



# Cell-cultured meat

## Safety considerations and research priorities

Kimberly Ong, Ph.D.

Vireo Advisors, LLC

June 22, 2022







## **Safety Initiative (2020 – ongoing)**

Lack of publicly available data to demonstrate the safety of cell-cultured meat and seafoods.

## **Safety Initiative 1.0 - Industry**

Isha Datar, Jeremiah Johnston, Yadira Tejeda-Saldana, Breanna Duffy, Paige Wilcoxson, Meera Zassenhaus, Michela Caffrey, Lanto Hariveloniaina, Morgan Zegelski; New Harvest. Jo Anne Shatkin, Cassidy Pomeroy-Carter, Megan Roberts; Vireo Advisors. Vincent Sewalt, IFF. Dwayne Holmes; Mosa Meat. Allen Gunn; Aspiration Tech. Natalie Rubio, Andrew Stout, John Yuen; Tufts University. Samuel Peabody IV; Texas Tech University. Vanessa Haley-Benjamin; University of Auckland. Alexis Garrett; University of Nebraska. Larisa Rudenko; Massachusetts Institute of Technology. Brian P. Sylvester, Cory Trio, Andrew Do; Covington & Burling LLP. Ronit Bakimer and Didier Toubia; Aleph Farms. Joshua March; Artemys Foods. Mariia Abyzova and Askar Latyshev; ArtMeat. Carrie Chan and Mario Chin; Avant Meats. Shannon Falconer; Because Animals. Oded Shoseyov and Tzvi Zvirin; BioBetter. Katie Kam; BioBQ. Iñigo Charola; Biotech Foods. Lou Cooperhouse, Lauran Madden, and Noreen. Hobayan; BlueNalu. Sebastian Rakers; Bluu Biosciences. Christophe Chantre, Grant, Michael Gonzalez, and Luke MacQueen; Boston Meats. Stefano Biressi, Luciano Conti, Giulia Fioravanti, and Stefano Lattanzi; Bruno Cell. Josh Pollack and Valentin Fulga; Cell Ag Tech. Sofia Giampoli; Cell Farm Food Tech. Viknish Krishnan-Kutty; Cellivate Technologies. Marianne Ellis and Illtud Dunsford; Cellular Agriculture Ltd. Leo Groenewegen; CellulaREvolution Ltd. Steven Rees and Jose **Safety Initiative 1.0 - Industry** Ian Johnson and John Pattison; Cultured Decadence. Morachis; Defined Bioscience, Inc. Brandon Chen and Shannon Cosentino-Roush; Finless Foods. Niya Gupta; Fork & Goode. Jalene Anderson-Baron and Matt Anderson-Baron; Future Fields. Nicolas Morin-Forest; Gourmey. Nick Beaumont; Heuros. Benjamina Bollag and Ruth Helen Faram; Higher Steaks. Yuki Hanyu; IntegriCulture. Vitor Santo; JUST. Tiziano Barberi and Dave Schnettler; Lab Farm Foods. Eric Jenkusky and Jed Johnson; Matrix Meats. Romana Vanova-Hrncirik; Meatable. David Kay, Eric Schulze, Meri Firpo, Deepti Kulkarni; UPSIDE Foods. Lavanya Anandan, Luke Grocholl, Dario Kolenko; Merck KGaA, Darmstadt, Germany. Fedon Moog; Mirai Foods. Cai Linton and Reka Tron; Multus Media. Shubhankar Takle; Myoworks. Nicholas Legendre, Alex Rajangam, Brian Spears; New Age Meats. Nieves Martinez Marshall and Michelle Lu; Novel. Farms. Masataka Minami; NUProtein. Patricia Bubner; Orbillion Bio. Nina Buffi, Witold Maniowski, Jordi Morales-Dalmau, Jan Saam; OSPIN Modular Bioprocessing. David Brandes and Paul Mozdziak; Peace of Meat. Ka Yi Ling and Durga Sathiakumar; Shiok Meats. Karolis Rosickas and Steve Oh; SingCell. Beth Loberant; SuperMeat. France-Emmanuelle Adil and Clément Carlier; Tiamat Sciences. George Peppou; Vow. Charles Cuerrier; Whiteboard Foods. Aryé Elfenbein; Wildtype.

