

Food and Feed from GE plants: US Regulatory Framework

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U.S. Food and Drug Administration
Protecting and Promoting *Your Health*



Overview



- ▶ FDA's Oversight of Food and Feed Safety
 - food safety requirements
 - how food safety requirements apply to food and feed from genetically engineered crops
 - plant biotechnology consultation programs



OIP
(international)

ORA
(enforcement)

CDER
drugs

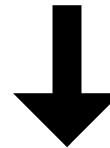
CBER
biologics

CDRH
med. devices

CFSAN
food
cosmetics

CVM
animal
drugs/feed

CTP
tobacco



Office of Food Additive Safety
College Park, Maryland



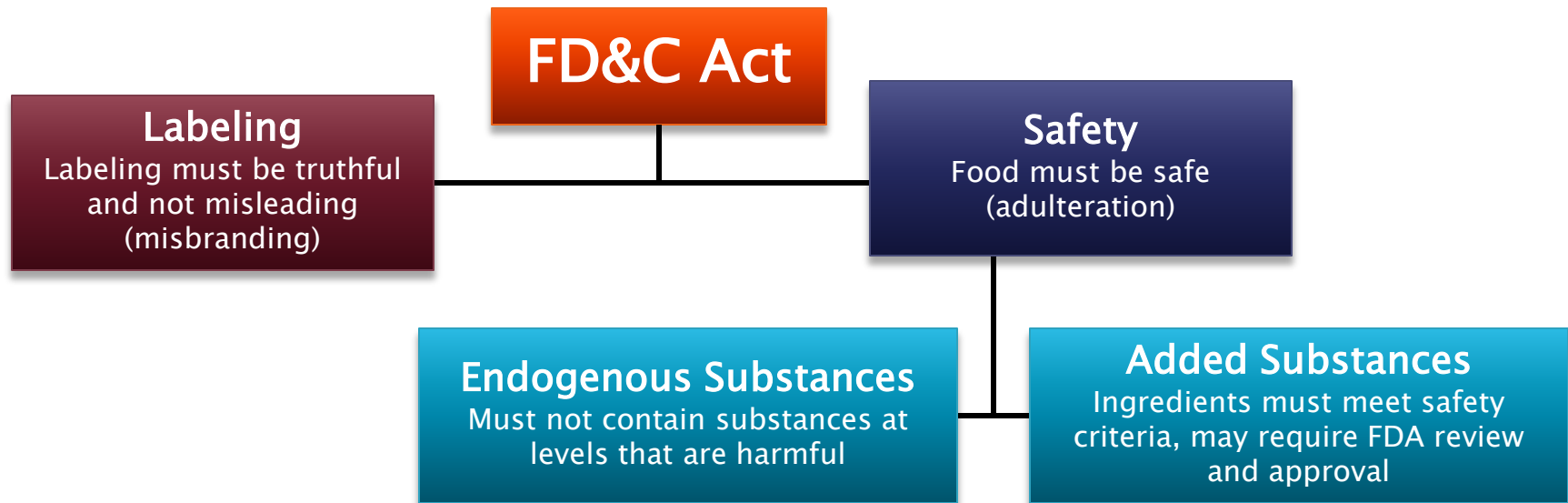
Regulation Under the Coordinated Framework



