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National Certification System for Tissue Culture Raised Plants (NCS-TCP) as the Unique Quality Management System for Plant Tissue Culture Sector: Its Inception, Evolution, Impact and way Forward

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Abstract: With rapid expansion of commercial tissue culture sector in the country, need was felt by Government of India to support this sector in ensuring quality of tissue culture plants through a well-organized robust quality management system. Accordingly, National Certification System for Tissue Culture Plants (NCS-TCP) was initiated by Department of Biotechnology (DBT), Government of India in year 2006 in line with gazette notification under the Seeds Act 1966. DBT was authorized as the Certification Agency for the purpose for certification of the tissue culture-raised propagules up to laboratory level and regulating its genetic fidelity. Various components of NCS-TCP namely Management Cell, Accredited Test Laboratories and Referral Centres were identified and operationalized. NCS-TCP is the first of its kind in the world and no other country has such organized system in place for certification of tissue culture plants. Biotech Consortium India Limited (BCIL) is assisting DBT in implementation of NCS-TCP since its inception. Over the one decade of its journey, NCS-TCP has become an effective and well established programme through attaining its objectives and gaining acceptance among stakeholders.

NCS-TCP has received a very enthusiastic response from the industry. In spite of the fact that the Recognition of companies under the NCS-TCP is not mandatory for the sale of tissue culture plants, majority of the leading tissue culture companies have got themselves recognized under this system. In addition to providing a mechanism for testing and supply of good quality planting material cost effectively, this system has had a significant impact in terms of strengthening the capacities of tissue culture companies, enhancing their visibility and market reach. NCS-TCP as the Quality management system for certification

of quality tissue culture raised plants has proved robust tool for facilitating healthy growth of Indian micro propagation industry.

This article aims at creating widespread awareness about the NCS-TCP.

Key words: certification, NCS-TCP, micro propagation, quality management system

1. INTRODUCTION

Micropropagation is the true to type propagation of selected clone using *in vitro* culture techniques. [1] It has been applied successfully to the production of more than 1000 species. Though in case of micro propagation, cost of production is higher than the other methods of vegetative propagation. The relatively high production cost of *in vitro* micro propagation compared with the conventional methods of propagation are compensated by the several benefits: (a) rapid propagation because of short propagation cycle (b) large volume propagation of high value ornamentals like orchids shrubs and trees (c) easy storage and transport of large number of plants (d) plant production independent of seasons (e) quick supply of plants with the change in demand. [2] Production of virus-free planting material is an ideal strategy to confine viruses and also to facilitate the movement of materials across the domestic and international boundaries. In order to minimise the risk of inadvertent propagation of virus infected plants and introduction of somaclonal variability, tissue culture raised plants need to be thoroughly indexed for freedom from viruses and checked for its true to typeness.

Commercialization of micropropagation was started in USA in 1970s for large scale propagation of orchids. Though the Indian micro propagation industry came into existence in late 1980s, it has expanded exponentially from 0.5 million annual capacity in 1988 to 190 million in 1996[3]. It has not grown at this pace in next 10 years i.e. from 1996 to 2005 as slight decline in the total installed capacity was reported. As per the market survey conducted by BCIL in 2006, 46 established operational

commercial tissue culture units were operational with an aggregate production capacity of 180 million plantlets per year. [4] In order to assist the Indian Plant Tissue Culture Sector, it was needed to identify gaps hindering the growth and provide the solution for advancement of this industry.

2. INCEPTION OF NCS-TCP

Although there are many technological constraints such as requirement of advance skill and special equipment/facility, labour intensive work, storage and logistics, short shelf life, contamination and mortality, but there was need for a robust quality management system focussing on two main crucial factors in commercial operation namely (i) freedom from viruses and (ii) true to type progeny plants. In the absence of any of these two characters the tissue culture raised plants are not acceptable to the farmers and it also poses threat of undesirable spread of viruses and distribution of substandard quality of plants. In order to minimize the risk of inadvertent micro propagation of virus infected plants and introduction of somaclonal variability, a tissue culture raised plant need to be thoroughly indexed for freedom from viruses and checked for quality. Considering the aforesaid fact Department of Biotechnology (DBT), Government of India undertook responsibility as Tissue Culture Certification Agency (TCCA) under the section 8 of the Seeds Act, 1966 (54 of 1966), Accordingly, DBT has established National Certification System for Tissue Culture Raised Plants (NCS-TCP) in the country. It was also noteworthy that prior to this initiative, the Department of Biotechnology, Government of India had established "National

