

US PBI UPDATE

SAA Congress

Cartagena, Colombia

Biotech WG



USDA Proposed Rule

- Significant revision of biotech regulation—known as Part 340
- Proposed new definitions that define initial scope of oversight
 - Definition of genetically engineered organism creates **upfront exclusions** of categories of products—targeted deletions, using DNA from sexually compatible plants or no foreign DNA present (null segregants)
- Rest of the rule a mixed bag
- Not sure what will happen to the proposal

FDA Request for Information

- Federal Register Notice asking for information and data around a set of questions
- When should a developer go through the FDA consultation process?
 - FDA 1992 policy statement provides adequate guidance
- Concern around “transparency” and the agency knowing how the technology will be applied and the commercial pipeline

Challenges in the U.S.

- A void if the USG does not engage internationally
 - Unclear how *ex partite* communication will affect USDA's ability to engage
- Unclear how FDA will use the responses to the RFI
- EPA has broad authority and unclear how they will/will not use it for PBI

Domestic Strategy

- Domestic
 - ✓ Value chain coalition
 - ✓ Overall statement from Administration on innovation
 - ✓ Consistency in approach by USDA, FDA, and EPA
 - ✓ Engagement of US internationally
 - ✓ Part 340 comments
 - ✓ RFI comments



QUESTIONS & ANSWERS

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