



Update on FDA's Activities Related to Biotechnology-Derived Plants and Animals

**Presentation to the FDA Science Board
June 26, 2017**



Outline

I. Overarching USG Effort

Modernizing the Regulatory System for Biotechnology Products

II. FDA-Specific Activities (related to Genome Editing)

- A. Regulation of Human and Animal Foods Derived from Genetically Engineered Plants
- B. Regulation of Animals with Intentionally Altered Genomic DNA



Modernizing the Regulatory System for Biotechnology Products

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Key Points Covered

- Federal Policy for the Regulation of Biotechnology – History
- Modernizing the Regulatory System -- Effort Initiated in 2015
- Public Engagement
- 2017 Update to the Coordinated Framework for the Regulation of Biotechnology
- Long-term National Strategy
- NASEM Study on Preparing for Future Products

U.S. Coordinated Framework for Regulation of Biotechnology - History

- Describes federal regulatory system for evaluating products of biotechnology
- Based on existing laws that provide basic network of agency jurisdiction (EPA, FDA, USDA)
- Established formal policy in 1986, last updated in 1992
- Articulated principles for regulatory oversight
 - Sought to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of industry
 - Promotes risk-based approach to regulation distinguishing between those organisms that require a certain level of federal review and those that do not.
 - The process of modification is thus independent of the safety of the organism. It is the characteristics of the organism, the environment, and the application that determine risk (or lack thereof) of the introduction, not the technique used to produce the organism.

Modernizing the Regulatory System

Ongoing effort, initiated in 2015, in response to an EOP Memorandum

Goal: Ensure public confidence in regulatory system and improve transparency, predictability, coordination, and efficiency of the regulatory system

Three key tasks:

1. Clarify roles/responsibilities of agencies that regulate biotechnology products (Publish update to Coordinated Framework)
2. Develop a long-term national strategy to ensure that the Federal regulatory system is well-prepared for the future products of biotechnology
3. Commission external analysis of future landscape of biotechnology products

Note: Human medical products not a focus of this effort

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.

Interagency Biotechnology Working Group

- Established a Biotechnology Working Group under the White House Emerging Technologies Interagency Policy Coordination Committee; Includes representatives from:
 - Executive Office of the President
 - EPA
 - FDA
 - USDA
- Federal Register notice Request for Information
 - Interagency Request for Information (RFI) to solicit relevant data and information, including case studies, that can assist in the development of Update to the Coordinated Framework and the long-term national strategy
 - Nearly 1,000 public comments in public docket

Public Engagement (1)

- 3 public meetings
- Hosted by EPA, FDA, USDA-APHIS
- Held in 2015-2016 at different locations in the U.S.
- Purpose
 - Describe current regulatory procedures and data elements of safety reviews through use of case studies
 - Solicit public input

Public Engagement (2)

- October 30, 2015: First public meeting – Silver Spring, MD
 - Discussed overview of Federal regulation of biotechnology products
 - Over 300 registered participants in-person or via webcast

- March 9, 2016: Second public meeting – Dallas, TX
 - Focused on clarifying current roles and responsibilities by discussing case studies of hypothetical products
 - Over 150 registered participants in-person or via webcast

- March 30, 2016: Third public meeting – Davis, CA
 - Focused on clarifying current roles and responsibilities by discussing case studies of hypothetical products; and
 - Gathered individual stakeholder input on three general thematic areas:
 - Governance
 - Education, communication, and outreach
 - Improving regulatory certainty
 - Over 300 registered participants in-person or via webcast

Task 1 - Publish Update to the Coordinated Framework

Objectives

- 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.

2017 Update to Coordinated Framework

2017 Update to the Coordinated Framework for the Regulation of Biotechnology, issued in January 2017

(https://www.whitehouse.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf)

- Issued in September 2016 as Proposed Update for public comment
- Finalized after considering public input

Key Themes

- Reaffirms principles for risk-based regulatory approach, elaborated in 1986 and 1992
- Describes FDA, EPA, and APHIS' scope of regulation, statutory bases, and regulatory processes
- Clarifies roles and responsibilities of the three agencies -- identifies the agencies that provide oversight for different products (e.g., foods, pesticides, industrial chemicals) derived from different GE sources (e.g., plants, animals, microbes)

