



Petition Process Improvement Project

**BRS Stakeholder Meeting
December 13, 2011
T. Clint Nesbitt**

Petition Process

- Developers of a GE organism may petition APHIS for a determination of “nonregulated status” (7 CFR 340.6)
- 1992-1999: average 178 days
- Current: 2-5 years or longer
- Backlog of 22 pending petitions



High Priority to USDA



“We have today roughly 23 pending deregulation efforts within USDA. These regulation efforts, at least the ones I'm familiar with, take somewhere between five and six years to get through, and they cost millions of dollars. And I've tasked our team to figure out a way in which we potentially can reduce the amount of time it takes to review and come to a decision.”

*-- Secretary Tom Vilsack
Speech to American Farm Bureau
January 10, 2011*



Petition Process Improvement Project

- Team composed of petition process experts
- Longevity and Associates: consultant on business process improvement
- Launched December 2010

- Goal:
Identify and implement solutions to significantly and measurably improve the speed and predictability of the petition process, without affecting the quality of decision making.

Lean Six Sigma



- **Lean**

- Remove/reduce steps that don't add value
- Reduce difference between work time and elapsed time

- **Six Sigma**

- Build controls to reduce variability to within acceptable levels

- **Theory of Constraints**

- Build process with capacity to keep up with demand



Lean Six Sigma “DMAIC”



