i) **Functional equipments** **(Including electronic weighing balance, pH meter, conductivity meter, microwave oven, de ionizer/distillation unit/RO water facility, autoclave etc.)**				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the experts committee during site visit		
		Descriptive information by company (if any)	Yes	No	Remarks (if any)
A7	**Maintaining class 100,000 sterility level through pressure module/ AHU/ HVAC/any other** (in case of any other, please mention the detail of nature of facility and its effectiveness).				
	Media storage room				
	Inoculation room				
	Incubation/Growth room				
A8	**Availability of pass box and or/other suitable mechanism for transfer of media into media storage room immediate after the autoclaving without men entering into the other area?** (Pass box should have see through windows and fitted with UV Light)				
A9	**Dedicated growth room/ transfer area**				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the experts committee during site visit		
		Descriptive information by company (if any)	Yes	No	Remarks (if any)
A10	Primary Hardening Area: Mist chamber/Green house/Polyhouse				
	(i) Insect-proof greenhouse/polyhouse with double door entry				
	(ii) Facility to maintain humidity for primary hardening area				
A11	Secondary hardening Area (Nursery Area)				
	(i) Dedicated double door entry to check insect entry				

S. No.	Particulars	Self Assessment by the Applicant (Yes/No)	Comments of the experts committee during site visit		
		Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(ii) Net house(s) covered with appropriate mesh to provide partial shade and without any openings to prevent insect entry				
A11	<u>Mother plant and Explant material</u> Getting 100% stock cultures/mother plants tested/indexed for freedom from all the known viruses as listed in NCS-TCP website/SOPs				
A 12	Certification of each batch of tissue culture plants produced during the last two years of recognition period				

Section-III: Part B – Other Parameters (Non-mandatory)