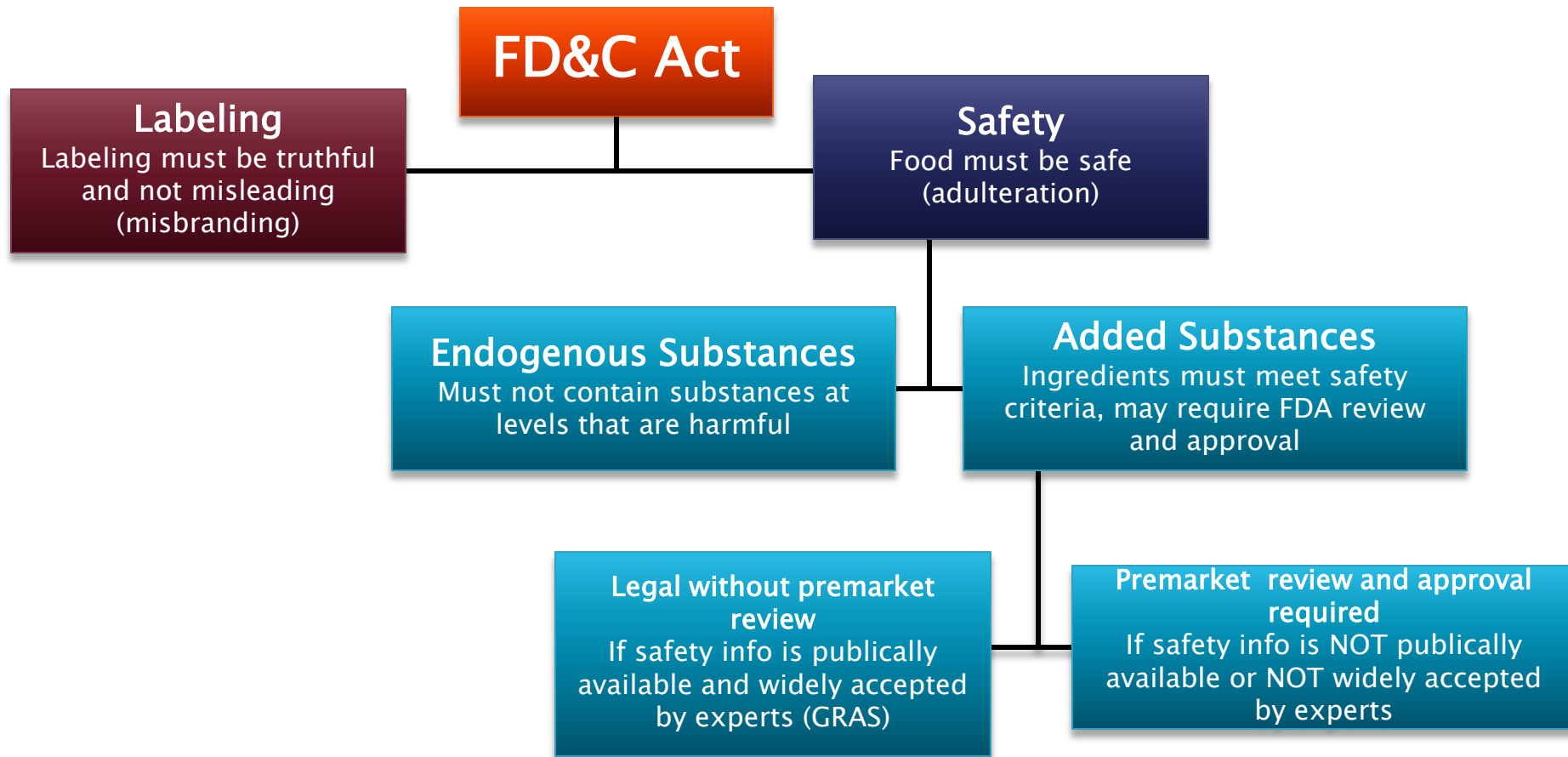
Food and Drug Administration

- ▶ Federal Food Drug and Cosmetic Act (FD&C Act): protects the public health by requiring the safety and proper labeling of food
 - FDA regulates foods and food ingredients introduced into or sold in interstate commerce
 - food means food or drink for man or other animals
 - food ingredients, whether directly added or food contact materials

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



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



Endogenous substances: conventional potato?

FD&C Act

Endogenous Substances
Must not contain substances
at levels that are harmful



Above 200
milligrams total
glycoalkaloid per
kilogram of potato



Below 200
milligrams total
glycoalkaloid per
kilogram of potato

Endogenous substances: GE potato?

