# Progress on Modernizing the Regulatory System for Biotechnology Products

## —Second Public Meeting—

March 9, 2016
9:30 AM – 1:00 PM

EPA Region 6 Main Office
1445 Ross Avenue, Room TBD
Dallas, TX

Robert McNally
*Director*
*Biopesticide and Pollution Prevention Division, Office of Pesticide Programs*
*US Environmental Protection Agency*

# OPENING REMARKS

Jeffrey Morris
*Deputy Director*
*Office of Pollution Prevention and Toxics*
*US Environmental Protection Agency*

# WELCOME

Robert McNally
*Director*
*Office of Pesticide, Bio-pesticide, and Pollution Prevention*
*US Environmental Protection Agency*

# REVIEW AGENDA

# Agenda

- Opening Remarks
- Modernizing the Regulatory System for Biotechnology
- Review of Public Comments to RFI
- Progress Update
- Regulation of Biotechnology Product Case Studies
  - Products for Human Food and Animal Feed
  - Products for Biomedical Application
  - Microbial Products for Pesticide or Industrial Application
  - Product with Other Applications
- Third Public Meeting
- Additional Information
- Public Comments

Robbie Barbero
*Assistant Director for Biological Innovation*
*White House Office of Science and Technology Policy*

# MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS

# Background

- June 1986: White House Office of Science and Technology Policy (OSTP) issued 51 FR 23302, The Coordinated Framework for the Regulation of Biotechnology
- February 1992: OSTP issued 57 FR 6753, an update to the Coordinated Framework
- January 2011: Executive Order 13563---Improving Regulation and Regulatory Review
- July 2015: Executive Office of the President (EOP) issued an memorandum directing US Environmental Protection Agency (EPA), US Food and Drug Administration (FDA), and US Department of Agriculture (USDA) to—
  - update the Coordinated Framework for the Regulation of Biotechnology by clarifying current roles and responsibilities;
  - commission an expert analysis of the future landscape of biotechnology products to support this effort; and
  - develop a long-term strategy to ensure that the Federal biotechnology regulatory system is prepared for the future products of biotechnology.

# 2015 Memorandum on Modernizing the Regulatory System for Biotechnology Products

## Goals and Guidance

- Federal agencies that regulate biotechnology products should continually strive to improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements. It is critical that these improvements
  - maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
  - establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and
  - promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.

# Principles Guiding the Regulation of Biotechnology Products

from the 1986 Coordinated Framework for the Regulation of Biotechnology and the 1992 update

- The process used to make a product does not determine the safety of or risk posed by the product; rather it is the characteristics of the organism, the environment into which it will be introduced, and the application of the organism that determine risk (or lack thereof) of a biotechnology product
- A risk-based approach to regulation should distinguish between those organisms that require a certain level of federal action and those that do not
- A risk-based approach properly protects public health and the environment against risk, and avoids hindering safe innovations
- Each agency will use its existing statutory authorities and regulatory programs to help ensure the safety of the biotechnology products
- Federal statutes and implementing regulations regulate products based on specific uses, which allows similar products (whether made using biotechnology or not) to be treated similarly by regulatory agencies
- Agencies should seek to operate their programs in an integrated and coordinated fashion
- Although there is some inconsistency in statutory nomenclature, reviews conducted by each regulatory agency is of comparable rigor
- Future scientific developments will lead to further refinements of Federal policies

# (1) Update the Coordinated Framework

- Clarify which biotechnology product areas are within the authority and responsibility of each agency;
- Clarify the roles that each agency plays for different product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment;
- Clarify a standard mechanism for communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function; and
- Clarify the mechanism and timeline for regularly reviewing, and updating as appropriate, the Coordinated Framework to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products.