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	INFRASTUCTURE (B1 -B7)						
B1.	**Washing Area:** (i) Is washing room connected with the media preparation room for transfer of washed vessel through covered passage?						
	(ii) Do you have availability good quality of running tap water?						
	(iii) Do you have separate basins for keeping glassware at different stages of washing?						
	(iv) Do you have provision for separate dipping of jars from the hardening area/infected cultures?						
	(v) Whether washing is done in enclosed or covered area?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
B2	Do you have plastic paint/water proof emulsion on the wall? • Media storage room • Inoculation room • Incubation/Growth room						
B3	**Media storage Room:** (i) Do you have adequate space for media storage (to store the sterilized media for at least 3 days)?						
	(ii) Do you have provision of UV lights in the room?						
B4.	**Inoculation Room** (i) Do you have laminar air flow cabinets fitted with manometers for checking pressure of airflow/hepa filters/UV Germicidal lamp?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(ii) Do you use glass bead sterilizer for sterilization of forceps/scalpel?						
B5	**Transfer of plantlets from growth room to grading room facility:**						
	(i) Do you have pass box facility for transfer of culture bottles from growth room to grading/transfer area? (Pass box should have see through windows and fitted with UV Light).						
	(ii) Do you have arrangement of washing of plantlets to remove culture medium?						
	(iii) Do you have organized grading system such as working table with grading scale and or/ pictorial map to facilitate grading of tissue culture plantlets?						
B6.	**Primary Hardening Area:** **Mist chamber/Green house/Polyhouse**						
	(i) Do you have yellow sticky traps for insect pest monitoring? (at the rate of one sticky trap per 10m^2area)						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(ii) Do you have facility to avoid contact of roots with ground soil?						
B7	**Secondary Hardening Area (Nursery Area)**						
	(i) Do you have yellow sticky traps for insect pest monitoring? (at the rate of one sticky trap per 10m^{2}area)						
	(ii) Do you have facility to avoid contact of roots with ground soil? (Not required if plants are sold early)						
Operational Requirements (B8 -B16)							
B8	**<u>Washing Area:</u>** (i) Is washing done mechanically/manually?						
	(ii) Is cleanliness being maintained?						
	(iii) Is drying of glassware done in ovens or at room Temperature						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
B9	**Discarding used agar:** (i) Do you autoclave the contaminated cultures? (*If no, please specify the procedure of decontamination)*						
	- Do you treat used agar at site? (If so indicate procedure being followed)/Discard at Pit which is to be used as nutrient for bio-fertilizer - Municipal garbage						
B10	**Media Preparation:** (i) Do you appropriately label the individual jar/tray?						
	(ii) Do you use the tissue culture grade chemicals?						
B11.	**Media Storage Room:** (i) Do you undertake regular particle count (at 6 months' interval) to						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	support maintenance of class 1, 00, 000 sterility level?						
	(ii) Do you monitor the airborne microbe through microbial plating? If so, its frequency.						
	(iii) Do you fumigate the room periodically with the sterilant. If so indicate frequency?						
	(iv) Range of number of days (minimum 3-4 days) for which media is stored prior to inoculation						
	(v) Provision of UV light						
B12	**<u>Inoculation Room:</u>** (i) Do you under take regular particle count (at six months' interval) to support maintenance of class 1, 00, 000 sterility level?						
	(ii) Do you fumigate room periodically with the sterilant. If so indicate frequency?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(iii) Do you monitor airborne microbe through microbial plating? If so, its frequency?						
	(iv) Are you following the maintenance schedule for laminar air-flow cabinets? - Cleaning of pre-filters - Checking air flow - Checking efficiency of HEPA filters by exposing plates						
B13.	**Incubation (Growth) room:** (i) Do you undertake regular particle count (six months interval) to support maintenance of class 1, 00, 000 sterility level?						
	(ii) Do you monitor the airborne microbe through microbial plating? If so, its frequency.						
	(iii) Is the temperature in the growth room maintaineduniform?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(iv) Do you fumigate the room periodically with the sterilant? If so frequency.						
B14.	**Transfer/Grading Room** (i) Do you undertake regular grading of the plantlets according to specific criteria established for each plant species?						
B15.	**Primary hardening** **(Mist chamber/Green house/Poly house)** (i) Trays properly labeled to tarce back the history of plants.						
	(ii) Maintaining records of: • Temperature • Humidity • Moratlity of plants • Insects on yellow sticky cards						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(iii) Do you monitor plants for their growth & any other feature?						
	(iv) Do you monitor insect vector species through yellow stick cards						
	(v) Do you monitor the temp/humidity/light intensity?						
	(vi) Do you label individual hardening trays convening the details of number of plants, date of transfer, batch number etc.?						
	(v) Do you use potable water/ good quality water for watering of plantlets? Please specify the TDS level						
	(vi) Do you avoid excessive watering and water-logging with drainage system						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
B16.	**Secondary Hardening (Nursery) Area** (i) Has the production of tissue culture raised plants reached to secondary hardening stage?						
	(ii) Do you monitor plants for their growth or any other feature?						
	(iii) Do you monitor the insect vectors by yellow stick traps?						
	(iv) Do you label individual batch convening the details of number of plants, date of transfer, batch number and batch size etc.						
	(v) Trays properly labeled for: • Tracing back the batch number • mortality of plants '						
	• insects in yellow sticky traps						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
Quality Practices (B17 -B18)							
B17.	**<u>Multiplication cycle</u>** (i) Are you restricting number of multiplication cycles?						
	(ii) Are you strictly monitoring the procedures while transferring plantlets from: - Growth room to transfer area - Greenhouse to shade area - At the time of dispatch						
	(iii) Are you following the SOPs as guidelines?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
B18.	**Overall Quality of Plants** (i) Do you ensure that plants are fully hardened and transplantable size at the time of dispatch?						
	(ii) In case of ex-agar plants, it is ensured that plantlets should be appropriate size to ensure their survival during transport/transplantation in greenhouse/nursery						
	(iii) Do you provide handout to the farmers along with plants covering the package of practices for cultivation of particular species?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
Section III- Part C (Reporting/Documentation/Records)							
C-1	**Mother plant and Explant material:** (i) Do you have clearly defined criteria (species wise) for the selection of elite plants?						
	(ii) Do you keep proper record for mother stock (such as unique code no. and passport data of the mother plant)?						
	(iii) Record for testing of stock culture/mother plant tissue						
C-2	**Media Preparation:**						
	(i) Calibration records for measuring equipment						
	(ii) Records for decontamination/discard of used agar						
	(iii) Stock solution, media preparation and autoclave cycle						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
C-3	**Media storage Room:**						
	(i) Do you maintain record for monitoring of the airbornemicrobe through microbial plating?						
	(ii) Do you keep record of routine screening of media for any contamination?						
	(iii) Do you maintain record for fumigating the room periodically with the sterilant?						
C-4.	**Inoculation Room**						
	(i) Do you maintain record for monitoring of the airborne microbe through microbial plating?						
	(ii) Do you maintain records for fumigating the room periodically with the sterilant?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(iii) Do you maintain record keeping for: - Efficiency of operators (through monitoring number of jars handled, multiplication rate, contamination losses, rooting percentage and general health of the culture etc.) (iv) Calculating multiplication fold at the end of each passage						
C-5	**Incubation/Growth room:** (i) Do you maintain record for: - Contaminated cultures - Continuous temperature recording device - Light intensity/duration						
	(ii) Do you make production schedules based on the protocol efficiency?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
C-6	Do you maintain particle count data in support of sterility class 100,000?						
	• Media storage Room						
	• Inoculation Room						
	• Incubation/Growth room						
C-7	**Primary Hardening Area** **(Mist chamber, Green house/Poly house):** (i) Do you keep record of number of plant lets transferred/dead plants maintained batch-wise?						
	(ii) Do you maintain record of any treatments given to the plants (fertilizer applications/ insecticide/fungicidal; sprays etc)?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
	(iii) Do you maintain record of incidence of insect pests/diseases/vectors?						
C8	**Secondary hardening Area (Nursery):** (i) Do you keep record of number of plants transferred/dead plants maintained batch-wise?						
	(ii) Do you maintain record of any treatments given to the plants (fertilizer applications; insecticidal/fungicidal sprays etc)?						
	(iii)Do you maintain record of incidence of insect pests/diseases/vectors?						

S. No.	Particulars	Self Assessment by the Applicant			Comments of the experts committee during on-site visit		
		Yes	No	Descriptive information by company (if any)	Yes	No	Remarks (if any)
C 9	**Farmer's Advisory/Feed back:** Do you provide printed leaflets regarding package of practices for cultivation of tissue culture raised plants?						
	(i) Do you maintain record of farmers' feedback/data regarding field performance of tissue culture raised plants (if any)?						
	(ii) Are you following the unique code/batch number of certified T.C. plants till dispatch (as per SOPs)?						
C-10	**Certification of Tissue Culture Raised Plants** Do you maintain record for certification of each batch of tissue culture plants?						

