

Regulating the Future of Food: A Global Perspective

Dr Hannah Lester

CEO at
Atova Regulatory Consulting

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Introduction to Food Regulation

Introduction to Food Regulation

- ✓ Food safety
- ✓ Food quality
- ✓ Labelling & claims
- ✓ Consumer confidence
- ✓ International trade
- ✓ Protection of animals & the environment

Food regulation crucial for protection public health, ensuring food quality, promoting sustainability and maintain consumer trust in the food chain.

Framework for responsible food production, distribution and consumption

Emerging Food Technologies

THE 2023 CELL – BASED / CULTIVATED PROTEIN LANDSCAPE

AIR-BASED PROTEIN

Arkeon Avecom
CALYSTA CIRCE
Spira econutri
SOLAR FOODS
String Deep Branch

BEEF

ALEPH FARMS biftek.co
BioBQ CND DaNAgreen LABFARM
meatleo MIRAI FOODS seqwith
mosa meat Quest Meat SCIFI
ALT TLAS BeneMeat MEAT

BIOPRINTING

COCUUS
NOVAMEAT
TissenBioFarm
vivax bio

BIOREACTORS

culture
MGTBIO
NEB unicorn
ERIDIA

CELL LINES

Cell 4 Food
QPO
Sea 2 Cells
ROSLIN Technologies

FERMENTATION (EGGS, DAIRY, HONEY)

bee-io Fermify Formo EGSTACY EVERY
helaina mayamilk MeliBio planetary opalia
OTTO ONEGO remilk. shiru Better Dairy
Bon Vivant change FOODS Daisy Lab
New Culture motif Perfect Day REAL DEAL MILK STANDING OVATION
Those VEGAN COWBOYS

FATS

Impactfat yali bio
CUBIO HOXTON FARMS
Melt & Marble nourish INGREDIENTS

GROWTH FACTORS & MEDIA

FUROIQ HEUROS NUProtein
BioBetter Novella Qkine tiamat TRITON
Bright Biotech COORE Merck KGaA Darmstadt, Germany
multus media ORF PROPUSE SOPHIE'S BIONUTRIENTS Sticta

PET FOOD

FIVE LETTER FOODS
BECAUSE ANIMALS
BOND PET FOODS GOOD DOG FOOD
MEAT Pristine Pet Food WILD EARTH

PORK

edge FORK & GOOD
MEATABLE
MEWERY NEW AGE EATS Bio.Tech. Foods.
EVOLVED MEATS Hs MEAT TOMORROW

POULTRY

AIR PROTEIN
ClearMeat IntegriCulture
SuperMeat GOURMEY
VITAL MEAT BOND PET FOODS

TECH

BioRaptor luyef
FoldChanges
CELLREV OSPIN
μFraction ALFRED'S Food Tech
Gaia laboratories

MULTI-SPECIES + OTHER

3dbio A-life ArtMeat BIOMILQ
CellX CIRCE FLAVUOR meatiply Microharvest
MOGALE Moolec NOUBIO opalia Orillon STEM TurtleTree
unicorn Vow Yeastup Cellular Agriculture GAIA FOODS ivyfarm
MAGIC VALLEY Mission Barns MZANSI MEAT Co. RENAISSANCE FARMS Steakholder FOODS UPSIDE Foods

SCAFFOLDING (GELATIN, COLLAGEN)

cass materials Excell
Gelatex GELTOR OLIVEN novelfarms
POLYBION PROVENANCE tantti
Cellivate Technologies ECOVATIVE DESIGN JELLATECH our foods
MATRIX MEATS MICRO MEAT NOVA MEAT WHITEBOARD FOODS

SEAFOOD

avant BlueNalu
Bluu Biosciences Fisheroo forsea MAGICCAVIAR
Shiok Meats UMAMI wanda fish
CAT CELL AG TECH Cell AGRITECH CellMEAT Finless FOODS
MERMADE PEARLITA FOODS Sustineri Piscis

Emerging Food Technologies

- ✓ Risk assessment
- ✓ Science-based regulation
- ✓ Pre-market approval
- ✓ Labelling & transparency
- ✓ Consumer education
- ✓ Stakeholder engagement
- ✓ International collaboration