# Cultured Meat and Seafood Safety Initiative

*Food safety considerations and research priorities for the cultured meat and seafood industry*

## Comprehensive Reviews in Food Science and Food Safety

Kimberly Ong and Jo Anne Shatkin – Vireo Advisors  
Jeremiah Johnston and Isha Datar – New Harvest  
Vincent Sewalt – IFF  
Dwayne Holmes – Mosa Meat

DOI: 10.1111/1541-4337.12853

Received: 1 February 2021 | Revised: 31 August 2021 | Accepted: 4 September 2021

DOI: 10.1111/1541-4337.12853

COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY

Comprehensive  
REVIEWS  
WILEY

## Food safety considerations and research priorities for the cultured meat and seafood industry

Kimberly J. Ong<sup>1</sup> | Jeremiah Johnston<sup>2</sup> | Isha Datar<sup>2</sup> | Vincent Sewalt<sup>3</sup> |  
Dwayne Holmes<sup>4</sup> | Jo Anne Shatkin<sup>1</sup>

<sup>1</sup> Vireo Advisors, LLC, Boston, Massachusetts, USA

<sup>2</sup> New Harvest Inc., Cambridge, Massachusetts, USA

<sup>3</sup> IFF, Palo Alto, California, USA

<sup>4</sup> Mosa Meat, Maastricht, The Netherlands

### Abstract

Cell-cultured meat and seafood offer a sustainable opportunity to meet the world's increasing demand for protein in a climate-changed world. A responsible, data-driven approach to assess and demonstrate safety of cell-cultured meat and seafood can support consumer acceptance and help fully realize the potential of these products. As an initial step toward a thorough demonstration of safety,