Various forms pertaining to testing and certification are at NCS-TCP website:

a. Formats for testing of Mother plant tissue/Stock culture

S. No.	Annexure No.	Forms
1	Annexure-1A	Intimation form for Virus Indexing of Plant Tissue/Stock Culture(s)
2	Annexure-2A	Application for Virus Indexing of Plant Tissue/Stock Culture (s)
3	Annexure-3A	Job Card For Sample testing of plant tissue/stock culture(s)
4	Annexure-4A	Virus indexing Report for Plant Tissue/Stock Culture (s)
5	Annexure-5A	Sample Forwarded to Referral Laboratory
6	Annexure-6A	Master Report of virus indexing of plant tissue/stock culture(s)

b. Formats for Testing and Certification of Tissue culture raised plants

S. No.	Annexure No.	Forms
1	Annexure-1B	Intimation form for (Virus/genetic fidelity) Testing for Batch Certification of Tissue Culture Raised Plants
2	Annexure-2B	Application for (Virus/genetic fidelity) Testing for Batch Certification of Tissue Culture Raised Plants
3	Annexure-3B	Job Card for sample testing of TC raised plants
4	Annexure-4B	Test Report for Tissue Culture Raised Plants
5	Annexure -5B	Certificate of Quality
6	Annexure-7B	Tissue Culture Raised Plant "Not Approved for Certification"
7	Annexure-8B	Sample Forwarded to Referral Laboratory
8	Annexure-9B	Master Report of testing/certification of tissue culture plants by Accredited Test Laboratories

Application for Recognition of Hardening Center under NCS-TCP (NCS-TCP Form-3)

Section 1

1. Applicant Entity (Institute/Organization)
Name of Recognized Tissue Culture Production Facility:
Address of Recognized Tissue Culture Production Facility:
2. Recognition Detail of the main facility recognized under NCS-TCP
Registration No.:
Certification No.:
Date of Issue:
Valid up to:
3. Details of Hardening Center to be Recognized
Number of green house/poly-house and area of each
Number of nursery and area
4. In-charge of Hardening Center(s)
Name:
Designation:
Tel/Mob/Fax/ E-mail:
5. Capacity of Hardening Center (Plants in lakhs at a time)
6. Commencement of hardening operation

7. Plant species being hardened

8. Layout of hardening center(s) of recognized tissue culture production facility.

Note: *The layout should clearly indicate availability of transfer area, provision of area double door in hardening areas. A separate sheet needs to be enclosed.*

9. Staff Details (please provide details about qualification and relevant experience of technical and non-technical staff)

- **Technical**
- **Non-Technical staff**

10. Reporting system for technical supervision and monitoring of hardening process (Please attach a note on how the coordination is done between hardening center(s) and main tissue culture production facility.)

11. Mechanism in place for quality control and quality assurance

Declaration/Undertaking

I/we hereby declare that all the information/ particulars provided in the application are true and correct to the best of my knowledge. I/we further declare that I am/ we are making this application after meeting the eligibility criteria & requirements of mandatory enclosures and going through instructions/guidelines contained in Section-2 to this application.

I am/we are making this application after having understood the guidelines of National Certification System for Tissue Culture Raised Plants (NCS-TCP) framed by the Department of Biotechnology (DBT), Govt. of India, New Delhi developed on October 2006 and subsequent its amendments from time to time. The guidelines (available on the website www.dbtncstcp.nic.in) will be fully binding on the applicant

I/We also undertake that any dispute not resolved under NCS-TCP will be subject to jurisdiction of Delhi Courts

Date:_____

Place_____

In-charge of Hardening Centre

Authorized Signatory of Recognized TCPF

Section-2: General Information:

3. Eligibility Criteria:

- ❖ Facility should have capacity of hardening for of 0.5 million (5 Lakhs) plants per annum.
- ❖ Hardening facility should be operational at the time of application and site visit.

4. Fee Structure:

Fee structure for Recognition of Hardening Center(s) of Recognized Tissue Culture Production Facility

(Figures in Rs.)

Registration fee for recognition	500
Registration fee for renewal	250
Inspection and report preparation	1500
Processing and Certification	2000

Validity of Recognition of Hardening Center(s) of Recognized Tissue Culture Production Facility is Two Years subject to the Recognition of main tissue culture production facility.

* Registration renewal fee will be charged @ 50% of the registration fee.

Only Registration fee to be deposited at the time of Application submission, payable as Demand Draft in favor of "NIPGR"

3. Mandatory Enclosures to the application:

(i) A crossed Demand Draft drawn on any scheduled bank in favor of **"NIPGR"** payable at New Delhi for fees specified as above.
(ii) Labeled and numbered photographs showing Grading area; Double door entrance in Primary and Secondary Hardening Area Hardening Areas depicting plants
(iii) Layout/ Drawing of hardening facility depicting double door entrance, raised bed etc

4. Instructions & Guidelines:

(i) Applicants should use apply for recognition/ renewal of recognition strictly in the prescribed format.

(ii) Applicant should submit 5 copies of application to "**NCS-TCP Management Cell,** National Institute of Plant Genome Research (NIPGR), Aruna Asaf Ali Marg, New Delhi 110067.

(iii) Applicants are required further to go through the NCS-TCP guidelines & Standard Operating Procedures (SOPs) for Tissue Culture Production Facility available at www.dbtncstcp.nic.in and ensure they meet all the requirements.