# (2) Long-term strategy

- Increase Transparency
  - Establish a timetable and mechanisms to work with stakeholders to identify impediments to innovation, focusing on building new, and augmenting existing, stakeholder collaborations to inform efforts, increase transparency, streamline processes, reduce costs and response times, and ensure the protection of health and the environment;
  - Coordinate the development of tools and mechanisms for assisting small businesses developing biotechnology products to navigate the regulatory system;
  - Initiate development of a modernized, user-friendly set of tools for presenting the regulatory agencies' authorities, practices, and bases for decision making for the regulation of biotechnology products to the public, including digital services to improve the interactions between the FDA, EPA, USDA, the general public, and product developers and updating these tools and practices regularly to ensure optimal transparency; and
  - Proactively engage with the public to discuss how the Federal government uses a risk-based, scientifically sound approach to regulating the products of biotechnology, and clearly communicating to the public which types of products are regulated, which types of products are not regulated, and why.

# (2) Long-term strategy

- Support the science that underpins the regulatory system
  - Work with other Federal agencies, as appropriate, to develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities;
- Predictability and Efficiency
  - Develop a plan for periodic formal horizon-scanning assessments of new biotechnology products;
  - Identify changes to authorities, regulations, and policies, if any, that could improve agencies' abilities to assess expeditiously the potential impacts and risks arising from future products of biotechnology and to ensure the transparency, predictability, and efficiency of regulatory oversight for such products; and
  - Ensure that product evaluations are risk-based and grounded in the best science available, including regularly adjusting regulatory activities based on experience with specific products and the environments into which those products have been introduced.

Robbie Barbero
*Assistant Director for Biological Innovation*
*White House Office of Science and Technology Policy*

# PROGRESS TO DATE

# Modernizing the Regulatory System for Biotechnology Products: Progress to Date

- July 2015: Formed the Biotechnology Working Group under the auspices of the Emerging Technologies Interagency Policy Coordination (ETIPC) Committee
- October – November 2015: Request for Information (RFI) posted on the Federal Register
  - 903 comments received
- October 30, 2015: Public meeting at FDA White Oak Campus, Silver Spring, MD
  - USDA/APHIS, EPA, and FDA discussed Federal regulation of biotechnology products
  - Over 300 registered to attend in-person or via webcast
  - 17 oral comments

# Modernizing the Regulatory System for Biotechnology Products: Progress to Date

- January 2016: National Academies of Science announces study called "Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory Systems"
  - Major advances and potential new types of biotechnology products over the next 5–10 years,
  - Whether potential future products could pose different types of risk relative to existing products and organisms,
  - Areas in which the risks or lack of risk relating to biotechnology are well understood, and
  - What scientific capabilities, tools, and expertise may be useful to the regulatory agencies to support oversight of potential future products of biotechnology
- March 2016:
  - Website established: www.nas.edu/biotech
  - Provisional study committee to be announced in the coming days

# Modernizing the Regulatory System for Biotechnology Products: Progress to Date

- November 2015-Present: USDA, EPA, FDA, and EOP reviewed the public responses to RFI
- Ongoing: Updating Coordinated Framework and developing long-term strategy
- March 9, 2016: Second public meeting – Dallas, TX
  - Focused on clarifying current roles and responsibilities
- March 30, 2016: Third public meeting – Davis, CA
- Spring/Summer 2016: Update to Coordinated Framework will be made available for public comment

Robbie Barbero
*Assistant Director for Biological Innovation*
*White House Office of Science and Technology Policy*

# SUMMARY OF PUBLIC COMMENTS TO RFI

# Review of RFI Comments

- Written and oral comments were submitted by industry, academia, trade associations, consumer groups, environmental advocacy groups, individual consumers, foreign governments, and other organizations.
- The agencies received and reviewed approximately 900 written responses to the RFI and the Federal Register notice announcing the public meeting.
- The agencies also received and have reviewed oral comments made at the public meeting.
- What follows is a brief summary of the responses