Task 2 - Develop a long-term National Strategy

Objectives

- **Increasing Transparency**
 - Establish a timetable and mechanisms to work with stakeholders
 - Initiate development of a modernized, user-friendly set of tools for stakeholder communication and assisting small businesses
 - Proactively engage with public to discuss federal regulation
- **Increasing Predictability and Efficiency**
 - Develop a plan for periodic horizon-scanning of new biotechnology products
 - Identify changes to authorities, regulations, and policies, if any; and
 - Ensure that product evaluations are risk-based and grounded in the best science available
- **Supporting science that underpins the regulatory system**
 - Develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities

National Strategy

National Strategy for Modernizing the Regulatory System for Biotechnology Products, issued September 2016

(https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf)

- Sets forth a vision for ensuring U.S. regulatory system is equipped to assess risks, if any, of future products
- Identifies FDA, EPA, and USDA's ongoing and future activities

Key Themes

- Increasing transparency (e.g., active public communication; working with stakeholders; reducing burden to industry, particularly small businesses)
- Increasing predictability and efficiency (e.g., periodic horizon-scanning; ensuring risk-based product evaluations; identifying changes to regulations, policies)
- Supporting regulatory science (e.g., enhancing coordination with research agencies)

Task 3 – Commission External Analysis

- External, independent assessment of future landscape of biotechnology products that will identify:
 - Potential new risks and frameworks for risk assessment; and
 - Areas in which risks or lack of risks are well understood
- Intended to inform future policy making
- Commissioned by EPA, FDA, and USDA

NASEM Future Products Study

- Conducted by the National Academies of Science, Engineering, and Medicine (NASEM), initiated in early 2016
- Study focused on:
 - What will the likely future products of biotech be over the next 5-10 years?
 - What scientific capabilities, tools, and/or expertise may be needed by the regulatory agencies to ensure they make efficient and sound evaluations of the likely future products of biotech?
- NASEM published study report in March 2017
(<http://nas-sites.org/biotech/>)
- FDA (along with others in USG) currently reviewing study findings and will consider them in our ongoing and future biotechnology activities

Timeline

Date	Activity
July 2015	EOP Memorandum issued
October 2015	Request for Information issued for public comment
October 2015	Public meeting #1 (Washington, DC)
January 2016	Agencies commissioned NASEM study
March (early) 2016	Public meeting #2 (Dallas, TX)
March (end) 2016	Public meeting #3 (UC Davis, CA)
November 2016	<i>Draft</i> Update to Coordinated Framework issued for public comment National Strategy issued
January 2017	<i>Final</i> 2017 Update to Coordinated Framework issued
January 2017	Agency-specific documents issued for public comment
March 2017	NASEM completed study and issued report

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Genome Editing

- Public comments indicate stakeholders seek clarification on regulation of products of genome editing techniques
 - Clarification on how FDA's regulatory framework for GE plant-derived foods applies to those obtained through genome editing
 - Clarification on whether GFI 187 (on genetically engineered animals) applies to insertions/deletions/alterations obtained through genome editing
 - Broader USG and international regulatory context
- In the National Strategy document, FDA committed to working on this issue

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FDA Regulation of Human and Animal Foods Derived from Genetically Engineered Plants

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Key Points Covered

- 1992 Policy Statement
- Voluntary Premarket Plant Biotechnology Consultation Process
- New Technologies

Coordinated Framework

- FDA is the primary Federal agency responsible for ensuring the safety of food and food additives, except meat and poultry products.
 - Meat and poultry products are regulated by the U.S. Department of Agriculture (USDA)
 - FDA works closely on food safety matters with the U.S. Environmental Protection Agency (EPA), which reviews the safety of pesticides and sets tolerances for pesticide chemical residues in food.
 - EPA evaluates the safety of herbicides and insecticides that may be associated with genetically engineered crops.

"Food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article (21 U.S.C. 321(f)). "Food" includes human food, substances migrating to food from food-contact articles, pet food, and animal feed (21 CFR 170.3(m)).

1992 Policy Statement

- FDA issued a “Statement of Policy: Foods Derived from New Plant Varieties” (1992 policy statement)

57 FR 22984, May 29, 1992

- The 1992 policy statement clarifies FDA's interpretation of the Federal Food, Drug and Cosmetic Act (FD&C Act) with respect to foods derived from new plant varieties, including those developed through genetic engineering, and reflects FDA's current policy regarding such foods.