- **DEFINE**

- *Agreement on goals of project*

- **MEASURE**

- *Documentation of functioning of current process*

- **ANALYZE**

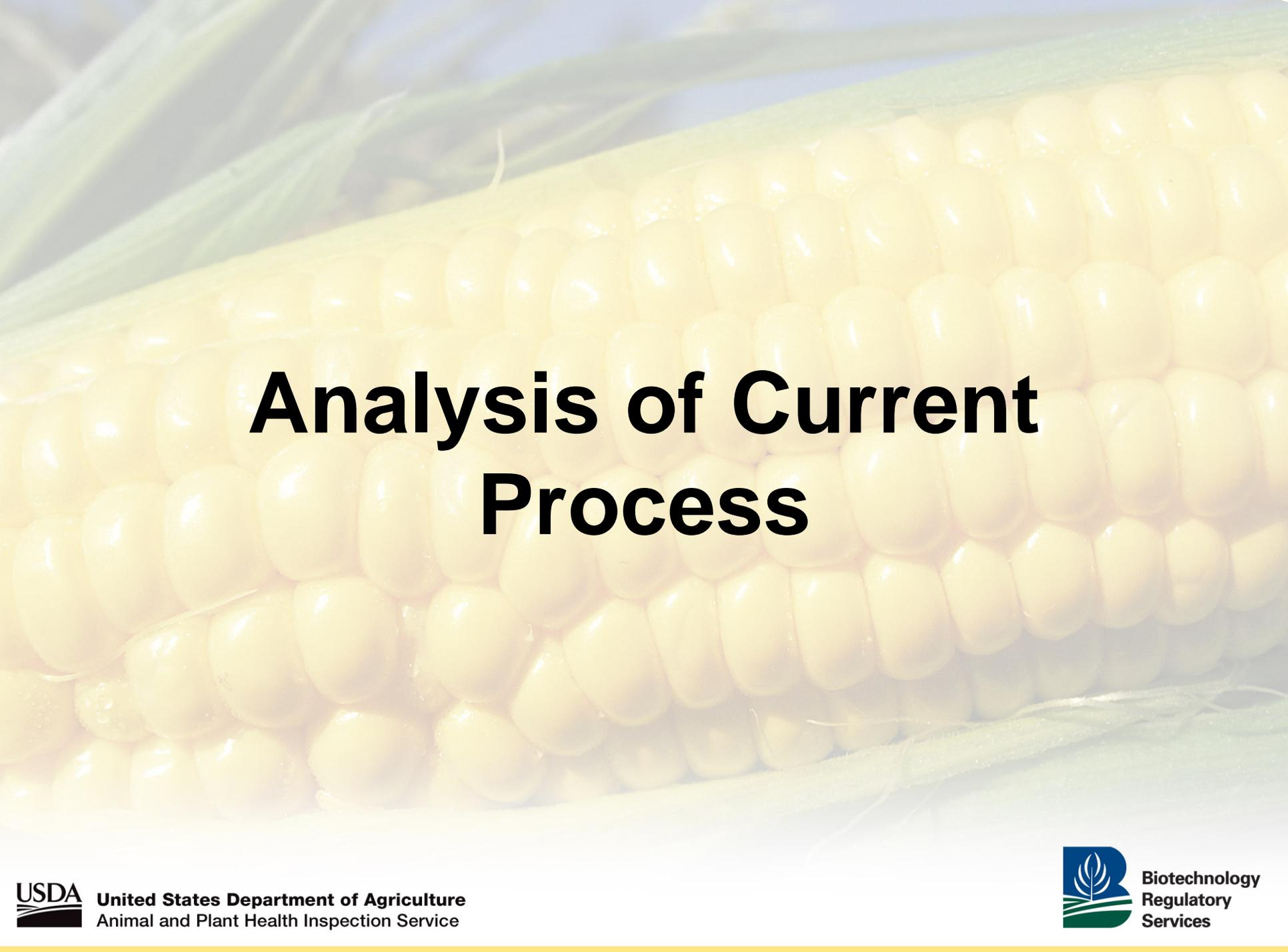
- *Identify root causes of problems*