FD&C Act

Endogenous Substances
Must not contain substances
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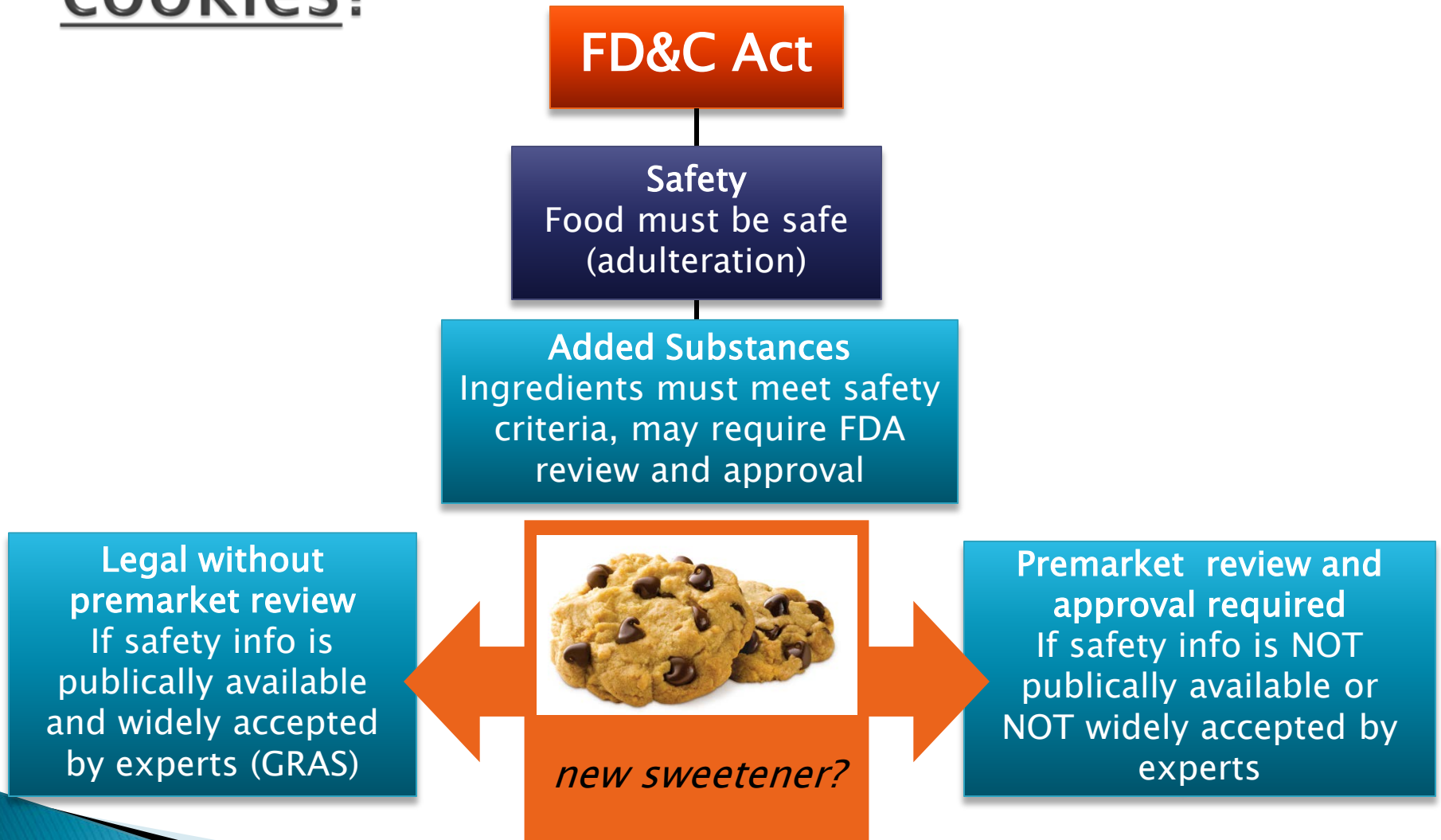