1992 Policy Statement

- Foods derived from genetically engineered plant varieties are regulated within the existing framework of the FD&C Act utilizing an approach identical in principle to that applied to foods developed by traditional plant breeding.
- The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food.
- The 1992 policy statement describes how certain safety provisions in the FD&C Act can be applied to foods from new plant varieties.
 - Section 402- Adulterated Food
 - Section 409- Food Additives

1992 Policy Statement

Section 402- Adulterated Food

- “Under section 402(a)(1) of the act, a food is deemed adulterated and thus unlawful if it bears or contains an added poisonous or deleterious substance that may render the food injurious to health or a naturally occurring substance that is ordinarily injurious.”

57 FR 22984 at 22988

- This safety standard applies to any plant variety, whether produced through traditional breeding or other human intervention.

1992 Policy Statement

Section 409- Food Additives

- New components of food will be regulated as food additives if they are not generally recognized as safe (GRAS), subject to certain exceptions.
21 U.S.C. 321(s); 21 CFR 170.3(e)(1)
- Food additives require premarket review and approval before they can be lawfully marketed.
- The safety standard for use of a food additive is reasonable certainty of no harm under the conditions of intended use in food.
- In order for use of a substance to be GRAS:
 - there must be reasonable certainty of no harm under the conditions of intended use and general recognition of that fact, or
 - for a substance used before 1958, experience based on common use in food.

1992 Policy Statement

- Producers of new foods have an obligation under the FD&C Act to ensure that the foods they offer consumers are safe and otherwise in compliance with applicable legal requirements.

57 FR 22984 at 22985

- “FDA has long regarded it to be a prudent practice for producers of foods using new technologies to work cooperatively with the agency to ensure that the new products are safe and comply with applicable legal requirements. It has been the general practice of the food industry to seek informal consultation and cooperation, and this practice should continue with respect to foods produced using the newer techniques of genetic modification.”

57 FR 22984 at 22991

Premarket Consultation Process

- While participation in the process is voluntary, compliance with the law is not.
- FDA's voluntary consultation process allows firms a premarket opportunity to ensure that their foods meet applicable safety and other regulatory requirements.
 - The consultation process provides an opportunity to identify safety and/or regulatory issues associated with the food that may warrant additional analyses prior to marketing.
 - For example, an added substance may be a food additive whose use requires premarket review and approval before it can be lawfully marketed.

Premarket Consultation Process

- The consultation process has two phases.
 - Initial consultation phase
 - Final consultation phase

Premarket Consultation Process

Initial Consultations

- FDA encourages developers to consult early in the development phase of their products, and as often as necessary.
 - Firms may engage in an initial consultation as early as the product concept stage of development.
- Developers meet with FDA to describe their product and present any initial data and information they have collected. FDA can provide feedback about food safety and other regulatory issues that may need to be considered prior to marketing.
- Initial consultations can help identify and facilitate resolution of safety, nutritional, and other regulatory issues and make the consultation process more predictable.

Premarket Consultation Process

Final Consultations

- Once a firm has accumulated the information that it believes is adequate to ensure that the product is safe and complies with the relevant provisions of the FD&C Act, the firm submits to FDA a summary of the safety and nutritional assessment that the firm conducted.

Premarket Consultation Process

Final Consultations

- The safety and nutritional assessment summary should contain sufficient information to demonstrate to agency scientists that the firm has identified and addressed all safety and regulatory issues.
- Consultation submissions are evaluated by a multi-disciplinary team of FDA scientists representing scientific expertise such as molecular biology, chemistry, toxicology, immunology, animal nutrition and any other expertise deemed necessary.

Premarket Consultation Process

- Once the consultation is complete and any safety or other regulatory issues have been resolved, FDA sends the firm a letter explaining that ...
 - Based on the information the firm has presented to FDA, FDA has no further questions concerning food and feed derived from the new variety at this time.
 - It is the firm's continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Premarket Consultation Process

- Completed consultations are disclosed on FDA's Internet site along with FDA's response letter to the developer and a note to the file that describes the consultation.

www.fda.gov/bioconinventory

Biotechnology Consultations on Food from GE Plant Varieties

The inventory below lists all completed Biotechnology consultations on Genetically Engineered foods evaluated under FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieties. Completed Consultations on Foods from Genetically Engineered Plants describes the information categories available in this inventory. We intend to update this inventory within one month after completing a consultation.

