Morgan Lewis

REGULATION OF CELL-BASED MEAT AND OTHER MODIFIED FOODS

2018 FDLI Annual Conference
Robert G. Hibbert,
May 3, 2018

Legal Landscape

- **USDA/FSIS**
  - Federal Meat Inspection Act (FMIA) (21 U.S.C. §§ 601-695)
    - "**Meat food product**" defined as:
      - any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. (21 U.S.C. 601(J))
  - "Meat" defined as the part of the muscle of any cattle, sheep, swine or goats which is skeletal or which is found in the tongue, diaphragm, heat or esophagus… (9 C.F.R. 301.2)."
- **FDA**
  - Federal Food, Drug and Cosmetic Act (FD&C Act) authorizes FDA to regulate all foods through post-marketing mechanisms such as inspections, testing, and enforcing adulteration and misbranding standards and good manufacturing practices. Primary jurisdiction ceded to FSIS for meat and meat food products.

Agency Jurisdiction

- Does USDA/FSIS have jurisdiction?
- <u>Argument for:</u>
  - Inherent characteristics of cell-cultured meat is, at the cellular-level, actual meat
- <u>Argument against:-</u>
  - Skeletal and Carcass
- <u>Significance:</u>
  - Industry and consumers are accustomed to USDA's mark of inspection and grading

- Does FDA have jurisdiction?

<u>Argument for:</u>

FDA has broad authority regulate foods

General experience with new food ingredients

<u>Argument against:</u>

Inherent characteristics of cell-cultured meat is, at the cellular-level, meat

FDA does not have experience with issues associated with meat products

<u>Significance:</u>

No mark of inspection or grading

Labeling Issues

- **USDA**
  - USDA may establish a definition and standard of identity or composition whenever "necessary for the protection of the public" (FMIA § 607(c))
  - USDA has established approximately 80 standards for meat and poultry products
- **FDA**
  - FDA may establish a definition and standard of identity for food to "promote honesty and fair dealing in the interest of consumers" (FD&C Act § 401)
  - FDA has established over 280 standards established
- Decline in the establishments of food standards over the years
- Proliferation of new foods that did not conform to standards of identity
- Growing acceptance of association of traditional nomenclature and non-traditional products

Biography

Robert G. Hibbert advises clients in the food and agricultural industries on federal regulation, particularly relating to the US Department of Agriculture (USDA), as well as the US Food and Drug Administration (FDA). Clients seek his counsel on labeling, advertising, recalls, food safety compliance, animal health, and new product development issues. Bob's experience with civil litigation in federal court includes successful challenges to the scope of USDA jurisdiction and authority over major segments of the food processing industry.

