

Confinement Systems Analysis

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19 Apr 2005

Crops are confined when ...

- not approved for commercial release and/or no tolerances are in place
 - *an insect resistant crop while in development*
- channeling is required
 - *asynchronous approvals*
- products are not intended for foods
 - *a PMP or PMI crop*
- identity preservation is needed
 - *a value-added specialty crop*

Confinement systems analysis

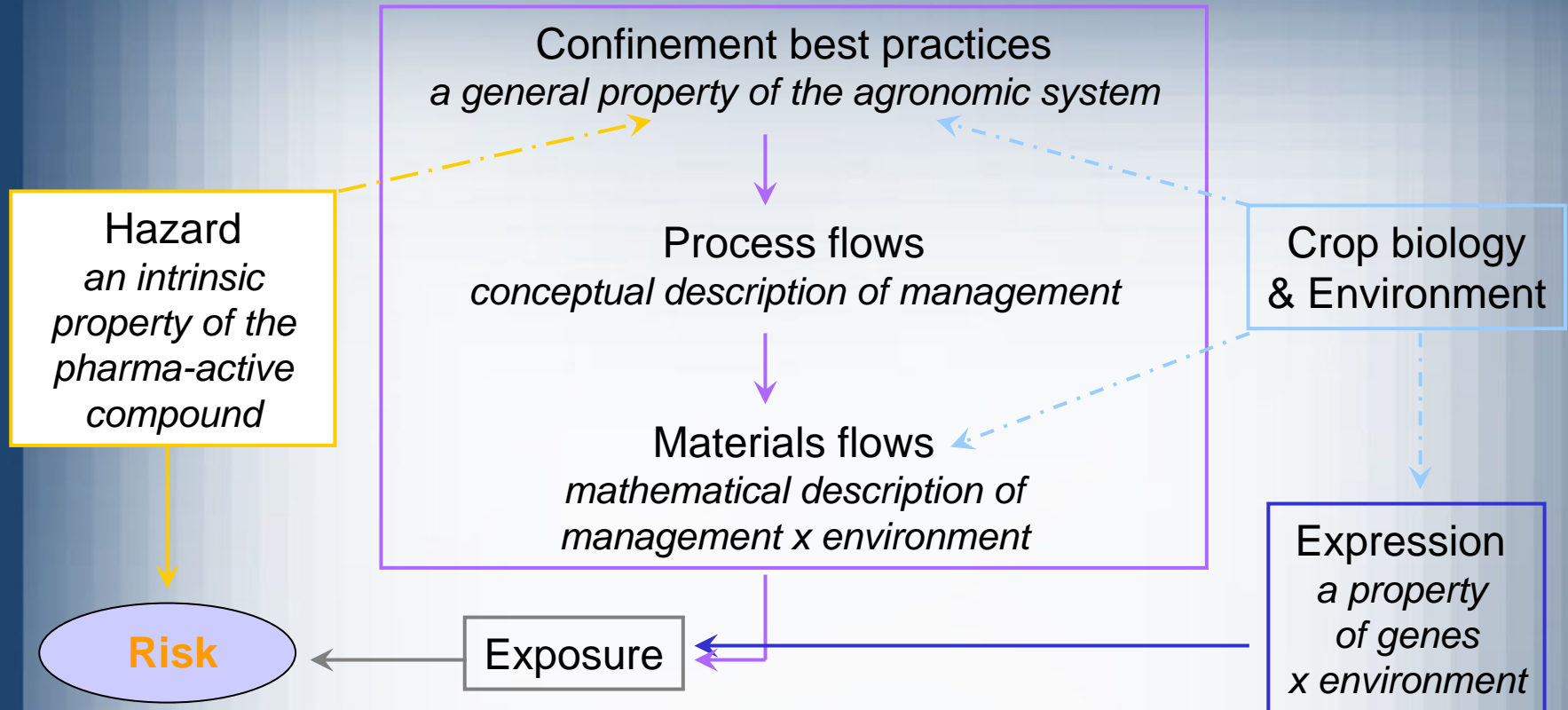
- describe the processes for confinement
- analyze for probable confinement loss
- identify uncertainties in confinement integrity
- address uncertainties

BIGMAP Confinement Project

A model system focused on:

- corn
- plant manufactured pharmaceutical
- systems analysis
- quantitative exposure assessment
- identification and communication of uncertainties

BIGMAP Confinement Project



Why focus on confinement?