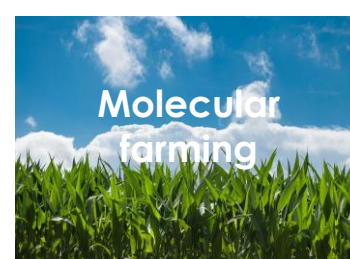
Regulating new food is complex – need a balance between fostering innovation and ensuring the safety, quality of the emerging technologies

Regulators need to be agile, collaborative and committed to implementing policies that support innovation in the food industry.

Food Safety

Approach to Food Safety

Increasing complexity



Data requirements and approach to safety dependent on multiple factors

For many regions there are no guidance documents

Exact approach case-by-case basis

Scienced-based risk assessment following existing principles of food safety

Identify food hazards and risks and put in place mitigation steps

Approach to Food Safety



Cell cultured meat

- ✓ Source
- ✓ Identity
- ✓ Sterility
- ✓ Isolation protocol
- ✓ Gene editing
- ✓ Cell storage



- ✓ Cell culture media
- ✓ Antibiotics
- ✓ Growth factors
- ✓ Animal serum
- ✓ Scaffolding
- ✓ Residues/metabolites

No clear guidance

Cell cultured products Cell-lines

Identity

Sterility

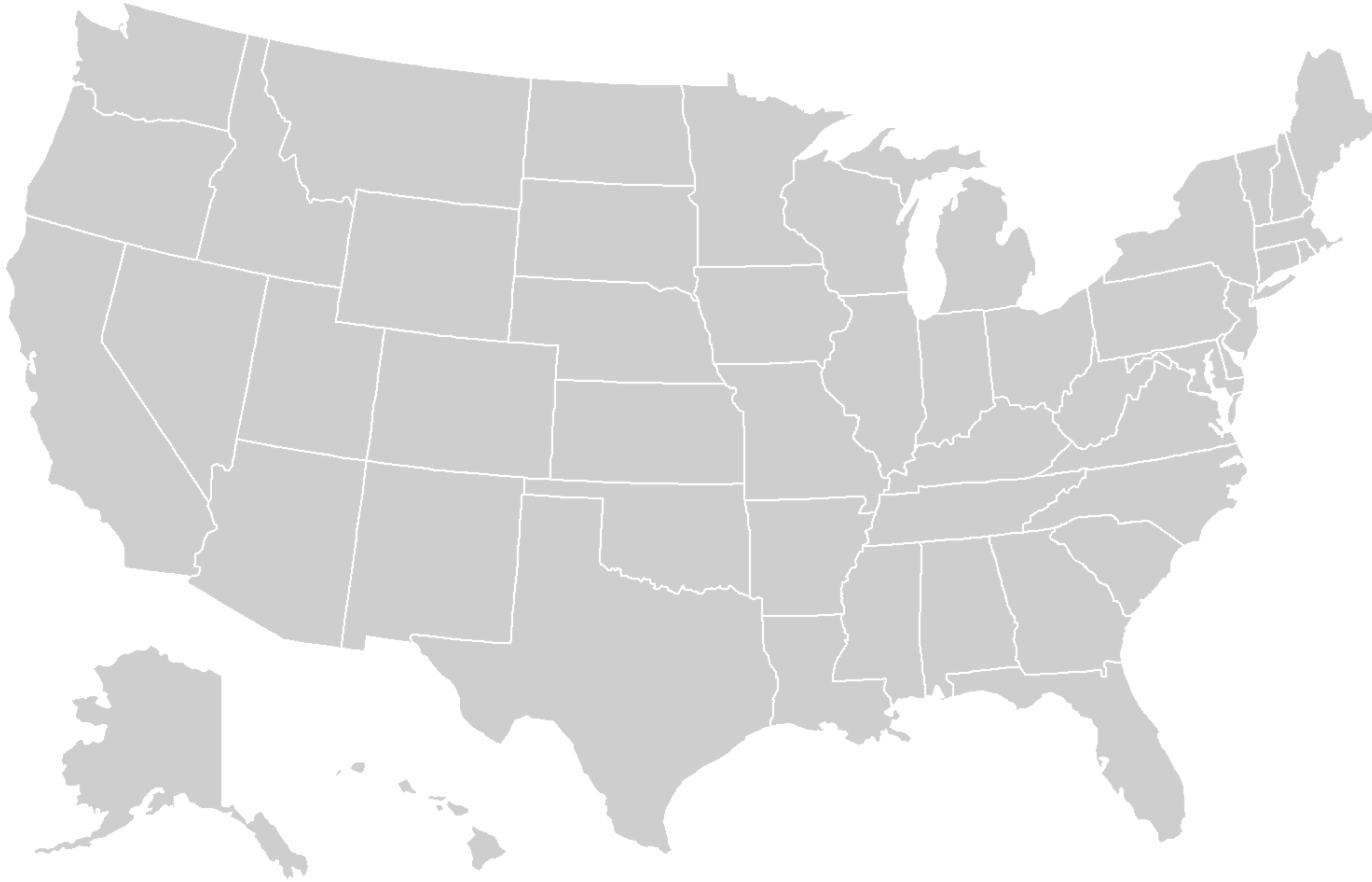
Stability



Approach dependent on species and
cell type

Current Regulatory Landscape

USA



Food and Drug
Administration



United States
Department of
Agriculture

Two regulatory bodies

No novel food regulation

GRAS, FAP, NDI

Defined framework for
cultivated meat

Flexible on bioengineered
foods

Timelines dependent on route

Singapore



- One regulatory body
- One phase to authorisation
- Fast and predictable
- Pre-submission advice
- Draft dossier review
- 9-12 months approval time
- Flexible on GMOs
- Flexible on labelling (use of cultivated, cultured permitted)