- **IMPROVE**

- *Select and develop solutions*

- **CONTROL**

- *Implement and monitor changes*



Analysis of Current Process



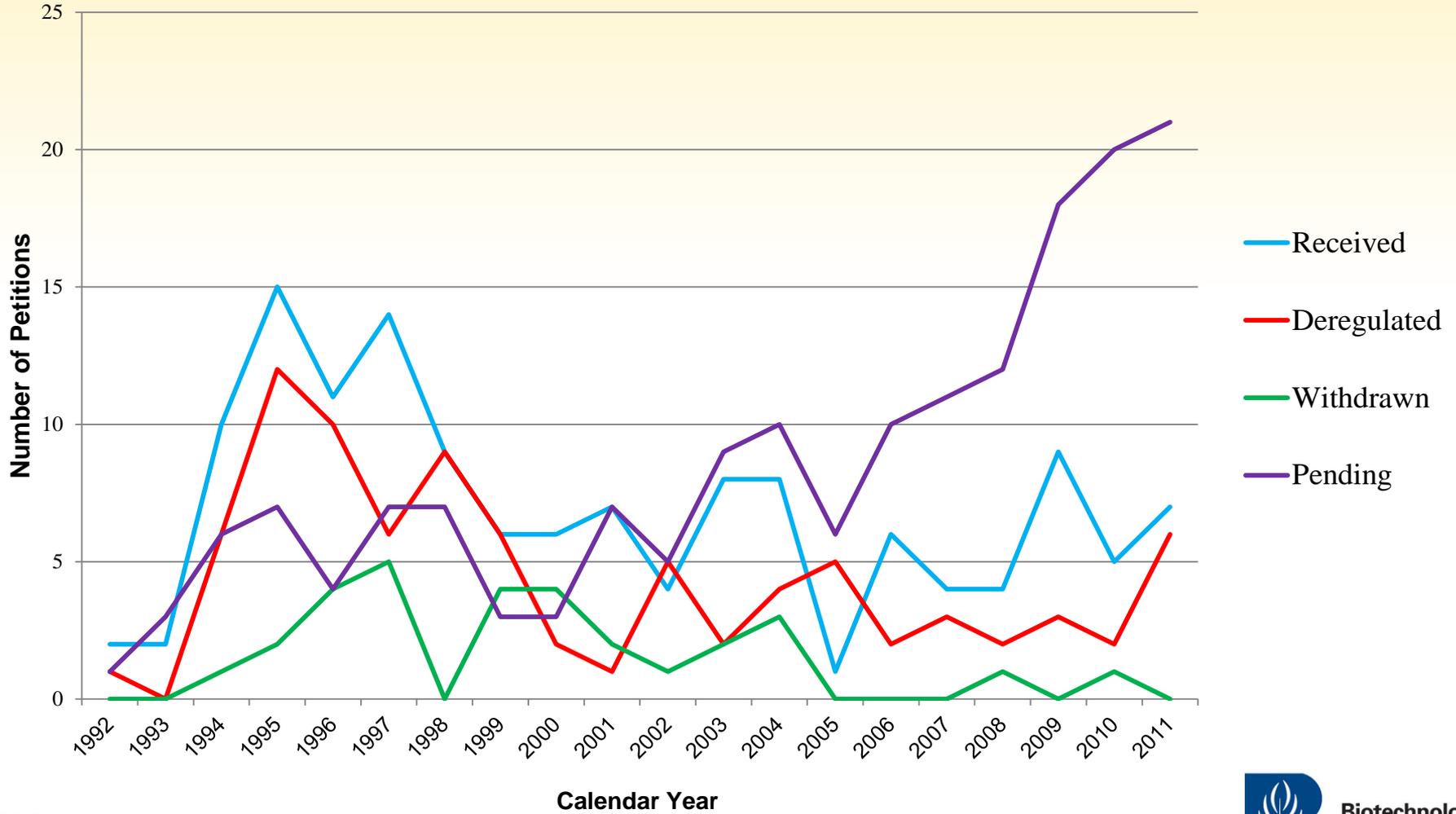
Two-Tier Data Collection