Facility of Virus Diagnosis and Quality Control” a multi-Institutional collaborative programme with the goal of ensuring production of virus-free plants through tissue culture. The main centre was at ICAR-IARI, New Delhi with five satellite research centres located at various part of country. [5] NCS-TCP is a unique quality management system for tissue culture industry, which is first of its kind in the world. It is very comprehensive system involving many components for its effective implementation namely NCS-TCP Management Cell at Biotech Consortium India Limited (BCIL), two Referral Centres, and

Accredited Test Laboratories (ATLs). Recognized Tissue Culture Production Facilities are responsible for production and distribution of certified quality tissue culture plants through NCS-TCP.

3. ORGANIZATION STRUCTURE OF NCS-TCP AND ROLE/ RESPONSIBILITY IN BRIEF

NCS TCP is well organized and consists of various components for smooth functioning of the certification programme. The organization structure of NCS TCP is mentioned below at Figure 1.

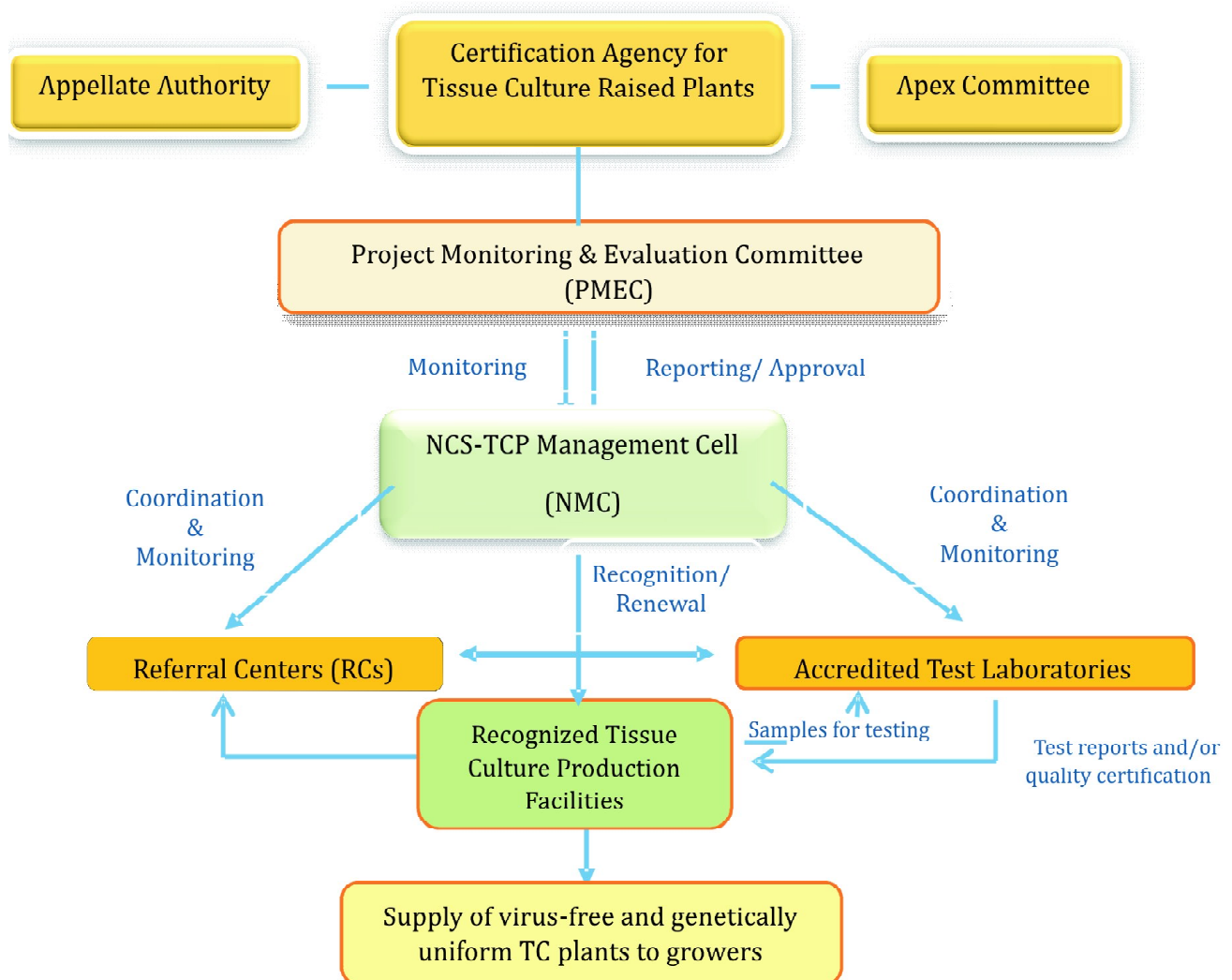


Figure 1: Organization structure of NCS-TCP (source- www.dbtncstcp.nic.in)

Responsibility of various components of NCS-TCP

- **Department of Biotechnology (DBT):** DBT ensures successful implementation of NCS-TCP in the country. DBT Recognizes to tissue culture companies and accredits Test Laboratories based on the conformity with NCS-TCP guidelines. Accredited Test Laboratories certifies tissue culture plants of recognized tissue culture companies on behalf of DBT. Thus, DBT is overall responsible for smooth operation of NCS-TCP.
- **Biotech Consortium India Limited (BCIL):** BCIL assists DBT in implementation of NCS-TCP as the Management Cell. BCIL is assisting DBT in Accreditation of Test Laboratories and Recognition of Tissue Culture Production Facilities. BCIL also coordinates the various components and monitoring the activities of Accredited Test Laboratories and Recognized Tissue Culture Companies.
- **Referral Laboratories:** Referral laboratories are responsible for developing protocols and providing technical guidance to Accredited Test Laboratories. Referral Laboratory also performs conformity test in case of dispute on result of the test conducted. There are two Referral laboratories (i) Referral Center for Virus Diagnosis – Division of Plant Pathology, Indian Agriculture Research Institute (IARI), New Delhi and (ii) Referral Centers for Genetic Fidelity – ICAR – National Research Centre for Plant Biotechnology, New Delhi.