# Generalized process diagram

**Modifier Steps  
(Optional)**

Slaughter

Biopsy

Genetic  
modification

Use of adherent  
surface

Cell isolation

Cell selection

Expression  
regulation

Cell storage

**Process Steps**

Target  
tissue/cell  
procurement

Production  
cell  
preparation

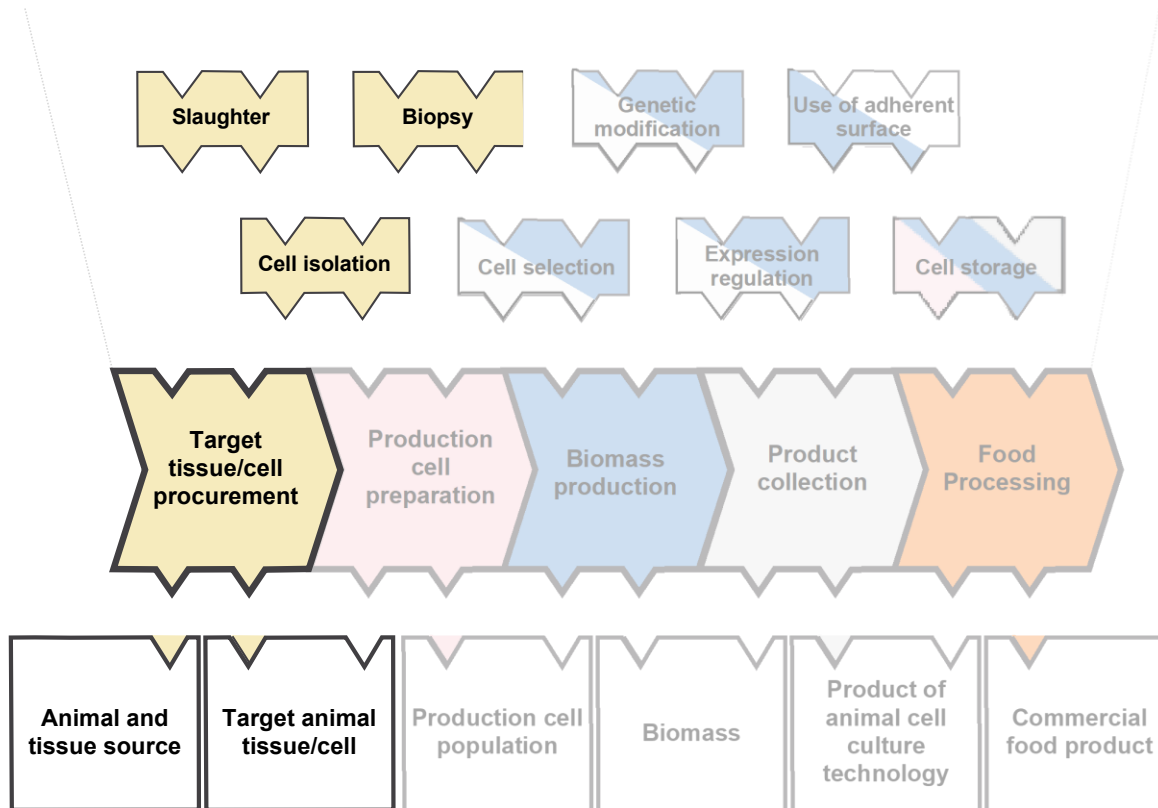
Biomass  
production

Product  
collection

Food  
Processing

## Generalized process diagram

# TARGET TISSUE/CELL PROCUREMENT



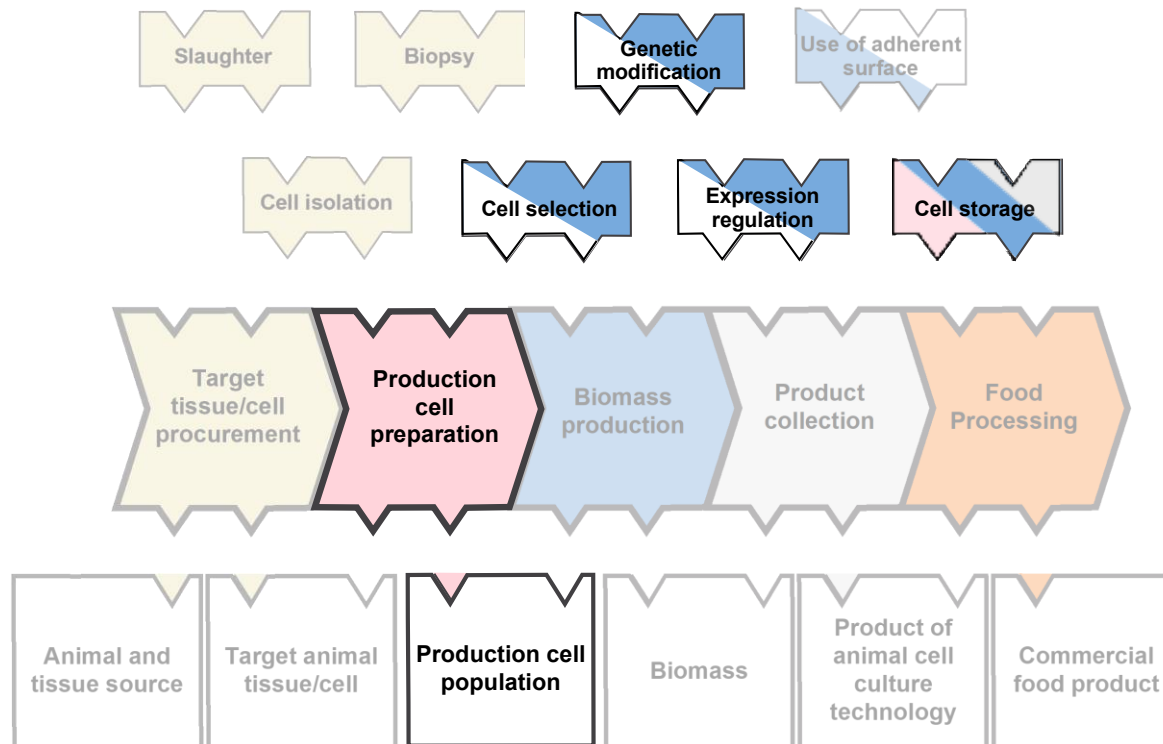
- Tissues and cells procured from dead animals ('slaughter') or live animals ('biopsy'), and isolation of specific cell types





