

# Exciting Regulatory Update (the Sequel)

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Jeannie Perron, JD, DVM  
April 29, 2019

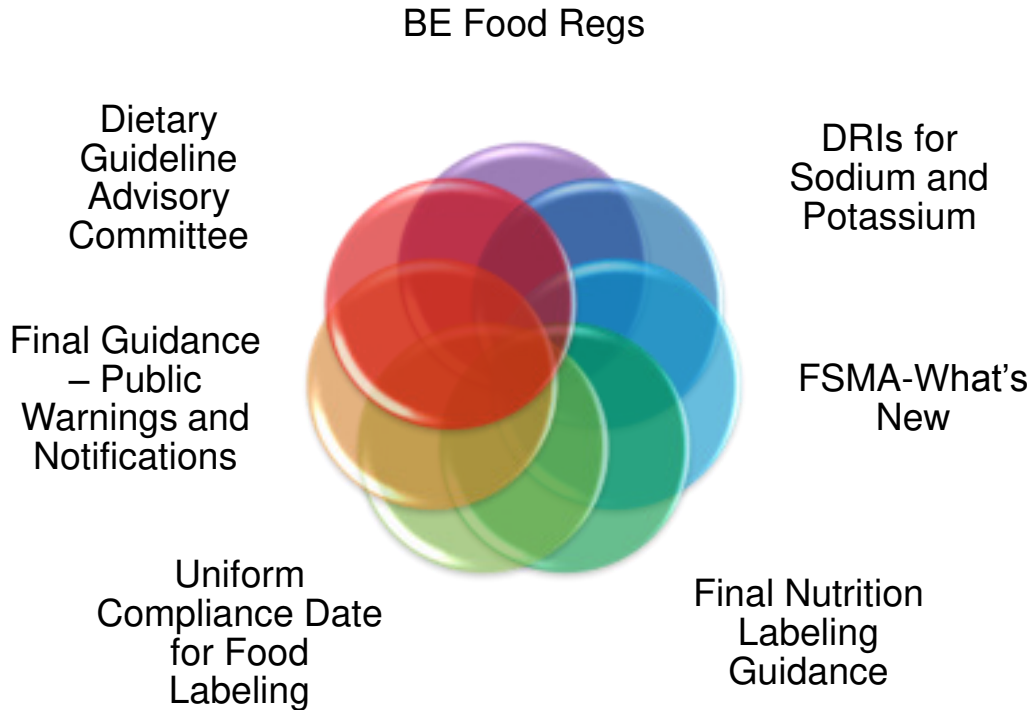
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# TOC

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# Bioengineered Food Regulations



The proposed regulations have been under review at the Office of Management and Budget since December

- we've never even seen them!



Law (enacted 7/29/16) gave USDA 2 years to establish "National Bioengineered Food Disclosure Standard"



USDA still clings to the position that it can publish final regulations by July 2018

**From 2018**

# Bioengineered Food Regulations

30  
Questions  
promulgated  
Summer  
2017 -  
112,000  
responses



Questions  
directed to

What does “contains  
genetic material” mean?

Is there a threshold?

What about highly refined ingredients?

How do you prove a  
negative?

What terms may be  
used?

**From 2018**

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# Bioengineered Food Regulations – 2019



Published regs December 21, 2018

“BE Food” = “food that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.”

Does not cover certain highly refined products, such as oil and sugar, if modified genetic material cannot be detected through a validated testing process.  
Does not cover incidental additives.

# Bioengineered Food Regulations

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Food served in a restaurant or similar retail food establishment

Food produced by a very small food manufacturer (< \$2.5 million)

No ingredients intentionally contain a BE substance (up to a technically unavoidable 5% each ingredient)

Food from an animal fed a BE substance

Food certified under the NOP

**EXEMPT**

# Bioengineered Food Regulations



## Marking

- Text statement
  - “Bioengineered food” if all BE
  - “Contains a bioengineered food ingredient” if not
- Symbol