- **Accredited Test Laboratories (ATLs):** ATLs test and certify tissue culture plants of recognized tissue culture production facilities. Based on the Test Report, each Accredited Test Laboratories are authorized to issue the “Certificate of Quality” for the tissue culture raised plants (CQ-TCP) on behalf of the Certification Agency. Currently five Accredited

Test Laboratories are operational in the country housed at Central Potato Research Institute (CPRI), Shimla, University of Agricultural Science (UAS), GKVK, Bangalore, Vasandatdada Sugar Institute (VSI), Pune, Indian Institute of Sugarcane Research (IISR), Lucknow and NRC Banana (NRCB), Trichy.

- **Recognized Tissue Culture Companies:** Companies recognized under the system have the responsibility to adopt the NCS-TCP guidelines and Standard Operating Procedures (SOPs) in order to produce and distribute quality tissue culture plants to the farmers. Currently 87 tissue culture companies are recognized under NCS-TCP.

The entire system works under active supervision of Project Monitoring and Evaluation Committee (PMEC). Approval on Guidelines and its revisions, SOPs and policy decision is granted by the Apex Committee. In addition to the above, there is panel of eminent experts who joins the site visit on invitation of NCS-TCP Management Cell for on-site assessment of tissue culture companies for the purpose of recognition and subsequent renewals

4. PROGRESS MADE IN LAST 10 YEARS

- **Recognition:** Process of recognition started in February 2007. Number of recognized tissue culture company reached a milestone of 100 in year 2015. Although the recognition was not mandatory, almost all the leading tissue culture companies got themselves recognized. Number has declined in last two years since renewal was granted to only those companies which complied with batch certification as per the NCS-TCP guidelines. Some of the companies didn't initiate batch certification and their recognitions were not approved while renewal. **Figure 2** depicts the trend for recognition of tissue culture companies under NCS-TCP.