*an unwanted
consequence of
confinement loss*

$$\text{Risk} = f(\text{Exposure}, \text{Hazard})$$

an attribute of the product

$$\text{Exposure} = f(\text{Expression}, \text{Confinement})$$

an attribute of the system

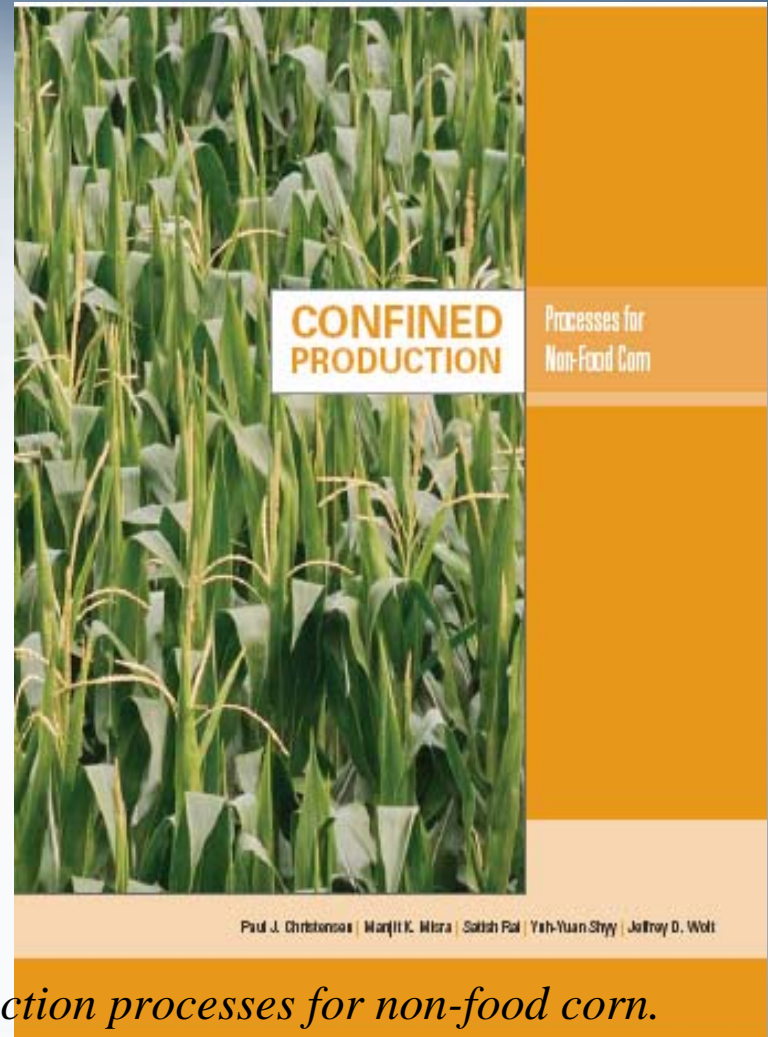
as Confinement \longrightarrow 100%

Risk \longrightarrow 0%

regardless of product specific attributes

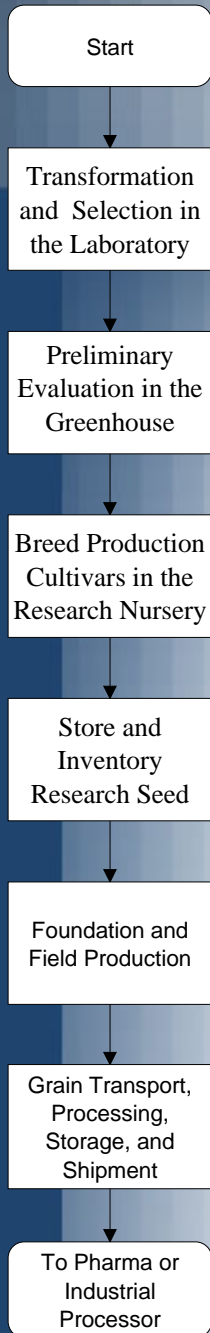
Define processes for confinement

pharma crop systems
are intended by
design to be uniquely
separate from the
food supply through
rigorously managed
confinement
measures