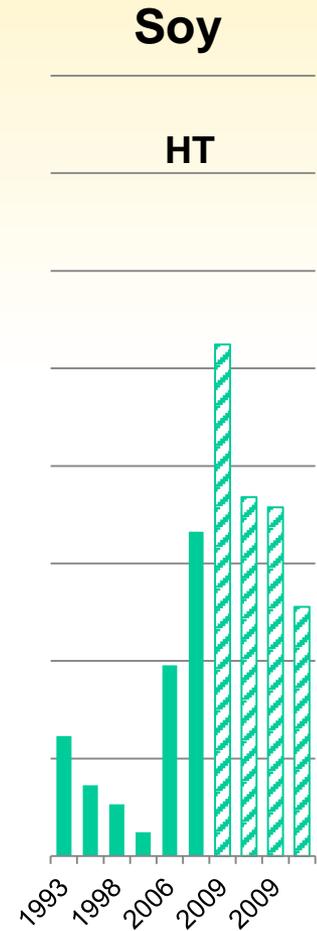
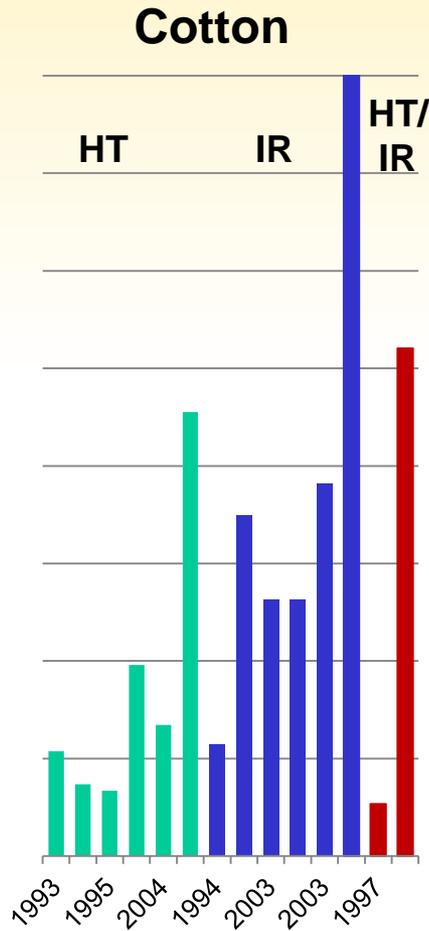
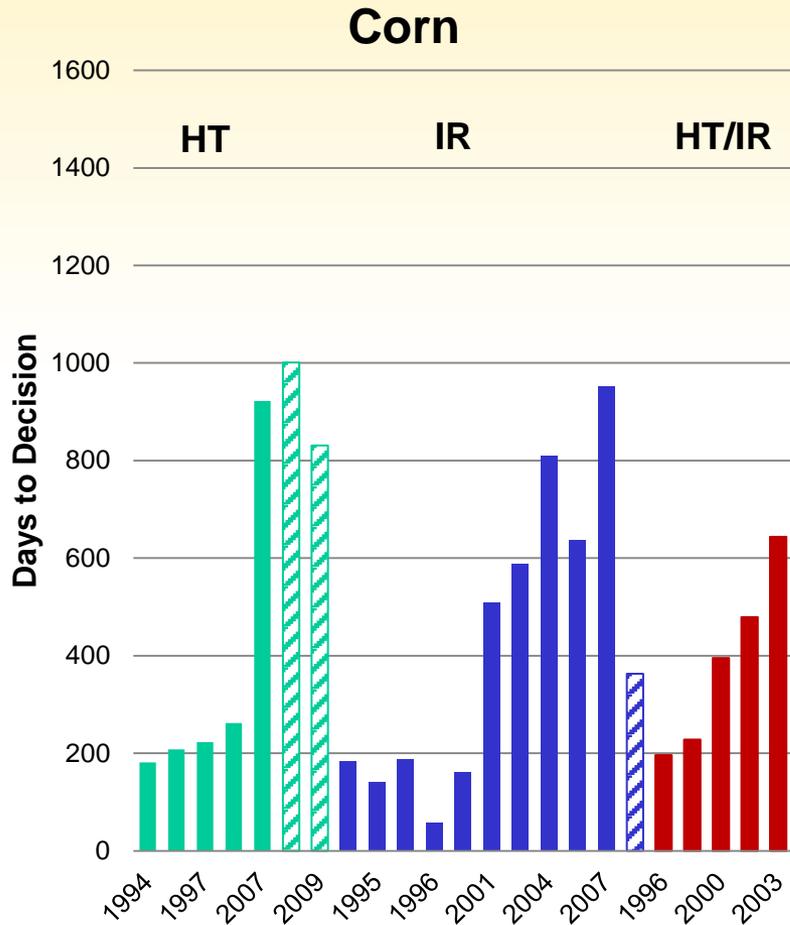
- High-level historical data
 - All petitions since 1992 (131 total)
 - Public and internal databases