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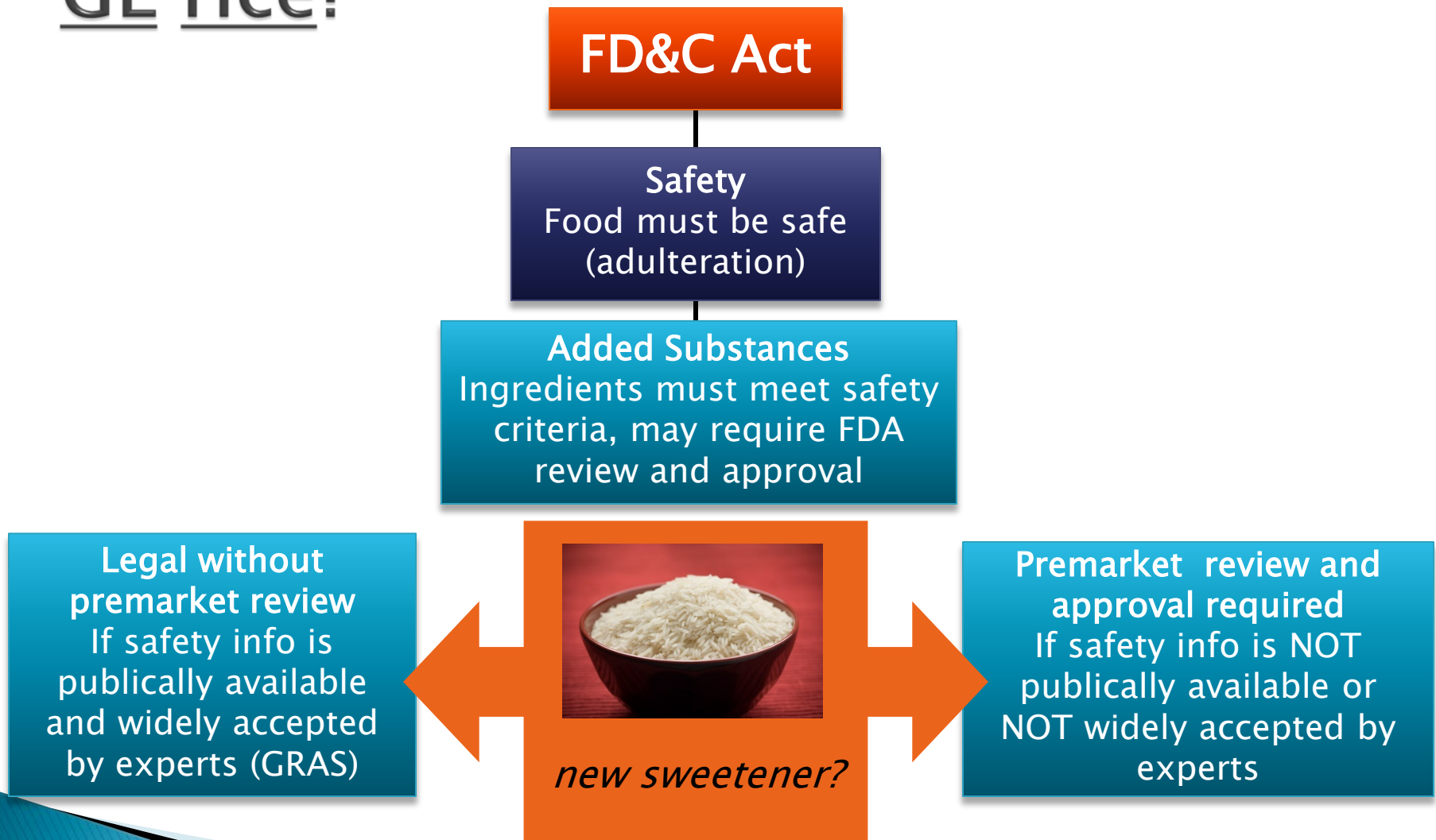


Below 200
milligrams total
glycoalkaloid per
kilogram of potato

Added substance: added to cookies?



Added substance: added to GE rice?

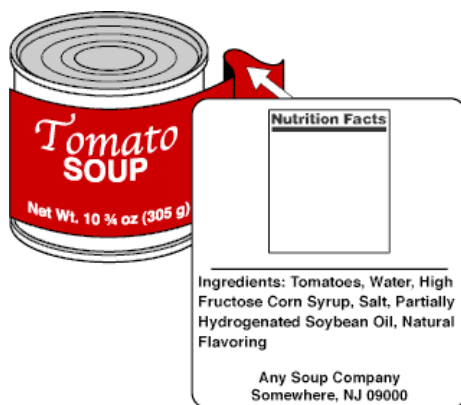


Labeling Authority

FD&C Act

Labeling

Labeling must be truthful
and not misleading
(misbranding)