# Summary of RFI Comments: General Responses (1 of 2)

- Favored the use of risk-based, science-based regulatory systems and a coordinated framework that facilitates (or does not stifle) innovation and reduces burden to industry, particularly to small businesses
- Requested balance between the level of regulation and the degree of risk posed by a new trait or an existing trait in a new environment
- Noted that the complexities of the current regulatory system have made it difficult for small companies and academics to navigate the system
- Sought uniform regulation across products rather than regulation based on the process of production
- Funding agencies should support more risk assessment research for biotechnology products

# Summary of RFI Comments: General Responses (2 of 2)

- Discussed expanding exemptions and fast-tracking product reviews for familiar products
- Recommended regulating based on process, using genetic engineering, in and of itself, as the trigger for mandatory premarket review of products, with independent testing of ecological and health risks
- Recommended agencies harmonize their regulatory approaches with Codex guidelines and coordinate with international regulatory partners
- Noted that the range of traits in GE products on the market is very small, so past safety evaluations cannot apply to more diverse technologies now in development
- Suggested manufacturers publish safety data early in development process

# Summary of RFI Comments: Recommendations Related to Public Education, Awareness, and Outreach

- Supported agencies taking action regarding public education, awareness, and training on genetic engineering, generally, as well as on specific applications
- Facilitate coordinated public outreach sessions with the agencies
- Develop simple and easy-to-understand information about how agencies regulate products and coordinate their respective roles/responsibilities and provide information on a single U.S. government website
- Share scientific evidence and information underlying regulatory decisions with the public
- Develop safety and security training programs for researchers and hobbyists
- Establish standards for information sharing and harmonizing protocols across agencies
- Suggested that filling regulatory gaps, clarifying agency roles and responsibilities, and conducting risk assessments for novel products will build public confidence

# Summary of RFI Comments: Recommendations Related to Coordination among Regulatory Agencies

- Coordinate among regulatory agencies, including on risk assessments and data collection on unintended consequences
- Create a “review” board consisting of representatives from all three regulatory agencies to review all new genetically engineered and non-genetically engineered crops
- Establish a group of experts under NAS (with representation from each regulatory agency) to determine whether a product is exempt from review, and creating and publishing decision trees for developers to determine whether products are exempt
- Streamline regulatory processes and procedures to expedite reviews or approvals
- Coordinate among relevant agencies such that the burden on industry with respect to obtaining multiple permits for conducting trials could be reduced
- Establish a centralized coordinating office or a “single window” for entry for service of regulatory submissions for biotechnology products
- Group similar products into categories and appoint primary agency in charge of oversight for each product area

# Summary of RFI Comments: Other Recommendations

- Identify and establish appropriate restrictions related to genetically engineered plants (e.g., restrictions on “herbicide-tolerant” or “pesticide-tolerant” crops), restrictions on where and how genetically engineered (GE) crops are grown so as to minimize potential for cross-contamination; and/or restrictions on privately-owned GE seed stock
- Adopt a U.S. Federal regulatory policy for low level presence of GE sources in food, feed, and seed
- Clarify how products of genome editing are regulated
- Fund risk assessment research to support creation of regulatory exemptions
- Grant confidential business information status less freely
- Exempt DNA from the TSCA review process
- Impose more post-market requirements and lighten pre-market requirements
- Assess the risk of products evolving beyond designed capacity and identify possible interactions between products and environment in which it is kept
- Clarify agency roles on field trials and dual-use products
- Clarify the regulation of genetically engineered insects
- Implement post-market surveillance programs to ensure the traceability of genetically-engineered ingredients or components of products

US Department of Agriculture / Animal and Plant Health Inspection Service
US Environmental Protection Agency
US Food and Drug Administration

