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Alternative Proteins: Milk Without the Cow

Dairy Forum
Scottsdale, AZ
January 28, 2020

FOLEY
FOLEY & LARDNER LLP

Science

FDA tries to take the reins on regulating cultured meat

THE WALL STREET JOURNAL

[Business | Journal Reports: Technology](#)

Lab-Grown Meat Raises Regulatory Questions

Forbes

There's The Beef But Where's The Cow?

WHAT IS MEAT, ANYWAY? LAB-GROWN FOOD SETS OFF A DEBATE



The Boston Globe

Company is making 'milk without the moo'

QUARTZ

Plant-based dairy has New Competitor in Flora-Based Foods

Cell Culture Technology + The Regulatory Conversation

FOOD navigator-usa

Real Cheese... Without Cows?

The New York Times

Got Impossible Milk? The Quest for Lab-Made Dairy



How close are we to a hamburger grown in a lab?



Meat lobby wants USDA to ban 'clean meat' makers from calling their products meat

The Washington Post
Democracy Dies in Darkness



Lab-grown dairy: The next food frontier

Why cattle ranchers and tech start-ups are beefing over the meaning of 'meat'

engadget

Lab-grown meat is inevitable. Will we eat it?

With the science coming together, the biggest challenge is getting people on board.

THE WALL STREET JOURNAL

BUSINESS

Sizzling Steaks May Soon Be Lab-Grown

Startups raising funds to produce meat from cells cultivated in bioreactors



Here comes lab-grown dairy: milk proteins made without animals

FDA: Existing Precedents

- Broad authority to regulate foods
- Determines **safety of new food ingredients including in plant-based foods, seafood, and meat and poultry products**
- Regulates **food products of biotechnology including GE animals**
- Regulates **microbial, algal, and fungal cells generated by large-scale culture** and used as direct food ingredients; **animal cell culture technology in therapeutic settings; and processing, manufacture, and packaging of seafood** (except catfish)



Cow-Free Dairy Regulatory Pathway

■ **Pre-Market Safety (FDA)**

- Substances used in manufacturing
- Assessment of whether manufacturing changes or affects identity, conditions of use, purity, toxicity, or safety
- Identity, history of safe use, common knowledge of safety, technical effect and intended use, margin of exposure
- Consultation process, food additive / GRAS process?

■ **Manufacturing Process**

- Hazard analysis and control measures, GMP
- Preventive controls

■ **Labeling**

- Product name (e.g., qualifies as “milk” products?)
- Other claims (Flora-based, Lactose Free, etc.)
- Necessary to disclose production process on labeling?

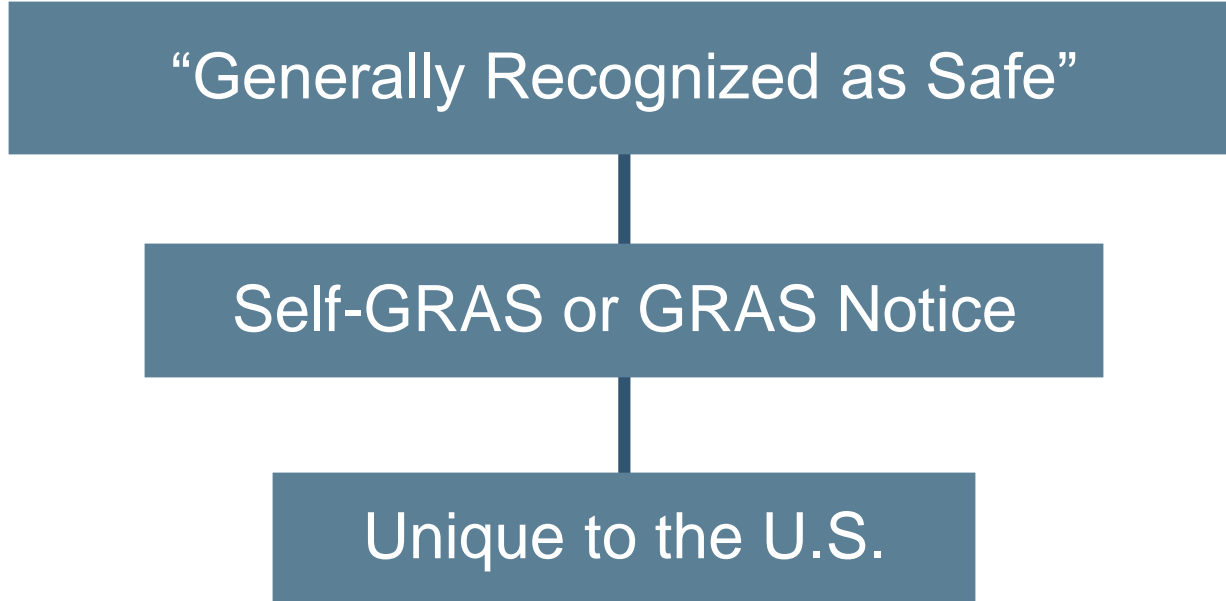
Safety Considerations & Potential Hazards

