

Quality Management Systems: Safeguarding Seed Supply

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Background of a Quality Management System (QMS)

What is it?

- A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.
 - # A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

Some components

- // Quality policy: states your commitment
- // Standard Operating Procedures: those processes that help deliver on the commitment
- // System for Auditing; Corrective Actions: ensuring processes are followed and if not, correcting that
- // Customer Feedback: are you meeting your commitment?
- // Continuous Improvement: continually evaluate how things are done and if they can be improved (e.g., simplified, sped up)
- // Risk Assessment and Risk Management: what are the risks to meeting your commitment? Have you mitigated them?

Reminder of Seed Industry

The seed industry goal: generate and deliver a product that meets customer needs

- // Timing: delivered when its needed
- // **Cost**: delivered at the right cost
- // Quality: germination, vigor, hybridity, healthy seed

Failure to meet these can lead to a loss of customers

Great efforts made by many companies in the vegetable seed industry to safeguard seed supply and deliver the right quality

Some of these efforts are:

- // Field management practices (Best Management Practices)
- // Standard operational practices (sorting, sanitation, treating, etc.)
- // Standard quality tests developed and implemented

Quality - Management System

Phytosanitary vs Quality

Phytosanitary Targets

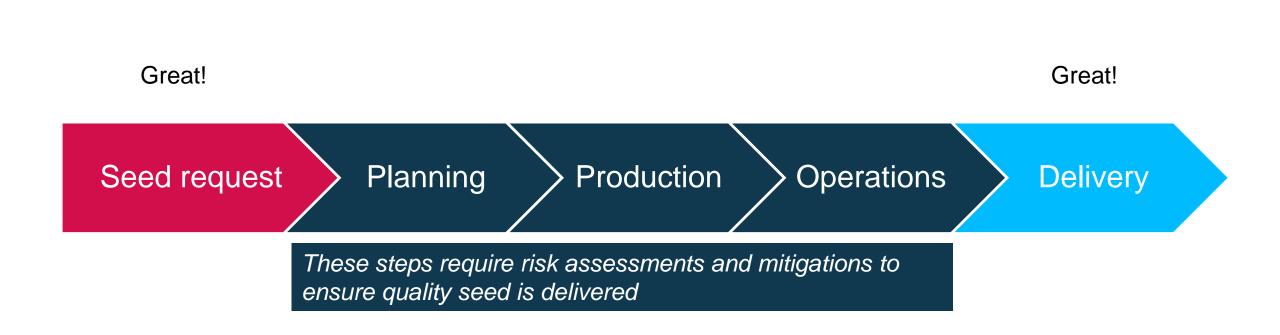
- // Those pests which are regulated, that is, for which a declaration has to be made as a part of seed movement/import
- // These pests pose a phytosanitary risk in that it may reduce ag productivity or endanger native species
- // Phytosanitary measures are used to enable seed movement
 - // Measures may include field inspection, seed testing, fumigation

Quality Targets

- Those pests which are seed-borne and seed transmitted for which industry has developed routine processes to mitigate
- // These pests pose a quality risk in that they may reduce ag productivity for the company and/or for the customer
 - // Additionally they may pose a phytosanitary import risk
- // Industry management processes may include field hygiene practices, field inspection, seed testing, seed treatments

Business

Regulatory



The Seed Increase Cycle

Examples of Best Management Practices: Planning





Planning > P

- Parental Seed Selected
 - Parental seed is clean (passed internal tests)
- Country, site placement: production standard identified
 - Pests pressures is known: Practices have been identified to manage pressure
 - REASONABLE and FEASIBLE!
 - Pests pressures unknown: appropriate risk assessment and mitigation
- Seed shipped to location
- Training of growers on what is expected
- Training of growers, field reps on diseases