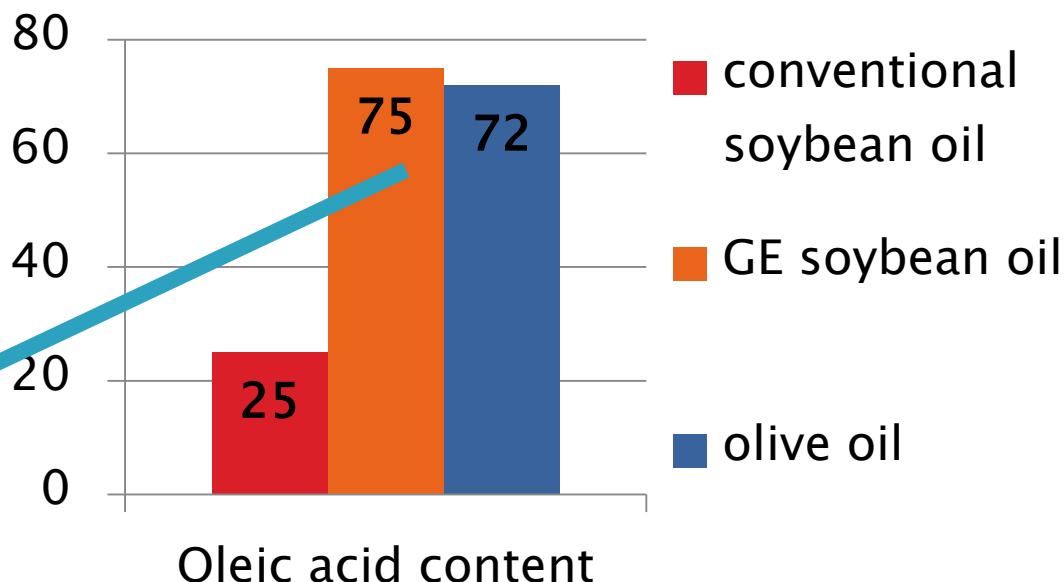
- ▶ Common or usual name
- ▶ Material facts: safety, composition, or usage
- ▶ Historically, plant breeding techniques have not been considered material

Labeling authority: change in composition?

FD&C Act

Labeling
Labeling must be truthful
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(misbranding)