## Generalized process diagram

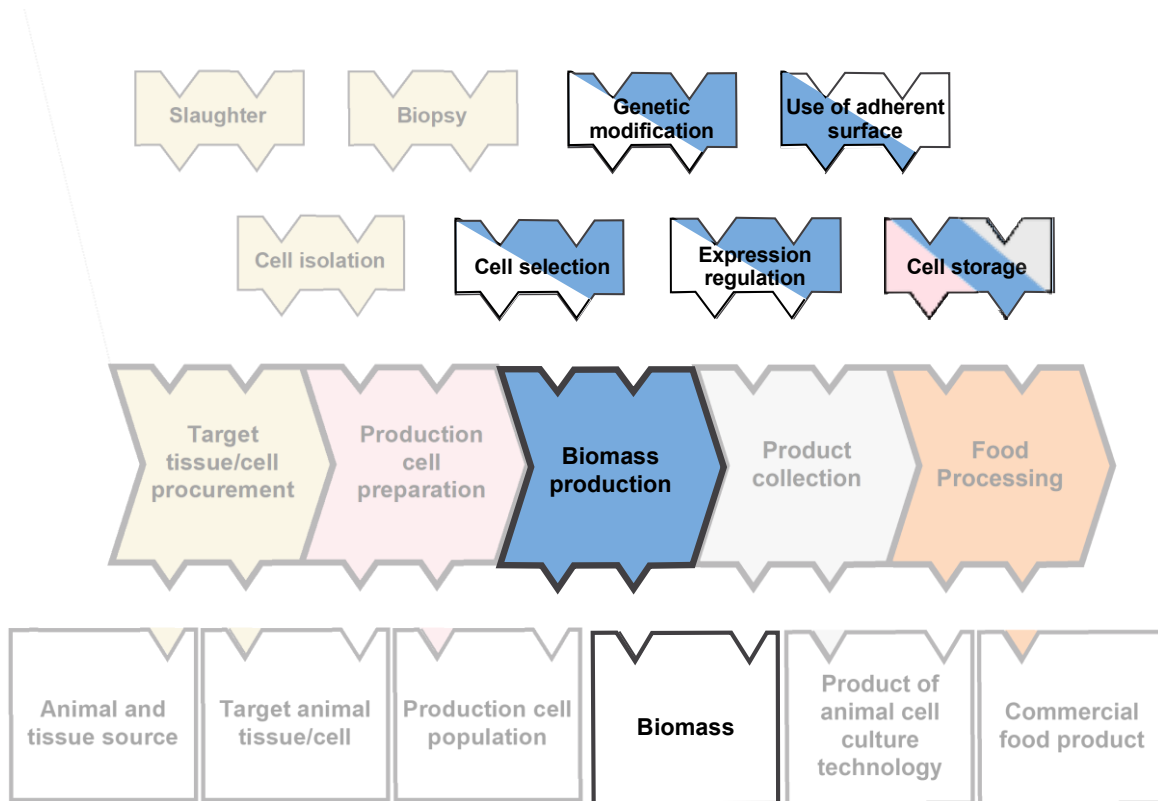
# PRODUCTION CELL PREPARATION



- Existing cells are developed into the desired starting cell types through culture and optimization
- *Cell selection*: Selection of cells with desirable traits (natural or with *genetic modification* or *expression regulation*)
- *Cell storage*: Cells may be frozen and stored

