

GAPS, FSMA and the Produce Rule



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Third Party Audits

- Buyer-driven
- Met needs of industry to reduce risk and liability of foodborne illness outbreaks
- Good Agricultural Practices
 - USDA GHP/GAP, Harmonized GAP
 - SQF, Primus, BRC, Global GAP
- Not a government regulation

FSMA

- Food Safety Modernization Act
- Under FDA
- Produce Rule
- First time fresh fruit and vegetable production has been regulated for microbial food safety

Are you covered by FSMA?

- If you produce and sell fresh produce and gross more than \$25,000 in produce sales, you're covered by the rule

Qualified Exemptions

- Average gross sales of food sold in previous 3 years is <\$500,000 avg.
AND
- Sell majority of produce to qualified end users:
Restaurants, retail food establishment in same state or within 275 miles of where produce was grown



Qualified Exemptions

- Exemption can be revoked
 - FDA must send notice listing reasons, give opportunity for the farm to respond
 - If actions taken by farmer are insufficient, FDA may proceed with revocation
 - Also opportunity for reinstatement of exemption
 - If outbreak was found not to have originated at farm
 - Conditions responsible for outbreak were addressed and risk mitigated

What counts toward my \$500,000?

- As far as we can tell –
- ALL FOOD, including produce, meat, animal feed, sales from farm stand, etc.
- The \$500,000 counts “all food” instead of only the produce portion

Food Safety Preventive Controls Rule

- **Do growers fall under two regulations?**
 - **PC Rule:** Focus on the manufacturing, processing, packing or holding of human food
 - Initial concern that some growers would fall into this regulation in addition to the produce rule
 - New definitions of farm, sales, holding, and packing activities have changed this