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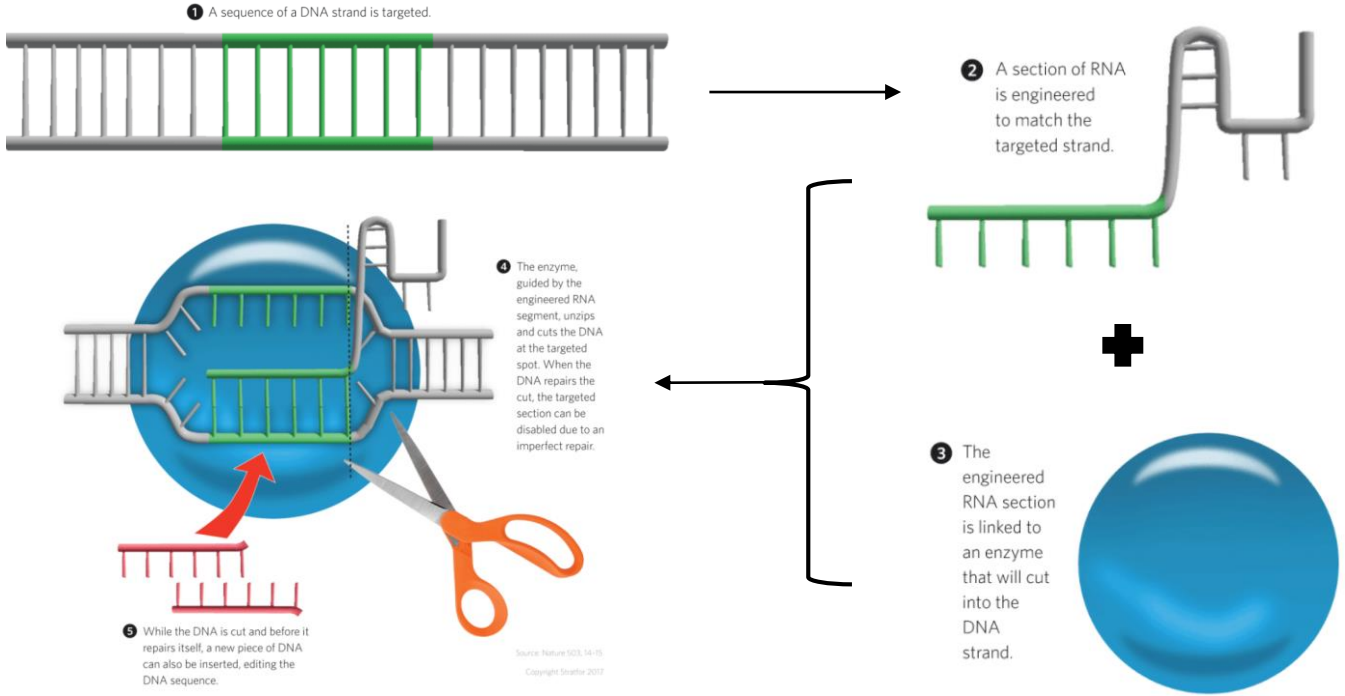
What is genome editing?

- The ability to make specific genetic changes within a genome
  - Specific location
  - Specific type of alteration (insertion, deletion, point mutation, allelic swap)
  - Specific final sequence
- Takes advantage of errors in normal DNA repair processes
  - Zinc Finger Nucleases
  - Meganucleases
  - Transcription Activator Like Effector Nucleases (TALENs)
  - Clustered regularly interspaced short palindromic repeats (CRISPRs)

Five Steps to Gene Editing



Source: https://worldview.stratfor.com/article/biotechnology-biotech-china-united-states-crispr-genome-agriculture-trade-war

Secretary Perdue Issues USDA Statement on Plant Breeding Innovation

(Washington, D.C., March 28, 2018)

- "Under its biotechnology regulations, USDA does not regulate or have any plans to regulate plants that could otherwise have been developed through **traditional breeding techniques as long as they are not plant pests or developed using plant pests.** This includes a set of new techniques that are increasingly being used by plant breeders to produce new plant varieties that are indistinguishable from those developed **through traditional breeding methods.** The newest of these methods, such as genome editing, expand traditional plant breeding tools because they can introduce new plant traits more quickly and precisely, potentially saving years or even decades in bringing needed new varieties to farmers."

Source:
https://content.govdelivery.com/accounts/USDAAPHIS/bulletins/1e591cd

Secretary Perdue Issues USDA Statement on Plant Breeding Innovation

(Washington, D.C., March 28, 2018)

- "Under its biotechnology regulations, USDA does not currently regulate, or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long **as they are developed without the use of a plant pest as the donor or vector and they are not themselves plant pests.** This can include plant varieties with the following changes:
  - **Deletions—**the change to the plant is solely a genetic deletion of any size.
  - **Single base pair substitutions**—the change to the plant is a single base pair substitution.
  - **Insertions from compatible plant relatives**—the change to the plant solely introduces nucleic acid sequences from a compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding.
  - **Complete Null Segregants**—off-spring of a genetically engineered plant that does not retain the change of its parent."

