2022 Stakeholder Meeting
Questions and Answers
Chat Box questions that were not answered during the meeting

How much of the genome is examined when applying for exemption? Is there any oversight of the genome for anything outside the trait being inserted?
Answer: For part 1 of the question, generally the entire genome (or known genome) is subject to examination for the retention of exogenous DNA sequences or secondary targets, though whether retention of any exogenous DNA sequences is intended or unintended is dependent on the exemption being claimed. For part 2, again the entire genome (or known genome) is subject to examination for unintended modifications.

Subray mentioned that 10 more staff members were hired in the last 2 years. And I thought I heard him say that they also hired 5 more recently. How many new hires in BRAP have been brought on since the revised regulations were implemented vs. how many employees have left since that time? How many analysts/biotechnologists are there currently in BRAP? Does BRAP have a hard time finding candidates with the appropriate qualifications and skills for the job?
Answer: Since March 2020, 15 staff members have joined BRAP and 4 staff members have departed. Excluding supervisors, BRAP presently has 25 staff members who are biological scientists or biotechnologists who support permitting applications, Confirmation Requests, and Regulatory Status Review requests. For certain practice areas, we have had challenges building well-qualified candidate pools and have overcome this recently by enhancing and expanding recruitment efforts with universities, professional organizations, and scientific publications.

Did Subray say that plants modified for pharmaceutical, or phytoremediation were not eligible for the RSR process?
Answer: The permitting provision in the regulations specifies that "a plant that encodes a product intended for pharmaceutical or industrial use" may not be imported, moved interstate, or released into the environment without a permit. 7 CFR 340.2(e). Plants engineered to produce industrial compounds include those plants that meet the following three criteria: (1) The plants are engineered to produce compounds that are new to the plant; (2) the new compound has not been commonly used in food or feed; and (3) the new compound is being expressed for non-food, non-feed industrial uses. 70 Fed. Reg. 23009 (May 4, 2000).

If there is time, can the 1st panel group confirm that there are 34 RSR's submitted? does this include only those that are technically complete or is it all of them that are submitted?
Answer: As of December 8, 2022 (the date of the stakeholder meeting), BRS held 34 active Regulatory Status Review requests.

BRS committed in the preamble of the Part 340 final rule that they would publish a list of taxa containing plant pests on its website. When will BRS release its list of taxa of plant pests? What has been holding up its release?
Answer: Given the level of other work currently underway, BRS expects to publish a list of taxa in fiscal year 2024.

Will the Guide for microbe permit applications be issued as a draft and then open for public comment?
Answer: Yes. BRS will seek public feedback on the draft Guide for Submitting Permit Applications for Modified Microorganisms. BRS anticipates making this draft Guide available for review and comment in Spring 2023.

Question: Please explain why we proceed with deregulating traits vs. labeling and tracking this new technology... as we can see that this is going to be a major hurdles when it comes to international trading in the future.
Answer: The Animal and Plant Health Inspection Service administers 7 CFR part 340, promulgated using authority from the Plant Protection Act, to ensure that certain organisms developed or modified using genetic engineering are safe for plant health and agriculturally important resources. In contrast, the Agricultural Marketing Service administers the National Bioengineered Food Disclosure Standard, which is promulgated under the amended the Agricultural Marketing Act of 1946, to establish a standard for disclosing any food that is or may be "bioengineered" (as defined by Congress). As a whole, when engaging with international partners, USDA works to promote science-based decisions for international trade of all agricultural products. In this regard, APHIS supports the efforts of the Foreign Agricultural Service to build a level playing field for U.S. agricultural products with trading partners and we, at BRS, engage with our regulatory counterparts to explain APHIS regulations and decision-making.

Given the direction in the US towards problem formulation as a part of the exemption/not subject to regulation process, this moves away from a process-based trigger for regulation common in other jurisdictions. To what extent is this specifically stressed in international discussions?
Answer: BRS has reached out to many countries both one-on-one and in multi-lateral forums to describe our revised regulations, including the scientific underpinnings for modified plants that are exempt from regulation and the process we use when conducting a Regulatory Status Review. During these conversations, we always explain that one of the goals of the revised regulations is to focus on the characteristics of the product and not the method used to produce it.

Are there discussions with USDA-AMS regarding aligning technical definitions regarding the National Bioengineered Food Disclosure Standard (such as, for instance, what "cannot be created through conventional breeding or found in nature" on a technical level in BRS's view vs. AMS's view?)
Answer: Yes.

If the PPRA finds a scientifically credible plant pest risk, but also finds a benefit to plant health that might outweigh the impact posed by the plant pest risk, what decision will the agency make?
Answer: Under the Regulatory Status Review process, we consider whether a modified plant may plausibly pose a pathway to increased plant pest risk relative to an appropriate comparator (generally a non-modified plant of the same species). If BRS determines a plant is unlikely to pose an increased plant pest risk relative to a comparator, the plant is not subject to the regulations. In the context of this review, BRS' evaluation focuses on plant pest risk.