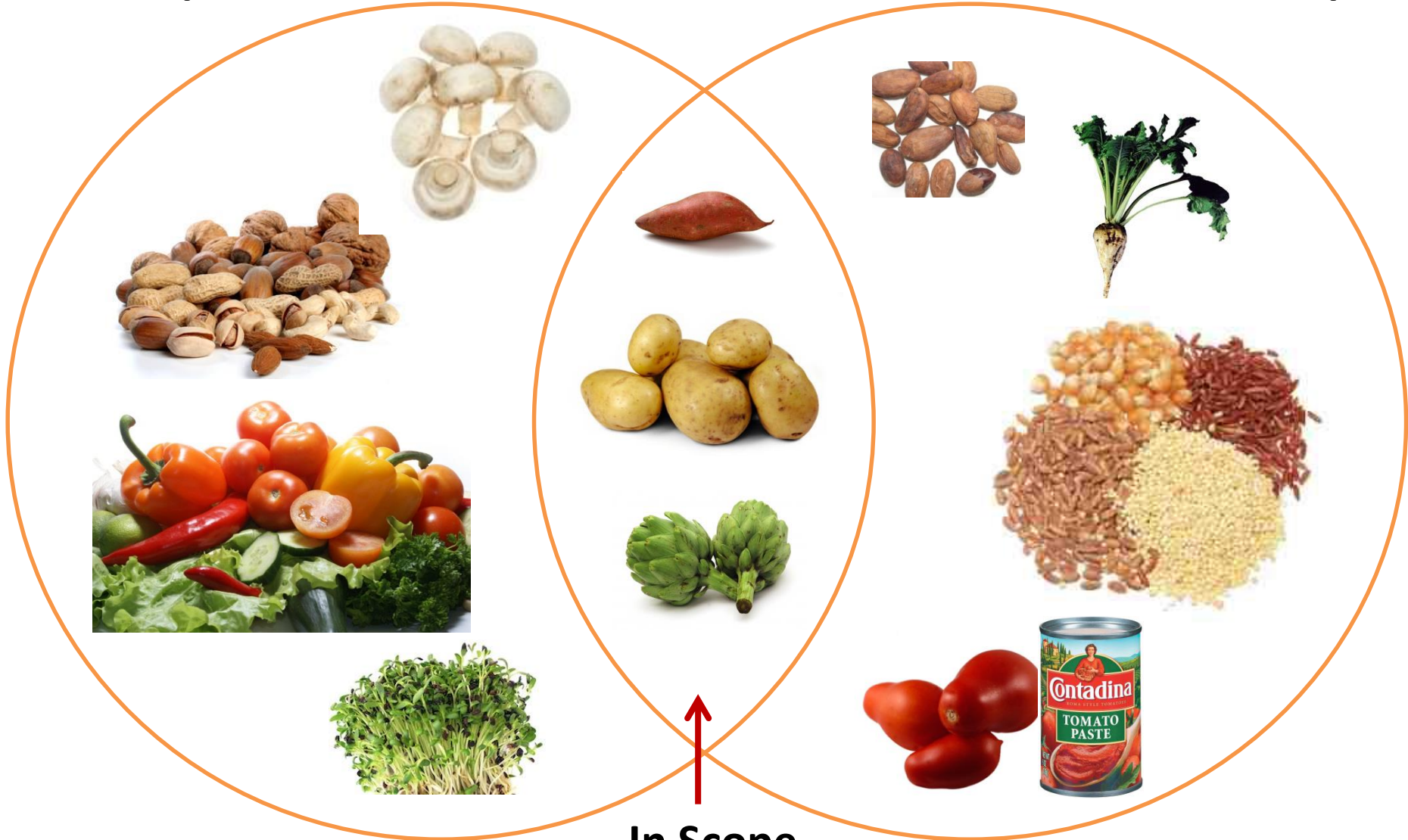
Farm Definitions

- A primary production farm is an operation under one management, in one general area devoted to growing crops, harvesting crops, and/or raising animals. It can pack or hold raw agricultural commodities grown by the farm, or by other farms, and perform limited manufacturing and processing activities such as drying and curing onions or cutting leaves off a head of cauliflower for packing.
- A secondary activities farm is an operation not located on the primary production farm, but it is still devoted to harvesting, packing and/or holding raw agricultural commodities. It must be majority owned by the primary production farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the secondary activities farm.

Produce Safety Rule

In Scope

Out of Scope



In Scope,
but Exempt

Vegetable coverage

- All vegetables for fresh eating are covered
 - Some discrepancies:
 - Onions are exempt
 - Beets are exempt (includes greens)
- How does it work if you grow a wide range of commodities?
 - Basically, you will need to comply with the rule
 - You don't water test just for lettuce..