## Generalized process diagram

# BIOMASS PRODUCTION



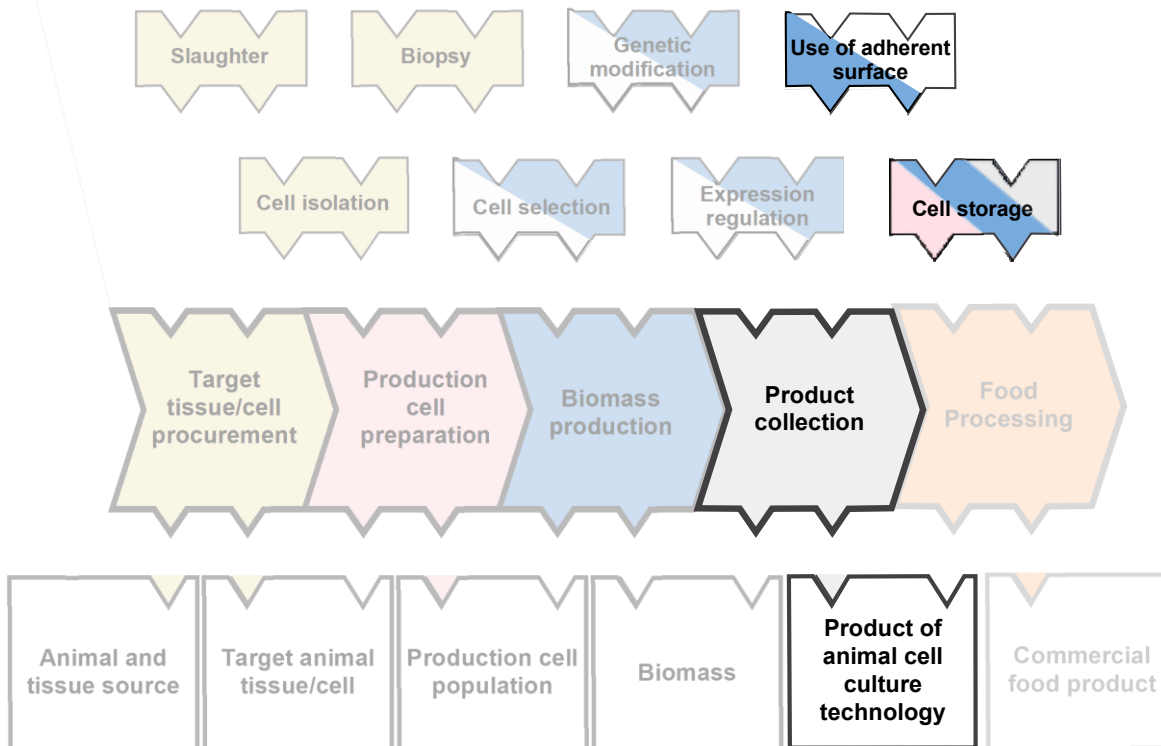
- Increase biomass
- Proliferation: Cells placed in bioreactors
- Differentiation: Change culture media, environmental conditions, adherent surfaces
- *Use of adherent surfaces:* scaffolds and microcarriers
  - Natural, synthetic, composites
  - Recombinant technology, fermentation, extrusion, bioprinting