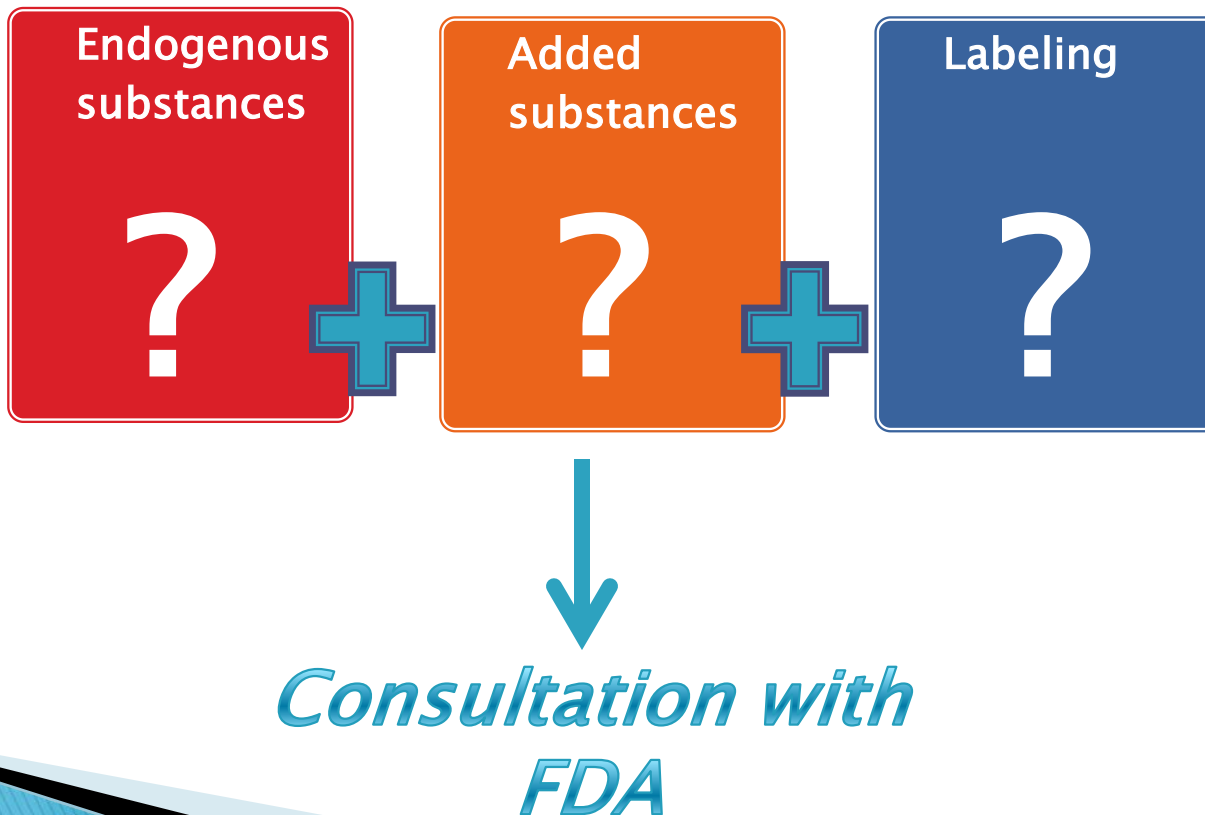
*High-oleic acid
soybean oil*



Statement of Policy (1992): Foods Derived from New Plant Varieties

- ▶ Is the new plant variety intended for use in food or feed?
- ▶ Could it contain an endogenous substance at levels that are harmful?
- ▶ Could it contain an added substance that requires premarket review and approval?
- ▶ Could its composition, safety, or usage be different?

Statement of Policy (1992): Foods Derived from New Plant Varieties



Two Consultation Processes

	New Protein Consultation (NPC)	Biotechnology Final Consultation (BNF)
Purpose?	<ul style="list-style-type: none">• To evaluate safety of new proteins prior to inadvertent entry into food supply	<ul style="list-style-type: none">• To resolve safety, nutritional, and regulatory issues prior to marketing
When to consult?	<ul style="list-style-type: none">• During development when the new protein could inadvertently enter food supply	<ul style="list-style-type: none">• After the developer has completed its safety assessment, prior to marketing
What is considered?	<ul style="list-style-type: none">• Information about protein (potential for toxicity or allergenicity)	<ul style="list-style-type: none">• Information about endogenous and added substances