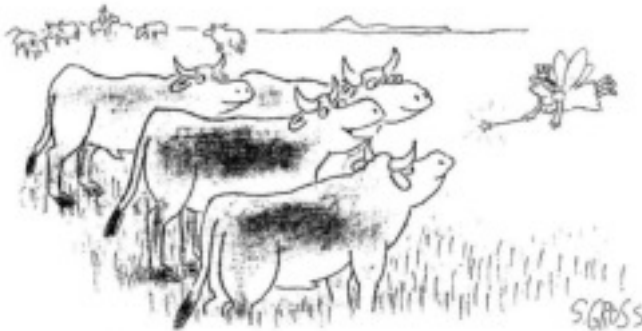
## Marking

- Electronic or digital link
- Text message disclosure

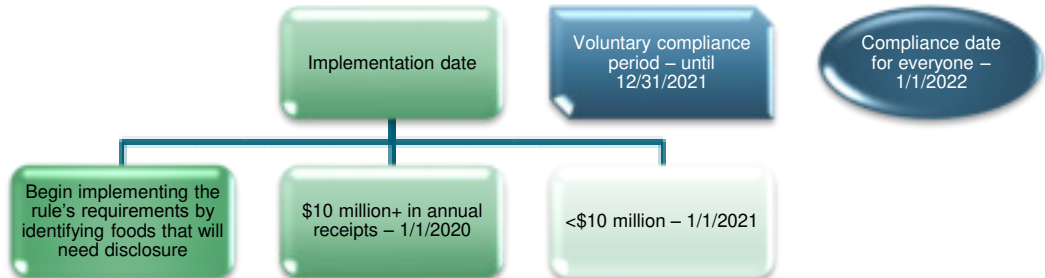
*Voluntary for  
“derived from”*

Record-keeping requirements

# Bioengineered Food Regulations



*"We would like to be genetically modified to taste like Brussels sprouts."*



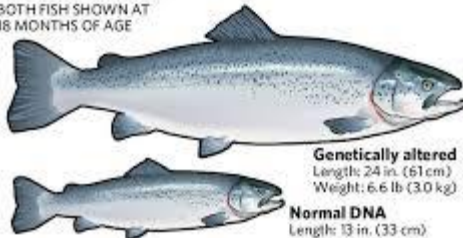


# Just for fun

The guidance on how to label food derived from GE Atlantic Salmon has also been revised

## It's all about size

BOTH FISH SHOWN AT  
18 MONTHS OF AGE



- AquaBounty AquAdvantage salmon can reach adult size in 16 to 18 months instead of 36 months for regular Atlantic salmon. These transgenic salmon eat 25 per cent less feed and are about 20 per cent more efficient at converting that food to flesh.



## DRIs for Sodium and Potassium

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# Potassium

A bunch of yellow bananas is positioned behind the word 'Potassium' and the three red boxes, serving as a background for the potassium-related content.

### Established adequate intake (AI)

- Adult male 3400 female 2600 mg/day
- Differences for children, pregnancy, lactation

“Moderately strong evidence” that potassium reduces BP especially among hypertensive adults

Can't establish a chronic disease risk reduction intake (CDRR) level.

# DRI for Sodium and Potassium



## Sodium

- Established adequate intake (AI)
  - Adult male, female, pregnancy, lactation 1500 mg/day
  - Differences for children
- Chronic disease risk reduction intake (CDRR) level and USDA DRI 2300 mg/day
  - Differences for children

# Sodium

Reducing sodium  
greater effect in  
hypertensive adult  
than normotensive

Effect on  
chronic disease  
risk cannot be  
characterized

Moderate to high  
evidence  
intake/response  
relationship to

cardiovascular  
disease

hypertension

systolic bp

diastolic bp



# Sodium

FDA says  
Americans  
consume on  
average 3400  
mg/day

- ~50% higher than CDRR and USDA Dietary Guidelines DRI
- >100% higher than 1500 mg/day recommended for hypertensive people



FDA 2016  
voluntary proposal  
for 10-year target  
of 2200 mg/day



Industry impact

# New FSMA Stuff

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## Intentional Adulteration Rule

### Compliance date



July 26, 2019 All others

July 27, 2020 Small businesses

July 26, 2021 Very small business

### Revised Draft Guidance



March 2019

Added sections on education, training, and experience and vulnerability assessment examples

# Intentional Adulteration Rule

Requires firm to draft a food defense plan

- Vulnerability assessment
- Mitigation strategies



## Exemptions

- Very small business
- Holding of food (except liquid storage tanks)
- Packaging/labeling
- Others

# Final Nutrition Labeling Guidance

Issued in November 2018

FDA had said

Labels must be revised for food initially introduced into interstate commerce on or after compliance date

New guidance

Products labeled (label placed on product) on or after compliance date must comply  
Stickering is OK





# Final Nutrition Labeling Guidance

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- **Most addresses added sugars**
  - **Clarifies FDA position on what fruit and vegetable-based ingredients are added sugars**
  - **Added sugars do include maltodextrins, corn syrups and certain other ingredients**



# Uniform Compliance Date for Food Labeling

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Uniform compliance date for  
final food labeling regs for  
FDA and USDA

Jan. 1, 2022

Food introduced  
into interstate  
commerce on or  
after that date

For food labeling  
regs published  
Jan 1, 2019 to  
Dec. 31, 2020

# Recalls – Public Warning and Notification

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## Final guidance – 2/19

FDA may  
“supplement”  
firm’s public  
warning when

- an ongoing warning is not prompt or effective
- the firm’s warning is “deficient in any respect”
- New adverse events in a completed recall
- FDA feels like it

FDA may  
issue a public  
warning when

- a firm refuses to issue its own public warning
- the recalling firm considers the recall to be a class 2, but FDA decides to issue a public notice anyway