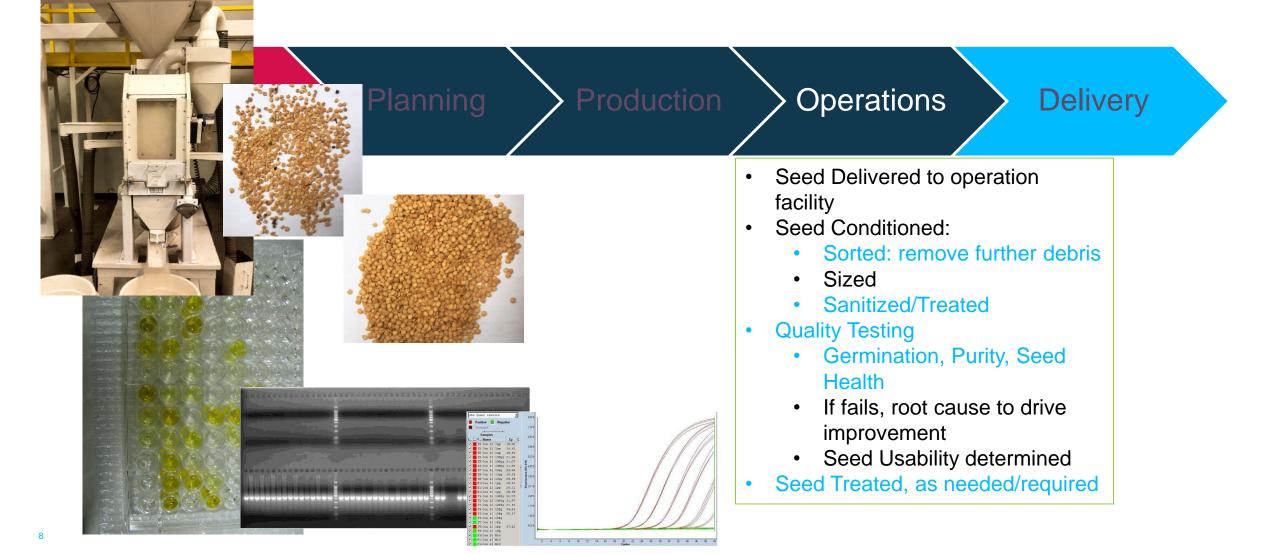
BAYER E R **Examples of Best Management Practices: Production**







Examples of Best Management Practices: Operations



Why are there so many examples of best management practices in seed production process?

Desired outcome is fixed: Reliability of Quality Seed Supply!

But...

Are the same risk factors present in all production areas?

Are the same mitigation processes able to be applied in all production areas?

Answer: NO!

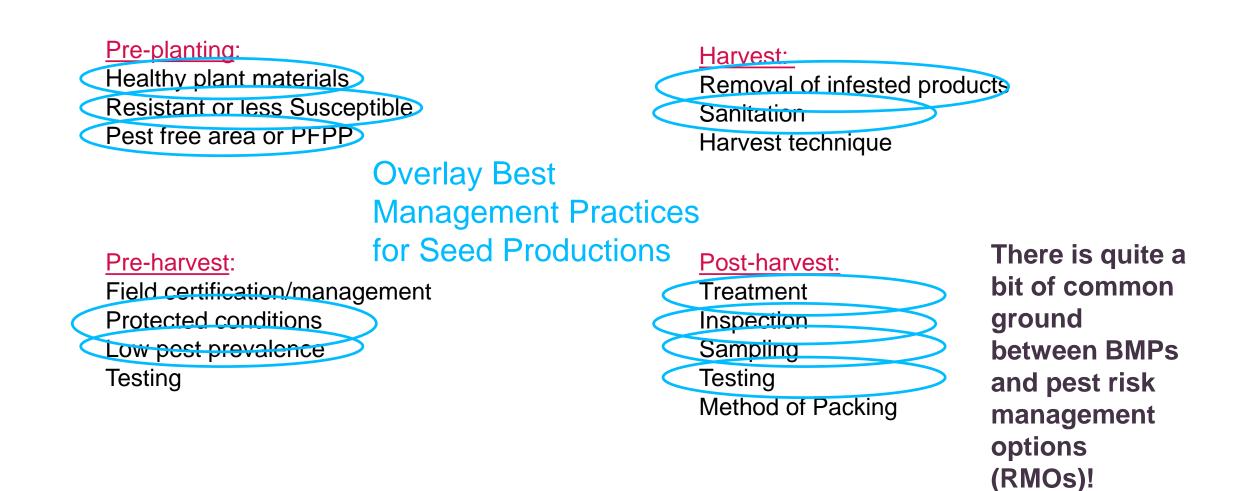
Reality: Many factors determine what practices can be used