European Union



European Commission



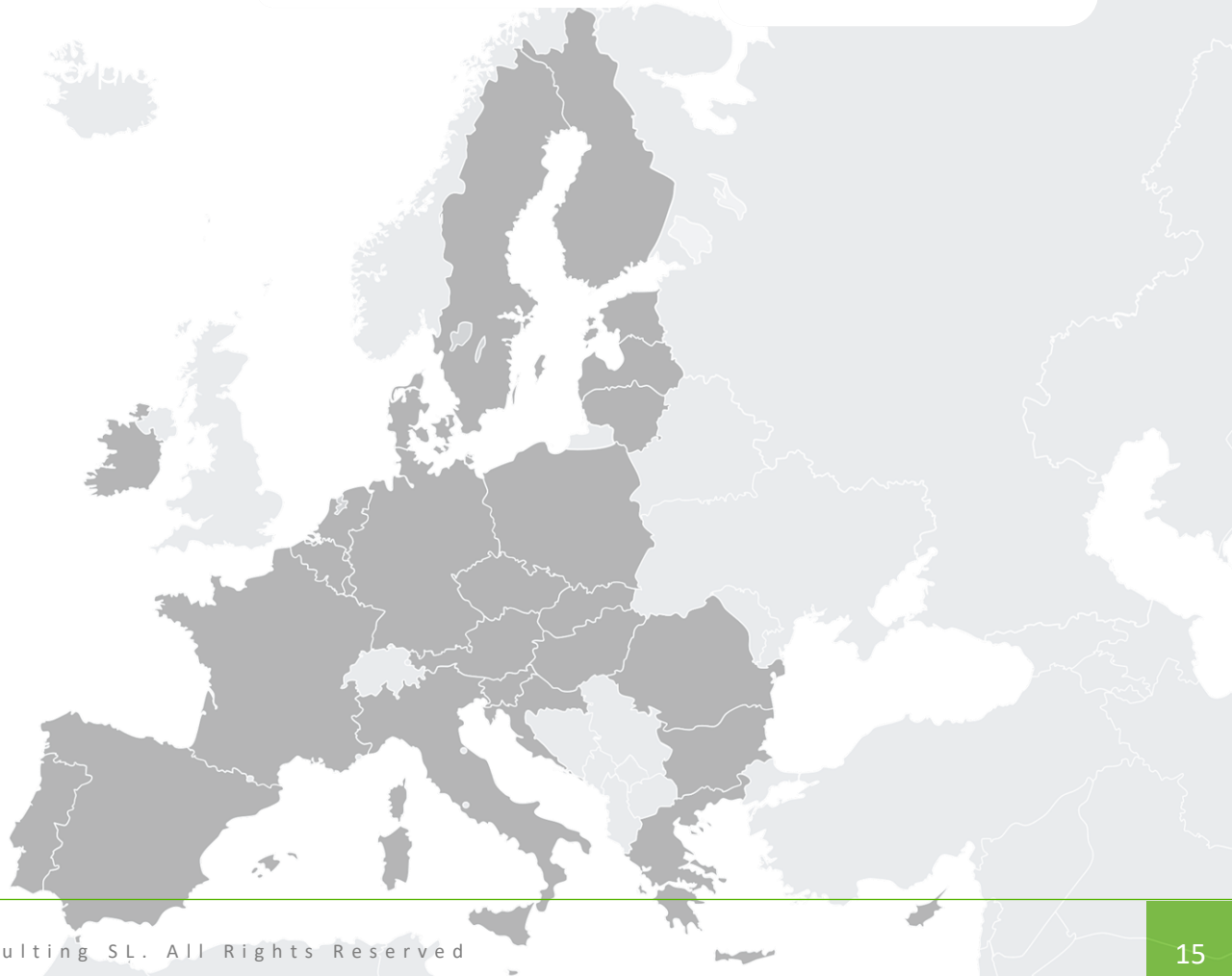
Complex novel food framework

Two regulatory bodies

Two phases to authorization

Novel food guidance & other guidelines to follow

Separate GM food regulation



EU novel food authorisation process



Timeline from submission to authorisation ca. 1.5 years

EU QMV, 55% EU MS representing 65% of EU population!

1.5 years is not so bad....
But what's the reality?