Christensen et al. 2005. *Confined production processes for non-food corn.*

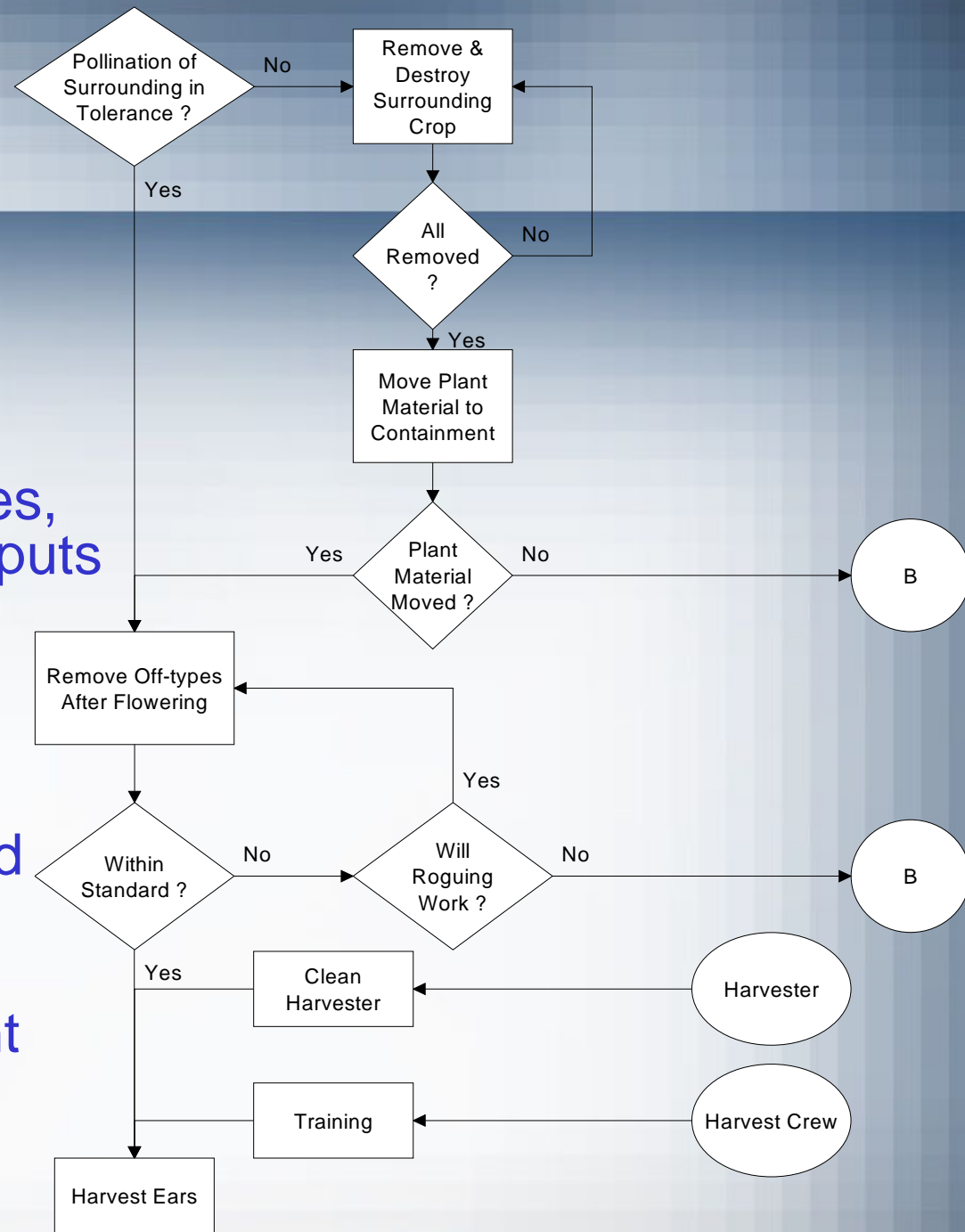
Systems description



- identification of critical systems that must be defined, controlled and maintained
- critical actions must be repeatable and measurable
- system design must allow for changing needs
- regulatory and customer requirements must be identified and incorporated into the system

