

Breakout Session Notes
Modernizing the Regulatory System for Biotechnology Products
March 30th, 2016, Davis, CA

Background:

On July 2, 2015, the Executive Office of the President (EOP) issued a memorandum 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 public health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers. As part of this process, EPA, FDA, and USDA held three public meetings to share ideas and gather feedback.

Breakout listening session themes:

The agenda for the March 30, 2016 public meeting in Davis, CA provided 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 was provided. Individuals attending the meeting were asked to sign up to participate in a breakout session for one thematic area when they arrive at the meeting site. The goal was to collect individual input from the participants, not to provide collective advice or recommendations from the breakout groups. This document provides a summary of the breakout session notes.

Note: Participants of the breakout sessions represented a wide variety of viewpoints and perspectives. These included, but were not limited to interested citizens, commercial biotechnology developers, academic researchers and leadership, and those wanting to limit or eliminate biotechnology development. These notes do not represent a consensus, but rather attempt to capture the individual contributions of those present who voiced their views to the two questions that were the focus of this session. As such, opposing views are sometimes recorded in succession.

Breakout Session 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?*

Session Notes

Broaden governance concept to wider community

- e.g. farmers; affected industry groups (not just individual regulated companies):
 - Enzyme Technical Association (ETA), Biotechnology Innovation Organization (BIO; formerly the Biotechnology Industry Organization), Algae Biomass Organization (ABO), grower groups
- Engagement is more than talking to one another.
- Governance is global. Economy is global, should look globally at governance.
 - For Example: the Organization for Economic Cooperation and Development (OECD) working groups on Biotechnology, Nanotechnology and Converging Technologies (BNCT), Working Group on Harmonization in Regulatory Oversight of Biotechnology (WGHROB) and Task Force for the Safety of Novel Foods and Feeds (TF).
- Bring to the discussion non-regulatory federal government agencies.
- Funding agencies support technology development. Funding agency standards are de facto governance. (e.g. National Institute Health Guidelines (NIH), other agency stipulations in Funding Opportunity Announcements (FOAs)). Funding agencies also need to provide support and fund research that informs future regulatory actions for the technologies they help develop:
 - Should involve developers and civil society, including having these groups giving input into the funding agenda.
- Insufficient public support for funding of risk assessment research. Would be useful to have more funding on central issues to risk assessment.
- Review committees made up of independent scientists and independent research are needed.

Identify governance functions of non-governmental participants

- Stewardship practices of organizations, companies. Stewardship practices are an important part of governance. Stewardship ensures quality regardless of process, e.g., Excellence Through Stewardship (ETS) program.
- Trade issues are an important part of this discussion and are not represented at the meeting. (Response: U.S. Trade Representative (USTR) is part of the update to the Coordinated Framework's Biotechnology Working Group (BWG)).

Communications among governance components is critical

- May use suggestions from Breakout Group on Education, Communication and Outreach.
- Maybe there is a role for the public to articulate the information they want.
- Science is hard to explain to non-scientists:

- Government needs to be more pro-active in reaching out to non-scientists so that they understand what they do. (For example, different age groups receive info differently).
- Not listening to stakeholders does not engender trust. All voices need to be heard and should not be demeaned.
- Understand how the public connects to science, how science connects to the public, and how it's different for different generations and may be changing over time.

Access to information is a required component of good governance

- There needs to be information on places other than government websites and to deliver the information to the public rather than expecting the public to get it.
- Coordinated Framework is arcane and so it makes answering questions hard/unclear:
 - Need some place for average persons to get answers (especially to common public questions that are associated with biotech).
- Use multiple means to reach the targeted audiences.
- Need more generalized access to Intellectual Property to bring to debate.
- Some misinformation, on all sides of the debate, being disseminated to the public by various groups via internet based/cloud communications.

Comments not totally germane to this session

Common theme for conference. New technologies not included in discussion

- Current regulations not appropriate for gene editing technologies.
- Capacity to perform reviews needs to be expanded for new products because new product developments outstrip existing capacity.
- Some people don't agree that genetic engineering (GE) is the same as plant breeding.
- Agencies should say that products of GE are from traditional plant breeding to avoid distrust among the public.

Other topics

- Not a lot of trust when assessment comes from company making the product.
- Should look at products and means of manufacturing these products.
- Some people are morally opposed to these products.
- Indirect benefits of this technology are not understood by consumers.
- Folks should be able to farm the way they want.

Breakout Session 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?*

Session Notes

- During the education, communication, and outreach breakout session some themes that emerged were:
 - the value that GE products provide to the public;
 - concern about the safety of GE organisms;
 - new products of biotechnology;
 - centralization of processes that span the three agencies that currently regulate GE material; and
 - best platforms and tools that government agencies can employ to communicate with the public.
- Participants asked that the USDA conduct a study on the environmental impact of deregulated GE organisms that have been released into the environment (commercialize) over the last 30 years. Other participants explained that such studies have already been conducted and findings indicate that there are less pesticides and herbicides used and higher yields. This exchange stimulated a request that the benefits of GE products be explained by the agencies to the public in lay terms.
- There were specific requests that the discussion of the process or way in which GE organisms are created should be separated from the benefits. The public would like a simple easy way to evaluate the benefits of GE organisms such as a Miles per Gallon (MPG) or energy efficiency sticker consumers see on energy related products they purchase. One participant suggested a life cycle analysis that could standardize the environmental impacts in such a way that the benefits of a particular crop would be obvious, such as 1-5 rating scale where the higher number means more benefits.
- Some participants expressed concerns about the safety of GE products and asked that information be provided to the public about whether these products are found in food (including animals that have been fed GE feed). Some tools suggested to address these concerns included a label on the product or a barcode that links to information for the public.
- There were inquiries as to how new technologies, such as new gene editing techniques, would be regulated. Participants expressed frustration at the lack of consistent messaging and they asked that different types of GE technology be categorized as posing different levels of risk.
- Some suggestions of platforms to disseminate information included:
 - an updated website and/or a centralized call center;

