

Application for Recognition of Tissue Culture Production Facility
NCS-TCP Form-2

Section 1

Registration No. _____ Date of Registration: _____ (For BCIL office Use only)		
1. Applicant Entity (Institute/Organization)		
Name of organization:		
Location of Tissue Culture Production Facility:		
Location of Hardening Facility (if located in separate location):		
2. Mailing Address:		
H. No.	Street:	Road:
Town/City:	DST/State/UT:	Pin Code:
Tel:	Fax:	Email:
3. Head of the Organization:		
Name & Designation:		Ph. /Mob. no:

4. Laboratory-In charge	
Name & Designation:	Ph./ Mob. no.:
5. Particulars of Laboratory	
Public Sector <i>(tick appropriately)</i>	
- National Laboratories (CSIR/ICAR etc)	<input type="checkbox"/>
- State Funded Laboratories	<input type="checkbox"/>
- Universities	<input type="checkbox"/>
Private Sector <i>(tick appropriately)</i>	
- Public Limited	<input type="checkbox"/>
- Private Limited	<input type="checkbox"/>
- Proprietorship	<input type="checkbox"/>
- Partnership	<input type="checkbox"/>
NGO	
Others	
6. Installed Production Capacity/ Annum	
7. Production of Different Crops in Last Financial Year <i>(No. of plants in millions)</i>	
8. Month and Year of Commencement of Production	
9. Year-wise Annual Turnover in INR (for last three years)	
10. Plant Species Being Multiplied at Commercial Level	
- Domestic Market	
- Export Market (please indicate if it is on buy back arrangement)	

11. Plant Species proposed to be commercialized which are under R&D stage at Present:
12. Number of Staff Engaged in <ul style="list-style-type: none">- Production (Technical and Non-technical)- Research- Supervisor- Marketing
13. Details about name, qualification and relevant experience of technical and research staff up to supervisor level <i>(Please enclose separate sheet)</i>
14. Enclosures to the Application: (i) _____ (ii) _____ (iii) _____
15. 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.

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

Date:

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Place:

Signature /Name/ Designation of Authorized Person

Section-2: General Information:

1. Eligibility Criteria:

- ❖ Any Tissue Culture Production Facility (Public sector, Private sector, NGO and others) engaged in production of Tissue Culture Plants with minimum production capacity of 0.5 million (5 Lakhs) plants per annum.
- ❖ Tissue culture production facility should be fully operational (including all areas of laboratory and hardening facility) at the time of application and site visit.

2. Fee Structure:

Particulars of Fee	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	2000	2000	2000
Inspection and report preparation fee	2000	6000	10000
Processing and Certification fee	5000	5000	5000

NB: (i) Only registration fee need to be submitted at the time of application and other fees such as inspection fee and processing and certification fee would be charged on the later stage of application;

All the fee payment should be made through online transfer:

Beneficiary Name: BCIL Ac NCSTCP
Account No.: 0158201031402
Type of account: Current Account
Bank: Canara Bank
Branch: Deendayal Marg New Delhi
IFSC code: CNRB0000158
Email: ncstcp@biotech.co.in

3. Mandatory 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*

4. Instructions & Guidelines:

- (i) Applicants should apply in separately prescribed formats for recognition/ renewal of recognition.
- (ii) Applicant should submit 5 copies of application to **“NCS-TCP Management Cell”, Biotech Consortium India Limited, 5th Floor, Anuvrat Bhawan, 210 Deendayal Upadhyaya Marg, New Delhi-110002.**

Section III

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

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

Section-III: Part A - Infrastructure

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)	
A1.	<p>*Do you have the following areas clearly demarcated*</p> <ul style="list-style-type: none"> ▪ Washing Room (s) Specify size/area ▪ Media Preparation Room (s) Specify size/area ▪ Media Storage Room (s) Specify size/area ▪ Inoculation Room (s) 				

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	<p>Nos/Specify/size area</p> <ul style="list-style-type: none"> ▪ Growth Room (s) Nos/Specify size/area ▪ Transfer/ grading Room (s) Specify size/area ▪ Acclimatization ▪ Green house/ poly house (s) Nos/Specify size/area ▪ Nursery/ Shade house Area (s) Nos/Specify size/area: 				
A2.	<p>*Do you have restricted entry through change area to the sterile areas consisting of following three areas:</p> <p>i. Media storage room(s)</p>				

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		YES	NO	Descriptive information (Please enclose sheet if required)	
A3.	<p>ii. Inoculation room(s)</p> <p>iii. Growth room(s)</p> <p>*Has the layout of laboratory building planned to avoid crisscross movement of men and materials between sterile and non sterile area</p>				
A4.	<p>*Do you have fire fighting system at your facility (If so, are they maintained regularly)</p> <ul style="list-style-type: none"> ▪ Emergency exit ▪ Path showing strip for emergency exit ▪ Fire Alarm/ Smoke alarm ▪ Fire Extinguisher 				