Source:
https://content.govdelivery.com/accounts/USDAAPHIS/bulletins/1e591cd

FDA Current and Proposed Regulation for Plants and Animals

- Voluntary consultation for genetically engineered plants
  - "substantial equivalence"
  - Everyone has complied
- Proposal for gene edited plants
- Mandatory pre-market approval for engineered animals – "new animal drug"
- Proposal for same treatment for gene edited animals
- Over and/or under regulation

Issues

- Science and Risk Based Oversight
- GMO/Not a GMO
- Transparency
- Trade and Markets

Gene-edited, cold-storage potatoes

- Calyxt has used TALEN technology to inactivate a single endogenous gene responsible for sugar accumulation when stored at cold temperatures

Gene-edited, hypoallergic peanuts

- Aranex Biotech is developing “hypoallergic” peanuts by switching off 3 genes that encode for the proteins that cause allergic reactions.

Gene-edited, gluten-reduced wheat

- Institute of Sustainable Agriculture in Cordoba
- Used CRISPR to delete 35 out of 45 genes that code for α-gliadin

Regulation of Cell-Based Meat and other Modified Foods

Nicole Negowetti

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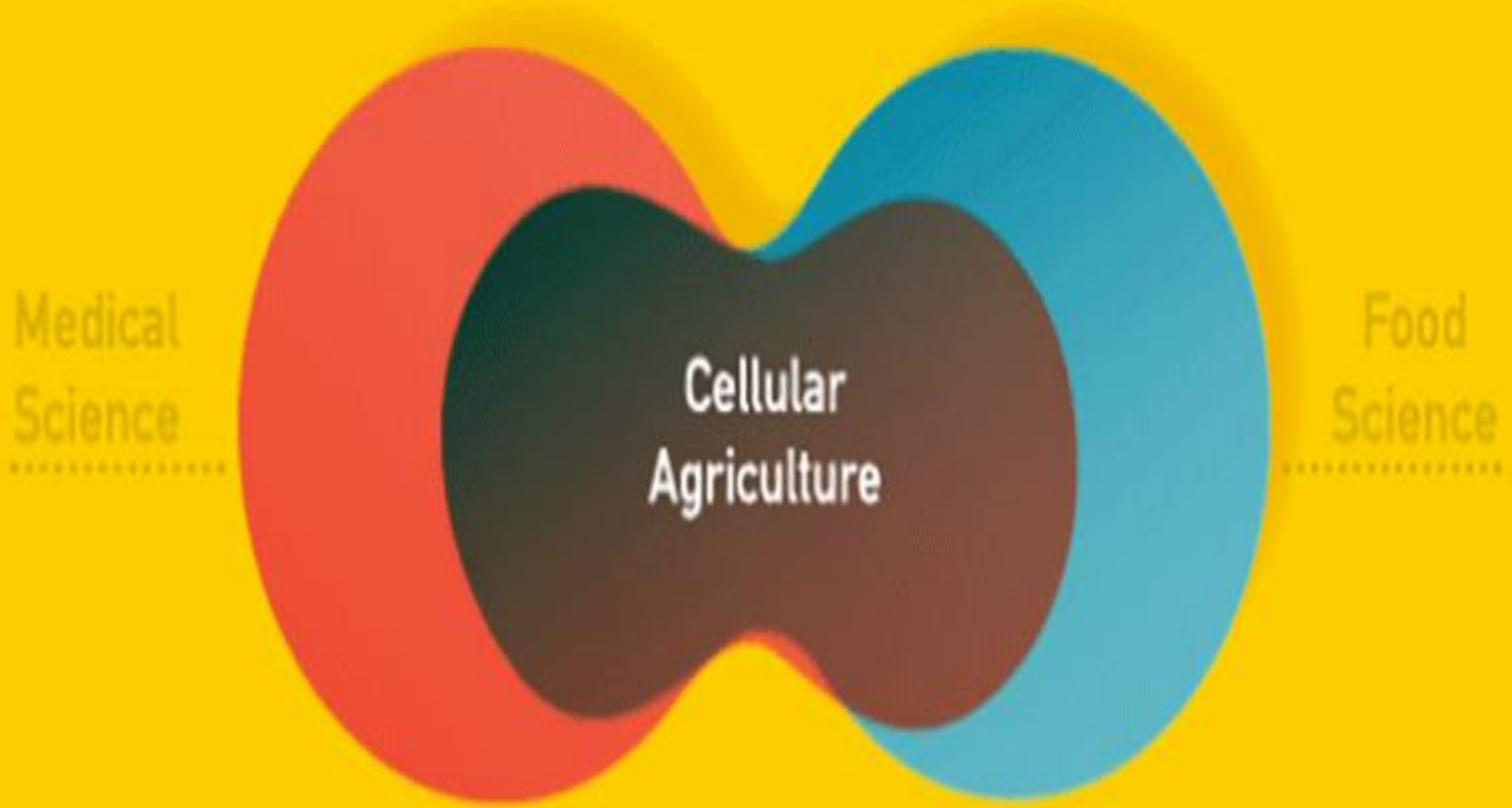
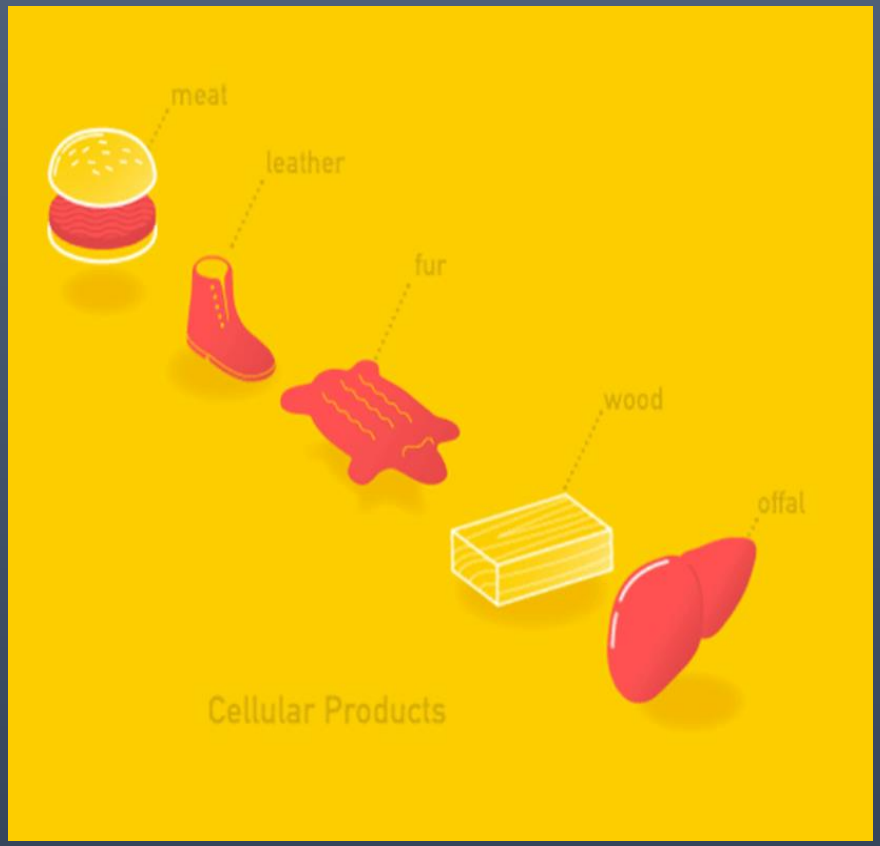
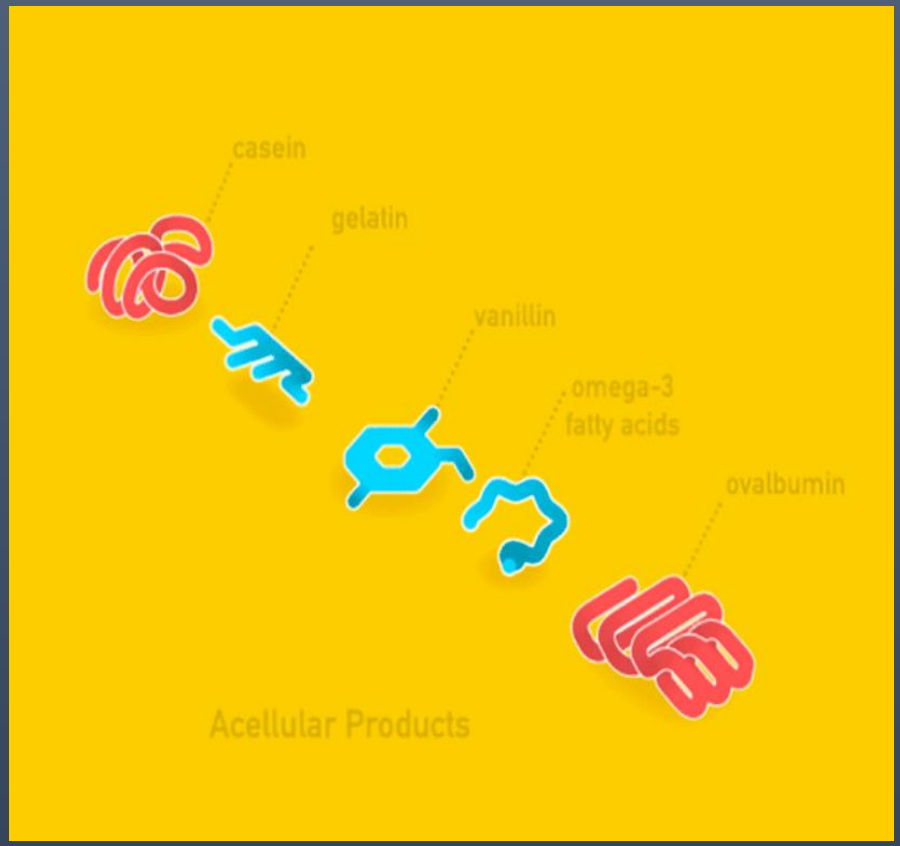

