Exciting Regulatory Update (the Sequel)

Jeannie Perron, JD, DVM

April 29, 2019

TOC

BE Food Regs

Dietary Guideline Advisory Committee

DRIs for Sodium and Potassium

Final Guidance – Public Warnings and Notifications

FSMA-What's New

Uniform Compliance Date for Food Labeling

Final Nutrition Labeling Guidance

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

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

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

Bioengineered Food Regulations

Marking

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

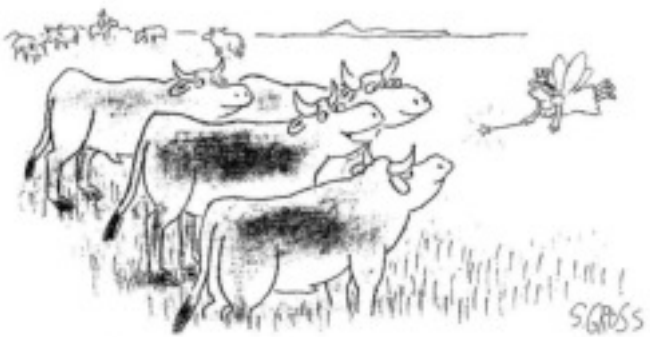
Marking

- Electronic or digital link
- Text message disclosure

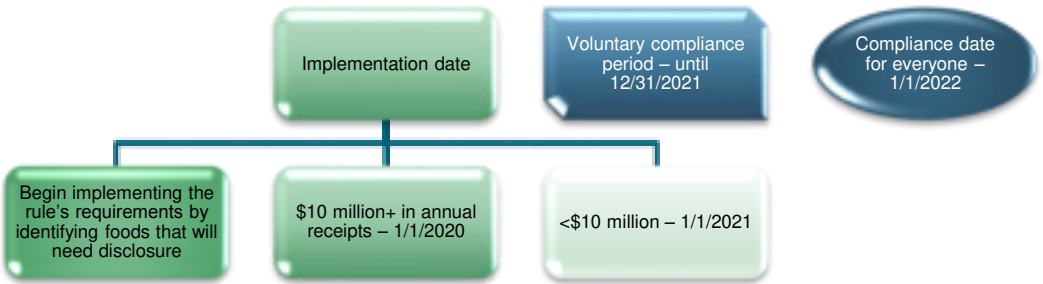
Voluntary for "derived from"

Record-keeping requirements

Bioengineered Food Regulations

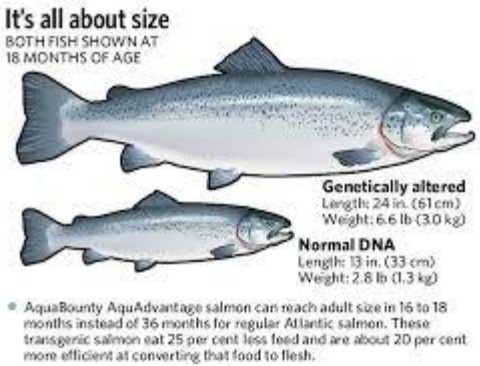


"We would like to be genetically modified to taste like Brussels sprouts."

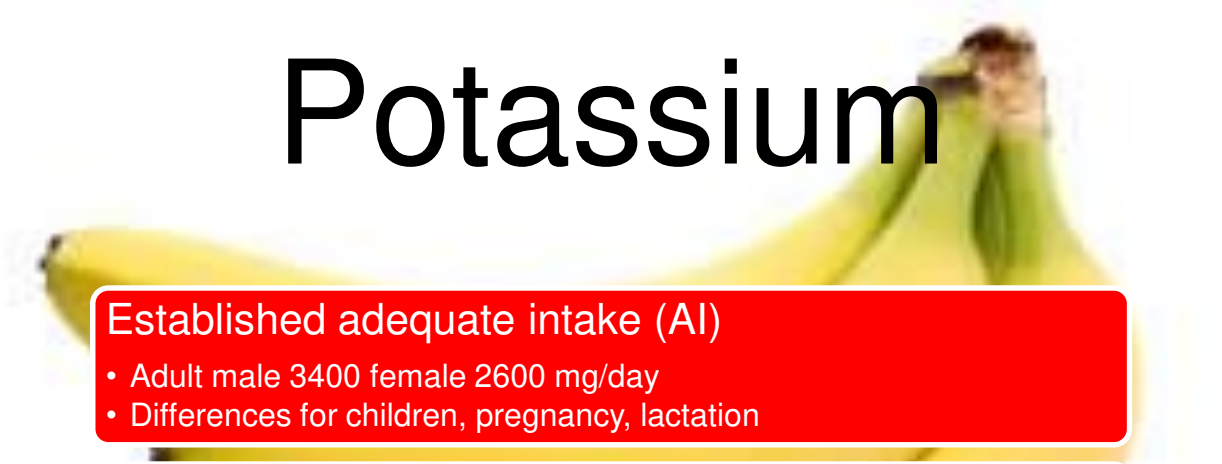


Just for fun

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



DRIs for Sodium and Potassium



Potassium

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.