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A5.	<p>*Do you have power backup arrangement?</p> <p><i>(If so indicate capacity of generator & percentage of power covered by backup generator)</i></p>				
A6.	<p>*Do you have following provisions in change area before entering into sterile areas of tissue culture production facility?</p> <ul style="list-style-type: none"> • Hand and leg washing facility • Air curtain and or/Air shower facility • Dress change cubicle • Dress storage cabinet 				
A7.	<u>Washing Area:</u>				

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)	
	<p>(i) *Do you have dedicated washing room?</p> <p>(ii) *Is washing room connected with the media preparation room for transfer of washed vessel through pass box or a closed corridor?</p> <p>(iii) Do you have availability of running tap water?</p> <p>(iv) Do you have separate basins for keeping glassware at different stages of washing?</p> <p>(v) Do you have provision for separate dipping of jars from the hardening area/infected cultures?</p> <p>(vi) Whether washing is done in close or open area?</p>				

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A8.	<p><u>Media Preparation:</u></p> <p>(i) *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.)</p> <p>(ii) Equipment details:</p> <ul style="list-style-type: none"> - Autoclave <ul style="list-style-type: none"> ▪ Number/capacity ▪ Single door/double door - Other equipments <p>(iii) *Do you have pass box and or/other suitable mechanism for transfer of</p>				

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	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.	<u>Media storage Room:</u> (i) *Are you maintaining class 100,000 sterility level through pressure module/AHU/ HVAC/any other? (in case of any other, please mention the detail of				

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A10.	<p>nature of facility and its effectiveness).</p> <p>(ii) Do you have adequate space for media storage (to store the media for at least 3 days)?</p> <p>(iii) Do you have provision of UV lights in the room?</p> <p>(iv) Do you have plastic paint/water proof emulsion on the wall?</p> <p><u>Inoculation Room</u></p> <p>(i) *Are you maintaining class 100,000 sterility level through pressure</p>				

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	<p>module/AHU/ HVAC/any other? (in case of any other, please mention the detail of nature of facility and its effectiveness).</p> <p>(ii) Do you have plastic paint/water proof emulsion on the wall?</p> <p>(iii) Do you have laminar air flow cabinets fitted with manometers for checking pressure of airflow/hepa filters/UV Germicidal lamp?</p> <p>(iv) Do you use glass bead sterilizer for sterilization of forceps/scalpel?</p>				

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		YES	NO	Descriptive information (Please enclose sheet if required)	
A11.	<p><u>Incubation: Growth room related activities</u></p> <p>(i) *Are you 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.)</p> <p>(ii) Do you have plastic paint/water proof emulsion on the walls</p>				

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A12.	<p><u>Transfer of plantlets from growth room to grading room facility:</u></p> <p>(i) *Do you have dedicated growth room/ transfer area?</p> <p>(ii) 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).</p> <p>(iii) Do you have arrangement of washing of plantlets to remove culture medium?</p> <p>(iv) Do you have organized grading system such as working table with grading scale and or/ pictorial map to facilitate grading of tissue culture plantlets?</p>				

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A13.	<p><u>Primary Hardening Area:</u></p> <p>Mist chamber/Green house/Polyhouse</p> <p>(i) *Do you have insect-proof greenhouse/ polyhouse with double door entry?</p> <p>(ii) *Do you have misting facility in the primary hardening area?</p> <p>(iii) Do you have yellow sticky traps for insect pest monitoring? (at the rate of one sticky trap per 10m²area)</p> <p>(iv) Do you have raised bed/ to avoid contact of roots with ground soil?</p>				

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A14.	<p><u>Secondary hardening Area (Nursery Area)</u></p> <p>(i) *Do you have double door entry to check insect entry?</p> <p>(ii) *Do you have net house(s) covered with appropriate mesh to provide partial shade and without any openings to prevent insect entry?</p> <p>(iii) Do you have yellow sticky traps for insect pest monitoring? (at the rate of one sticky trap per 10m²area)</p> <p>(iv) Do you have raised bed/ to avoid contact of roots with ground soil?</p>				
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)	
B1.	<p><u>Washing Area:</u></p> <p>(i) Is washing done mechanically/manually?</p> <p>(ii) Is cleanliness being maintained?</p> <p>(iii) Is drying of glassware done in ovens or at room Temperature</p>				