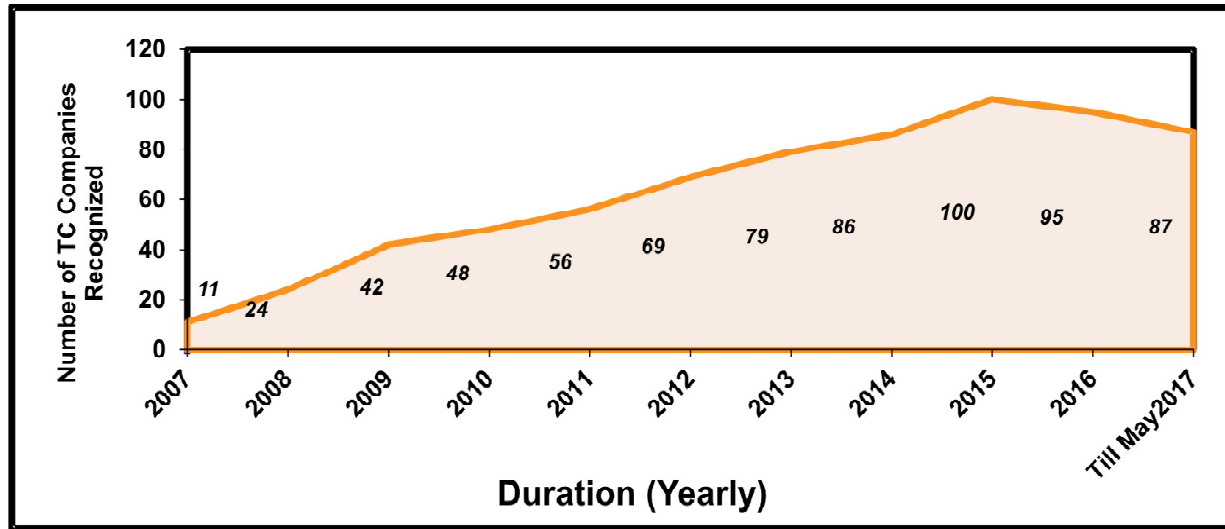


Figure 2: Number of companies recognized TCPFs since 2007

Recognized companies are spread across the country except states where commercial tissue culture units are not present or operational. Cluster of these companies are located in Maharashtra, Gujrat and Karnataka. Location of recognized tissue culture facilities and accredited test laboratories are illustrated at Figure 3.

- **Significant volume for testing of stock culture**

As per the NCS-TCP Guidelines, indexing of explants/stock culture for all the known viruses for particular plant is required prior to mass multiplication. It is desired to adopt the same by the recognized companies. Moreover, new applicants get recognition if they start testing of viruses for stock culture. Batch of tissue culture plants of recognized companies is certified if the explants/stock culture (from which batch is derived) was tested for viruses. So far, more than 80000 samples of stock culture/explants have been tested.

- **Certification of tissue culture raised plants**

Tissue culture companies after getting recognized under NCS-TCP become eligible for certifying their batch of tissue culture plants from any Accredited Test Laboratories under NCS-TCP. It is the utmost responsibility of recognized companies to distribute certified plants to grower. Maintaining batch with unique code number is important so that there should be traceability from selection of mother plants upto dispatch. Certification of tissue plants

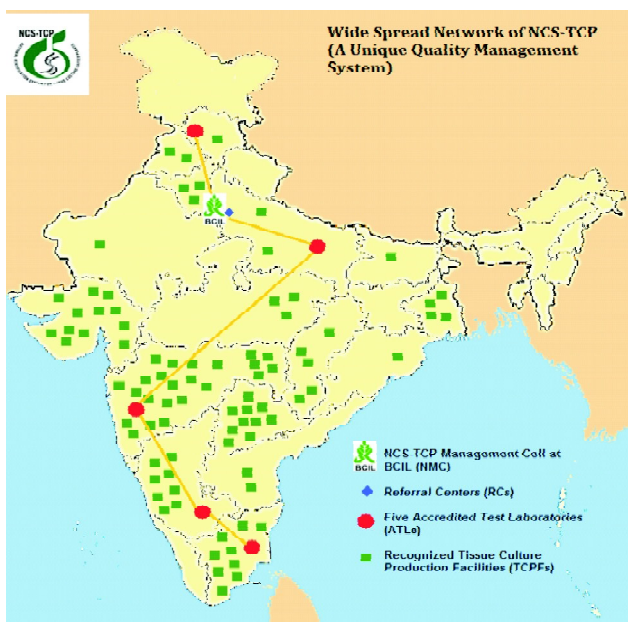


Figure 3: Widespread network of NCS-TCP indicating cluster of recognized companies

culture plants along with certification label was initiated in year 2013. Now the complete procedure and system is in place.