- Detailed data collection
 - All petitions since 2005 (30 total)
 - Chronologies reconstructed from primary data
 - Petition documents, email, personal interviews
 - Work time estimates

Petition Activity

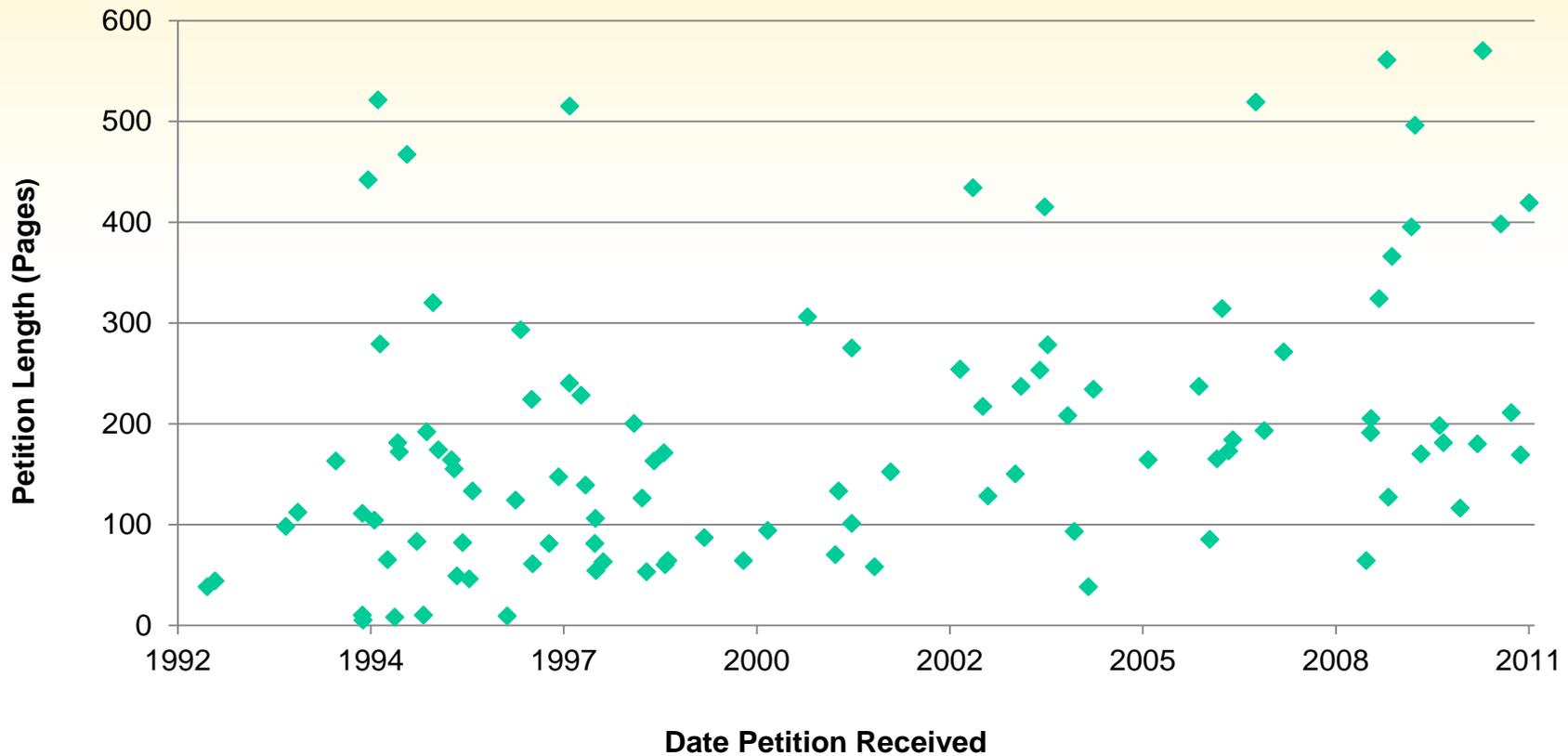


Common Crop-Trait Combinations

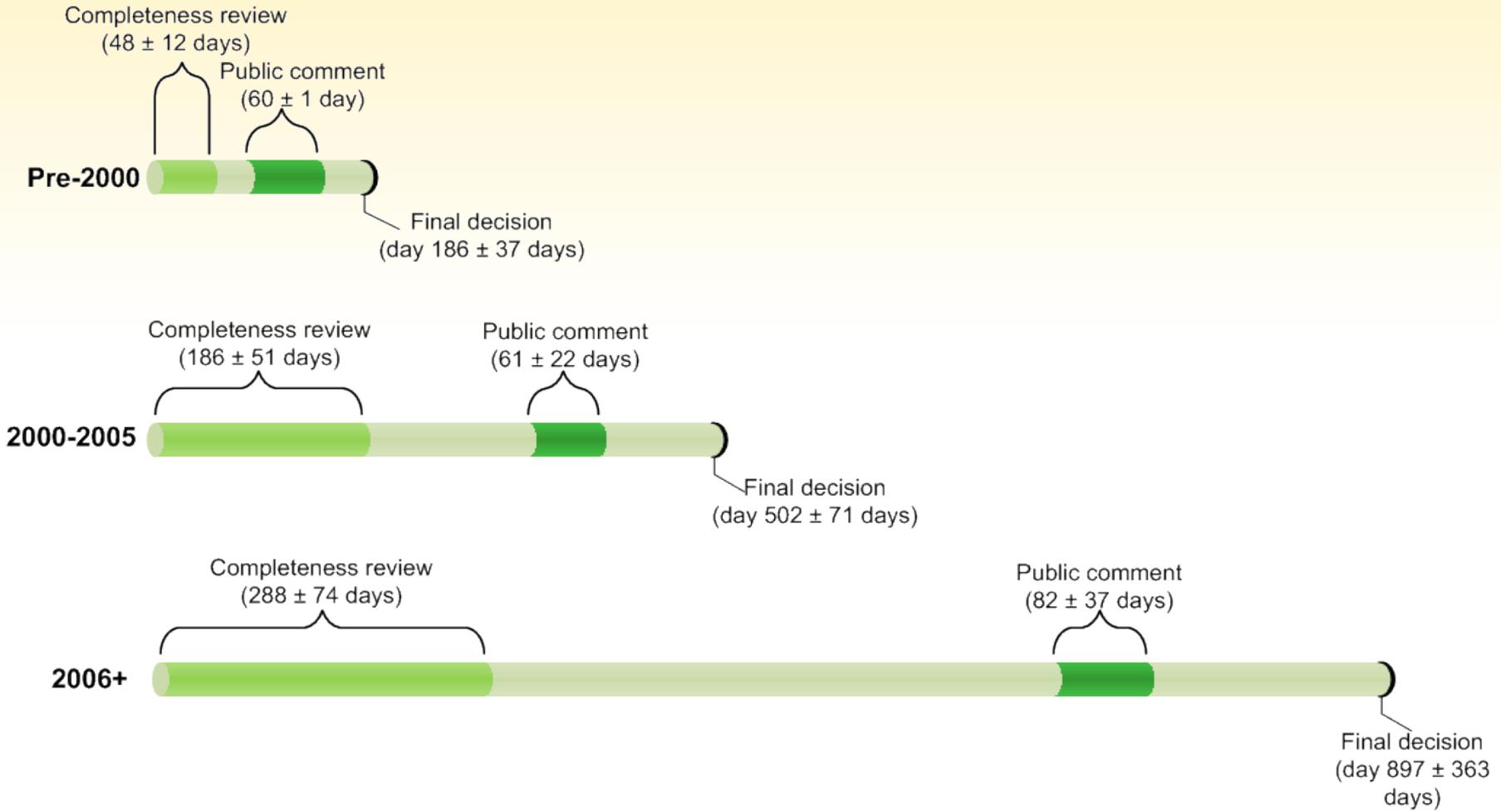


Crosshatched bars are *pending* petitions, with elapsed days as of 12/1/11.

Petition Length



Historical Trends



Summary Observations

- Large slowdown and increased variation of all major steps, beginning in late 1999
- Some process changes
 - Publication of petition after completion of analysis (2002)
 - More withdrawals, extensions prior to 2000
 - More reopening of comment periods after 2000
- Process steps variable at detailed level
- Work time is small portion of elapsed time



Root Causes



- Common explanations not supported
 - Increased petition volume, petition complexity, length, etc.
- Primary root causes related to management of process
 - Unclear/variable process steps, without deadlines
 - Challenges tracking work in progress
 - Competition with other priorities for resources



Improved Petition Process



United States Department of Agriculture
Animal and Plant Health Inspection Service



