

Breakout listening sessions at March 30th public meeting

Background

On July 2, 2015, the Executive Office of the President (EOP) issued a memorandum¹ directing the primary agencies that regulate the products of biotechnology—the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—to update the Coordinated Framework for the Regulation of Biotechnology by clarifying current roles and responsibilities, develop a long-term strategy to ensure that the Federal biotechnology regulatory system is prepared for the future products of biotechnology, and commission an expert analysis of the future landscape of biotechnology products to support this effort. Through these updates, the Administration has the goal of ensuring public confidence in the regulatory system and improving the transparency, predictability, coordination, and, ultimately, efficiency of the biotechnology regulatory system. The Administration is undertaking this update with a view that regulatory approaches should protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers.

Breakout listening sessions themes

The agenda for the March 30, 2016 public meeting in Davis, CA provides time for breakout sessions, focusing on three general thematic areas relevant to the tasks assigned to the EPA, FDA, and USDA in the July 2015 EOP memorandum. A set of questions to be considered under each thematic area is provided. Individuals attending the meeting will be asked to sign up to participate in a breakout session for one thematic area when they arrive at the meeting site. During each breakout session, the goal is to collect individual input from the participants, not to provide collective advice or recommendations from the breakout groups. Note takers will summarize the input collected during the breakout sessions and will report out to the plenary session, which will subsequently become a part of the public meeting transcript and added to the docket.

Breakout Theme 1 – Governance

Governance is a broad term that includes, but goes beyond, government activities. For example, other public or private organizations such as companies, universities and research institutes, trade associations, scientific societies, foundations, consumer organizations, non-profits, and individual citizens may also play a role in oversight of biotechnology.

1. What is the role of stakeholders outside of government? How can the regulatory agencies engage non-governmental stakeholders as participants in governance of biotechnology?
2. Is there a role for other government agencies or offices (for example, non-regulatory agencies or offices) in the governance of biotechnology?

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https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

Breakout Theme 2 – Education, Communication, and Outreach

The July 2015 memorandum instructs agencies to, among other things, initiate development of a modernized, user-friendly set of tools for presenting the regulatory agencies' authorities, practices, and bases for decision making.

1. What are the needs of various stakeholders for understanding and accessing information on regulatory agency activities? What specific information is needed? How could this information be delivered?
2. How should information be presented for various stakeholders to make regulatory agency activities clear and understandable?

Breakout Theme 3 – Improving Regulatory Certainty

Regulatory agencies are charged with protecting public health and the environment.

1. What specific aspects of regulatory processes or procedures can regulatory agencies improve to make regulatory oversight for products of biotechnology more transparent, coordinated, predictable, and efficient while continuing their primary role(s)?
2. What specific information can regulatory agencies, or other agencies and offices, provide to biotechnology product developers, especially small businesses, to assist in their efforts to navigate the regulatory system?