# REGULATION OF BIOTECHNOLOGY PRODUCTS



# Agency Protection Goals for the Regulation of Biotechnology Products

| Agency | Statute | Protection Goals |
|---|---|---|
| USDA/APHIS | Animal Health Protection Act (AHPA) | Protect livestock from animal pests and disease risks |
| USDA/APHIS | Plant Protection Act (PPA) | Protect agricultural plants and agriculturally important natural resources from damage caused by organisms that pose plant pest or noxious weed risks |
| EPA | Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) | Eliminate unreasonable adverse effects upon man and the environment<br>• For environmental and occupational risks, this involves comparing economic, social, and environmental risks and benefits associated with pesticide use<br>• For dietary or residential human health effects, the sole standard is the safety of exposure |
| EPA | Food, Drug, and Cosmetics Act (FD&C Act) | Ensure dietary exposure to pesticide chemical residues in or on food are safe |
| EPA | Toxic Substances Control Act (TSCA) | Ensure the manufacture, processing, distribution in commerce, use, or disposal of chemical substances, or any combination of such activities with such substances does not present unreasonable risk of injury to health or the environment |
| FDA | FD&C Act<br>Public Health Service Act | Ensure food is safe, sanitary, and properly labeled<br>Ensure human and veterinary drugs are safe and effective<br>Ensure there is a reasonable assurance of safety and effectiveness of devices intended for human use<br>Ensure cosmetics are safe and properly labeled<br>Ensure public health and safety are protected from electronic product radiation<br>Regulate tobacco products |

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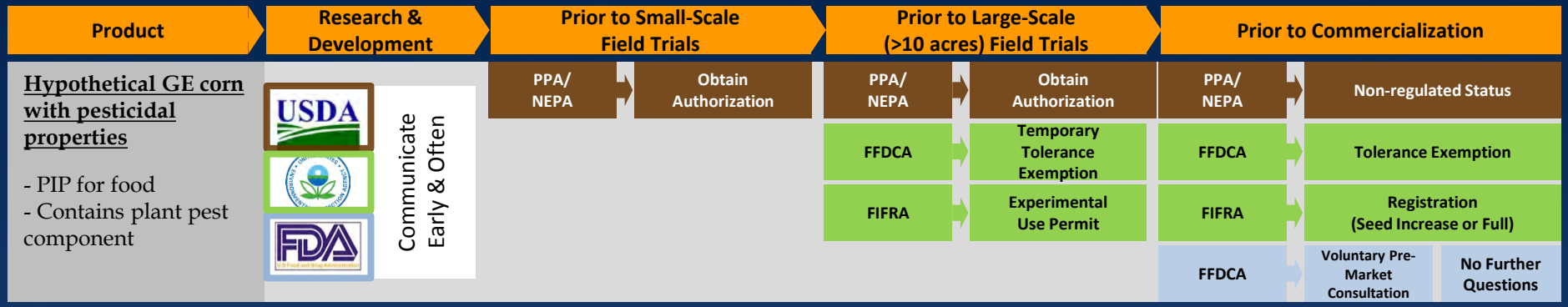
FDA U.S. Food and Drug Administration

# Case Study: Products for Human Food and Animal Feed




*Note that in many cases, products of biotechnology also have post market monitoring and reporting requirements that will apply but are not depicted here. More information on such requirements are available in relevant agency regulations and guidances.*

# Product: Hypothetical GE Corn with Pesticidal Properties

- Typical Major Milestones During Product Development—USDA/APHIS
  - During R&D phase
    - Notification for interstate movement or import
  - Prior to small- or large-scale field trials
    - Notification or permit for interstate movement, import, or release
    - Fulfill National Environmental Policy Act (NEPA) obligations
      - Confined field trials usually are categorically excluded actions under NEPA
  - Prior to commercialization
    - May petition for non-regulated status
    - NEPA-usually an EA-could be an Environmental Impact Statement (EIS)

# Product: Hypothetical GE Corn with Pesticidal Properties

- Typical Major Milestones During Product Development—EPA
  - During R&D phase
    - N/A
  - Prior to small-scale field trials (cumulative plot size <10 acres)
    - N/A
  - Prior to large-scale field trials (cumulative plot size >10 acres)
    - Obtain a temporary tolerance or tolerance exemption for the residues of the pesticidal trait in the food if GE corn will enter the food supply
    - Obtain an experimental use permit (EUP)
  - Prior to commercialization
    - Obtain tolerance or tolerance exemption for the residues of the pesticidal trait in the food if GE corn will enter food supply
    - Register GE corn Plant-Incorporated Protectant (PIP)