Fruit coverage

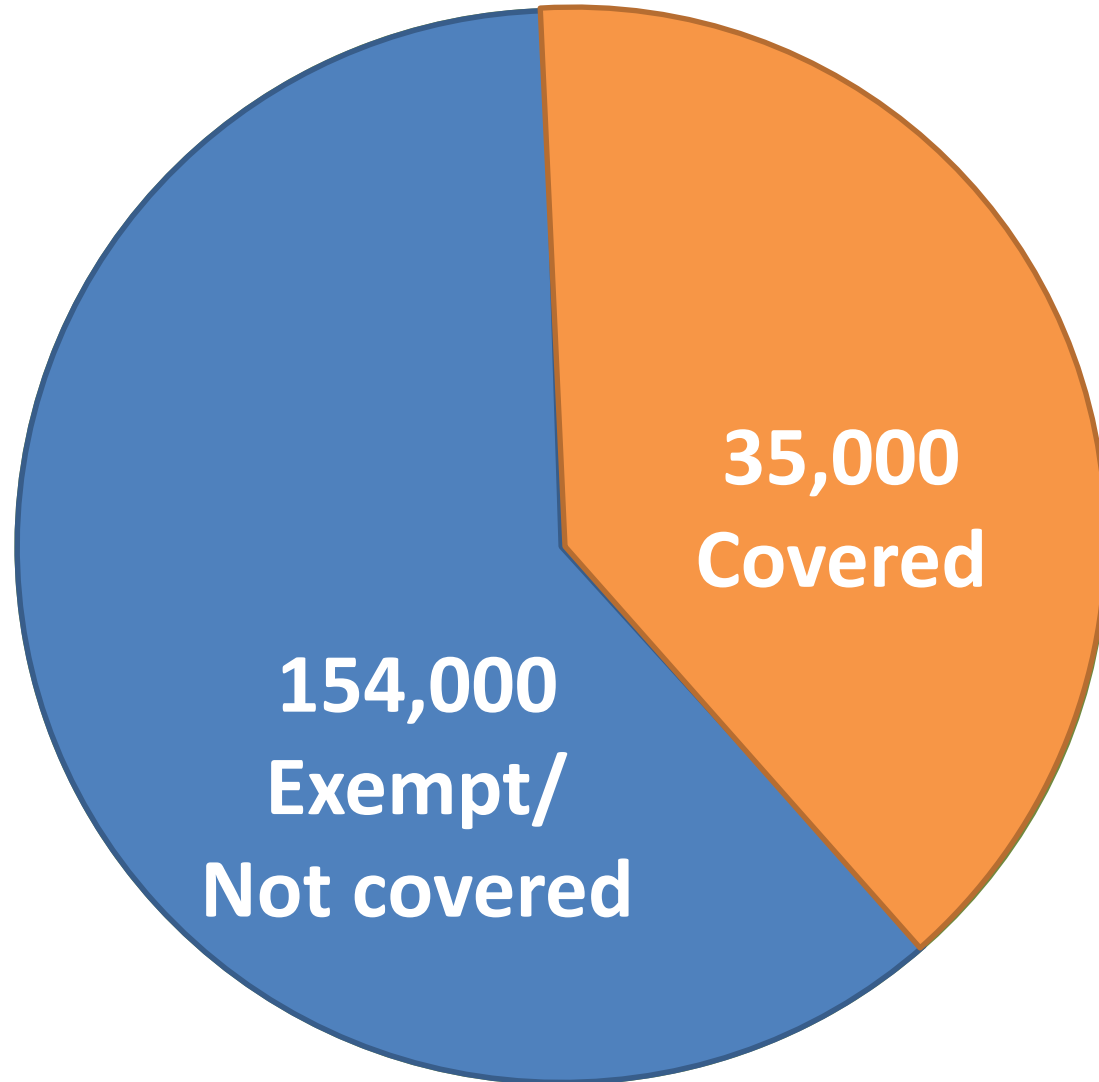
- All fruit for fresh eating is covered
- Not covered if destined for processing

Updated Exemptions

1. Produce rarely consumed raw
2. Produce destined for 'kill-step' processing
3. Produce for personal/on-farm consumption
4. Make <\$25,000 in all produce sales (3 year average)



Produce Farms Exempt or Not Covered by the Produce Rule



Produce Rule: Areas of Focus

- Agricultural water
- Biological soil amendments
- Domesticated and wild animals
- Personnel qualifications, training, and health and hygiene
- Equipment, tools, buildings, and sanitation