Average timelines¹

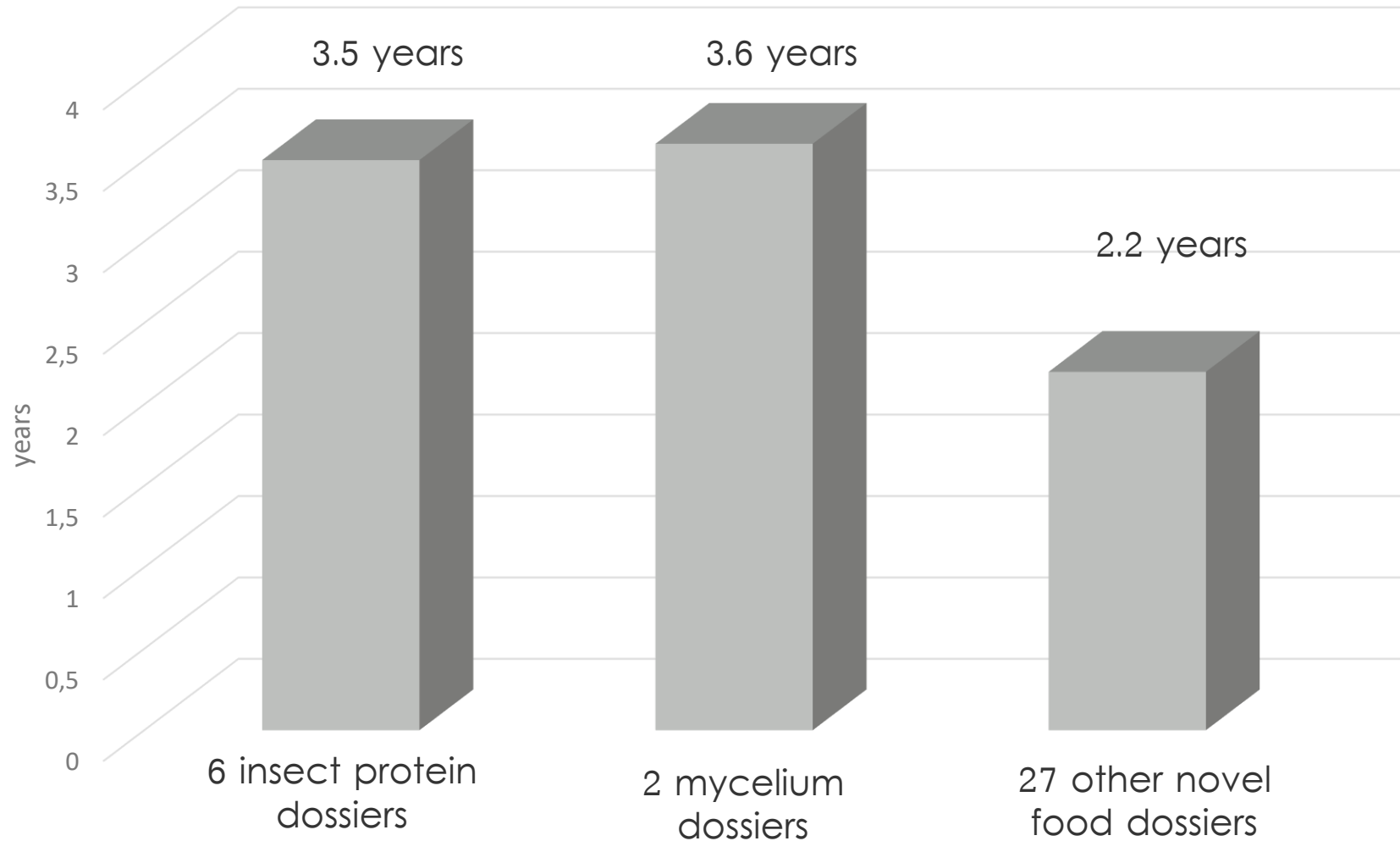


Average timeline from submission to authorisation ca. 2.5 years

Fastest = 1 year, 6 months
Longest = 5 years
Average 3 x clock-stops

¹Unpublished analysis performed by Atova – based on 35 approved novel food dossiers for which all data points were available. Analysis did not include modification of use dossiers