# Public recall notices

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Class 1 (some Class 2s)



Widely-distributed product



Food recall after illness/injury



More likely to be eaten by vulnerable population



Manufacturing deviation can cause significant health risk (*e.g.*, botulism)

# Public recall notices

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Can make a Class 2 or 3 recall look like a  
Class 1

# New Dietary Guidelines Advisory Committee



Meeting now

Public can

- Submit comments
- Attend meetings
  - In person
  - Via webinar

Plan to  
release new  
guidelines by  
the end of  
2020

# New Dietary Guidelines Advisory Committee

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- Dietary patterns
- Beverages
- Added sugars
- Types of dietary fats
- Seafood
- Frequency of eating
- Birth to 24 months
- Current dietary intake and nutrients of public health concern

Looking  
at

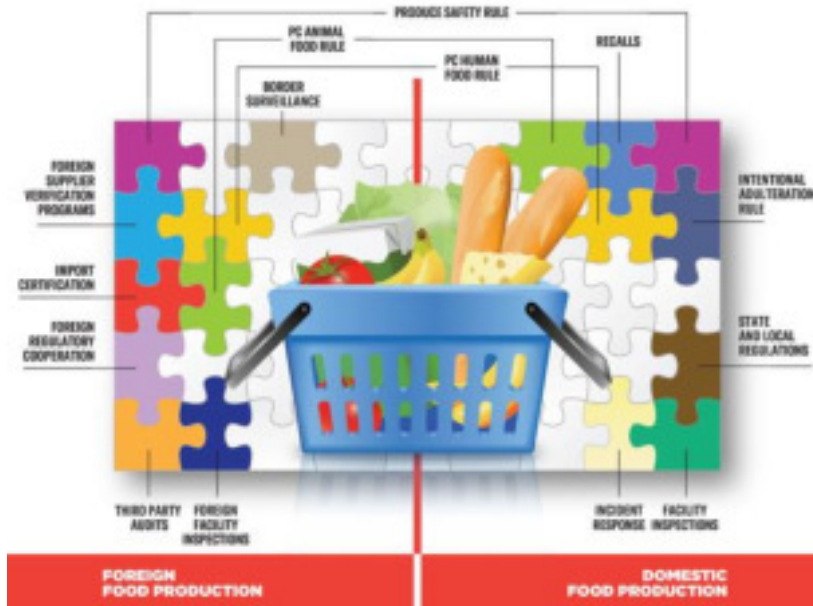




# FDA Strategy for the Safety of Imported Food

## PIECING TOGETHER THE PUZZLE OF IMPORTED FOOD SAFETY

The FDA oversees the safety of most of the human and animal food consumed in the United States. An overarching goal of the agency is to ensure that Americans can be confident that food imported from other countries is held to the same safety standard as food produced domestically. To that end, the agency brings together many elements to help ensure that our food is safe to eat, no matter where in the world it is produced. You'll see in the graphic below that despite some differences, many of the same regulations and tools impact both foreign and domestically produced foods.





# FDA Strategy for the Safety of Imported Food

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Preventing food safety problems in foreign supply chain before entry



Detecting/refusing entry of unsafe foods at the border



Responding rapidly when learn of unsafe imported foods



Create effective/efficient food import program

# FDA Strategy for the Safety of Imported Food

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"We serve authentic Mexican food made in Singapore by a company managed in India using ingredients imported from Poland, Norway and Korea."



"You need two more gazelles."

Ensure Food Meets  
U.S. Food Safety  
Requirements

Optimize foreign  
inspections

Importer use of  
verified foreign  
suppliers through  
FSVP

Reliable audits as in  
Accredited Third-  
Party Certification  
Program

Incentivize importers  
to use Voluntary  
Qualified Importer  
Program

Leverage regulatory  
counterparts with  
strong food safety  
systems

Increase  
awareness/training so  
foreign suppliers can  
produce safe food

# FDA Strategy for the Safety of Imported Food

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## Border Surveillance Prevents Entry of Unsafe Foods

- Enhance/refine import screening/entry review processes
- Optimize physical examination/sampling
- Strategic use of import alerts/certifications
- Improve testing methods/tools to determine admissibility

Enhance border surveillance with state and other partnerships

# FDA Strategy for the Safety of Imported Food

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## Rapid/Effective Response to Unsafe Imported Food

- Maximize FDA response effectiveness to an imported food event
- Enhance imported food safety recalls
- Use information-sharing opportunities to prepare for and respond to unsafe food imports

# FDA Strategy for the Safety of Imported Food

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## Effective and Efficient Food Import Program Objective

- Develop a comprehensive global inventory of food facilities and farms and assess the cumulative oversight applied to the global inventory
- Ensure effectiveness of import activities *via* performance assessment and continuous improvement



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