## Generalized process diagram

# PRODUCT COLLECTION

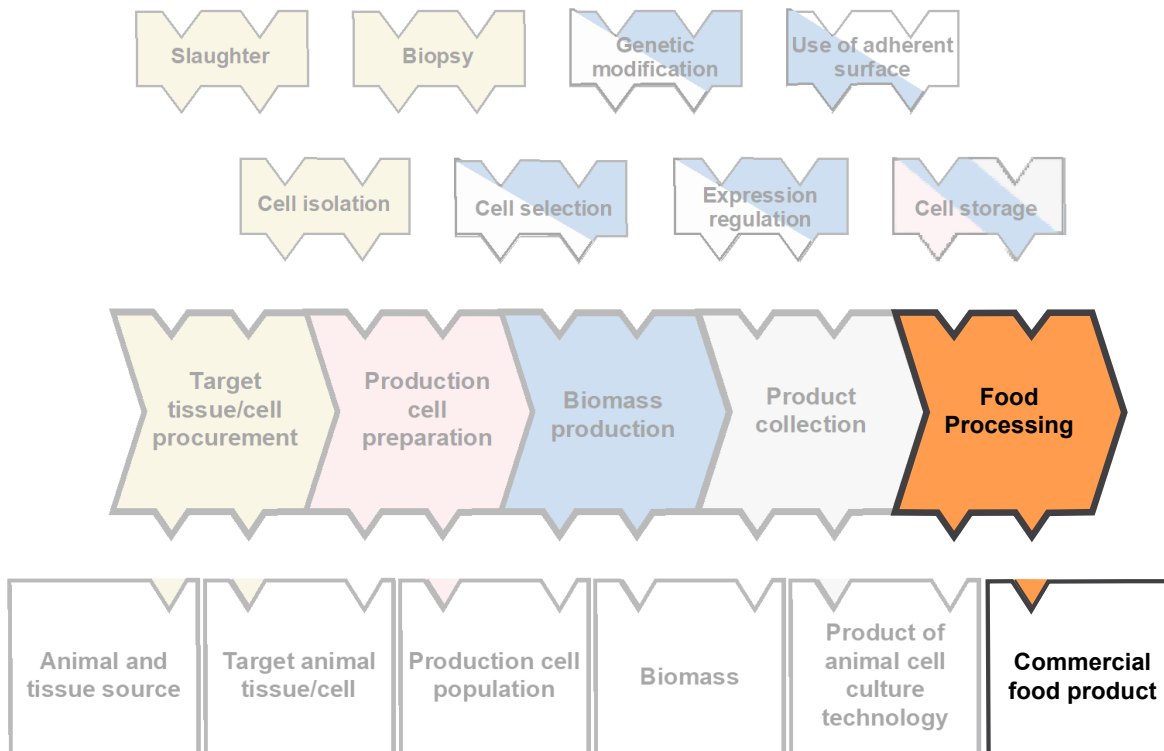


- After desired biomass grown, product is collected
  - Cells do not remain viable
- *Adherent surfaces* may be removed enzymatically, chemically, and/or mechanically
  - Some adherent surfaces remain in product



## Generalized process diagram

# FOOD PROCESSING



- After cells or tissues collected, the cell-cultured product is formulated into commercial food products
- Mixed with additives and other ingredients
- May mimic existing products
- May be processed, *e.g.* sterilization, enzyme treatment, smoking, drying, high pressure processing, or novel methods to combine tissues and components of meat or seafood

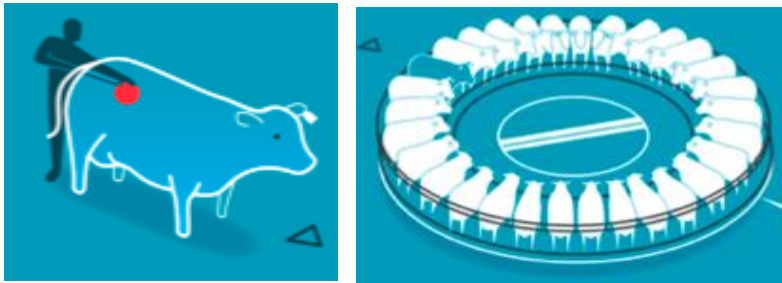


# Hazard Considerations



# *Source animal*

- Contamination during biopsy
- Transmit infectious disease
  - Virus, parasites, prions



## **Hazard prevention**

Animals sourced from pathogen-free herds with health screening programs

Testing for agents of disease

Avoidance of specific tissues



# *Microbiological contamination*

- Bacteria, fungi, viruses
  - *Mycoplasma* - Resistant to antibiotics, pass through filters, grow slowly
- Contamination from conventional agriculture different from cultured meat
- ‘Sterile’ products – potential for colonization?

## **Hazard Prevention**

Quarantine of new cells

Inactivation – heat, irradiation, filtration

Good Manufacturing Practice and aseptic production

Regular observation, screening, and testing



# *Inputs*

- Animal-based components
- Growth factors
- Allergens
- Cryoprotectants
- Scaffolds/microcarriers
- Antimicrobials
- Unintended chemical substances
  - *Leachables from disposables, equipment, packaging, cleaning products*

## **Hazard prevention**

Avoidance of animal-derived products

Use of food-grade substances

Risk assessment of all inputs



# *Genetic changes*

- Mutagenesis, selective breeding, genetic engineering
- Long term culture - Genetic drift

## **Potential Hazards**

Alteration of protein expression levels and expression of novel products, removal of nutrients, production of anti-nutrients, allergens

# Safety assessment

## Similarity

- How do cultured meat products compare to 'conventional' meat?

## Hazards

- Are there inputs, by products, residues that are not typically eaten or could be unsafe?

## Challenges

*What is different?*  
Determination of similarity to conventional products

*Is it novel?*  
Identifying what is novel

*Is it present in final food?*  
Performing whole-food testing  
*It is higher/lower concentration?*

- Solubilization for *in vitro* tests
  - Whole-food feeding to animals
- How much will we eat?*  
*Is it safe?*

## **Safety Initiative 2.0 - Regulatory scientists**

# Safety Initiative 2.0 - Regulatory scientists

WORKSHOP 2022

Methods, specification development  
Data gaps  
Research priorities  
Collaboration



Thank you!