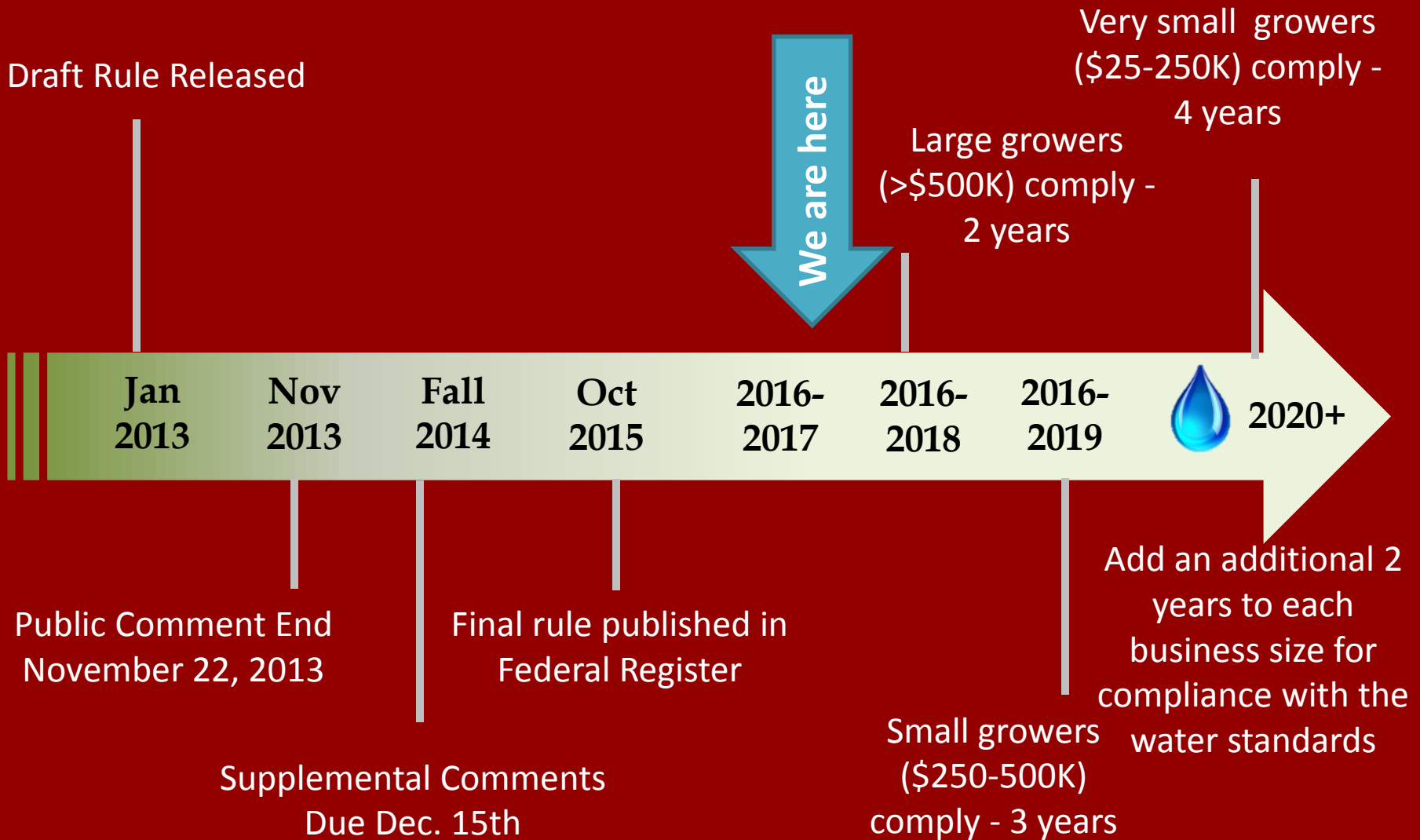
Proposed Exemptions

Application of Exemptions Based on Produce Sales

Large Business	>\$500,000
Small Business	\$250,000-\$500,000
Very Small Business	\$25,000-\$250,000
Not covered	<\$25,000



FSMA Time Frame



But I already have GAP certification!

- USDA or other third party certifications are not transferable to FSMA requirements
- There is a lot of overlap, but some differences
- **No matter what certifications you have, you still need to get a FSMA one day food safety training certificate**
 - More on this later
- FSMA will likely not suffice for most buyers

Updated: Agricultural Water Standards & Testing Requirements

Surface water requirements:

- <126 CFU/MPN generic *E. coli* per 100 ml, geometric mean (n=5) AND a statistical threshold value of <410 CFU/MPN generic *E. coli* per 100 ml
- Testing dependent on water quality profile
- There will be an online FDA calculator...you put in your water test results and it gives you the geometric mean and STV



How Often Should You Test Surface Water?