Average timelines: Deep dive

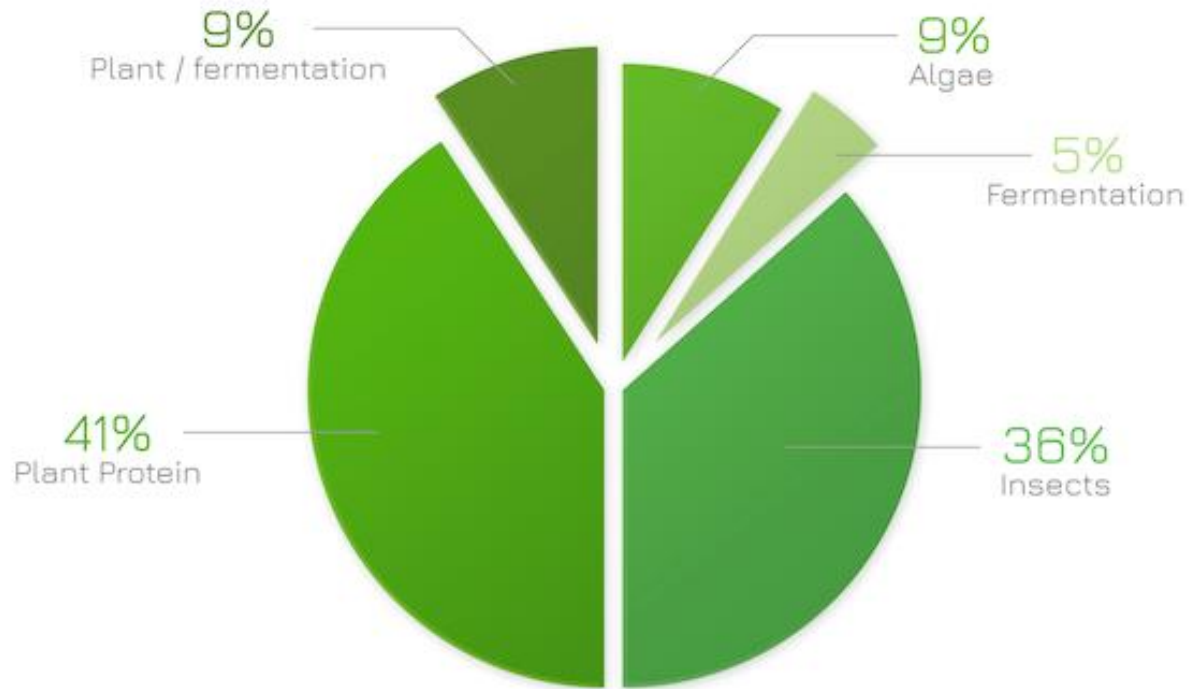


Current Status of Regulatory Approvals

Current status of approvals

	Region	Plant-based proteins	Insects	fermentation	Precision fermentation	Precision fermentation (GM food)	Cultivated meat
1	EU	✓	✓	✓	✗	✗	✗
2	USA	✓	✓	✓	✓	✓	✓
3	SGA	✓	✓	✓	✓	✓	✓

Current status of EU novel food approvals



- No new proteins from precision fermentation approved but...
- Perfect Day & Remilk dossier submitted
- No cultivated meat... dossiers submitted yet!

GM Food in the EU

Soy leghaemoglobin case study

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

GRAS Notices

FDA Home | Generally Recognized as Safe | Food Ingredient & Packaging Inventories | GRAS Notices | GRN No. 737

GRN No. 737

Soy leghemoglobin prep

Intended Use: ground beef analogue products intended to

Basis:

Notifier:

Notifier Address:

GRAS Notice (releasable information):
Part 2:
Part 3:

Date of closure:

FDA's Letter: FDA has no questions (in PDF) (80 KB)

Notes: Resubmission of GRN 540

2362

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Also approved in Canada, USA, Singapore, Australia/NZ, among others...

GMO

Food and Feed - Regulation (EC) No 1829/2003

EFSA-Q-2019-00651 | Status: Ongoing Risk Assessment | Clockstop expected until: 30/04/2022 | Last updated: 07/02/2022

[Share](#) [Print Question](#)

Subject

Request for placing on the market of Soy Leghemoglobin produced from genetically modified *Pichia pastoris* (EFSA-GMO-NL-2019-162)

Timeline

23-10-2022
Risk Assessment Deadline

Output

No Output has been formed yet

Evidence and supporting

Type	Name
Additional Evidence	Acknowledgement
Additional Evidence	Summary
Additional Evidence	MS Request
Additional Evidence	Validity letter
Additional Evidence	2021-12-21 EFSA to appl_stop the clock 1_AP162

General Info

Applicants
Impossible Foods Inc.
[Presubmission advice](#)