Section III. ASSESSMENT REPORT FOR RECOGNITION OF HARDENING CENTER(S) UNDER NCS-TCP

(*marked parameters are mandatory requirements. Site visit would be organized on compliance with mandatory requirements during self assessment. Shaded column to be filled by applicant as self assessment)

Section II: Part A-Infrastructure

. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
		YES	NO	Descriptive information (Please enclose sheet if required)	
1.	**Do you have the following areas clearly demarcated*** ▪ Transfer/ Grading Area (s) Specify area ▪ Acclimatization ▪ Green house/ poly house (s) Specify area ▪ Nursery/ Shade house Area (s) Specify area: ▪ Do you have a separate misting facility (ies) If so, its area				

S. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
		YES	NO	Descriptive information (Please enclose sheet if required)	
2.	**Power backup*** Do you have power backup arrangement? *If so indicate capacity of generator & percentage of power covered by backup generator)*				
3.	**Do you have transfer area with the following facilities?** (i) Do you have arrangement of washing of plantlets to remove culture medium (ii) Are plants graded? If so do you have organized grading system such as working table with pictorial map of the handled plant species				

S. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
		YES	NO	Descriptive information (Please enclose sheet if required)	
4.	**<u>Primary Hardening Area:</u>** **Mist chamber/Green house/Polyhouse** **(i) Do you have insect-proof greenhouse/ polyhouse with double door entry*** (ii) Do you have facilities for monitoring*: - Temperature - Humidity (iii) Do you have yellow sticky traps for insect pest monitoring (iv) Do you have raised bed/ to avoid contact of roots with ground soil				

5.	**<u>Secondary hardening Area (Nursery Area)</u>** **(i) Double door entry to check insect entry*** (ii) **Availability of net house* (to providepartial shade and prevent insect entry)** If so, its mesh size. (iii) Do you have yellow sticky traps for insect pest monitoring (iv) Do you have raised bed/ to avoid contact of roots with ground soil				

Section-III: Part B - Operational Requirements

S. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
		YES	NO	Descriptive information (Please enclose sheet if required)	
6.	**<u>Primary hardening</u>(Mist chamber/Green house/Poly house)** (i) Do you monitor plants for their growth & anyother feature? (ii) Do you monitor insect vector species through yellow stick cards? (iii) Do you monitor the temp/humidity/light intensity? (iv) Do you label individual hardening trays convening the details of number of plants, date oftransfer, batch number etc. (v) Do you use potable water/ good quality water for watering of plant lets. Please specify the TDS level. (vi) Do you avoid excessive watering and water-logging with drainage system				

S. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
		YES	NO	Descriptive information (Please enclose sheet if required)	
7.	**Secondary Hardening (Nursery) Area** (i) Has the production of tissue culture raised plants reached to secondary hardening stage? (ii) Do you use potable water/ good quality water for watering of plants? Please specify the TDS level. (iii) Do you monitor plants for their growth or any other feature? (iv) Do you monitor the insect vectors by yellow stick traps? (v) Do you label individual batch convening the details of number of plants, date of transfer, batch number and batch size etc. (vi) Do you avoid excessive watering and water-logging with drainage system (vii) Do you undertake regular weeding and remove dead plants				

Section-III: Part C - Human Resource and Manpower

S. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
		YES	NO	Descriptive information (Please enclose sheet if required)	
8	**Competent technical supervision and effective monitoring of entire production process:** *Indicate management/operational structure & their qualification. Please also specify their role & responsibilities* (i) Do you have accountable in-charge/supervisor for hardening facilities (ii) Do you provide training to the supervisor/operators *If so, internal training or external training*				

Section-III: Part D - Overall Quality Management and Certification

S. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
		YES	NO	Descriptive information (Please enclose sheet if required)	
9	**Plant Certification** (advisable during first application and Mandatory of Renewal) *(i)* Are you getting virus indexing of tissue culture raised plants done batch-wise? *If yes, give details of the laboratory where this testing is done.* (ii) Are you getting the genetic fidelity testing done through molecular markers? (If yes Give details of testing viz., name of laboratory/test results				

Section-III: Part E - Reporting System, documentation					
S. No.	**Particulars**	**Self Assessment By the Applicant**			**Comments of the experts committee during on-site visit**
		YES	**NO**	**Descriptive information** **(Please enclose sheet if required)**	
10.	**<u>Primary Hardening Area (</u>Mist chamber, Green house/Poly house):** (i) Do you keep record of number of plant lets transferred/dead plants maintained batch-wise (ii) Do you maintain record of any treatments given to the plants (fertilizer applications/ insecticide/fungicidal; sprays etc)? (iii) Do you maintain record of incidence of insect pests/diseases/vectors?				
11.	**<u>Secondary hardening Area (Nursery):</u>** (i) Do you keep record of number of plants transferred/dead plants maintained batch-wise (ii) Do you maintain record of any treatments given to the plants (fertilizer applications; insecticidal/fungicidal sprays etc)? (iii) Do you maintain record of incidence of insect pests/diseases/vectors?				

S. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
		YES	NO	Descriptive information (Please enclose sheet if required)	
12.	**<u>Overall Quality of Plants</u>** (i) Do you provide printed leaf lets regarding package of practices for cultivation of tissue culture raised plants (ii) Do you maintain record of farmers' feedback/data regarding field performance of tissue culture raised plants (if any)				

Assessment Report on Accreditation of Laboratory Facilities for Virus Diagnosis/Genetic Fidelity Testing of Tissue Culture Raised Plants.