Search and display hints:

- Select the BNF No. below to view the record details, including the FDA memo (note to file), added protein or DNA, in tended effect, and developer.
- Select the FDA Letter Date to view the text of the agency's response to the scientific and regulatory assessment submitted by the developer during the consultation (also available on the record details page).
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom right of the data table.
- To search for a specific term, enter the term in the Search box and select Show Items to display only those records that contain the selected term. (The search results also includes terms not shown on this page, but included in the full record on the detail page.)
- The search results will return hits of records containing words that include the search term. For example, a search for the color red will return results that include terms such as **red** use and **altered**. To limit results to only the searched term, place a space before and after the word in the basic search or in the advanced search "this exact phrase" field.

Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Basic Search **Advanced Search**

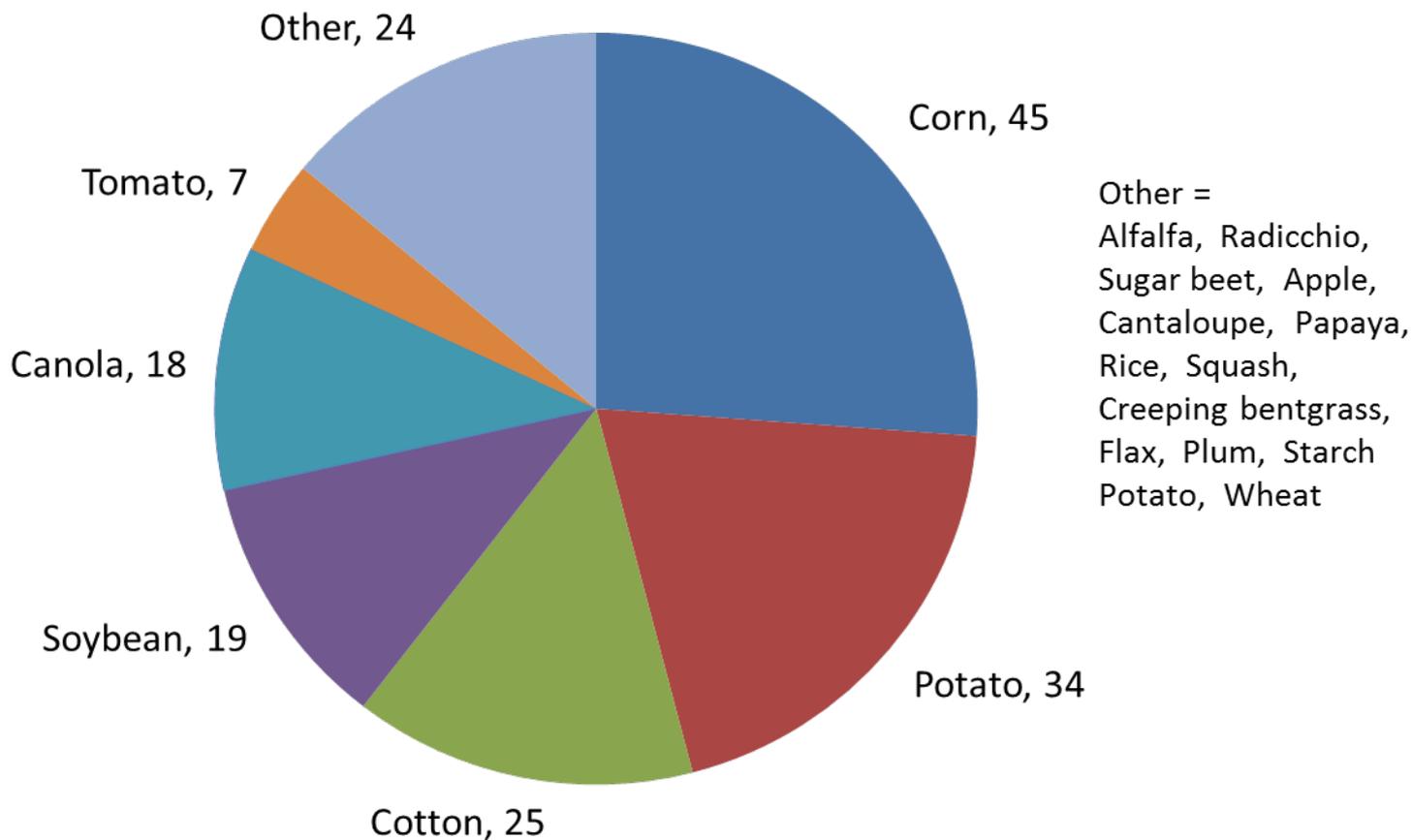
Search: Show Items Clear

Records Found: 176 Show All Page 1 of 4

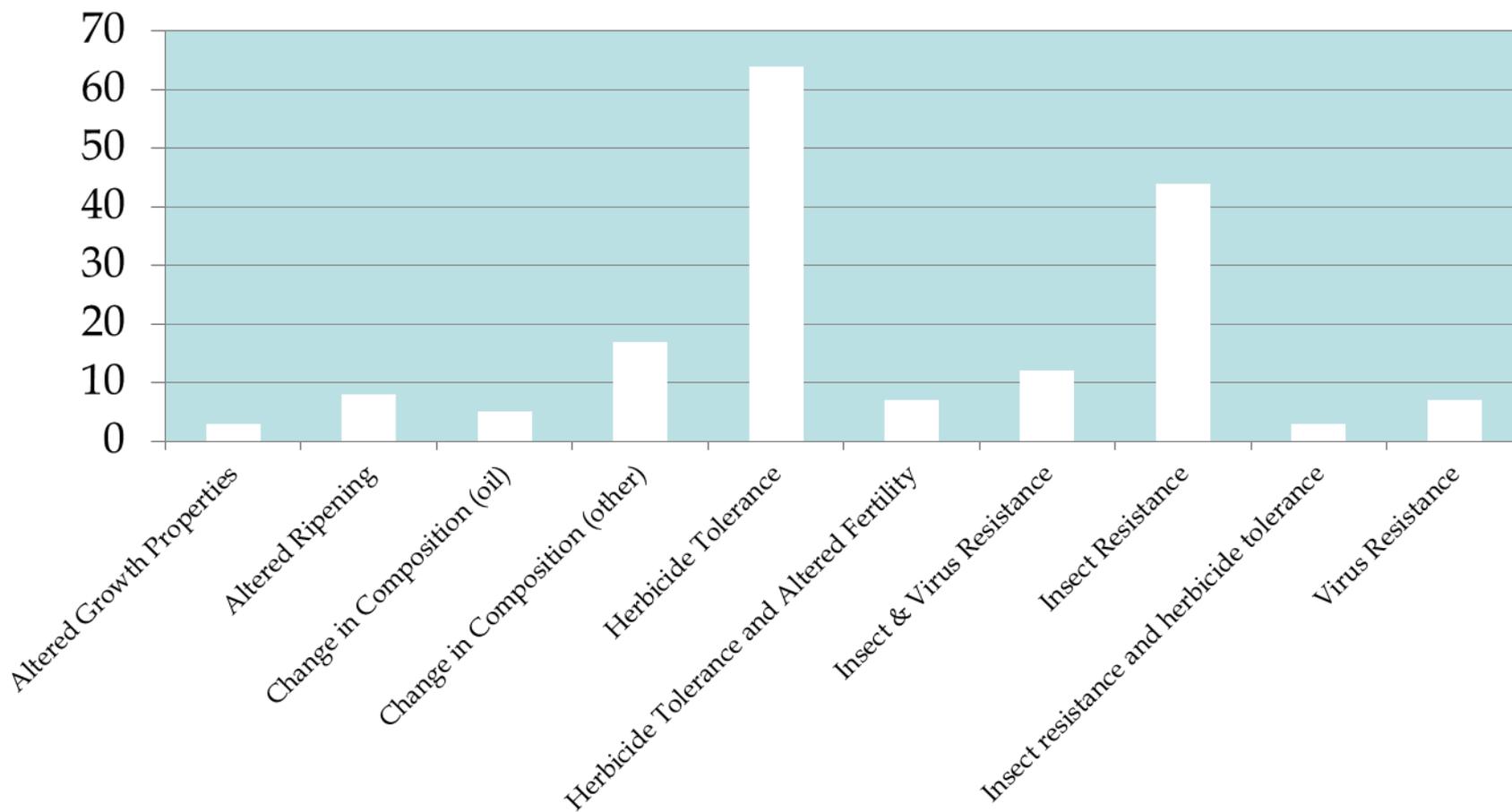
BNF No.	Traits	Food	Event Designation Unique Identifier	FDA Letter Date (sorted ZA)
153	Change in composition and pest resistance	Potato	X17 SPS-000117-5	Feb 21, 2017
153	Change in composition and pest resistance	Potato	Y6 SPS-000119-7	Feb 21, 2017
149	Altered Composition resulting in Altered Color	Pineapple	Event EF2-114 FDP-00114-5	Dec 14, 2016
152	Change in Composition (other)	Potato	V11 SPS-000111-6	Aug 19, 2016
151	Insect resistance and herbicide tolerance	Corn	MZIR098 SYN-000098-3	Apr 29, 2016
148	Herbicide tolerance	Corn	MON-87419 MON-87419-8	Mar 11, 2016
150	Herbicide tolerance	Corn	MZHG0JG SYN-0000JG-2	Feb 23, 2016
146	Altered composition (other) and Blight Resistance	Potato	WB	Jan 12, 2016