**Biotechnology
Regulatory
Services**

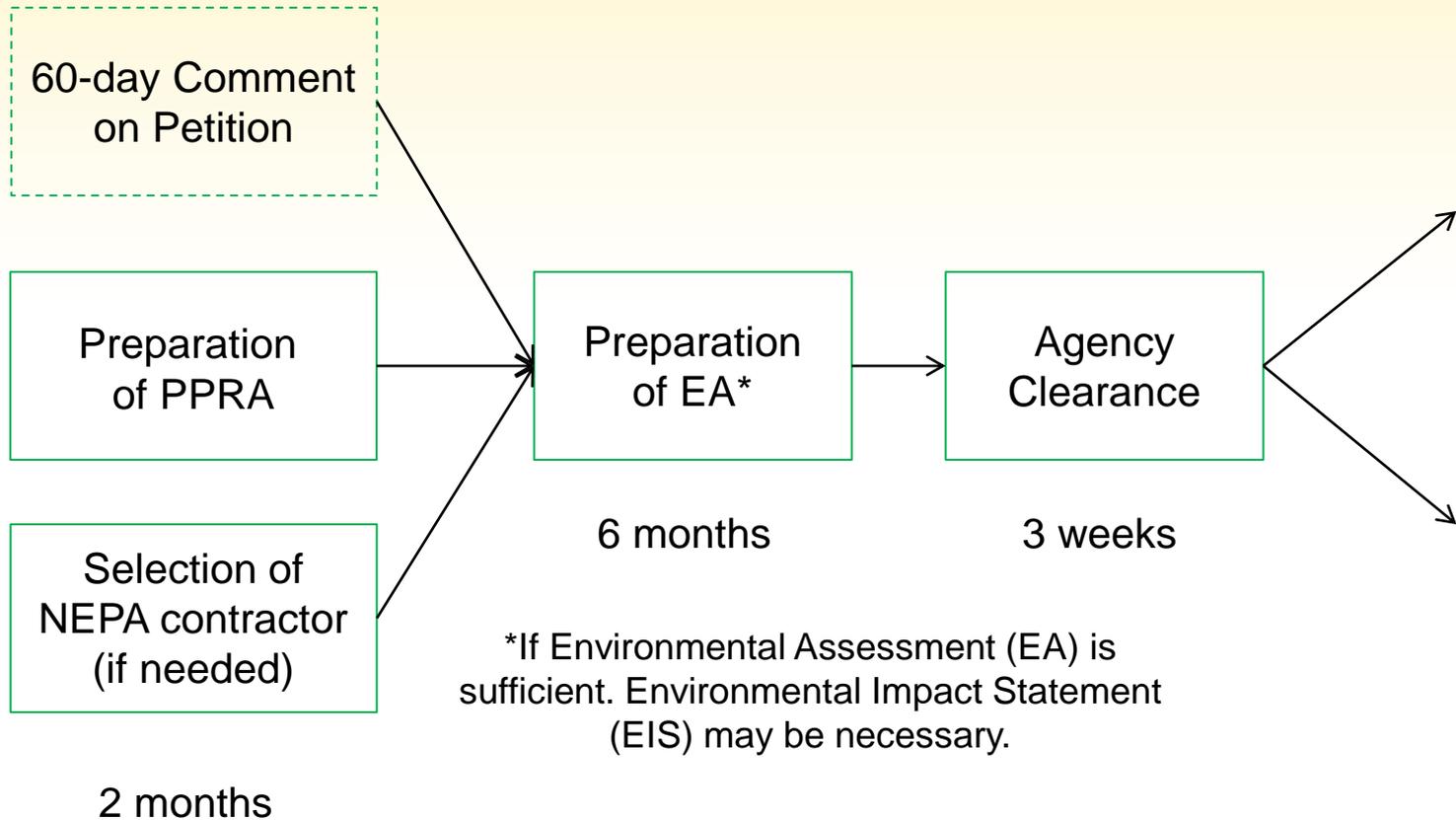
Highlights

- Streamlined, standardized process with defined deadlines
- Resource management and tracking tools
- Clearer separation of plant pest risk assessment (PPRA) and National Environmental Policy Act (NEPA) functions
- Earlier opportunity for public involvement

Improved Process



Improved Process (cont'd)



Improved Process (cont'd)

Path 1
Common
crop-trait
combinations

30-Day public
review on final EA,
preliminary
determination

1 month



Review of
new information
(if any)

1 week?



Final
Determination

If no information
received which would
change determination

or

Path 2
New crop-trait
combinations,
new issues

30-Day comment
on draft EA

1 month



Revision of EA
Preparation of
determination

1 month

If FONSI
reached



Agency
Clearance

3 weeks



Final EA,
Determination
In FR



NEPA Pilot



- Ongoing pilot to evaluate options to support NEPA analysis
 - Petitioner-provided environmental reports (ER)
 - Petitioner-funded NEPA preparation through cooperative agreements
- Improved petition process sets aside 6 months for EA
 - Standard timeframe for contractors
 - Pilot could identify additional time savings
- If petitioner elects to submit ER:
 - Should submit before NEPA analysis begins (i.e. before end of 60-day comment period on petition)
 - Will be made available to the public
 - If appended to petition, will be published with petition