<table>
<tr><td colspan="3">Applicant:</td></tr>
<tr><td colspan="3">Head of the Institute:</td></tr>
<tr><td colspan="3">Mailing Address:</td></tr>
<tr><td>City:</td><td>State/Province:</td><td>Pin Code:</td></tr>
<tr><td>Tel:</td><td>Fax:</td><td>E-mail:</td></tr>
<tr><td colspan="3">In-charge of the Testing Unit:
• Virus Testing:
• Genetic fidelity testing:</td></tr>
<tr><td colspan="3">Inspected by:
1. ……..
(Name & Designation)
2 ……
. (Name & Designation)
3. ……..
(Name & Designation)</td></tr>
<tr><td colspan="3">Dates of Inspection of Facility:</td></tr>
</table>

Instruction for Accreditation Panel (AP):

Completion of Report:

1. This format has been designed as an aid to auditors to ensure that the essential elements outlined in the standard '**Guidelines for Accreditation of Laboratory Facilities for Virus Diagnosis/Genetic Fidelity Testing of Tissue Culture Plants'** established by the **Department of Biotechnology, Ministry of Science & Technology** are complied with.
2. The AP may modify the questions on the checklist with additions and/ or deletions as appropriate. It is requested that the additions be included in the additional pages and deletions be marked with 'Not applicable (N/A)'.

Submission of Report:

1- The AP should complete the report form for each accreditation option.
2- This should be submitted with the audit report to: **The Head, NCS-TCP Management Cell,** National Institute of Plant Genome Research (NIPGR), Aruna Asaf Ali Marg, New Delhi 110067.

Part-I

Requirement	**Compliance (Yes/ No/ NA)**	**Comments**
A-Human Resources		
1. Scientist		
a. Qualification & Experience • Virologist • Molecular Biologist b. Job description		
2. **Technical Personnel**		
a. Qualification & Experience • i • ii • iii b. Job description c. Need for External training d. Records of previous trainings of staff • i • ii • iii		
B. Physical Facility		
1- Laboratory and office space enclosed in such way to prevent unauthorized entry		
2a- The facility conforms to and has documentation of all national and local requirements		
2b- Personnel know about and have access to these		

documents 3a- A work area that is dedicated to the function of virus diagnosis/quality testing of tissue cultures of plants has appropriate space for its operation		
3b- The work space is designated to avoid contamination of virus tests from other sources in the facility 3c- Adequate space and facility to avoid contamination or mixing of samples		
4. The entity has space and equipment to administer virus diagnosis/quality testing including: a. Filing b. Reporting c. Office and equipment d. Computers/printers		
Glasshouse/Green House Facility		
5. The entity has insect-proof glasshouse/green house facility for conducting biological test		
C- Methods of Testing and Inspection		
1a- The entity has a Quality Manual or equivalent documentation for sampling, virus diagnosis/quality testing of tissue cultures of plants. 1b- This manual is readily accessible to personnel		
2-The entity can demonstrate conformance to the manual and effective operation on quality system by internal audits		

D- Equipment & Procedures		
General equipment		
- Digital top pan/Analytical balance		
- Deep Freezer (-70, -20)		
- Distilled/RO/Millopore Unit		
- Hot plate/magnetic stirrer		
- pH & Electrical Conductivity meter		
- Autoclave		
- Laminar flow hoods		
- Incubation chambers		
- Refrigerator 4_o C		
- Micropipettes		
- Vortex mixer		
- Micro-oven		
- Tissue grinder/Pestle mortar/Como-drill		
- Centrifuge		
Others		

Specific equipments for virus indexing		
Serological Test		
ELISA Reader with printer		
All components of ELISA		
Microplate Shaker		
Specific antisera		
Multi channel Pipette		
Molecular Test		
Thermal cycler		
Gel electrophoresis unit (Horizontal) with power pack		
Gel documentation Unit with printer		
Specific primers		
DNA probes		
Special Equipments for Genetic Fidelity Testing		
DNA extraction equipment		
Gel electrophoresis unit (Horizontal) with power pack		
Gel documentation Unit with printer		
Specific primers		
DNA sequencing gel system		
Specific markers (RAPD/ISSR/SSR/AFLP/SCAR)		
Hybridization oven		
UV cross linker		
E- Additional Information		

Requirement	**Compliance (Yes/ No/ NA)**	**Comments**

Part-II

Request for Corrective Actions

<table>
<tr><td rowspan="5">A</td><td>Entity:</td><td>Date:</td></tr>
<tr><td colspan="2">Register Number</td></tr>
<tr><td colspan="2">Area/ Activity:</td></tr>
<tr><td colspan="2">Description of Non-Conformity:</td></tr>
<tr><td colspan="2">Non-Conformity with (standards/ regulation)</td></tr>
<tr><td></td><td colspan="2">Date to conduct corrective action:</td></tr>
<tr><td></td><td colspan="2">Lead Auditor
Name:
Signature:

Auditee
Name:
Signature:</td></tr>
<tr><td>B</td><td colspan="2">Adopted action to correct non-conformity and prevent repetition

Auditee Signature: Date:</td></tr>
</table>

Recommendation of Accreditation Panel

1._____ _____

(Name & Designation) (Signature of Auditor/date)

2_____ _____

. (Name & Designation) (Signature of Auditor/date)

3._____ _____

(Name & Designation) (Signature of Auditor/date)

Assessment of Renewal of Accredited Test Laboratory (ATL)

<table>
<tr><td colspan="3">Name of Accredited Test Laboratory:

Accreditation No:

Date of Accreditation and Period of Validity:
Accreditation:
1st Renewal:
2nd Renewal:
Validity:
Date of Last Assessment:</td></tr>
<tr><td colspan="3">Head of the Institute:</td></tr>
<tr><td colspan="3">Mailing Address:</td></tr>
<tr><td>City:</td><td>State/Province:</td><td>Pin Code:</td></tr>
<tr><td>Tel:</td><td>Fax:</td><td>E-mail:</td></tr>
<tr><td colspan="3">In-charge of divisions ATL:

• Virus indexing: ……
• Genetic fidelity testing: ……..</td></tr>
</table>

Signature of Head of the Institute: …….