Food Crops Evaluated To Date



Traits Evaluated To Date



Premarket Consultation Process

- **The consultation process protects public health.**
 - The consultation process provides for a rigorous, case-by-case food safety evaluation that is consistent with the approach described by Codex Alimentarius.
 - *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003)*
 - Based on FDA's evaluations, foods from GE plants that have completed the consultation process are as safe as comparable foods from non-GE plants.
- **The consultation process is working.**
 - The process has been operating for over 20 years and firms continue to routinely use the process.

New Technologies

- New technologies have been developed that may be used to produce new plant varieties.
 - “Genome editing” is a term used to describe a relatively new set of technologies that enable one to make precise changes in the DNA of a plant, animal or other living organism.
 - Genome editing technologies can be used to introduce, remove, or substitute DNA at a specific site in the organism’s genome.
 - Genome editing is being performed using, for example, clustered regulatory interspersed short palindromic repeat associated nucleases (CRISPR), zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs), meganucleases and oligonucleotide-directed mutagenesis (ODM).

New Technologies

- On January 18, 2017, FDA announced a Request for Comments (RFC) seeking public input to help inform its regulatory approach to human and animal foods derived from plants produced using genome editing.
(82 FR 6564-6566, January 19, 2017)
- The RFC asks for data and information in response to questions about the safety of foods from genome edited plants.
 - How is FDA's knowledge of and experience with current plant varieties relevant to the safety assessment and regulatory status of food from genome edited plant varieties?
 - Are there categories of genome edited plant varieties that are unlikely to present food safety risks different from or greater than those for traditional plant breeding?
 - Are there categories that are more likely to present food safety risks relative to traditionally-bred plants ?
 - How can FDA help small firms engage with the agency about genome edited plant varieties?

New Technologies

- The RFC comment period closed June 19, 2017.
- FDA received over 500 comments.
- FDA is working to assemble and review the comments received.

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FDA Regulation of Animals with Intentionally Altered Genomic DNA

Laura Epstein, J.D.
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Key Points Covered

- What laws apply?
- FDA Guidance #187: Current and Draft Revised
- Regulatory Process

Statutory Authority

Federal Food, Drug, and Cosmetic Act (FD&C Act)

- Products are regulated; not processes

National Environmental Policy Act (NEPA)

- Procedural; agencies must evaluate impacts of “agency actions”

Federal Food, Drug, & Cosmetic Act

- Section 201(g): “the term drug means ... (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals...”
- Section 201(v) “The term ‘new animal drug’ means any drug intended for use for animals other than man ...”

FD&C Act New Animal Drug Provisions

- § 512(a): In general, an unapproved animal drug is unsafe
 - § 512(b)(3), 512(j) Exception for investigational new animal drugs
- § 501(b)(5): An unsafe new animal drug is adulterated

National Environmental Policy Act (NEPA)

- Requires Federal agencies to consider the environmental impact of their major and final agency decisions.
- Relevant implementing regulations:
 - CEQ
 - FDA
 - Approvals are among the major agency actions triggering environmental assessment under the National Environmental Policy Act (NEPA)
- Endangered Species Act analysis also required where relevant.



GUIDANCE



Current Guidance for Industry 187: GE Animals

- Issued in 2009
- Definition of “article”
 - rDNA construct intended to affect the structure or function of the animal
- All GE animals in a lineage are covered
- Event-based, case-by-case evaluation
- Enforcement discretion for some animals
- Most animals require approval prior to marketing
- Post-market surveillance

What's New Since FDA Issued GFI 187?