Medical Science
Cellular Agriculture
Food Science

Cellular Agriculture

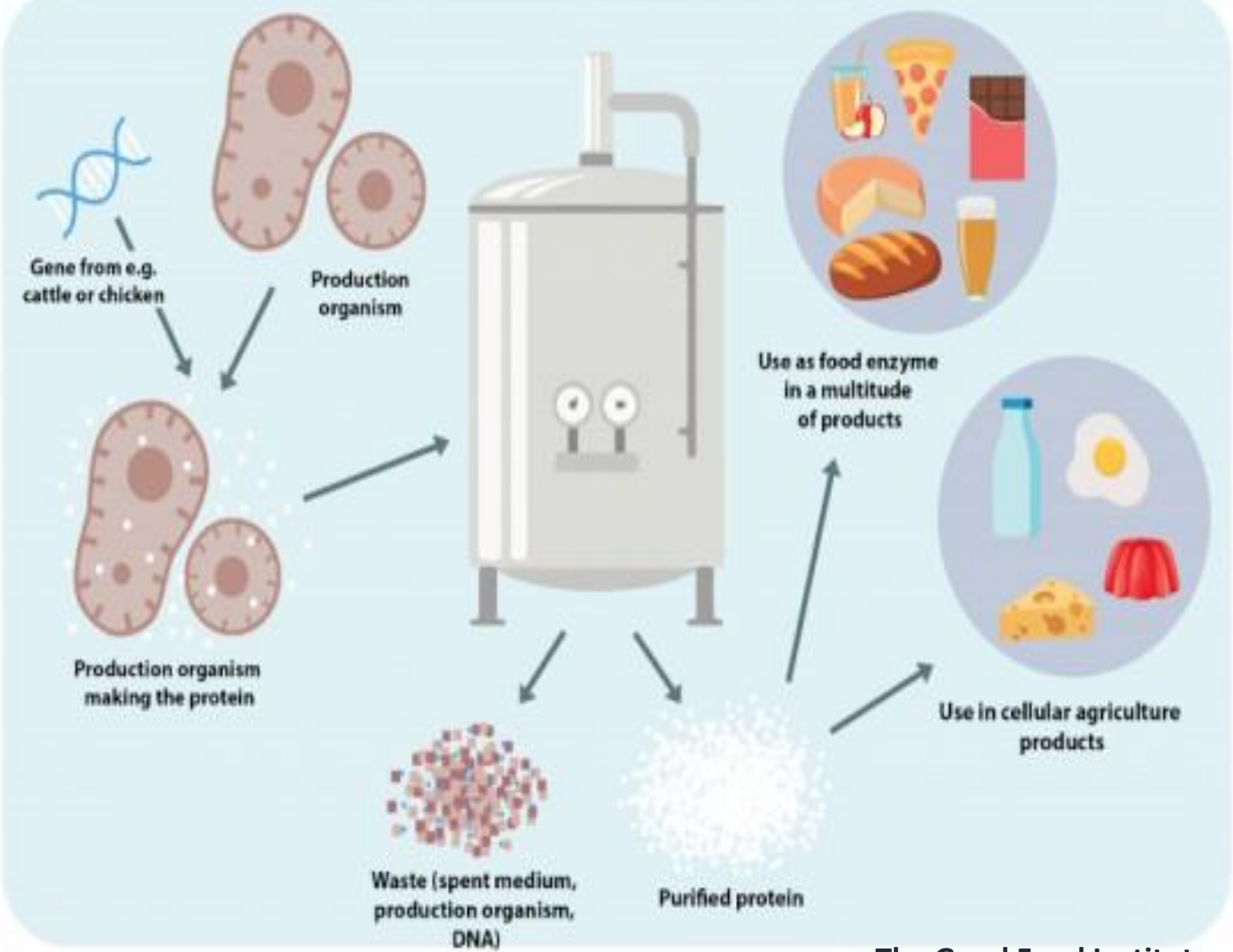
Cellular Products



Acellular Products



Credit: New Harvest



The Good Food Institute

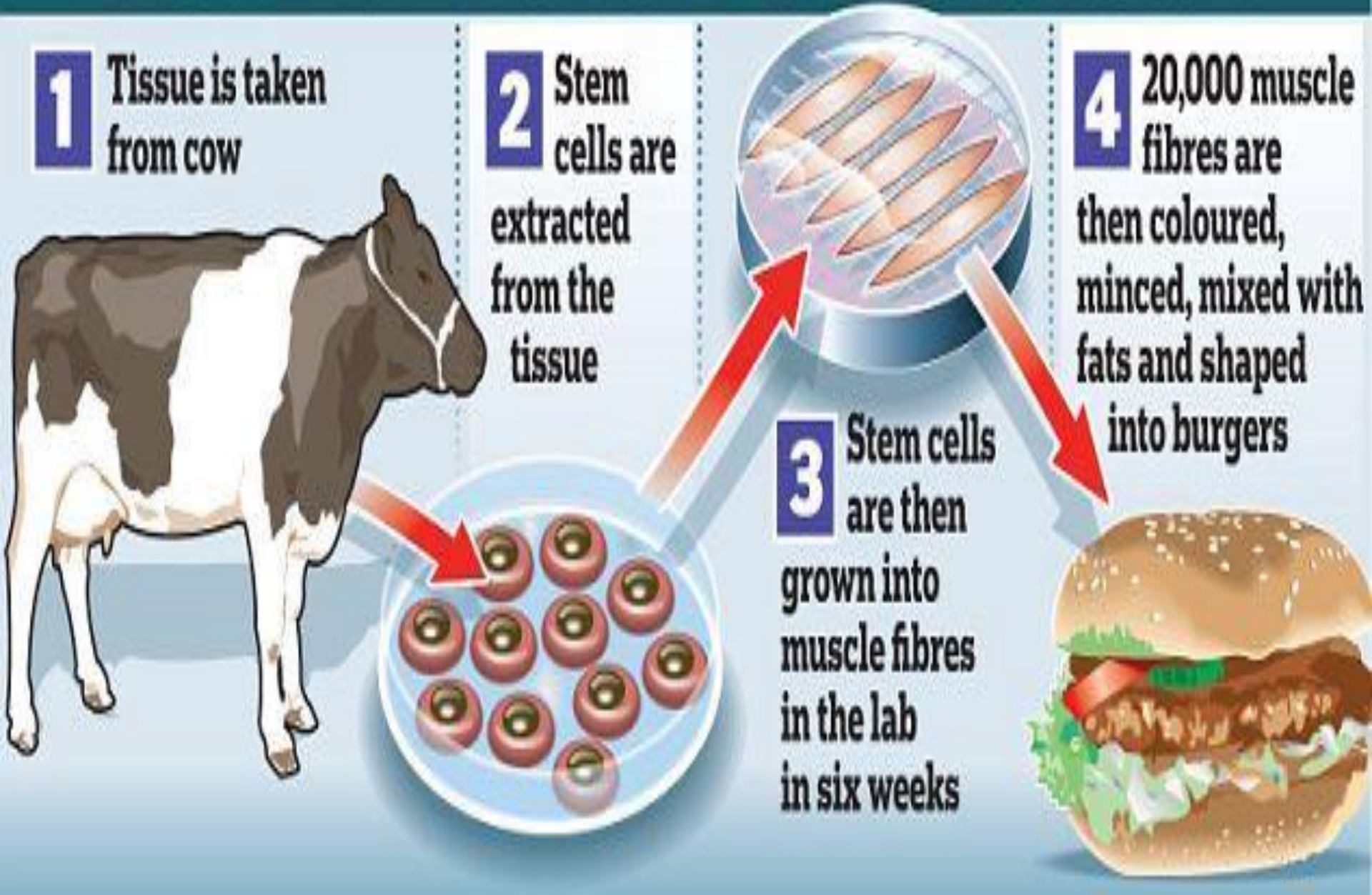
Animal-Free Milk

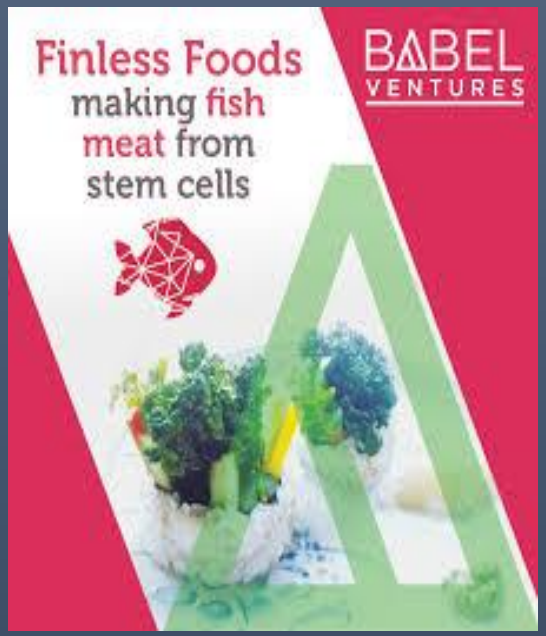
- Milk proteins are made in yeast, rather than in mother cows.
- Yeast is reprogrammed to produce milk proteins by inserting the genes for casein and whey proteins into the yeast cells.
- The yeast culture consumes simple sugars to produce the exact same milk proteins that a lactating cow would produce.
- The fats are sourced from plants. The proteins, fats, and water are combined to make milk.