Question number
EFSA-Q-2019-00651

Question type
Application

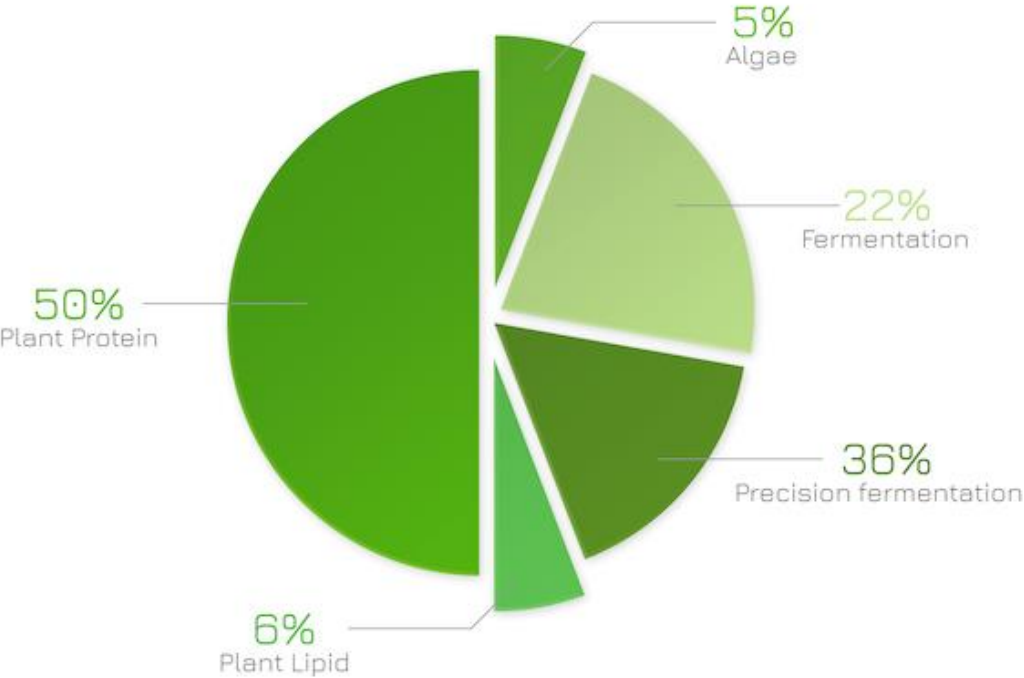
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GMO Food Submitted 2019... may get EFSA opinion late 2023!

GM Food route slow & unpredictable!

Status of current protein approvals

United States



USA
25 GRAS notices
18 "approvals"

- 6 precision fermentation with GRAS no questions letters
- 2 FDA no questions letters for cultivated meat, plus GOI & label approval by USDA

Analysis performed by Amgen in January 2023

Status of current protein approvals

Singapore



- No positive list of approvals
- Soy leghaemoglobin
- Solein® single cell microbial protein
- Cultivated chicken

Challenges and Future Outlook

Challenges

General challenges

- ✓ Regulatory gaps
- ✓ Technology outpacing regulatory knowledge
- ✓ Little published data to inform regulators
- ✓ Minimal collaboration between regulators
- ✓ Resource constraints
- ✓ Lack of international standards & harmonisation
- ✓ Methods of analysis
- ✓ Import/export rules

EU challenges

- ✓ Political environment
- ✓ Conservative member states
- ✓ EU slow to implement regulatory reforms
- ✓ Transparency regulation adds extra complexity
- ✓ Highly negative stance on GMOs

Reasons to be cheerful: Global perspective

- ✓ FAO report on food safety of cultivated meat
- ✓ Increasing amount of cooperation & collaboration between regulators
- ✓ FSANZ received first cultured meat dossier – 15 month timeline
- ✓ UK reviewing their novel food framework
- ✓ USA has given the green light to



Gourmey's cultivated foie gras

Reasons to be cheerful: EU

- ✓ EFSA risk assessment incredibly thorough
- ✓ EFSA getting used to transparency regulation so timelines should improve
- ✓ More EC/EFSA stakeholder engagement
- ✓ In May, EC/EFSA said they are ready & waiting for cultivated meat/seafood dossiers!
- ✓ The sooner we get dossiers in the sooner the EC/EFSA will be forced to think about cultivated meat!
- ✓ EFSA updating their NF guidance
- ✓ EU approved a draft proposal for a new regulation on new genomic techniques in plants:
 - ✓ NGT recognised as more targeted and lower risk compared to classical GM techniques
 - ✓ NGT plants that are the same as their native counterparts not regulated under the GM regulation & will fall under novel food or equivalent
- ✓ EU's draft protein strategy was released:
 - ✓ Says novel food authorisations should be based solely on safety
 - ✓ Calls for more R&D into alternative proteins
 - ✓ Policy action to simplify and speed up the novel food approval process

What do we need for regulating the future of food in the European Union?

What we need from EC & EFSA

- ✓ Meaningful pre-submission advice from EFSA
- ✓ Updated fit-for-purpose/flexible EFSA guidance
- ✓ Clear position on gene edited cells & new genomic techniques
- ✓ Rethink on presence of host strain DNA of GM processing aids
- ✓ Faster timelines (or deal on 1.5 years)!



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Thank you for listening!

hannah@atovaconsulting.com

www.atovaconsulting.com