- a centralized application for GE developers instead of using up to three agencies' processes that are often different;
- public would like open and continued communication with the agencies including a chat box or forum for discussion on the agencies' website;
- suggestion that the website for the public could have varying levels of information for individuals who prefer lay terms to experts in the field. This information should include clear, concise definitions that are shared by all of the agencies;
- other suggestions for outreach included, infographics and public relations on social media to explain the benefits of GE technology and how agencies conduct risk assessments. Participants mentioned that the USDA should hire a public relations representative and market the benefits and safety of GE products.

Breakout Session 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?*

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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)?

Participant Responses

- FDA review should be mandatory (not voluntary).
- It makes no sense to regulate the process used to engineer a product. Do not regulate process, but regulate the products – change the triggers for oversight.
- APHIS' plant pest-based trigger should be changed. The trigger should be trait-based.
- Adjust risk assessment and regulation. Regulate the phenotype, move away from case-by-case assessment.
- Need for predictability.
- There are enough unintended changes such that the process of genetic engineering should be the regulatory trigger.
- New processes often leave little genetic residue. The regulatory process should focus on the biology of the end product.
- There is a need for clarity from FDA as to when something will be treated as a food additive and when it will be treated under the Generally Recognized as Safe (GRAS) provisions.
- There should be mandatory labelling of food containing GMO ingredients.

- There should be differentiation between the process for producing something (e.g. genetically engineered (GE) microbe) and the product (protein for food). The protein should not be regulated differently than any other proteins just because it is from a GE organism. Regulators should only consider the properties of the protein.
 - Food produced using GE organisms should not be regulated any differently than other foods if the GE organisms are not present in the final food and the final food is equivalent to food not produced using GE organisms.
 - Foods produced from GE organism should be regulated differently than other foods. Because of the process, they might not be safe.
 - If facilities sending and receiving GE organisms meet performance standards for containment, APHIS should not regulate interstate movement.
 - Agencies should provide training/workshops and templates for applicants. Training or guidance is needed to clarify jargon. Communication should be improved by using non-jargon terms.
 - USDA is taking too long on permits and “Am-I-Regulated” letters. There should be mandatory timelines and penalties for USDA if timelines are not met.
 - We need a new definition of GE that does not include cases where no DNA is inserted.
 - Better define terms such as “GE,” –increases predictability for applicants.
 - Be more transparent with data requirements and regulatory triggers.
 - Reduce regulatory burden, especially costs.
 - Current regulations are unclear. This results in unforeseeable timelines and cost, which, in turn, results in lost opportunities. You can’t raise capital with unpredictable costs.
 - Agencies should define the “bare-bones” dataset. The multinational corporations submit too much and new applicants can’t tell what is actually needed. The required minimal dataset should be based on science.
 - There should be a single access point to the three agencies. Not one agency regulating, but one entity that acts as the access point and coordinates with the others; an ombudsman for the developer trying to navigate the regulatory process.
 - Decision tree might be helpful to clarify oversight over specific product.
 - Consider not regulating products of new gene editing techniques when there is no inserted DNA. If these same things happen in nature (equivalency), the final product should not be regulated.
 - Guidance for food production using GE organisms (food does not contain GE)—“processing aid.”
 - Not regulate processes to align with international trade.
 - There is a lack of clarity for engineered animals to be used as foods. Why are they regulated differently (new animal drug paradigm) than GE plants used for food. Clarify how GE animals are regulated; especially what is the trigger for an animal drug. GE animals produced for food should not be regulated as an animal drug.
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?

Participant Responses

- An explanation is needed as to why products are regulated by certain agencies. It should be explained based on the product, not the process. Especially for alleles that are equivalent to those that occur in nature. Provide a scientific rationale.
- There should be a GRAS list of genetic elements that have been used over and over which can be used without triggering regulation.
- There should be no list/no “get out of jail” for any genetic elements when it comes to regulating biotech products. Unintended consequences should be considered case-by-case.
- Guidelines for substantial equivalency needed. Clarify the basis of equivalence. In what way does a new GE organism have to be similar to a non-GE to be considered equivalent (and therefore approved).
- Regulations should be based on a risk-benefit analysis. The agencies should be required to provide a scientific justification as to why the biotech product is required to be regulated.
- Agencies should provide a list of resources on the web site including consultants who can help with navigate the system.
- Find a way to increase efficiencies when multiple agencies are looking at the same data. There could be a coordinated review where different agencies look at different data in the dossier (e.g. only FDA should look at allergenicity, not EPA).
- Coordinate between agencies through MOUs to reduce burden to provide data.
- Coordinated information package that goes out to all agencies at the same time.
- There should be only one dossier and each agency gets what they need from parts relevant to them.
- There should be a sophisticated IT system for the common dossier described above that helps the developer in assembling the package. Each agency accesses it there. Create semantic framework, similar to patent law language, to create a more unified regulatory framework and clarify roles of the agencies. And to aid in identifying parts of an application relevant to individual agencies, see XML.
- Explore a coordinated information package on the international scale.
- Similar products should be regulated similarly under the law.
- Use of case precedence in regulatory review.
- Guidance for minimal information on data requirements. What kinds of data are required, which kinds of analytical methods are acceptable?