

Questions and Answers
Quality Management Systems (QMS)
Required for CSGA Certification of Breeder Seed Crops

- **Q. WHEN** was the requirement put in place for Breeder status seed crops, certified by the CSGA, to be produced within an audited Quality Management System (QMS)?
- **A.** The QMS audit or assessment requirement was in place for all Breeder seed plots, which were issued CSGA crop certificates, produced in the 2004 crop year in Canada.
For winter multiplications (usually outside of Canada) Breeder seed crop certificates were not subject to this QMS audit requirement until the winter and spring of 2005.

- **Q. WHEN** is the requirement taking place for Breeder status seed crops, certified by the CSGA, to be produced within a third-party audited Quality Management System (QMS)?
- **A.** The requirement for third-party audits or assessments of the QMS is in place for all Breeder seed plots in Canada that are issued CSGA crop certificates in the 2007 crop year.
For winter multiplications (usually outside of Canada) Breeder seed crop certificates issued in the winter and spring of 2008 would be subject to this QMS audit requirement.

- **Q. HOW** will the audit or assessment process work?
- **A.** As outlined in extensive discussions with Plant Breeders, when applying for certification on CSGA's ***Application for Breeder Seed Crop Certificate (Form 43)***, (available at: <http://www.seedgrowers.ca/cropcertification/breederseed.asp?lang=e>)
Plant Breeders are asked to declare:
 - a) if the Breeder Seed was produced within a third-party audited Quality Management System (QMS);
 - b) the date of the last audit; and
 - c) the name of the auditor.

- **Q. WHO** are the third-party **auditors or assessors** qualified to provide audits for this CSGA requirement?
- **A.** For CSGA Breeder seed crop QMS audits:
Third-party auditor means: "a person who is independent of those who provide as well as those who use the (audited) product or service". Definition reference for third-party includes ISO Guides 65 and 39, as well as, ISO 17000.
Qualified auditors include QMS assessors from the Canadian Seed Institute (CSI), who have been trained to conduct CSGA Breeder seed crop QMS audits, and experienced third-party auditors who have completed ISO Lead Auditor Training recognized by RABSQA International or the International Register of Certificated Auditors (IRCA), the two major certification bodies for ISO auditors.

Note: CSI assessors have been specifically trained for the document and record verification required for Breeder seed crop QMS assessments.

A national list of CSI accredited assessors is available at:
http://www.csi-ics.com/pdfs/Assessor%20List_Seed.pdf

- **Q. HOW will the audit or assessment process work? Will CSGA have to approve quality manuals?**
- **A.** No, CSGA will NOT be approving quality manuals. Plant Breeders are responsible for their own quality manuals that describe varietal identity preservation measures.
After several years of extensive discussions, CSGA sent the following information, in fall 2003 and spring 2004, to seed companies in Canada and to all CSGA recognized 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 (available at: http://www.seedgrowers.ca/pdfs/forms/Breeder%20QMS_CropCert-Assessment-CHECKLIST_English_20060207..pdf)
 3. *Q's and A's on Assessments of Breeder Seed Production QMS*
 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 those 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 that, for assessed element(s), the quality manual describes varietal preservation procedures, and that records exist to verify that the procedures were followed.

- **Q. HOW will the audit or assessment process work? Who determines a pass or fail? Does the assessor, 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) 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 are responsible for implementing any corrective actions identified by assessments of their QMS.

- **Q.** What are the **fees** for a third-party audit or assessment?
- **A.** Plant Breeders should contact assessors directly as fees vary considerably among independent assessors depending on the specific audit situation.

- **Q.** **Outside of Canada**, what are the requirements for Breeder seed production for CSGA certification?
- **A.** Most 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*, available at: http://www.seedgrowers.ca/pdfs/forms/Breeder%20QMS_CropCert-Assessment-CHECKLIST_English_20060207..pdf, most AOSCA agencies could provide the third-party audit service that is required.