- Consider and develop appropriate controls for potential hazards that may arise during all stages of production
- Understand the safety profile of ingredients and processing aids
- Leverage best practices from traditional food production context
- Consider how these products will compare to traditionally produced dairy products from a compositional nutritional and organoleptic standpoint

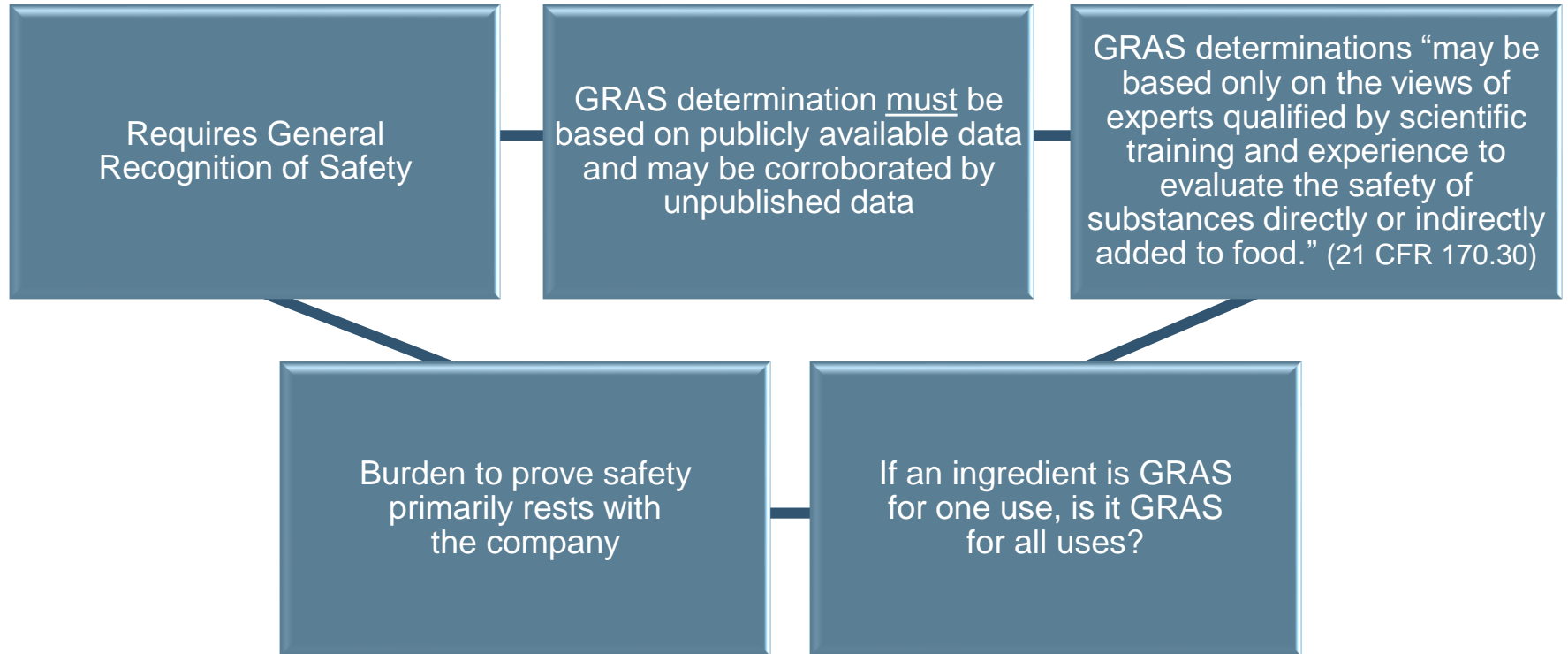
Box 2-3. Example Hazard Analysis Work Sheet (Also see Form 2-B, Appendix 2)²