DRIs 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

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

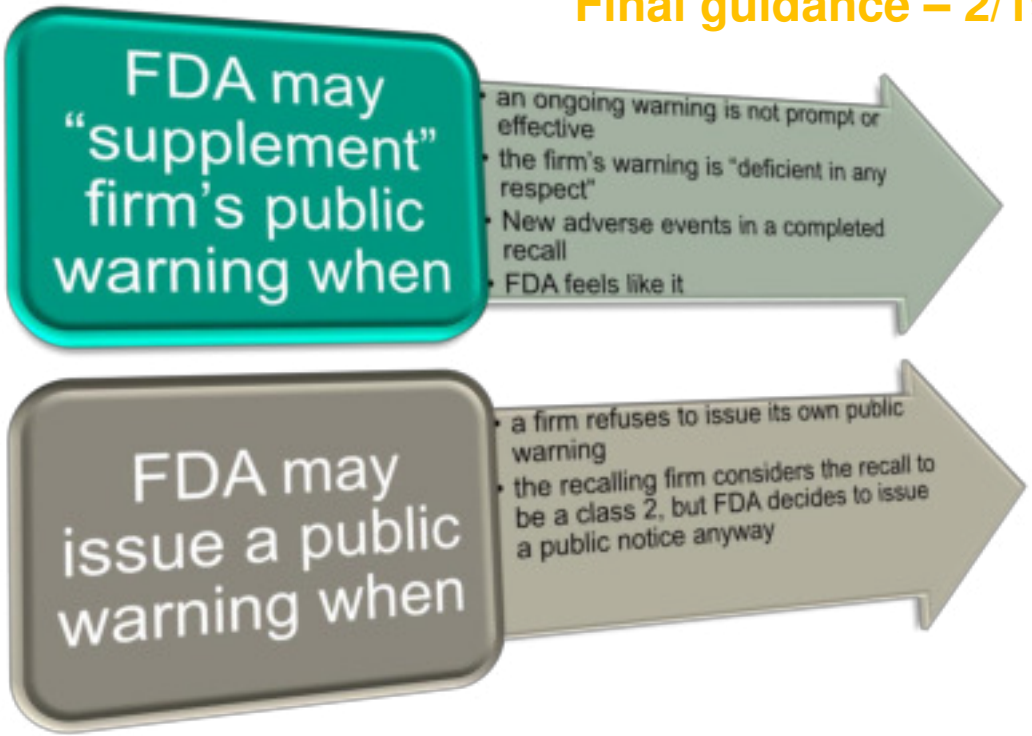
Final Nutrition Labeling Guidance

- 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

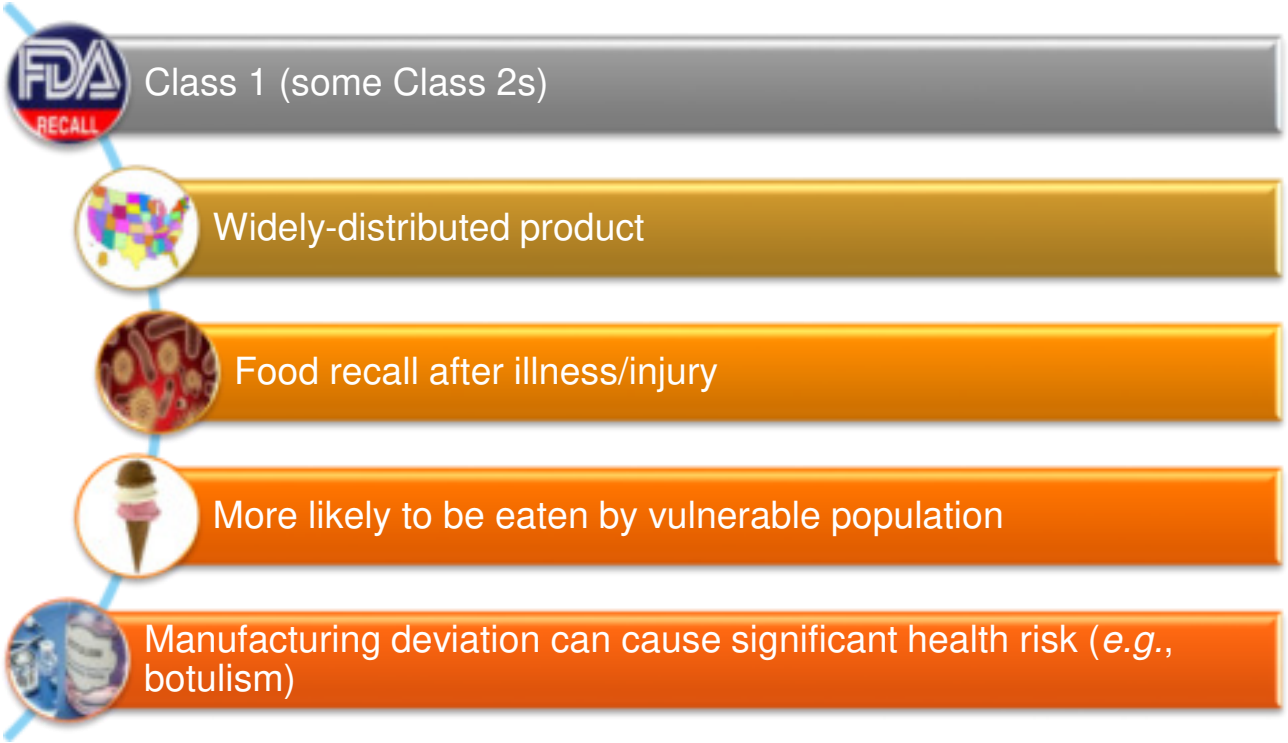
Uniform Compliance Date for Food Labeling

Recalls –Public Warning and Notification

Final guidance – 2/19



Public recall notices



Public recall notices

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

New Dietary Guidelines Advisory Committee

"Who ordered the nuggets!!!"

Meeting now

Public can

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