Implementation

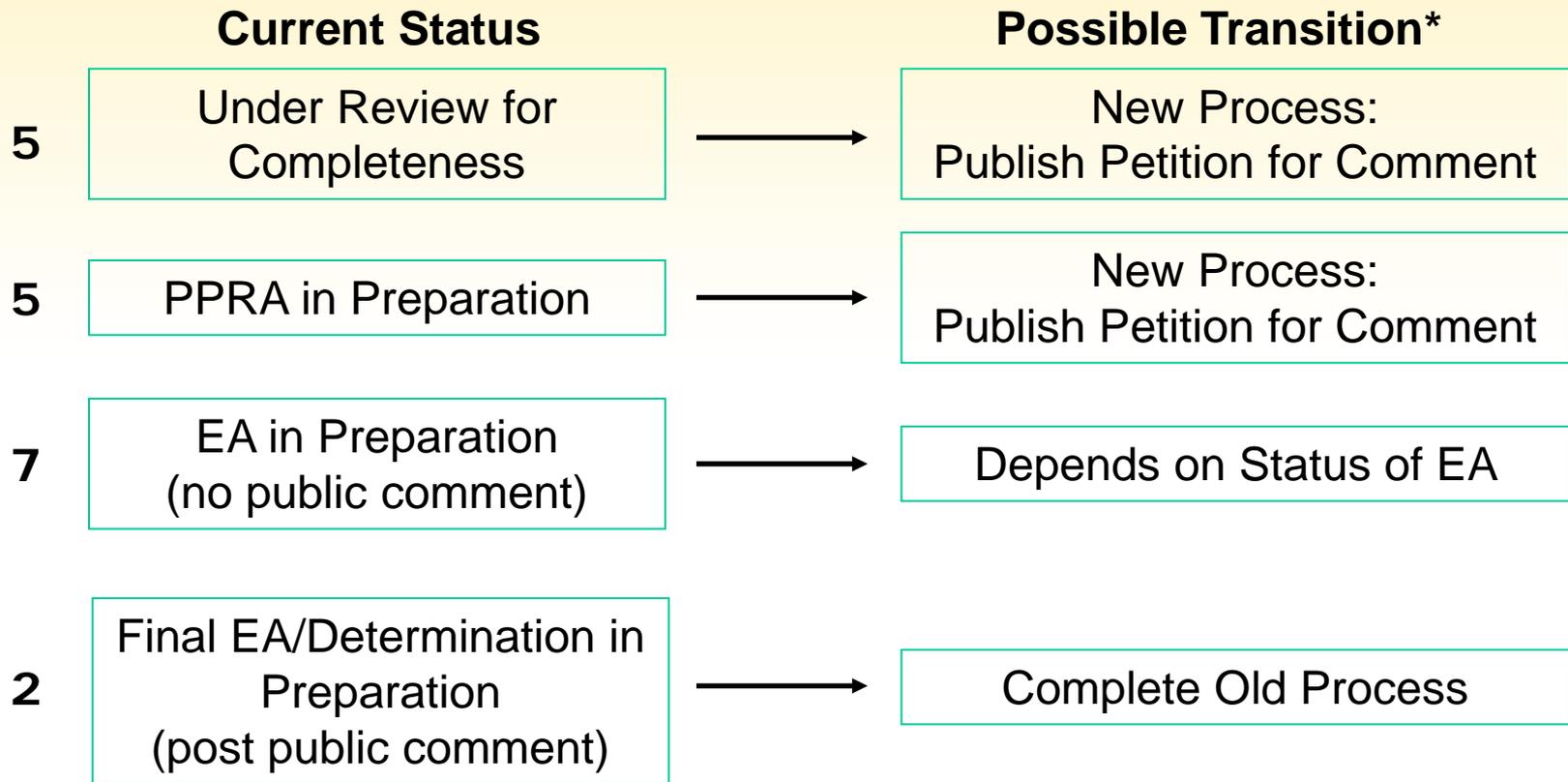


General Implementation Plan



- Behind-the-scenes improvements phased in now
 - New process steps, deadlines, etc.
 - Building improved tracking systems
- Changes to public engagement will be detailed in upcoming FR notice
 - Will **not** be implemented until after publication
- Phase-in dependent upon where petitions are in process

Petition-by-Petition Phase In



*Actual transition will depend upon status of petition when FR notice is published.

Stay Tuned...

- *Federal Register* notice on new public engagement changes
- Information posted on web
- Stakeholder emails
- Communication with petitioners about specific petitions



Thank You!

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