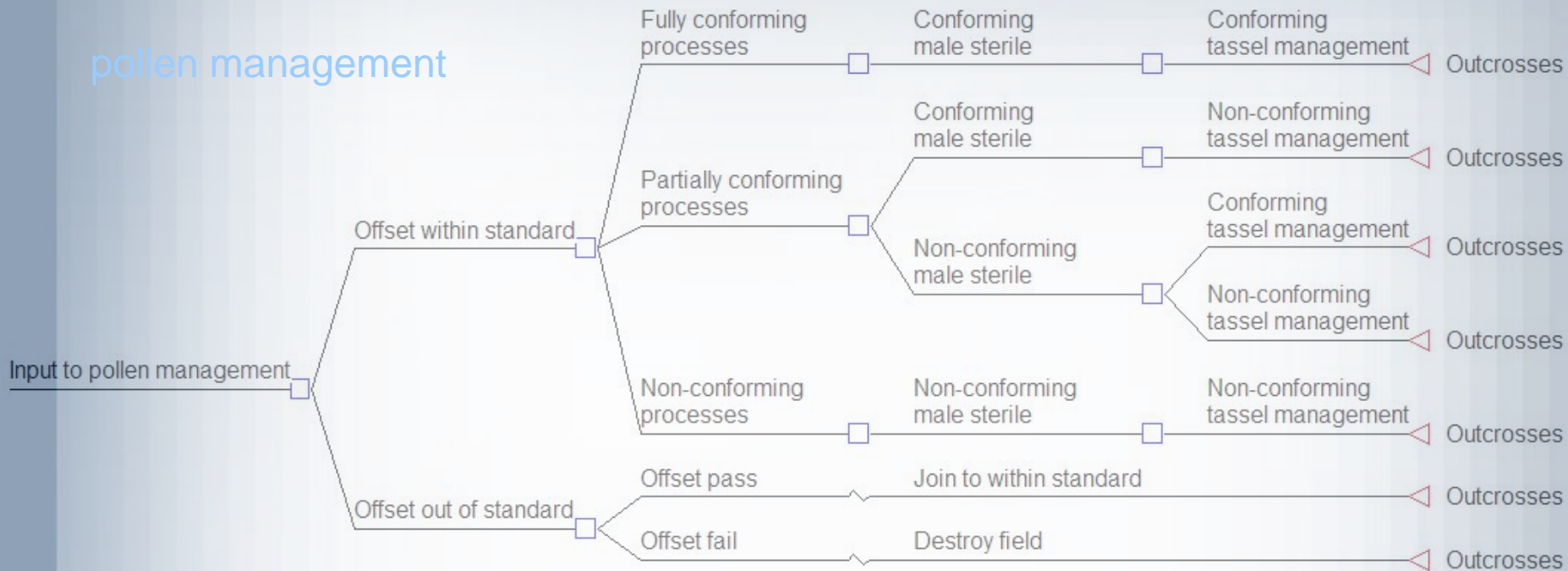
Process Management Implementation

- Identify critical processes
- Analyze all processes, including inputs, outputs and material that escapes
- Document critical processes
- Train employees and communicate expectations
- Define measurement criteria
- Audit the process