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B2.	<p><u>Discarding used agar:</u></p> <p>(i) Do you autoclave the contaminated culture/media? <i>(If no, please specify the procedure of decontamination)</i></p> <p>(ii) Do you treat used agar at site? (If so indicate procedure being followed)</p> <ul style="list-style-type: none"> - Discard at Pit which is to be used as nutrient for bio-fertilizer and or/ - Municipal garbage 				

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B3.	<p><u>Media Preparation:</u></p> <p>(i) Do you appropriately label the individual jar/tray?</p> <p>(ii) Do you use the AR/tissue culture grade chemicals?</p>				
B4.	<p><u>Media Storage Room:</u></p> <p>(i) Do you undertake regular particle count (at 6 months' interval) to support maintenance of class 1, 00, 000 sterility level?</p> <p>(ii) Do you monitor the airborne microbe through microbial plating? If so, its frequency.</p>				

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		YES	NO	Descriptive information (Please enclose sheet if required)	
B5.	<p>(iii) Do you fumigate the room periodically with the sterilant. If so indicate frequency?</p> <p>(iv) Range of number of days (minimum 3-4 days)for which media is stored prior to inoculation</p> <p><u>Inoculation Room:</u></p> <p>(i) Do you under take regular particle count (at six months' interval) to support maintenance of class 1, 00, 000 sterility level?</p> <p>(ii) Do you fumigate the room periodically with the</p>				

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		YES	NO	Descriptive information (Please enclose sheet if required)	
	<p>sterilant. If so indicate frequency?</p> <p>(iii) Do you monitor the airborne microbe through microbial plating? If so, its frequency?</p> <p>(iv) Are you following the maintenance schedule for laminar air-flow cabinets?</p> <ul style="list-style-type: none"> - Cleaning of pre-filters - Checking air flow - Checking efficiency of HEPA filters by exposing plates <p>(v) Do you fumigate the room periodically with the sterilant?</p>				

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B6.	<p><u>Incubation (Growth) room:</u></p> <p>(i) Do you undertake regular particle count (six months interval) to support maintenance of class 1, 00, 000 sterility level?</p> <p>(ii) Do you monitor the airborne microbe through microbial plating? If so, its frequency.</p> <p>(iii) Is the temperature in the growth room maintained uniform?</p> <p>(iv) Do you fumigate the room periodically with the sterilant? If so frequency.</p>				

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B7.	<p><u>Transfer/Grading Room</u></p> <p>(i) Do you undertake regular grading of the plantlets according to specific criteria established for each plant species?</p>				
B8.	<p><u>Primary hardening (Mist chamber/Green house/Poly house)</u></p> <p>(i) Do you monitor plants for their growth & any other feature?</p> <p>(ii) Do you monitor insect vector species through yellow stick cards?</p> <p>(iii) Do you monitor the temp/humidity/light intensity?</p>				

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B8.	<p>(iv) Do you label individual hardening trays conveying the details of number of plants, date of transfer, batch number etc.?</p> <p>(v) Do you use potable water/ good quality water for watering of plant lets. Please specify the TDS level.</p> <p>(vi) Do you avoid excessive watering and water-logging with drainage system</p>				

S. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
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B9.	<p><u>Secondary Hardening (Nursery) Area</u></p> <p>(i) Has the production of tissue culture raised plants reached to secondary hardening stage?</p> <p>(ii) Do you use potable water/ good quality water for watering of plants? Please specify the TDS level.</p> <p>(iii) Do you monitor plants for their growth or any other feature?</p> <p>(iv) Do you monitor the insect vectors by yellow stick traps?</p> <p>(v) Do you label individual batch conveying the details of number of plants, date of transfer, batch number and batch size etc.</p>				

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		YES	NO	Descriptive information (Please enclose sheet if required)	
	(vi) Do you avoid excessive watering and water-logging with drainage system (vii) Do you undertake regular weeding and removal of dead plants				
Section-III: Part C- Quality Practices					
C1.	<u>Multiplication cycle</u> (i) Are you restricting number of multiplication cycles? (ii) Are you strictly monitoring the procedures while transferring plantlets from: <ul style="list-style-type: none"> - Growth room to transfer area - Greenhouse to shade area - At the time of dispatch 				

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C2.	<p><u>Overall Quality of Plants</u></p> <p>(i) Do you ensure that plants are fully hardened and transplantable size at the time of dispatch</p> <p>(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</p> <p>(iii) Do you provide handout to the farmers along with plants covering the package of practices for cultivation of particular species</p>				

S. No.	Particulars	Self Assessment By the Applicant			Comments of the experts committee during on-site visit
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Section-III: Part D - Human Resource and Manpower					
D1.	Competent technical supervision and effective monitoring of entire production process: <i>Indicate management/operational structure & their qualification. Please also specify their role & responsibilities</i>				
D2.	Do you have accountable in-charge/supervisor for at least lab facilities and hardening facilities?				
D3.	Do you provide regular training to the supervisor/operators? <i>If so, internal training or external training)</i>				