Name & Designation: …….

Date: …….

Part-1

Note: 1. Part 1 of this assessment form (except last shaded column) to be filled by in-charge virus indexing. Last column would be filled by expert team while on site assessment.

2. Please enclose a separate sheet, if required.

	Status at the time of Accreditation	**Change, if any**	**Remark by expert team**
Part 1 (A) Human Resource			
1.Scientists			
Virologist: (i) Name & designation			
Qualification			
Experience			
(ii) Name & designation			
Qualification			
Experience			

2. Technical Personnel			
(i) Name and designation:			
Qualification			
Experience			
Relevant previous trainings, if any			
(ii) Name and designation:			
Qualification:			
Experience:			
Relevant previous trainings, if any			
Part 1 (B) <u>Physical Facility</u>			
	Status of compliance at the time of accreditation	**Current status of compliance**	**Remark by expert Accreditation committee**
1- Laboratory and office space, dedicated for the facility and enclosed in such way to prevent unauthorized entry			
2 - Adequate facilities to avoid contamination or mixing of samples			
3 - Insect proof Glasshouse/Green House			

Part 1 (C)Standard Operating Procedures			
		Current status of compliance	**Remark by expert Accreditation committee**
1. Adoption of SOPs including formats and maintenance of records such as (i) Communication receipt from NMC/DBT (ii) Test/certification register (iii)Test reports/certificate (iv) Deployment of label (v) Calibration record of equipments (vi) Internal and external training record (vii) Any other relevant document	Not to be filled by ATL		
2. Fee charged as per the NCS-TCP norms			
4. Time taken (no. of days) for issuance of test report/certificate (i) Maximum (ii) Minimum (iii) Average			
5. Suggestion for improvement of SOP, if Any			

Part 1 (D) **Equipment**		
General equipments	**Working condition** **(Good/ Satisfactory/ Poor)**	**Remark by expert Accreditation Committee**
Digital top pan/Analytical balance		
Deep Freezer (-80°C)		
Deep Freezer (-20°C)		
Distilled/RO/Millipore Unit		
Hot plate/Magnetic stirrer		
pH meter		
Conductivity meter		
Autoclave		
Hot air oven		
Laminar flow hoods		
Incubation chambers		

Refrigerator 4°C		
Micropipettes		
Vortex mixer		
Micro-oven		
Tissue grinder/Pestle mortar/Como-drill		
Refrigerated centrifuge		
Centrifuge		
Water batch		
Others		
Specific equipment for Serological Test		
ELISA Reader with printer		
Microplate Shaker		
Multi channel Pipette		

Specific equipment for Molecular Test		
DNA extraction equipment		
Thermal cycler		
Gel electrophoresis unit (Horizontal) with power pack		
Gel documentation Unit with Printer		
Gel electrophoresis unit (Horizontal) with power pack		
Hybridization oven		
UV cross linker		
Consumable	**Availability (Y/N)**	**Remark by expert Accreditation Committee**
Specific antisera		
Specific primers/marker		
DNA probes		
Part 1 (E)<u>Any other Information</u>		

Part 1 (F)<u>Report of test done and certificate issued to Recognized Tissue Culture Production Facility*</u>					
		1st Year* **(.....)**	**2nd Year*** **(.....)**	**3rd Year*** **(.....)**	**Remark by expert Accreditation Committee**
Number of sample tested for virus indexing	Stock culture/mother plants				
	Tissue culture raised plants				
Number of sample tested report issued	Stock culture/mother plants				
	Tissue culture raised plants				
Number of certificate issued					
Number of certificate issued					
Number of certification labels issued					
Volume of plant certified (detail of certification ,if any)					

Number of sample found positive during virus indexing				
**A copy of Master sheet needs to be enclosed*				

.....

Date: Name &Signature of In-charge Virus testing

Part-2

Note: 1. Part 1 of this assessment form (except last shaded column) to be filled by in-charge genetic fidelity testing. Last column would be filled by expert team while on site assessment.

2. Please enclose a separate sheet, if required.

	Status at the time of Accreditation	**Change, if any**	**Remark by expert Accreditation Committee**
Part 2 (A) <u>Human Resource</u>			
1.Scientists			
A. Molecular Biologist: (i) Name & designation			
Qualification			
Experience			
(ii) Name & designation			
Qualification			
Experience			
2. Technical Personnel			

(i) Name and designation:			
Qualification:			
Experience:			
Relevant previous training, if any			
(ii) Name and designation:			
Qualification:			
Experience:			
Relevant previous training, if any:			
Part 2 (B) <u>Physical Facility</u>			
	Status of compliance as per accreditation	**Current status of compliance**	**Remark by expert Accreditation Committee**
1- Laboratory and office space, dedicated for the facility and enclosed in such way to prevent unauthorized entry			
2 - Facilities to avoid adequate contamination or mixing of samples			