# Product: Hypothetical GE Corn with Pesticidal Properties

- Typical Major Milestones During Product Development—FDA
  - During R&D phase
    - N/A
  - Prior to small-scale field trials
    - May provide information for consideration and initiate consultation about food safety and other FDA-related regulatory issues
  - Prior to large-scale field trials
    - If not already done, may provide information for consideration and initiate consultation about food safety and other FDA-related regulatory issues
  - Prior to commercialization
    - Developer is strongly encouraged to complete a voluntary consultation with FDA to help ensure any food safety or other regulatory issues are resolved

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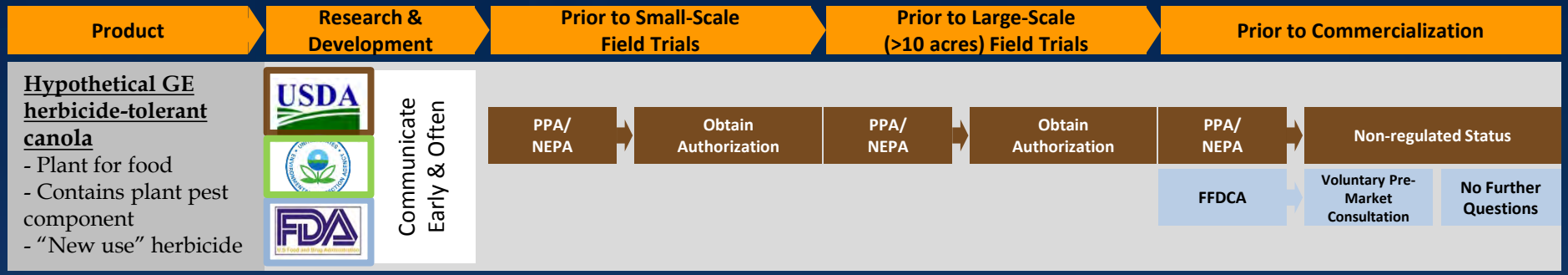
# Case Study: Products for Human Food and Animal Feed




*Note that in many cases, products of biotechnology also have post market monitoring and reporting requirements that will apply but are not depicted here. More information on such requirements are available in relevant agency regulations and guidances.*

# Product: Hypothetical Herbicide-Tolerant Canola

- Typical Major Milestones During Product Development—USDA/APHIS
  - –During R&D phase
    - Notification for interstate movement or import
  - –Prior to small- or large-scale field trials
    - Notification or permit for interstate movement, import, or release
    - Fulfill National Environmental Policy Act (NEPA) obligations
      - –Confined field trials usually are categorically excluded actions under NEPA
  - -Prior to commercialization
    - May petition for non-regulated status
    - NEPA-usually an EA-could be an Environmental Impact Statement (EIS)

# Product: Hypothetical Herbicide-Tolerant Canola

- Typical Major Milestones During Product Development—EPA
  - During R&D phase
    - N/A
  - Prior to small-scale field trials
    - N/A (provided Herbicide-X-treated-canola is kept out of the food supply)
  - Prior to large-scale field trials
    - Obtain a temporary tolerance for Herbicide X if Herbicide-X-treated-canola will enter the food supply and Herbicide X residues are not covered by an existing tolerance
    - Obtain an experimental use permit (EUP) for Herbicide X
  - Prior to commercialization
    - Obtain a tolerance for Herbicide X
    - Amend Herbicide X registration

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FDA U.S. Food and Drug Administration

# Product: Hypothetical Herbicide-Tolerant Canola

- Typical Major Milestones During Product Development—FDA
  - During R&D phase
    - N/A
  - Prior to small-scale field trials
    - May provide information for consideration and initiate consultation about food safety and other FDA-related regulatory issues
  - Prior to large-scale field trials
    - If not already done, may provide information for consideration and initiate consultation about food safety and other FDA-related regulatory issues
  - Prior to commercialization
    - Developer is strongly encouraged to complete a voluntary consultation with FDA to help ensure any food safety or other regulatory issues are resolved