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Section-III: Part E - Overall Quality Management and Certification					
E1.	<p><u>Mother plant and Explant material</u></p> <p>(i) <i>*Are you sending the stock cultures/mother plants procured locally for virus testing for all the known viruses? If so, details of the lab where testing is done.</i></p> <p>(ii) <i>*Are you importing stock cultures from outside sources? If yes, Give the details of import of culture and phytosanitary certification; and laboratory testing for viruses after its import.)</i></p>				

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E2.	<p><u>Plant Certification</u> (advisable during first application and Mandatory in case of Renewal)</p> <p>(i) Are you getting virus indexing of tissue culture raised plants done batch-wise? <i>If yes, give details of the laboratory where this testing is done.</i></p> <p>(ii) Are you getting the genetic fidelity testing done through molecular markers? (If yes Give details of testing viz., name of laboratory/test results)</p>				

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Section-III: Part F -Reporting System, documentation					
F1.	<p><u>Mother plant and Explant material:</u></p> <p>(i) Do you have clearly defined criteria (species wise) for the selection of elite plants?</p> <p>(ii) Do you keep proper record for mother stock (such as unique code no. and passport data of the mother plant)?</p>				
F2.	<p><u>Discard of used agar:</u></p> <p>(i) Do you keep record of decontamination/autoclaving of infected cultures?</p> <p>(ii) Do you keep record of discarding of agar?</p>				

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F3.	<p><u>Media Preparation:</u></p> <p>(i) Are you keeping calibration record (at annual basis) of all analytical and measuring equipments?</p> <p>(ii) Are you keeping proper records for?</p> <ul style="list-style-type: none"> - Stock solution preparation - Media preparation - Autoclave cycle <p>(iii) Do you give emphasis on efficiency of the operators engaged in media preparation (volume, number of jars, wastage etc.?)</p>				

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F4.	<p><u>Media storage Room:</u></p> <p>(i) Do you maintain particle count data in support of sterility class 100,000?</p> <p>(ii) Do you maintain record for monitoring of the airborne microbe through microbial plating?</p> <p>(iii) Do you keep record of routine screening of media for any contamination?</p> <p>(iv) Do you maintain record for fumigating the room periodically with the sterilant?</p>				

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F5.	<p><u>Inoculation Room</u></p> <p>(i) Do you maintain particle count data in support of sterility class 100,000?</p> <p>(ii) Do you maintain record for monitoring of the airborne microbe through microbial plating?</p> <p>(iii) Do you maintain records for fumigating the room periodically with the sterilant?</p> <p>(iv) Do you maintain record keeping for:</p> <ul style="list-style-type: none"> - Efficiency of operators (through monitoring number of jars handled, multiplication rate, contamination losses, rooting percentage and general health of the culture etc.) 				

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	- Calculating multiplication fold at the end of each passage				
F6.	<p><u>Incubation/Growth room:</u></p> <p>(i) Do you maintain particle count data in support of sterility class 100,000?</p> <p>(ii) Do you maintain record for:</p> <ul style="list-style-type: none"> - Contaminated cultures - Continuous temperature recording device - Light intensity/duration <p>(iii) Do you make production schedules based on the protocol efficiency?</p>				
F7.	<p><u>Primary Hardening Area (Mist chamber, Green house/Poly house):</u></p> <p>(i) Do you keep record of number of plant lets transferred/dead plants maintained batch-wise</p> <p>(ii) Do you maintain record of any treatments given</p>				

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F8.	<p>to the plants (fertilizer applications/ insecticide/fungicidal; sprays etc)?</p> <p>(iii) Do you maintain record of incidence of insect pests/diseases/vectors?</p> <p><u>Secondary hardening Area (Nursery):</u></p> <p>(i) Do you keep record of number of plants transferred/dead plants maintained batch-wise</p> <p>(ii) Do you maintain record of any treatments given to the plants (fertilizer applications; insecticidal/fungicidal sprays etc)?</p>				

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F9.	<p>(iii) Do you maintain record of incidence of insect pests/diseases/vectors?</p> <p><u>Farmer's Advisory/Feed back:</u></p> <p>(i) Do you provide printed leaf lets regarding package of practices for cultivation of tissue culture raised plants?</p> <p>(ii) Do you maintain record of farmers' feedback/data regarding field performance of tissue culture raised plants (if any)?</p> <p>(iii) Do you maintain unique code for each batch of production to trace back history of tissue culture plants supplied to farmers?</p>				