**Kimberly Ong**

kong@vireoadvisors.com

<https://www.VireoAdvisors.com>

# Acknowledgements

Jo Anne Shatkin and the team at Vireo Advisors  
Isha Datar, Dwayne Holmes, Yadira Tejada-Saldana, and the  
team at New Harvest

Vincent Sewalt; IFF  
Dwayne Holmes; Mosa Meat  
Allen Gunn; Aspiration Tech  
Natalie Rubio, Andrew Stout, John Yuen; Tufts University  
Samuel Peabody IV; Texas Tech University  
Vanessa Haley-Benjamin; University of Auckland  
Alexis Garrett; University of Nebraska  
Larisa Rudenko; Massachusetts Institute of Technology  
Brian P. Sylvester, Cory Trio, Andrew Do; Covington & Burling LLP  
Ronit Bakimer and Didier Toubia; Aleph Farms  
Joshua March; Artemys Foods  
Mariia Abyzova and Askar Latyshev; ArtMeat  
Carrie Chan and Mario Chin; Avant Meats  
Shannon Falconer; Because Animals  
Oded Shoseyov and Tzvi Zvirin; BioBetter  
Katie Kam; BioBQ  
Iñigo Charola; Biotech Foods  
Lou Cooperhouse, Lauran Madden, and Noreen  
Hobayan; BlueNalu  
Sebastian Rakers; Bluu Biosciences  
Christophe Chantre, GrantMichael Gonzalez, and Luke  
MacQueen; Boston Meats  
Stefano Biressi, Luciano Conti, Giulia Fioravanti, and Stefano  
Lattanzi; Bruno Cell  
Josh Pollack and Valentin Fulga; Cell Ag Tech  
Sofia Giampoli; Cell Farm Food Tech  
Viknesh Krishnan-Kutty; Cellivate Technologies  
Marianne Ellis and Illtud Dunsford; Cellular Agriculture Ltd.  
Leo Groenewegen; CellulaREvolution Ltd.  
Ian Johnson and John Pattison; Cultured Decadence  
Steven Rees and Jose Morachis; Defined Bioscience, Inc.  
Brandon Chen and Shannon Cosentino-Roush; Finless Foods

Niya Gupta; Fork & Goode  
Jalene Anderson-Baron and Matt Anderson-Baron; Future  
Fields  
Nicolas Morin-Forest; Gourmey  
Nick Beaumont; Heuros  
Benamina Bollag and Ruth Helen Faram; Higher Steaks  
Yuki Hanyu; IntegriCulture  
Vitor Santo; JUST  
Tiziano Barberi and Dave Schnettler; Lab Farm Foods  
Eric Jenkusky and Jed Johnson; Matrix Meats  
Romana Vanova-Hrncirik; Meatable  
David Kay, Eric Schulze, Meri Firpo, and Deepti Kulkarni;  
UPSIDE Foods  
Lavanya Anandan, Luke Grocholl, and Dario Kolenko; Merck  
KGaA, Darmstadt, Germany  
Fedon Moog; Mirai Foods  
Cai Linton and Reka Tron; Multus Media  
Shubhankar Takle; Myoworks  
Nicholas Legendre, Alex Rajangam, and Brian Spears; New Age  
Meats  
Nieves Martinez Marshall and Michelle Lu; Novel Farms  
Masataka Minami; NUProtein  
Patricia Bubner; Orbillion Bio  
Nina Buffi, Witold Maniowski, Jordi Morales-Dalmau, and Jan  
Saam; OSPIN Modular Bioprocessing  
David Brandes and Paul Mozdziak; Peace of Meat  
Ka Yi Ling and Durga Sathiakumar; Shiok Meats  
Karolis Rosickas and Steve Oh; SingCell  
Beth Loberant; SuperMeat  
France-Emmanuelle Adil and Clément Carlier; Tiamat Sciences  
George Peppou; Vow  
Charles Cuerrier; Whiteboard Foods  
Aryé Elfenbein; Wildtype