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# Products for Human Food and Animal Feed

Questions & Answer Session

# Case Study: Products for Biomedical Application

| Product | Investigational Trials | | | Prior to Commercialization | | |
|---|---|---|---|---|---|---|
| **Hypothetical GE Rabbit**<br>• Contains engineered rDNA construct (new animal drug)<br>• Produces recombinant human insulin (new drug) | USDA, EPA, FDA: Communicate Early & Often | FFDCA | Investigational New Animal Drug File | Investigational New Animal Drug Exemption | FFDCA | Applications: NADA & NDA | Approvals: NADA & NDA |

**Note that in many cases, products of biotechnology also have post market monitoring and reporting requirements that will apply but are not depicted here. More information on such requirements are available in relevant agency regulations and guidances.*

# Product: Hypothetical GE Rabbit

- Typical Major Milestones During Product Development—FDA
  - After animal lineage is established
    - Initiate discussion of GE rabbit with CVM
    - Open a investigational new animal drug (INAD) file with CVM
    - Submit data and information pertaining to GE rabbit lineage to INAD
  - Prior to clinical trials activities related to recombinant insulin
    - Obtain an investigational new drug (IND) exemption from CDER
  - Prior to commercialization
    - Submit a new animal drug application (NADA) for rDNA construct in the rabbit
      - Submit EA or claim a categorical exemption
    - Submit a new drug application (NDA) for recombinant insulin
      - Submit EA or claim a categorical exemption
    - Demonstrate GE rabbit and recombinant insulin meet safety and effectiveness standards

# Products for Biomedical Applications

Questions & Answer Session

# Case Study: Microbial Products for Pesticide or Industrial Application

| Product | Research & Development | Prior to Small-Scale Field Trials | Prior to Large-Scale (>10 acres) Field Trials or Pesticidal Intermediate | Prior to Commercialization |
|---|---|---|---|---|
| **Hypothetical Microbial Pesticide**<br>• Contains plant pest components<br>• GE bacterium increases herbivore resistance | Communicate Early & Often | PPA/ NEPA → Obtain Authorization | PPA/ NEPA → Obtain Authorization | PPA/ NEPA → Obtain Authorization |
| | | | FFDCA → Temporary Tolerance Exemption | Tolerance Exemption |
| | | FIFRA → Biotechnology Notification | FIFRA → Experimental Use Permit | FIFRA → Full Registration |

**Note that in many cases, products of biotechnology also have post market monitoring and reporting requirements that will apply but are not depicted here. More information on such requirements are available in relevant agency regulations and guidances.*

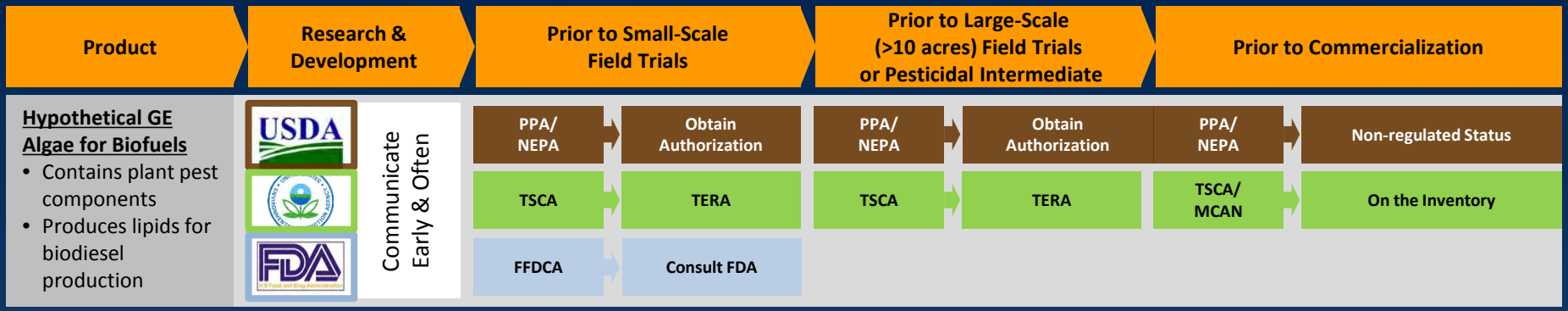
# Product: Hypothetical GE Microbial Pesticide—Plant Pest Components