Part 2 (C)Standard Operating Procedures			
		Current status of compliance	**Remark by expert team**
1. Adoption of SOPs including formats and records such as (i) Communication receipt from AU/DBT (ii) Test/certification register (iii)Test reports/certificate (iv) Deployment of label (v) Calibration record of equipments (vi) Internal and external training record (vii) Any other relevant document	Not to be filled by ATL		
2. Fee Charged as per the NCS-TCP norms			
3. Total number of test report issued			
4. Time taken (no. of days) for issuance of test report/certificate (i) Maximum (ii) Minimum (iii) Average			

5. Suggestion for improvement of SOP, if any	

Part 2 (D) <u>Equipments& Procedures</u>

General equipments	**Working condition (Good/ Satisfactory/ Poor)**	**Remark by expert Accreditation Committee**
Digital top pan/Analytical balance		
Deep Freezer -80°C		
Deep Freezer -20°C		
Distilled/RO/Millipore Unit		
Hot plate/Magnetic stirrer		
pH meter		
Conductivity meter		
Autoclave		

Hot air oven		
Laminar flow hoods		
Incubation chambers		
Refrigerator 4°C		
Micropipettes		
Vortex mixer		
Micro-oven		
Tissue grinder/Pestle mortar/Como-drill		
Refrigerated centrifuge		
Centrifuge		
Water batch		
Others		

Specific equipment for Molecular Test		
DNA extraction equipment		
Thermal cycler		
Gel electrophoresis unit (Horizontal) with power pack		
Gel documentation Unit with Printer		
Gel electrophoresis unit (Horizontal) with power pack		
Hybridization oven		
UV cross linker		
Consumable	**Availability (Y/N)**	**Remark by expert Accreditation Committee**
Specific antisera		
Specific primers/marker		

DNA probes		

Part 2 (E)Any other Information

Part 2 (F)Report of test done and certificate issued *

	1st Year* **(……..)**	**2nd Year*** **(……..)**	**3rd Year*** **(……..)**	**Remark by expert team**
Number of sample tested for genetic fidelity				
Number of test report issued				
Number of certificate issued				
Number of certification labels issued				
Volume of plant certified (detail of certification, if any)				
Number of sample showed genetic variation from mother plants				

**A copy of Master sheet needs to be enclosed*

.....

Date: Name &Signature of In-charge Genetic Fidelity Testing

Part –3

(*To be filled by the* Expert Accreditation Committee)

Non-conformities, if any, observed by the expert team

A	Entity: :	Date:
	Registration Number:	
	Area/ Activity:	
	Description of Non-Conformities:	
	Suggested corrective action(s) for each non conformities	

	Time frame to complete corrective action(s):
B	The above nonconformity report has been understood and is being acknowledged here with. Auditee Signature: Date:

	Observation and Recommendation of the Expert Accreditation Committee Whether the ATL is operational: YES ☐ NO ☐ (*If No please specify the reason, for the same.*)

	Additional Suggestion, if any:

	RECOMMENDATION (*Use separate sheet, if required*) 1._____ _____ (Name & Designation of the expert, Accreditation Committee) (Signature /date) 2._____ _____ (Name & Designation of the expert, Accreditation Committee) (Signature /date)

FORMAT FOR ASSESSMENT REPORT FOR RECOGNITION FOR TISSUE CULTURE PRODUCTION FACILITY UNDER NCS-TCP

The Application form covering Self Assessment report will be used by the expert committee during site visit. This form will be supplemented by Part 2 (Corrective action report) and Part 3 (Recommendation part). Format of part 2 and 3 is given below:

PART- 2

CORRECTIVE ACTIONS

(*To be filled in duplicate and one copy to be handed over to the company after site visit*)

Date	Name of organization	Registration Number:
S. No.	List of non-conformities	

S. No.	Additional suggestion/advise of Accreditation Panel (if any):
	Time frame for taking corrective action as per above non conformity (ies):
	Lead Auditor Name& Designation:_____Signature: _____ Auditee The above nonconformity report has been understood and is being acknowledged here with. Name& Designation:_____Signature: _____

Note: The observations/recommendations of Accreditation Panel are subject to approval of Department of Biotechnology, Govt. of India. The final decision would be conveyed in due course of time.

PART-3

RECOMMENDATION OF ACCREDITATION PANEL

(Tick any one)

1) **Recommended for Recognition:** As the company complies with all the mandatory parameters (marked as *****) along with other parameters listed in the assessment form.

2) **Not Recommended for Recognition:** As the company does not comply with even one of the mandatory parameter (marked as *****).

3) **To be considered for Recognition on completion of corrective action (s):** As the company complies with all the mandatory parameters (marked as *****) except non mandatory parameters, company would be advised to complete the corrective actions within one month in order to be considered for recognition under NCS-TCP.

Additional Remark (if any):

1._____ _____

(Name & Designation) (Signature of Auditor/date)

2._____ _____

(Name & Designation) (Signature of Auditor/date)

3._____ _____

(Name & Designation) (Signature of Auditor/date)

FORMAT FOR ASSESSMENT REPORT FOR RENEWAL OF RECOGNITION FOR TISSUE CULTURE PRODUCTION FACILITY UNDER NCS-TCP

The Application form covering Self Assessment report will be used by the expert committee during site visit. This form will be supplemented by Part 2 (Corrective action report) and Part 3 (Recommendation part). Format of part 2 and 3 is given below:

PART-G			
C.	**Standard Operating Procedure (SOPs) in terms of**	**Type of non-conformity observed**	**Suggested corrective Action / prevent measures**
C.1	Minimum organization structure		
C.2	Deviations from the SOPs provided by AU (if yes, please enclose a separate sheet stating that whether the Deviation is justified		

2.	**Additional Information**			
2.1	Crop wise actual production	**Crop**	**Production (Million/annum)**	
			Total	**For Domestic**
2.2	Future projections			
2.3	Any change in the scientific staff and managers since last visit			
2.4	Any expansion in production capacity			

	PART-2
	List of non- conformities observed during the site visit:

	Auditee: The above nonconformity report has been understood and is being acknowledged here with. **Name & Designation:** **Signature:**
	Signature/Name/Designation of Auditors with date: **1.**_____ **2.**_____ **3.** _____

Note: The observations/recommendations of Accreditation Panel are subject to approval of Department of Biotechnology, Govt. of India. The final decision would be conveyed in due course of time.