Increasing volume of plant certification by the recognized companies is highly encouraging. More than 175 million (largely banana) tissue

culture plants have been certified after operationalization of certification activity in year 2013-14. Recently demand for plant certification has picked-up significantly and more than 100 million plants have been certified in FY 2016-17 only (**Figure 4**).

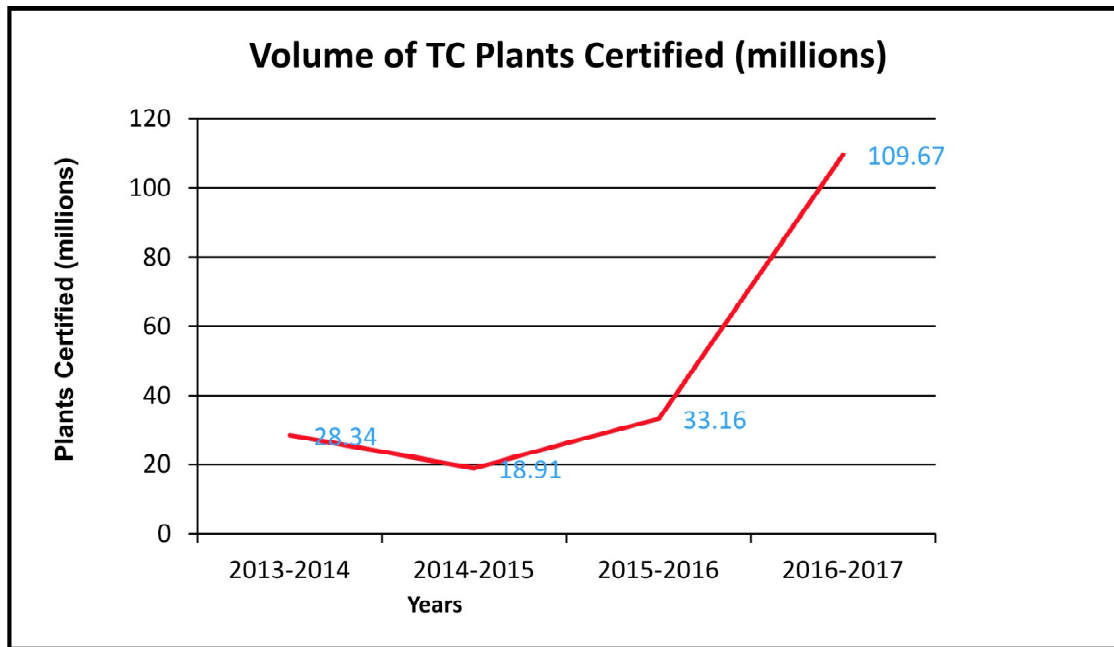


Figure 4: Increasing volume of plant certification

It is noteworthy fact that there has been no major virus outbreak in the last 10 years since the inception of the NCS-TCP in the country.

^[6] This outcome is due to increased number of stock testing and plant certification.

- **NCS-TCP guidelines**

The approved guidelines are in place which provides the requirements and procedures for Accreditation of Test Laboratories for virus diagnosis and genetic fidelity testing of tissue culture raised plants and Recognition of TCPFs. It also includes the standard criteria for Accreditation and Recognition of TCPFs, mechanism of grievance redressal and other procedural requirements.

- **SOPs for TCPFs and ATLS**

Standard Operating Procedures (SOPs) covering all the aspects of commercial tissue culture plant production has been developed and circulated to all Recognized tissue culture production facilities for ensuring Quality Management System. The standard process for production of tissue culture plants and formats for record keeping has also been devised in the SOPs. Similarly, SOPs for ATLS provide guidance for the Accredited Test Laboratories involved in virus/genetic fidelity testing and certification of tissue culture raised plants. The procedure for handling samples received from TCPFs has been described in details

- **Logo for NCS-TCP and Certification Label**

The logo of NCS-TCP has been registered under the Trade Mark Act, 1999 of the Government of India. This logo is the mark of quality in the area of plant tissue culture. It gives the enhanced visibility to the system.