- Typical Major Milestones During Product Development—USDA/APHIS
  - –During R&D phase
    - Permit and pesticide notice of arrival for import
    - Permit for interstate movement
  - –Prior to small- or large-scale field trials
    - Permit for interstate movement, import, or release
    - Fulfill NEPA obligations
      - –Confined field trials usually are categorically excluded actions
      - –Exceptions for new species or novel modifications that raise new issues (most likely an EA)
  - -Prior to commercialization
    - May petition for non-regulated status.
    - NEPA-usually an EA-could be an EIS

# Product: Hypothetical GE Microbial Pesticide—Plant Pest Components

- Typical Major Milestones During Product Development—EPA
  - During R&D phase
    - N/A
  - Prior to small-scale field trials
    - Submit biotechnology notification to determine if an experimental use permit (EUP) is required
  - Prior to large-scale field trials
    - Obtain a temporary tolerance or tolerance exemption if crops treated with GE microbial pesticide will enter food supply
    - Obtain an EUP
  - Prior to commercialization
    - Obtain a tolerance or tolerance exemption if crops treated with GE microbial pesticide will enter food supply
    - Register GE microbial pesticide

# Case Study: Microbial Products for Pesticide or Industrial Application




*Note that in many cases, products of biotechnology also have post market monitoring and reporting requirements that will apply but are not depicted here. More information on such requirements are available in relevant agency regulations and guidances.*

# Product: Hypothetical GE Algae for Biofuels

- Typical Major Milestones During Product Development—USDA/APHIS
  - –During R&D phase
    - Notification for import or interstate movement
  - –Prior to small- or large-scale field trials
    - Notification for interstate movement, import, or release
    - Fulfill NEPA obligations
      - –Confined field trials usually are categorically excluded actions
      - –Exceptions for new species or novel modifications that raise new issues (most likely an EA)
  - -Prior to commercialization
    - May petition for non-regulated status.
    - NEPA-usually an EA-could be an EIS

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FDA U.S. Food and Drug Administration

# Product: Hypothetical GE Algae for Biofuels

- Typical Major Milestones During Product Development—EPA
  - During contained R&D phase (e.g. lab development)
    - No reporting requirements
    - Technically qualified individual (TQI) assigned
    - Recordkeeping and other good laboratory practices (GLP) required
  - Prior to small-scale field trials
    - Submit a TSCA experimental release application (TERA) at least 60 days before field work
    - Obtain TERA approval
  - Prior to large-scale field trials
    - Submit a TSCA experimental release application (TERA) if the initial TERA did not cover all project phases
    - Obtain TERA approval
  - Prior to commercialization
    - Submit microbial commercial activity notice (MCAN) at least 90 days prior to initiation of manufacture, importation, or use
    - Submit a notice of commencement to have GE alga added to the TSCA inventory

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FDA U.S. Food and Drug Administration

