INTRODUCTION

Purpose

This document provides general guidance for the development of quality management practices for use in the development and production of seed products intended for food, feed, fiber or fuel use. The scope of this document encompasses guidance for the maintenance of product integrity and purity of both biotechnology-derived seed and non-biotechnology seed. Product integrity and product purity are defined, for the purposes of this Guide, in the Terms and Acronyms section. Due to its importance in seed quality management, the Guide also includes quality management processes that address plant pests and pathogens. The term "phytosanitary" is used throughout the Guide in regard to all measures and processes that prevent or control plant pests and pathogens which may affect seed quality, seed movement, and/or their introduction into new geographies.

This Guide is intended to serve as a reference document for companies developing individual quality management practices, operating procedures and disciplines consistent with the respective research, development and seed production systems of the entities involved. In determining how best to use this Guide, companies should consider the needs of the market place and customer demands so that the appropriate practices and procedures become a normal part of the business process. This Guide is structured to be interactive. Companies may choose to refer to the entire Guide or specific sections of the Guide (see section on Guide Organization below).

Tracking, recordkeeping, testing and other measures with appropriate oversight management systems are essential parts of product development and commercial life cycle for purposes of quality control and seed purity. Since maintaining a seed variety's trueness to type is critical for market acceptance and use, robust quality management practices are needed for both biotechnology or non-biotechnology derived crops. The practices outlined in this Guide are based on general quality management principles. Quality management systems, such as ISO 9001, provide structure and rigor to business practices by way of managing key process variables, thereby establishing routine and consistent output from their processes. In addition, these systems facilitate coexistence among growers, meeting customer expectations and mechanisms for continually improving the quality management system. An underlying consideration throughout this Guide is the importance of communication with neighboring seed growers, farms and residences as appropriate.

As advances in seed technology occur and developers gain additional insights into quality management practices through practical implementation, the provisions of the Guide will be reviewed and improved upon, as needed. This Guide contains the principles and key elements reflected in individual quality management programs, standard operating procedures (SOPs) or other appropriate operational documents.

Scope

This Guide covers those stages of the plant product life cycle from the point of incorporation of a trait into a breeding program through commercial seed production and
sale. This Guide does not cover the stages of trait discovery, product phase-out, product discontinuation or product retrieval. It is also not intended to address issues associated with product performance after sale.

**Guide Organization**

This Guide is organized in such a way to accommodate different seed business models and practices. This approach is intended to allow an organization to utilize the guidance for the respective areas in the seed life cycle which they perform. The life cycle within the scope of this document is represented in the Work Flow Diagram (figures 1 and 2 below).

For each stage of the life cycle there is a standard set of information presented that serves as step-wise guidance for developing the quality management practices. This standard set of information follows Hazard Analysis and Critical Control Points (HACCP) principles. Please note that the information presented in the Guide is not intended to be all inclusive, but instead represents a basic set of information which is generally applicable to most seed development and commercialization activities. It is recommended that companies utilize the guidance with consideration given to their specific products, activities, infrastructure, and customer and neighbor expectations.

The set of information is as follows:

1. **Analysis of Product Integrity and Control Concerns**
   The identification of potential risk at the respective life cycle stage which if left uncontrolled could affect product integrity

2. **Determine Control Points**
   Steps in the process identified as points to control the potential risk

3. **Establish Preventative Measures**
   Specific activities to be performed at the control points to manage the risk

4. **Establish Monitoring Procedures**
   Measures taken to verify the preventive measures are performed

5. **Establish Corrective Measures**
   In-process activities taken to address a failure to follow the preventive measures or to address a product determined to be out of specification

6. **Establish Verification Procedures**
   Activities taken to verify compliance with the quality management practices

7. **Establish Record Keeping and Documentation Procedures**
   Appropriate recorded information which allows one to verify compliance and reconstruction of all relevant activities after the fact

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**Hazard Analysis and Critical Control Points (HACCP)**

HACCP is an internationally accepted approach to ensure food safety that is applied throughout the food chain from primary production through to consumption of the food product. This Guide uses as its basis the approach used in HACCP.

HACCP is science-based and systematic and is used as a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. According to the *Codex Alimentarius* “the application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems.”

The HACCP system consists of seven principles, listed below, that are applied in a logical sequence.

1. **Principle 1:** Conduct a hazard analysis.
2. **Principle 2:** Determine the Critical Control Points.
3. **Principle 3:** Establish critical limit(s).
4. **Principle 4:** Establish a system to monitor control of the Critical Control Points.
5. **Principle 5:** Establish the corrective action to be taken when monitoring indicates that a particular Critical Control Point is not under control.
6. **Principle 6:** Establish procedures for verification to confirm that the HACCP system is working effectively.
7. **Principle 7:** Establish documentation concerning all procedures and records appropriate to these principles and their application.

**General Considerations**

There are general quality assurance considerations that are applicable to all of the processes covered in this Guide. Compliance with regulatory requirements is fundamental to all of the modules in this Guide, including those regulations directly related to seed labeling, to phytosanitary requirements and to the use of biotechnology. Therefore, use of this Guide will be complemented by a thorough understanding of the regulatory requirements that pertain to a company’s product. This Guide does not describe the details of compliance with these requirements.

In addition, training of personnel is relevant to all of the systems described in this Guide. Within the context of the Guide, it is assumed that appropriate training of personnel will be in place for the systems described.

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3 Ibid. 21.
4 e.g., *Federal Seed Act; Plant Protection Act; Federal Insecticide, Fungicide and Rodenticide Act; and Federal Food, Drug, and Cosmetic Act.*