Source: Surface Water	Testing Frequency
Baseline	20 samples over 2-4 years
Annually	Minimum 5 samples per year
If annual test does not support water quality profile	Current annual survey, combined with new data for a total of 20 samples



Establishing a Water Quality Profile

START:

Establish water quality profile
Take 20 samples over two years

ANNUALLY:

Take 5 samples
Compare to established water
quality profile

SAMPLING DOES MATCH PROFILE:
Continue to test 5 samples annually

TEN YEAR RE-EVALUATION:
Take 20 samples to establish a new
water quality profile

SAMPLING DOES NOT MATCH PROFILE:

Use the 5 annual samples, plus an
additional 15 new samples (20 total)
to establish a new profile

- **APPLY ALTERNATE METHODS:**
 - Time interval to achieve 0.5 log microbial die-off per day between water application and harvest
 - Time interval between harvest and end of storage to achieve microbial die-off
 - Other activities that may achieve microbial die-off, i.e. washing
 - Discontinue use

What does .5 log reduction per day mean??

- 1 log reduction per day means $1/10^{\text{th}}$ are left
- Day 1 – 1000, day 2 – 100, day 3 – 10
- .5 log reduction per day means about $1/3^{\text{rd}}$ left
- You only get to apply it for 4 days:
- **2700**, 900, 300, 100
- Please don't use water that reads 2700!

How Often Should You Test Ground & Public Water Sources?

Source	Testing Frequency
Ground	4 times during the growing season or over the period of a year
Public Water Source	Copy of test results or certificates of compliance



Post-Harvest Water Quality Criteria

Directly contacts produce after harvest:

- No detectable generic E. coli (drinking water quality)



Updated: Soil Amendments

- FDA has proposed deferring action on the use of raw soil amendments and has proposed to remove the 9 month application interval
- FDA will be working with USDA ARS to facilitate research, risk assessment, and incentivizing composting practices
- NOP Guidelines – 90 and 120 day harvest intervals



Equipment, tools, buildings

- Requirements are very similar to USDA GAPS requirements
 - No cleaning log records required
- Worker health and hygiene training
- Requirements for sanitation and maintenance
- Prevention of contamination of all food contact surfaces

What Can You Do NOW?

- Read FDA guidelines (link at end of presentation)
- Attend a FSMA grower training workshop
- Write a farm food safety plan
 - Start with basic risk assessment
 - Prioritize practices to reduce risks
- Stay up to date with the regulation and educational opportunities



What will be available from CCE?

- FSMA regulations include a **mandatory one day food safety training certification class**

Other resources

- ENYCHP – Myself, other vegetable educators
- FDA online resources
- Produce Safety Alliance

Cornell University
Department of Food Science

SEARCH CORNELL: **go**

Pages People [more options](#)

Produce Safety Alliance

Home News Resources FSMA The Alliance

Providing fundamental, science-based, on-farm food safety knowledge to fresh fruit and vegetable farmers, packers, regulatory personnel and others interested in the safety of fresh produce

Welcome to the Produce Safety Alliance (PSA) website!

[Click here](#) to view the press release.

The PSA is developing a nationwide curriculum to increase understanding of the principles of Good Agricultural Practices (GAPs) and to facilitate the implementation of food safety practices on fresh fruit and vegetable farms and in packinghouses. [View the PSA's current Curriculum Modules and Learning Objectives.](#)

PSA-FDA Question & Answer Series

PSA-FDA Question & Answer Series on FSMA Proposed Produce Safety Rule. [Click here](#) to listen to all of the recordings from March 18–May 13, 2013.

[Click here for the PSA October newsletter.](#)

Stay up-to-date!

Produce Safety ALLIANCE

Sign up for the Produce Safety Alliance listserve...

Join the PSA Listserve!

The listserve is a great way to receive the most current information related to educational and training opportunities, FSMA updates, and produce safety research and events.

Find us on Facebook



FDA Food Safety Modernization Act & Proposed Produce Safety Rule

- **Produce Rule:**
Focus on the growing, harvesting, and post-harvest handling of fresh produce
- Focus is on the prevention, not detection of issues (**no product pathogen testing required**)



fsma produce rule fact sheet

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[PDF] [FSMA Proposed Rule for Produce Safety - Food and Dru...](#)

[www.fda.gov/.../GuidanceRegulation/FS...](#) ▾ Food and Drug Administration ▾
Summary. On January 4, 2013, FDA released for public comment its proposed **rule** to establish science-based standards for growing, harvesting, packing and ...



Questions?