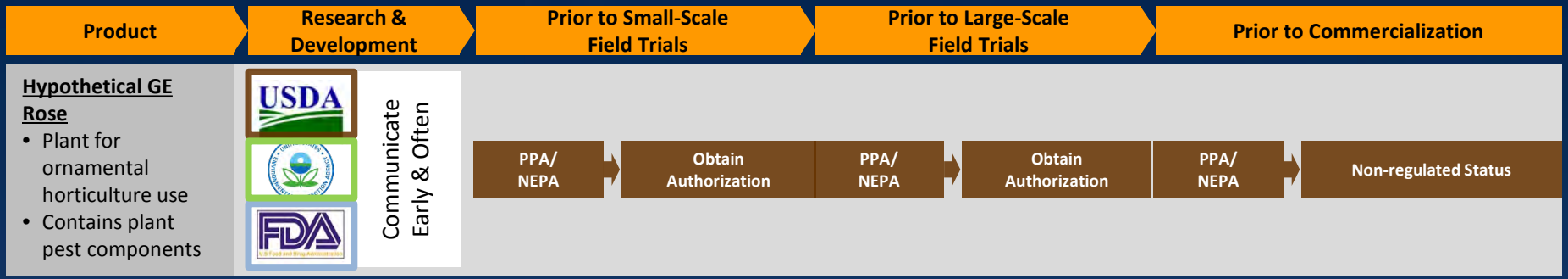
# Product: Hypothetical GE Algae for Biofuels

- Typical Major Milestones During Product Development—FDA
  - During R&D phase
    - N/A
  - Prior to small-scale field trials
    - May provide information for consideration and initiate consultation about food safety and other FDA-related regulatory issues
  - Prior to large-scale field trials
    - If not already done, may provide information for consideration and initiate consultation about food safety and other FDA-related regulatory issues
  - Prior to commercialization
    - Developer is strongly encouraged to consult with FDA to help ensure any food safety or other regulatory issues are resolved

# Microbial Products for Pesticide or Industrial Application

Questions & Answer Session

# Case Study: Products with Other Applications




*Note that in many cases, products of biotechnology also have post market monitoring and reporting requirements that will apply but are not depicted here. More information on such requirements are available in relevant agency regulations and guidances.*

# Product: Hypothetical GE Rose

- Typical Major Milestones During Product Development—USDA/APHIS
  - During R&D phase
    - Notification for import or interstate movement
  - Prior to small- or large-scale field trials
    - Notification for interstate movement, import, or release
    - Fulfill NEPA obligations
      - Confined field trials usually are categorically excluded actions
      - Exceptions for new species or novel modifications that raise new issues (most likely an EA)
  - Prior to commercialization
    - May petition for non-regulated status
    - NEPA-usually an EA-could be an EIS
  - Post-commercialization
    - Ensure GE rose is used as an ornamental (no food use)

# Products with Other Applications

Questions & Answer Session

Robbie Barbero
*Assistant Director for Biological Innovation*
*White House Office of Science and Technology Policy*

# THIRD PUBLIC MEETING

# Update to the Coordinated Framework: 3rd Public Meeting

- Date: March 30, 2016
- Location: University of California at Davis Campus
- More information (including the agenda and how to register) will be provided prior to the meeting on
  - Federal docket: http://www.regulations.gov/#!docketDetail;D=FDA-2015-N-3403
  - USDA website: coming soon

Moderator: Robbie Barbero

*Assistant Director for Biological Innovation*

*White House Office of Science and Technology Policy*

# PUBLIC COMMENT

# Public Comment

- Speakers TBD

# ADDITIONAL INFORMATION

# Additional Information

- 1986 Coordinated Framework for Regulation of Biotechnology
  - https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf
- 1992 Update to Coordinated Framework: Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment
  - https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753__1992.pdf
- 2015 EOP Memo and Blog post: Modernizing the Regulatory System for Biotechnology Products
  - https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf
  - https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology
- Other Relevant Policy Documents
  - "Improving Regulation and Regulatory Review", Executive Order 13563, January 18, 2011.
    - http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf
  - "Principles for Regulation and Oversight of Emerging Technologies", Memorandum for the Heads of Departments and Agencies, March 11, 2011.
    - https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf
  - "Identifying and Reducing Regulatory Burdens", Executive Order 13610, January 10, 2012.
    - https://www.whitehouse.gov/sites/default/files/docs/microsites/omb/eo_13610_identifying_and_reducing_regulatory_burdens.pdf