

Authorizations and Petition Improvement Process Updates

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BRS Stakeholder Meeting
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**Biotechnology Regulatory Services
Animal and Plant Health Inspection Service**

Design Protocol Review

- BRS reviews design protocols for field tests under notification
- We strive to constantly improve processes aimed at:
 - Ensuring protocols are adequate to maintain confinement and identity of regulated materials in field tests
 - Providing timely review



Design Protocol Review Cont.

- Being coordinated with BRS compliance staff to avoid duplication of efforts and ensure coordination of regulatory communication and actions
- Assuring consistency across applicants
 - all meet or exceed standards



Design Protocol Review Cont.

- Last year:
 - Announced new table of separation distances on our website
 - Changes to cotton design protocols



Design Protocol Review Cont.

- This year:
 - Focused on completing the work earlier and more quickly. Large developers encouraged to submit their protocols for major crops by September.
 - Most reviews completed ~1 month
 - Provided additional guidance on what wild relatives should be monitored near field trials of wheat and rape/canola.



Design Protocol Review Cont.

- Also this year:
 - Allowed landfills to be used as a method of final disposition. GE material must be treated as special waste:
 - Verification of receipt and that material is covered with soil by the end of the day
 - Any GE waste is eventually covered with several feet of soil
 - Additional guidance to be forthcoming



Design Protocol Review Cont.

- In coming year our goal is to provide crop-specific guidance on our website to facilitate design protocols



Other Changes

- Changes in the way permits and notifications are distributed among biotechnologists
 - Developers are likely to work with only one biotechnologist for any single crop
- Permit conditions and notification acknowledgement letters now urge developers to use Best Management Practices to help deter development of resistant weeds. Links will be provided to BMP resources.



Process Improvement Project

- Used “Lean Six Sigma” process improvement techniques
 - Streamlined, standardized process with defined deadlines
 - Resource management and tracking tools
 - Clearer separation of plant pest risk assessment and NEPA functions
 - Earlier opportunity for public involvement
- Will reduce timeline to 13-15 months
- No compromises to quality of analysis



General Factoids

- Original 2012 backlog of 23 petitions
 - Only 4 petitions from backlog remain
- The total number of pending petitions is now 8
 - Four awaiting an EIS
 - Other 4 following new process



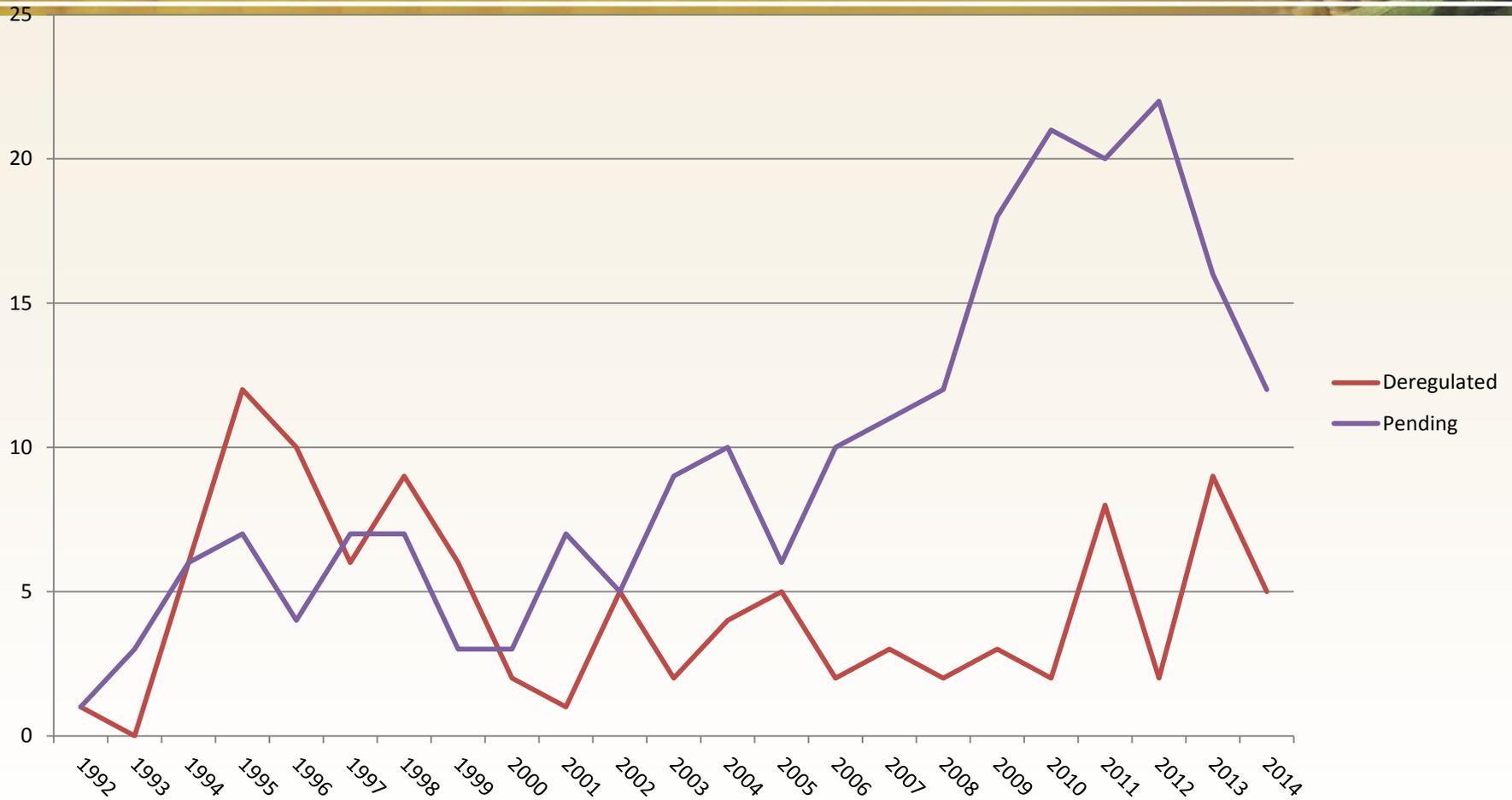
Time Savings

Process Step	#	Actual, Days	Previous, Days ¹	Days Saved
Petition Completeness	12	66	324	-258
Initial review	11	29	205	-176
Petitioner response	10	26	107	-81
Final petition review	10	29	39	-10
Draft PPRA	13	87	143	-56
60-Day Public Comment	15	60	N/A	
Draft NEPA document	11	275	213	+62
Total Process				
Path 1	3	648	1034	-386
Path 2	--			

¹Average from 2005 to implementation of improvements



Pending Petitions



Extension Project

- Under APHIS' "Alternatives to Rulemaking" initiative, the agency seeks to enact its core mission without imposing additional, burdensome regulations
- Expanding use of the extension process would:
 - Decrease the regulatory burden on developers
 - Save agency resources
 - Not compromise the scientific rigor of agency assessments



Extension Project Cont.

- In the project the agency will seek to:
 - Define eligibility criteria for extensions (how similar is similar)
 - Define information requirements and develop guidance.
 - Communicate improvements to stakeholders.



Any Questions?