Quantitative analysis of process uncertainties

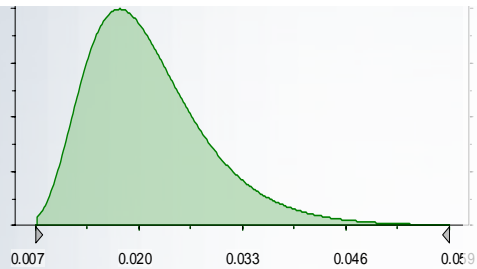
pollen management



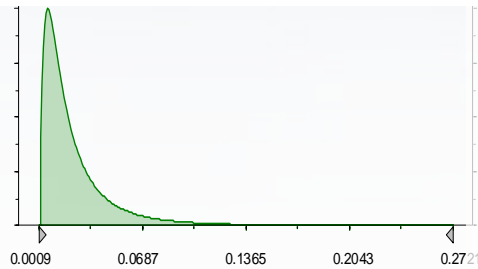
Probable confinement integrity

Describe distribution of material losses

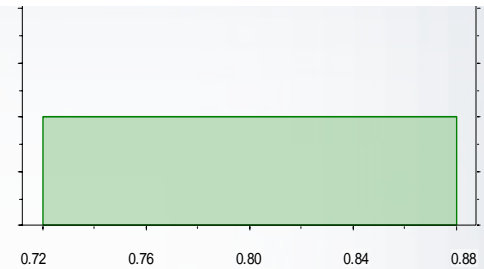
Preharvest loss



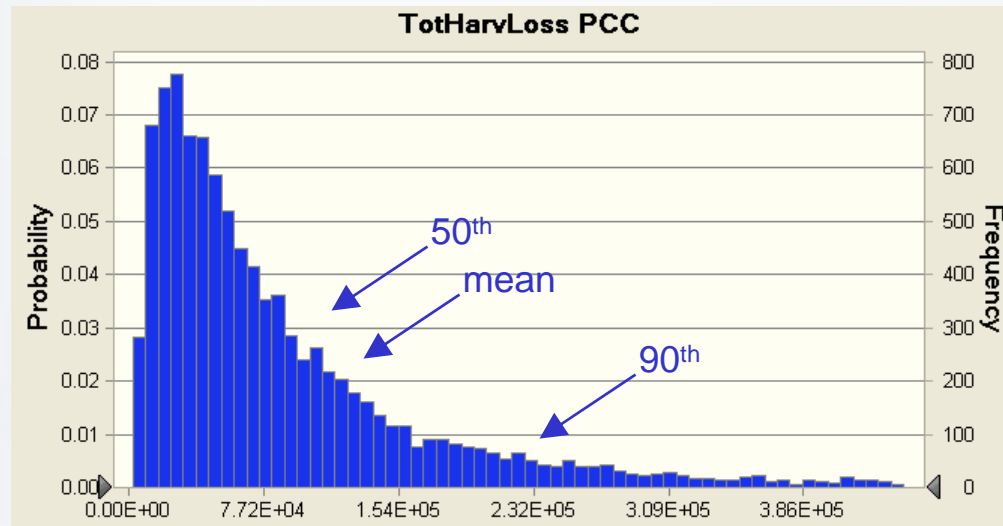
Combine efficiency



Recovery of dropped grain



*Forecast
probable
outcomes*



Understand process failures

<i>relative number of fugitives</i>	Deterministic result	Distributional result	
		50 th percentile	90 th percentile
<u><i>Outcrossing (to field at 1.61 km)</i></u>			
Fully conforming	1	6	16
Partially conforming			
Male sterility system		59	166
Detasseling		50	100
Male sterility system + Detasseling		500	1,000
Non-conforming		1,467	15,333
<u><i>Harvest loss (left in field)</i></u>			
Fully conforming	2,500	2,500	4,333
Partially conforming			
Combine		20,000	73,333
Ear picker		6,000	10,333
Non-conforming			
Combine		60,000	176,667
Ear picker		7,333	19,000
<u><i>Harvest loss (harvest mixing)</i></u>			
Fully conforming	nil	nil	nil
Partially conforming			
Combine		1,200	
Ear picker		120	
Non-conforming		30,000	

Uncertainties in confinement integrity

- failure rates for process compliance
- grain loss from equipment, clean out efficiencies, and recovery options
- physical description of long distance pollen flow

Addressing uncertainty through process design



Example:
selection of
equipment
and harvest
conditions
can
significantly
reduce
materials
left in the
field

Addressing uncertainty through monitoring and response

- monitor, model, and identify departures from confinement goals in real time
- identify at-risk receptor fields
- segregate product from at-risk field prior to harvest (channel or destroy)
- incorporate experience into process model

Summary

- the BIGMAP confinement project represents a model system for confinement integrity design and analysis
- attributes
 - focus on systems analysis for the confined crop
 - use of existing knowledge
 - quantitative exposure assessment to identify uncertainties
 - identification of uncertainties leading to improved confinement systems