- Emergence of new technologies; genome editing technologies such as CRISPR
- Need to understand risks
- Lower bar to entry: DIY

Draft Revised GFI 187: Regulation of Intentionally Altered Genomic DNA in Animals

- Issued in January, 2017. Comment period closed 6/19/17.
- Substance of guidance remains unchanged
- Scope expanded to “animals whose genomes have been intentionally altered”

What is the Regulated Article?

- 2009 GFI 187: the subject of the NADA is “the rDNA construct at a specific site in the genome”
- Draft revised GFI 187:
 - “For purposes of this Guidance, ‘altered genomic DNA’ refers to the portion of an animal’s genome that has been intentionally altered.
 - “Unless otherwise excluded...[it] is an animal drug within the meaning of section 201(g) of the FD&C Act because such altered DNA is intended to affect the structure or function of the body of the animal...
 - Altered genomic DNA may result from rDNA technology (i.e., non-specific gene insertion), genome editing technology (i.e., targeted DNA sequence changes including nucleotide insertions, exchanges, or deletions), or other technologies that introduce sequence-specific and/or site-specific changes to the genome of the animal.

Request for Comment

- NOA said we intend to modify regulatory approach based on comments/submission of evidence of low risk
- We asked for comments on:
 - Terminology: How do we refer to these animals?
 - Is there any existing empirical evidence demonstrating that certain types of genome editing may pose minimal risk?
 - Categories with no significant target animal, user safety, food safety, environmental risk?
 - Categories where evidence shows durability?
 - Degrees of introduced changes with less risk?
 - Degree of taxonomic relationship between introduced gene and animal influences health or trait expression?



REGULATORY PROCESS



Enforcement Discretion

- Enforcement Discretion:
 - Non-food animals regulated by other agencies
 - Animals raised in contained and controlled conditions, i.e. lab animals
 - Animals evaluated on a case-by-case basis, for risk, including environmental
- FDA's expectation ranges from no notification to submission of information demonstrating limited risk

What are Approval Requirements?

- Investigations: INAD requirements apply, 21 CFR Part 511
- Approval: NADA requirements in 512(b) of the act and 21 CFR Part 514 apply. Must demonstrate:
 - Safety to animal
 - Food safety (for food animals)
 - Effectiveness (ensure the article meets the sponsor claims)
- Environment: NEPA applies

NEPA Process for New Animal Drugs

- Sponsor submits claim of categorical exclusion or draft EA for INAD and NADA.
- Thus far, there have been no categorical exclusions for GE animals.
- Because the existence of an INAD or NADA is confidential, FDA does not typically publish a draft EA for comment; GE salmon and Oxitec mosquito are exceptions.
- EA leads to either finding of no significant impact or preparation of EIS.

Review Process

- Case-by-case evaluation
- Risk-based, phased review
 - Each of the major data-based sections reviewed when submitted
 - CVM issues a “section complete” letter when review is completed and found acceptable
 - Last section is “all other information,” providing any new information obtained or published since the completion of the previous major sections
- Once all sections are completed, sponsor requests an administrative NADA (i.e., no NADA pending until then)
- Once application submitted, FDA has 60 days to make a decision

Food Derived From Animals with Intentionally Altered Genomic DNA

- Regulation of NADs involves determining food safety
- Investigational animals: Must have prior authorization (21 CFR 511.1(b)(5))
- NADA: Same legal standard (reasonable certainty of no harm), regulations, and guidances apply
- Labeling: Regulated by CFSAN

Animals for Biopharmaceutical Production

- **Considerations**
 - Two regulated articles
 - Relevant center (CDER/CBER/CDRH) will regulate product derived from GE animal
 - NADA for rDNA construct, NDA/BLA/PMA/510(k) for derived product
- **Goals**
 - Risk-based, non-duplicative reviews
 - Coordinated with Human Product Center
 - Harmonized data/review requirements



When should you contact CVM?

- As animals are beginning to be developed
 - Call/email
 - General discussion
 - Jurisdiction determination
 - Invite you for a meeting
 - Make a recommendation as to whether/when you should open an INAD or submit to a VMF
 - Walk you through your general obligations and responsibilities
 - Regulatory
 - User Fee

Next Steps

- Docket closed on June 19, 2017
- Further guidance

For additional information

GE Plants:

<https://www.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/default.htm>

GE Animals:

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/default.htm>