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step B = biological C = chemical, including radiological P = physical	(3) Are any potential food safety hazards requiring preventive control? (Yes/No)	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supplier, other preventive control</i>	(6) Is the preventive control applied at this step? (Yes/No)

Establishing a Suitable FDA Status



Are My Inputs “GRAS”?



GRAS Notifications

- Additional step companies may voluntarily take for transparency purposes/supply chain diligence
- Company informs U.S. FDA of its GRAS determination and provides all supporting information to FDA
- Publicly available information needed to establish GRAS status
- Does not require public rulemaking process
- Manufacturer may meet with FDA prior to notification to review dossier and ask questions (FDA encourages)
- **Goal:** Obtain No Questions Letter from FDA

Labeling + Claims

- Do “flora-based” dairy products qualify as “milk” products?
- Flora-Based versus Plant-Based
- “Cow-Free Dairy”, “Lab-Made Dairy”
- Bioengineered



Labeling Developments

- **USDA’s Bioengineered Food Disclosure Final Rule** (Jan. 1, 2022 Compliance Date)
- **FDA Public Meeting to Discuss Modernizing Food Standards of Identity** (Sept. 27, 2019)
- **FDA Reviewing Comments on “Use of the Names of Dairy Foods in the Labeling of Plant-Based Products”** (83 FR 49101)



State Legislation – Examples

Labeling Laws Passed	Labeling Bills Proposed
<p>Maryland (SB 922)</p> <p>Louisiana (Act No. 184)</p> <p>North Carolina (SB 711)</p>	<p>Wisconsin (AB 515)</p> <p>West Virginia (HB 4095)</p> <p>Vermont (S 0207)</p> <p>Kentucky (SB 81)</p> <p>Oklahoma HB 2994)</p> <p>Virginia (SB 510)</p> <p>Arkansas (HB 1407)</p> <p>Indiana (HB 1350)</p>

Labeling & Consumer Perception

- **“The next big ice cream aisle addition will be dairy-free...kind of”**
(Quartz, July 11, 2019)
- **“Got Impossible Milk? The Quest for Lab-Made Dairy”** (NYT, Aug. 2, 2019)
- **“Cultured Meat Could Suffer the Same Fate as GMOs, New Research Suggests”**
(Forbes, July 11, 2019)
 - “Just what should people call it anyway? The framing of cultured meat as “lab meat” makes it sound high-tech, unfamiliar and unnatural”

Brian Sylvester's Thought Leadership

- ***Manufacturing Industry Advisor*, “Your Next Hamburger Could Be Slaughter-Free”** (June 19, 2019)
- ***Law360*, “Building the Regulatory Conversation on Cellular Agriculture”** (October 30, 2018)
- ***FDLI Update Magazine Extra*, “FDA Tackles Cell-Cultured Foods”** (July 19, 2018)
- ***Food Safety News*, “Clean Meat Staking its Claim Amid Regulatory Uncertainty”** (July 1, 2018)

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