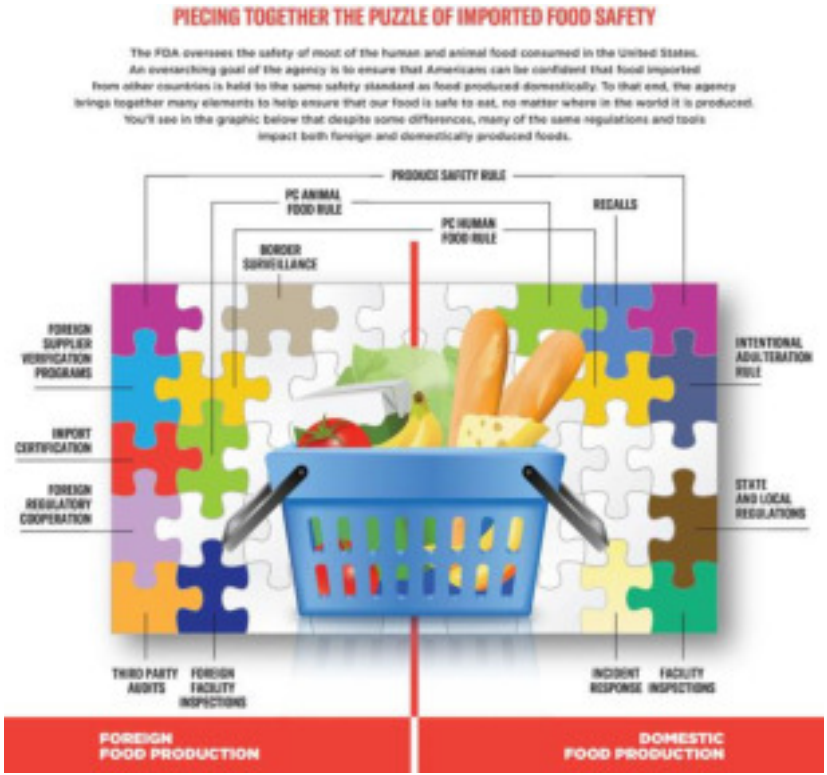
Plan to release new guidelines by the end of 2020

New Dietary Guidelines Advisory Committee

- 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



FDA Strategy for the Safety of Imported Food

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

"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

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

FDA Strategy for the Safety of Imported Food

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

"Welcome! Today's topic is 'How To Give A Presentation Without Losing Your Audience's Attention'. The End. Thank you for coming."