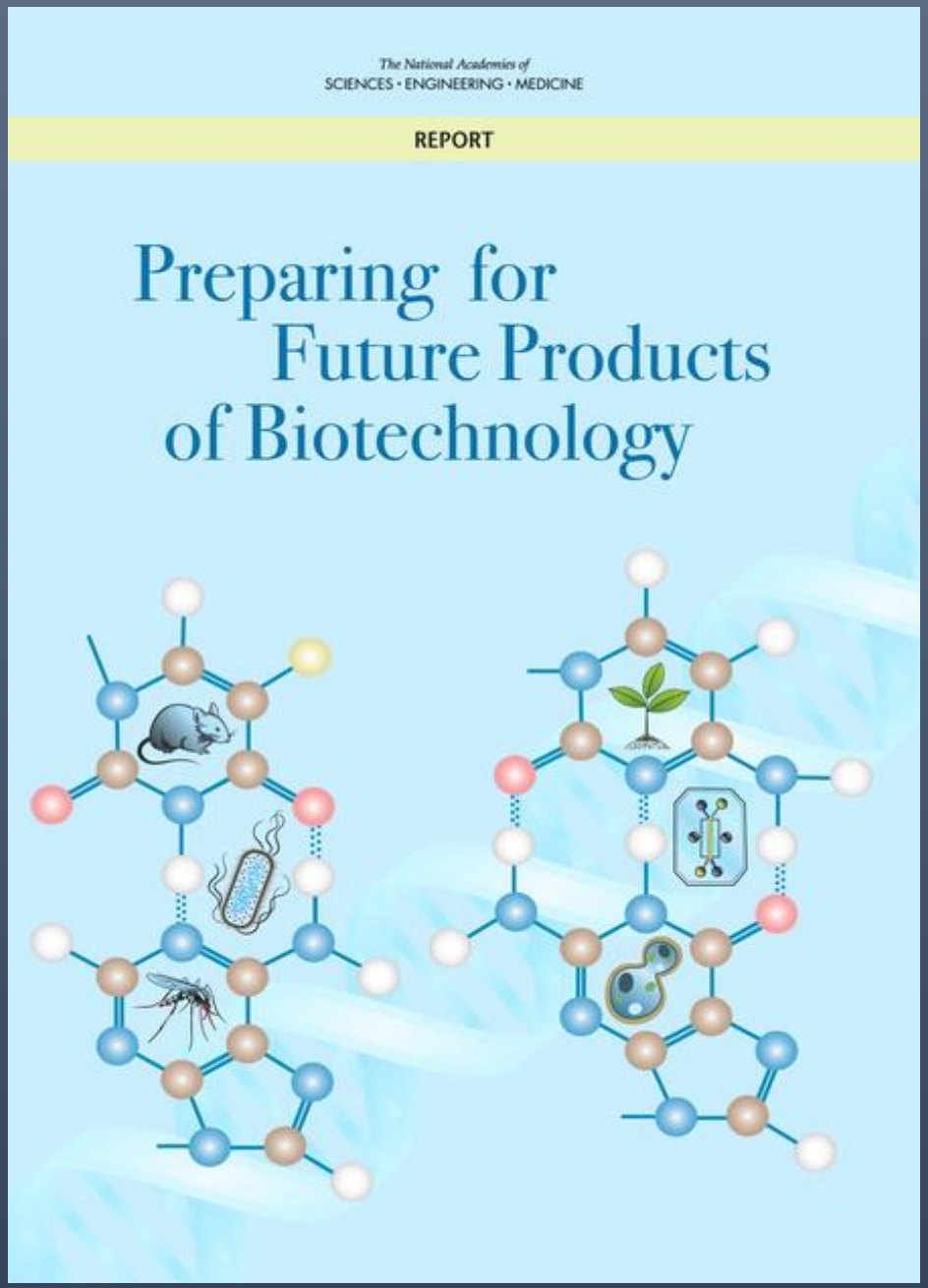
Chickenless Eggs

- Yeast is reprogrammed to produce egg white proteins by inserting the genes for egg white proteins into the yeast cells.
- As the yeast grows, it consumes sugar to produce the exact same egg white proteins that an ovulating hen would produce.
- After enough egg white proteins have been produced, the yeast and egg mixture is separated so only the egg white proteins remain.

HOW THE BURGERS ARE GROWN




Finless Foods
making fish
meat from
stem cells
BABEL
VENTURES



According to National Academies of Sciences, the profusion of biotechnology products over the next 5 – 10 years “has the potential to overwhelm the U.S. regulatory system.”

Regulatory Issues

- Jurisdiction: FDA or USDA (or both)?
- Regulatory pathway possibilities
  - Food additive
  - Generally Recognized as Safe (GRAS)
  - New Animal Drug Application (NADA)
  - Substantial equivalence
- Labeling