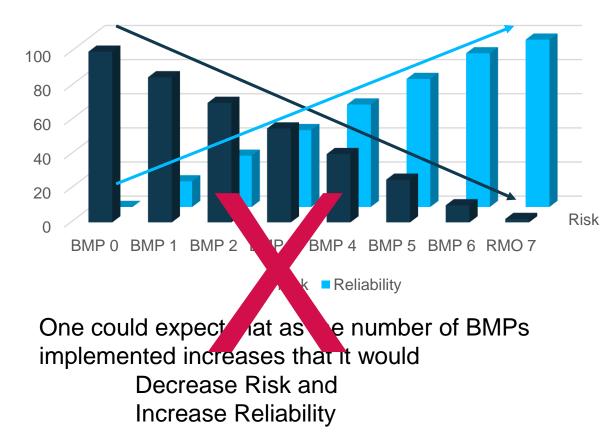
(ISPM 14 and 38) Systems Approach: a systems approach requires the integration of different measures, at least 2 of which act independently, with a cumulative effect

- // A systems approach, which integrate measures for pest risk management in a defined manner, could provide an alternative to single measures to meet ALOP of an importing country
- // Measures can be applied pre- or post-harvest wherever PPOs have the ability to oversee and ensure compliance
- // Per ISPM 38, measures for seed are
 - // Consignment inspection and testing for pests
 - // Field inspection for specified pests
 - // Pest free places of production or low pest prevalence
 - // Seed treatments
- While these are easy areas for PPOs to provide oversight and verify compliance, industry may be doing more

Per ISPM 14 Pest Risk Management Options



Expected relationship between Risk, Mitigations and Seed Supply Reliability



Significant Risk Reduction [and Seed Supply Reliability] can come from the Implementation of a few or the right BMPs

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Melon: According to ISF pest list there are 6 pests where seed is a pathway

Bacteria: Acidovorax citrulli

Fungi: Macrophomina phaseoli and Didymella bryoniae

Virus: CGMMV, MNSV, SqMV

Can the same BMPs be used for all pests? NO.

Example: Controlling the cucumber beetle populations that may introduce SqMV will not affect MNSV confidence.

Another example: Placing the crop under protected production (net, cage, glass house) will reduce the likelihood of introduced pests. Can you do this for 100 acres of production? NO.

Not all risk management options are equal for all pests; Sometimes it's not practical to implement certain BMPs

Systems Approaches: Opportunity and a Challenge

Opportunity and Challenge:

- If a company has implemented a program by which it assessing pest risk, has defined pest mitigation steps that are routinely audited and verified, and they have process checks throughout to ensure compliance and efficacy, is the existing regulatory seed movement requirements relevant? Is there another way to move seed as opposed to the existing system of individual disease specific declarations?
- // Concept: Acknowledge the broad impact that BMPs (as documented in a QMS) have on pest mitigation of seed
 - // How would this information be used by PPOs who are verifying?
 - // How would this information be used by PPOs wo are accepting seed imports?
- // Watch out: with regulation, it's easy to become too prescriptive
 - How do we transform current system to a system that still secures risk but permits the industry to continue to improve, embrace new technology, etc. in real time?



Conclusions

There are many practices in place today that seed companies use to mitigate (control or prevent) pest risk on seed production.

When compared with the RMOs of ISPMs, there is a great deal of common ground to industry BMPs

It is difficult to set one guidance on what BMPs are required for pest management as this is affected by many factors

Future looking: will need to work together (PPOs, industry) to determine how to capture the risk management impact that the best management practices in place by industry bring to the confidence in the phytosanitary status of seed lots



Thanks for the invitation!