The labels for Certified Tissue Culture Raised Quality Plants provides all the necessary information such as the name and address of the production facility where the plants has been produced, name of the contact person, Recognition number with validity, number of Certificate of Quality, botanical name and common name of the plant, batch number and batch size of the plants, stage of the tissue culture plants, name and details of the Label also contains barcode which provides all the information of testing with complete traceability.

- **Awareness at end user level**

The success of the certification of tissue culture raised plants depends on acceptance of the system by end users i.e. the farmers. Total 20 awareness programmes under NCS-TCP has been organized so far to popularize the system. This awareness programmes increased interest from companies for Recognition under NCS-TCP by Better interpretation of the Guidelines and criteria. Due to increased awareness, now progressive farmers are giving due attention to procure certified tissue culture plants from only Recognized tissue culture companies.

5. IMPACT OF NCS-TCP

The NCS-TCP has made significant impact in the last one decade of its implementation. The recognized companies are eligible for getting their planting material certified from the Accredited Test Laboratories. All these companies have adopted the Guidelines and Standard Operating Procedures

which ensure production of quality tissue culture plants. More than 90% of tissue culture companies have become a part of this programme ^[7].

The impact of NCS-TCP is evident in the following segments:

5.1. Capacity building

NCS-TCP provides guidance to entrepreneurs on establishment and operation of tissue culture facility as per the standards which facilitates production of quality tissue culture plants efficiently. ^[8] The process of Recognition of the Tissue Culture Production Facilities helps the tissue culture companies to improve their facility and adopt good manufacturing practices. During the site visits, the expert members find out the various non-conformities and suggest improvements for conformity with the standard guidelines. This helps them to ensure production of good quality tissue culture raised plants. Quality management system (QMS) has proved key factor for the healthy growth of this sector. ^[9]

5.2. Visibility at national level and facilitating increase in market reach

The “Certificate of Recognition” gives the company an edge over non-recognized companies in term of authentication of production process and quality of the plants. Even the small scale Recognized tissue culture companies may compete with big players as they also conform to the quality standards laid down by the Government of India. This helps in increasing the visibility resulting into increased market reach.

5.3. Healthy Growth of Tissue Culture Sector

After year 2006, this sector has witnessed exponential growth in terms of number of new units, gross production capacity and introduction of various new crops. Now, there are more than 150 commercial units in this field with the production capacity ranging from 0.5 million to 70 million plants per annum. The current cumulative annual production capacity of

micropropagation companies of India more than 500 million plants per annum. Commercialized crops include 70 % banana (mostly for domestic market), 20 % ornamental (mostly for export markets) and remaining covers potato, sugarcane etc.

The growth is driven by the acceptability of tissue culture plants resulting in good market scenario and supports extended by the Department of Biotechnology (DBT), Govt of India by creating conducive environment through the certification programme known as NCS-TCP.^[9]

In addition to the above major benefits, the following impacts have also been observed:

- The tissue culture industry particularly the recognized companies are well organized which facilitate healthy interaction among companies and concerned stakeholders for various issues pertaining to the quality.
- It was found from interaction with research institutes and companies that number of complaints from farmers have been decreased since last few years. However, this needs to be studied systematically.
- Recognition under NCS-TCP is also helping in international visibility paving the way for international collaborations.
- The concept of documentation and records maintenance has been established through this programme. This is helping the recognized companies in traceability of the history of end products.^[11]

6. WAY FORWARDS

- Standards to be developed for new crops which are introduced commercially time to time.
- Trait specific markers particularly for off-type should be developed and adopted by Accredited Test Laboratories.

- Regular training programme/consultation needs to be conducted at various level such as test laboratories, industry and farmers.
- Applications for recognition, renewal of recognition and certification should be processed online for expeditious operation and transparent services in time bound manner.
- Need for skill development to be addressed.

7. CONCLUSION

NCS-TCP is unique quality management system for plant tissue culture industry. It has not only facilitated production and distribution of quality planting materials but also provided platform for concerned stakeholders to work in close coordination for betterment of tissue culture industry and benefit of farmers.

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