

Questions and Answers
on
Quality Management Systems (QMS)
required for CSGA certification of Breeder seed crops

- **Q.:** **WHEN** will the audit requirement be put in place for Breeder status seed crops, certified by the CSGA, to be produced within an audited Quality Management System (QMS) ?
 - **A.:** This QMS audit or assessment requirement is in place for all Breeder seed plots, issued CSGA crop certificates, that are produced in the 2004 “crop year” in Canada.
For winter multiplications (usually outside of Canada) Breeder seed crop certificates would not be subject to this QMS audit requirement until the winter & spring of 2005.
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- **Q.:** **HOW** will the assessment process work?
 - A.:** As outlined in discussions with Plant Breeders over the past two years, when applying for certification, **CSGA’s “Application for Breeder Seed Crop Certificate” (Form 43) asks Plant Breeders to declare:**
 - a) If the Breeder Seed was produced within an audited Quality Management System (QMS);**
 - b) The date of the last audit; and**
 - c) The name of the auditor.**
 - **Q.:** **HOW** will the assessment process work?
Will CSGA have to “approve” Quality Manuals ?
 - **A.:** CSGA will NOT be “approving” Quality Manuals. Plant Breeders are responsible for their own Quality Manuals that describe varietal identity preservation measures.
After two years of extensive discussions, CSGA sent this Fall in 2003, and will send again next Spring in 2004, the following information to seed companies and Plant Breeders:
 - 1. revised “*Canadian Regulations and Procedures for Breeder Seed Crops – August 2003*”;
 - 2. CSGA’s “ASSESSMENT CHECKLIST” for Breeder Seed Production Quality Management Systems (QMS) that includes recommended Quality Manual Elements;
 - 3. “Q.’s & A.’s on Assessments” of Breeder Seed Production QMS; and
 - 4. references to quality management document templates and assessment services available from the Canadian Seed Institute (CSI).
 - **Q.:** **HOW** will the assessment process work?
What is an acceptable pass on the Quality Manual and Assessment ?
 - **A.:** The CSGA-recognized professional Plant Breeders are responsible for ensuring that:
 - 1. “Quality Manuals accurately describe each Element’s procedures”; and
 - 2. “Records are kept which verify that the procedures are being followed”.Plant Breeders develop their own Quality Manuals. The CSGA’s “ASSESSMENT CHECKLIST for Breeder Seed Production Quality Management System (QMS)” contains the Elements or sections that Plant Breeders recommended for Quality Manuals. The assessment or audit verifies for CSGA and the Plant Breeder simply that, for assessed Element(s), the Quality Manual describes varietal preservation procedures, and that Records exist to verify that the procedures were followed.
When applying for certification, **CSGA’s “Application for Breeder Seed Crop Certificate” (Form 43) asks Plant Breeders to declare:**
 - a) If the Breeder Seed was produced within an audited Quality Management System (QMS);**
 - b) The date of the last audit; and**
 - c) The name of the auditor.**

- **Q.:** **HOW** will the assessment process work?
Who determines a pass / fail ? Does CSI or CSGA or the Plant Breeder decide?

- **A.:** CSI's assessors provide conformity verification assessment services (normally for Approved Conditioners to verify compliance with federal Seeds Regulations) in this case for Plant Breeders to verify compliance with CSGA's Regulations for Breeder seed crop certification.

Federal Seeds Regulations prescribe that CSGA sets the standards for pedigreed seed crop certification, so CSGA (with expert technical advice from CSGA's Plant Breeders' and Standards Committees) interprets compliance with the standards for Breeder seed crop certification. In this case, compliance requires the Plant Breeder to provide evidence to CSGA that the Breeder plot being certified was produced within an audited QMS.

CSGA will audit "ASSESSMENT CHECKLISTS" as required but Plant Breeders will be responsible for implementing any corrective actions identified by assessments of their QMS.

- **Q.:** **WHO** are the **Assessors** trained to provide the auditing service for this requirement?

- **A.:** For third party auditing, CSI assessors are trained and accredited to do the Document and Record verification required for these assessments.

A national list of CSI Accredited Assessors is available at:

http://www.csi-ics.com/en/docs/Assessor%20List_Mar%2006.pdf .

If required, the CSGA may confirm, with the recognized Plant Breeder involved, the qualifications of other QMS assessors as well.

- **Q.:** What will be the **FEES** for this assessment ?
- **A.:** Plant Breeders should contact assessors directly as fees vary considerably among these independent assessors depending on the specific auditing situation.

- **Q.:** **OUTSIDE of Canada**, what are the requirements for Breeder seed production for CSGA certification?

- **A.:** Most of the Plant Breeders involved, in production of CSGA-certified Breeder plots outside of Canada, also produce Breeder seed crops for CSGA certification within Canada. Most of them expect to have their records available for the foreign production, that they have inspected themselves or supervised the inspection of, at the same time as their Canadian production documents are assessed. This would also reduce their assessment fees.

For exceptional situations where CSGA-recognized Plant Breeders only produce Breeder seed crops outside of Canada, representatives from member agencies of the Association of Official Seed Certifying Agencies (AOSCA) have agreed that, with CSGA's recommended "ASSESSMENT CHECKLIST", most AOSCA agencies could provide the third party audit service that is required.