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RECOMMENDATION OF ACCREDITATION PANEL

(Tick any one)

1) **Recommended for Renewal of Recognition:** As the company complies with all the mandatory parameters (marked as *****) along with other parameters listed in the assessment form.

2) **Not Recommended for Renewal:** As the company does not comply with even one of the mandatory parameter (marked as *****).

3) **To be considered for renewal of Recognition on completion of corrective action (s):** As the company complies with all the mandatory parameters (marked as *****) except non mandatory parameters, company would be advised to complete the corrective actions within one month in order to be considered for renewal of recognition under NCS-TCP.

Additional Remark (if any):

1._____ _____

(Name & Designation) (Signature of Auditor/date)

2._____ _____

(Name & Designation) (Signature of Auditor/date)

3._____ _____

(Name & Designation) (Signature of Auditor/date)

FORMAT FOR ASSESSMENT REPORT FOR RECOGNITION OF HARDENING CENTER UNDER NCS-TCP

The Application form covering Self Assessment report will be used by the expert committee during site visit. This form will be supplemented by Part 2 (Corrective action report) and Part 3 (Recommendation part). Format of part 2 and 3 is given below:

PART-2

CORRECTIVE ACTIONS

(*To be filled in duplicate and one copy to be handed over to the company after site visit*)

Note: The observations/recommendations of Accreditation Panel are subject to approval of Department of Biotechnology, Govt. of India. The final decision would be conveyed in due course of time.

Date	Name of organization	Registration Number:
S. No	List of non-conformities	
S. No	Additional suggestion/advise of Accreditation Panel (if any):	

	Time frame for taking corrective action as per above non conformity (ies):
	Lead Auditor Name& Designation:_____Signature: _____ Auditee The above nonconformity report has been understood and is being acknowledged here with. Name& Designation:_____Signature: _____

PART- 3

RECOMMENDATION OF ACCREDITATION PANEL

(Tick any one)

1) **Recommended for Recognition:** As the company complies with all the mandatory parameters (marked as *****) along with other parameters listed in the assessment form.

2) **Not Recommended for Recognition and suggested to reapply:** As the company does not comply with even one of the mandatory parameter (marked as *****).

3) **To be considered for Recognition on completion of corrective action (s):** As the company complies with all the mandatory parameters (marked as *****) except non mandatory parameters, company would be advised to complete the corrective actions within one month in order to be considered for recognition under NCS-TCP.

Additional Remark (if any):

1._____ _____

(Name & Designation) (Signature of Auditor/date)

Verification Report on corrective actions taken by Test Laboratories for Accreditation under NCS-TCP

Applicant:		Reg. No:
Mailing Address:		
City:	State/Province:	Pin Code:
Tel:	Fax:	E-mail:
Head:		
Audited by: (Name & Designation)		(Signature of Auditor/date)
Dates of Inspection of Facility:		

Verification report on Corrective Action(s)

A	Description of Non-Conformity (ies)	Action taken to correct each Non-Conformity(ies)
B.	Remarks on adequacy of corrective action(s): (Tick any one) • Completed: • Not Completed:	

C.	Recommendation of Expert/Accreditation Panel
D.	Expert/Assessor's Signature: Auditee's Signature:

Verification Report on corrective actions taken by Tissue Culture Production Unit for Recognition under NCS-TCP

Applicant:		Registration. No:
Mailing Address:		
City:	State/Province:	Pin Code:
Tel:	Fax:	E-mail:
Head:		
Verified by: 1. 2. 3.		
Dates of Verification:		

Verification report on Corrective Action(s)

A	Description of Non-Conformity (ies)	Action taken to correct each Non-Conformity(ies)
B.	Remarks on adequacy of corrective action(s): (Tick any one) • Completed: • Not Completed:	
C.	Recommendation of Expert/Accreditation Panel	
D.	Expert/Assessor's Signature: Auditee's Signature:	

Enclosure: 1. Previous Assessment Report/non conformity report
2. Report of corrective actions of company

Verification Report on corrective actions taken by Tissue Culture Production Unit for Recognition of Hardening Center under NCS- TCP

Applicant:		Registration. No:
Mailing Address:		
City:	State/Province:	Pin Code:
Tel:	Fax:	E-mail:
Head:		
Verified by: 1. 2. 3.		
Dates of Verification:		

Verification report on Corrective Action(s)

A	Description of Non-Conformity (ies)	Action taken to correct each Non-Conformity(ies)
B.	Remarks on adequacy of corrective action(s): (Tick any one) • Completed: • Not Completed:	
C.	Recommendation of Expert/Accreditation Panel	
D.	Expert/Assessor's Signature: Auditee's Signature:	

Enclosure: 1. Previous Assessment Report/non conformity report
2. Report of corrective actions of company