Elements of the Consultation Process

Developer submits safety and regulatory assessment

FDA team of experts evaluates the data and information

FDA requests additional information as needed

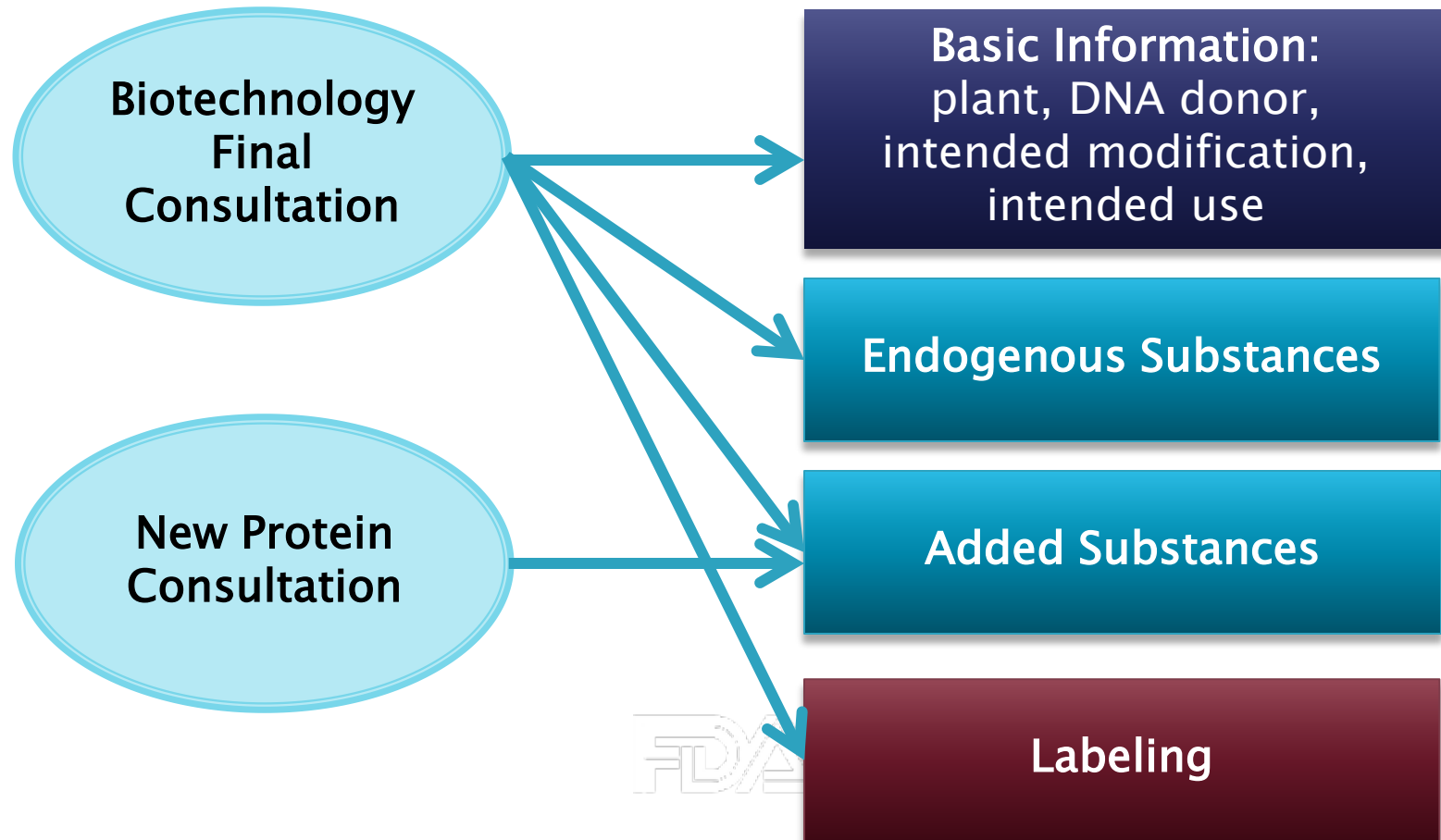
Repeat until safety and regulatory questions are resolved

FDA summarizes evaluation in a memo

FDA ends the consultation by sending a letter to the developer






Elements of the Safety Evaluation



Biotechnology Consultations on Food from GE Plant Varieties

Biotechnology Consultations on Food from GE Plant Varieties



[FDA Home](#) [Genetically Engineered Plants for Food & Feed](#) [Submissions on Bioengineered New Plant Varieties](#) [Biotechnology Consultations on Food from GE Plant Varieties](#)

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BNF No.	Traits	Food	Event Designation Unique Identifier	FDA Letter Date (sorted Z-A)
147	Altered Growth Properties	Corn	MON 87403 MON-87403-1	Jun 19, 2015
144	Insect Resistance	Soybean	MON 87751 MON-87751-7	May 27, 2015
132	Change in Composition (other)	Apple	GD743 OKA-NB001-8	Mar 20, 2015
132	Change in Composition (other)	Apple	GS784 OKA-NB002-9	Mar 20, 2015
141	Change in Composition (other)	Potato	F10 SPS-00F10-7	Mar 20, 2015

<http://www.fda.gov/bioconinventory>

FDA's Consultation Processes:

- Consultation with FDA is voluntary – no fees
- The FD&C Act places a legal burden on those who develop and sell food to ensure the food is safe – compliance is mandatory
- Consultation protects the public health
 - ensures safety and regulatory issues are resolved before the product enters the food supply
 - without being needlessly burdensome
- Consultation builds consumer confidence
 - ensures transparency of the safety and regulatory conclusions

For More Information

Internet:

FDA

<http://www.fda.gov/GEplantfoods>

Email:

- FDA India Office..... NDBoxFDAIndiaOffice@state.gov
- Biotech Program..... Robert.Merker@fda.hhs.gov
- NPC Program..... Carrie.McMahon@fda.hhs.gov