

Safety assessment requirements for innovation in food production: case study of cell based meat

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Standards & Scientific Advice

Nutrition and Food Safety Department

2024 EGYPTIAN GLOBAL FOOD SAFETY SYMPOSIUM (EGFoSS)

Modernized Food Regulatory Systems as an Engine of

Innovation and

Investment in the Food Production Sector

29 – 30 May 2024



World Health Organization

Food systems affect health in many ways. For example, worldwide **690 million people are hungry, 2 billion people have micronutrient deficiencies** and there are **677.6 million adults with obesity**; each year **zoonoses** are responsible for **2.5 billion cases of human illness** and **2.7 million human deaths worldwide**; at least **700 000 people die due to drug-resistant diseases**, **600 million cases of foodborne illnesses**; **44% of farmers are poisoned by pesticides**; and at least **170 000 agricultural workers are killed**.



7 YEARS TO MEET THE SDGS

Anthropocene era, highlighting human impact on the planet.

Current trends in food production and consumption are causing the ecosystems which support humanity to collapse. But it is possible to make the shift to a more sustainable food system; all it needs is political will, and science and evidence-based action.

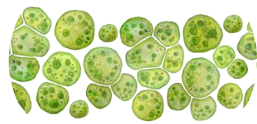
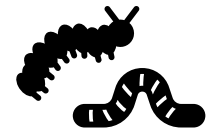
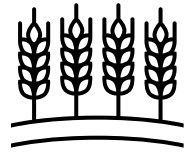
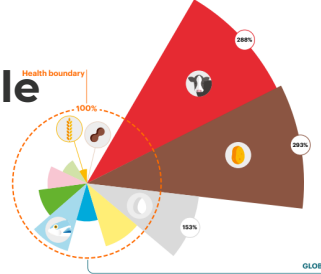
SUSTAINABLE DEVELOPMENT GOALS





Plant based food

- Significant dietary changes will be necessary to transition to sustainable healthy diets
- More sustainable agriculture practices
- Decreasing food waste
- More sustainable farming practices
- Circular economy
- meat produced in bioreactors
- Insects
- Microalgae





New technologies



Ethics/Animal welfare

Health considerations



Innovation

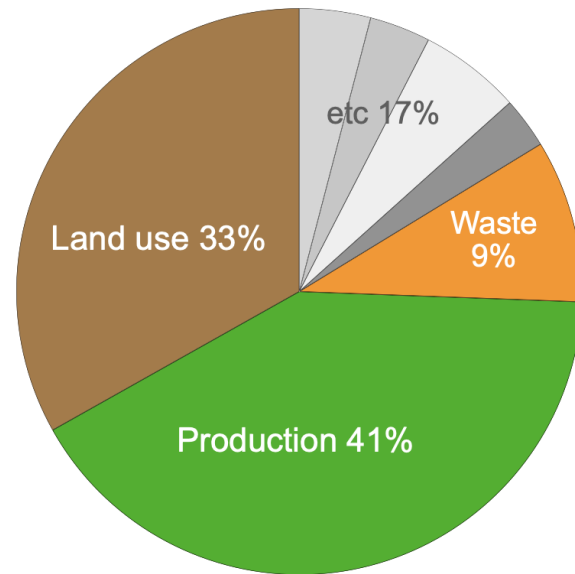
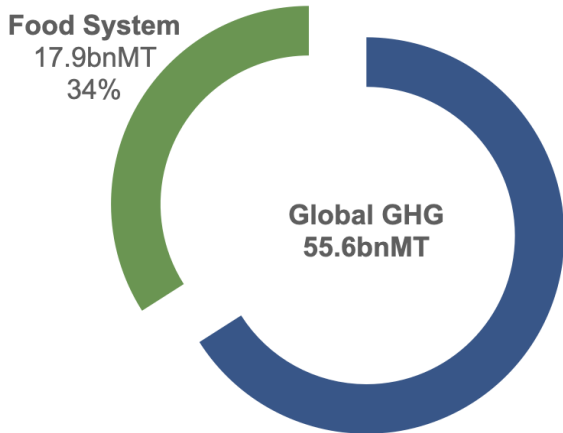
Environmental sustainability



Nutrient Composition

	100ml	250ml	
Energy	199kJ	500kJ	
	47kcal	120kcal	6% 28
Protein	0.5g	1.3g	
Carbohydrate	10.5g	26.3g	21%
of which sugars	trace	trace	
Fat	trace	trace	
of which saturates	trace	trace	
Fibre	trace	trace	
Sodium	trace	trace	
Salt equivalent	trace	trace	
*Guideline daily amounts			
Vitamins/Minerals			

Greenhouse Gas Emissions from the Food System

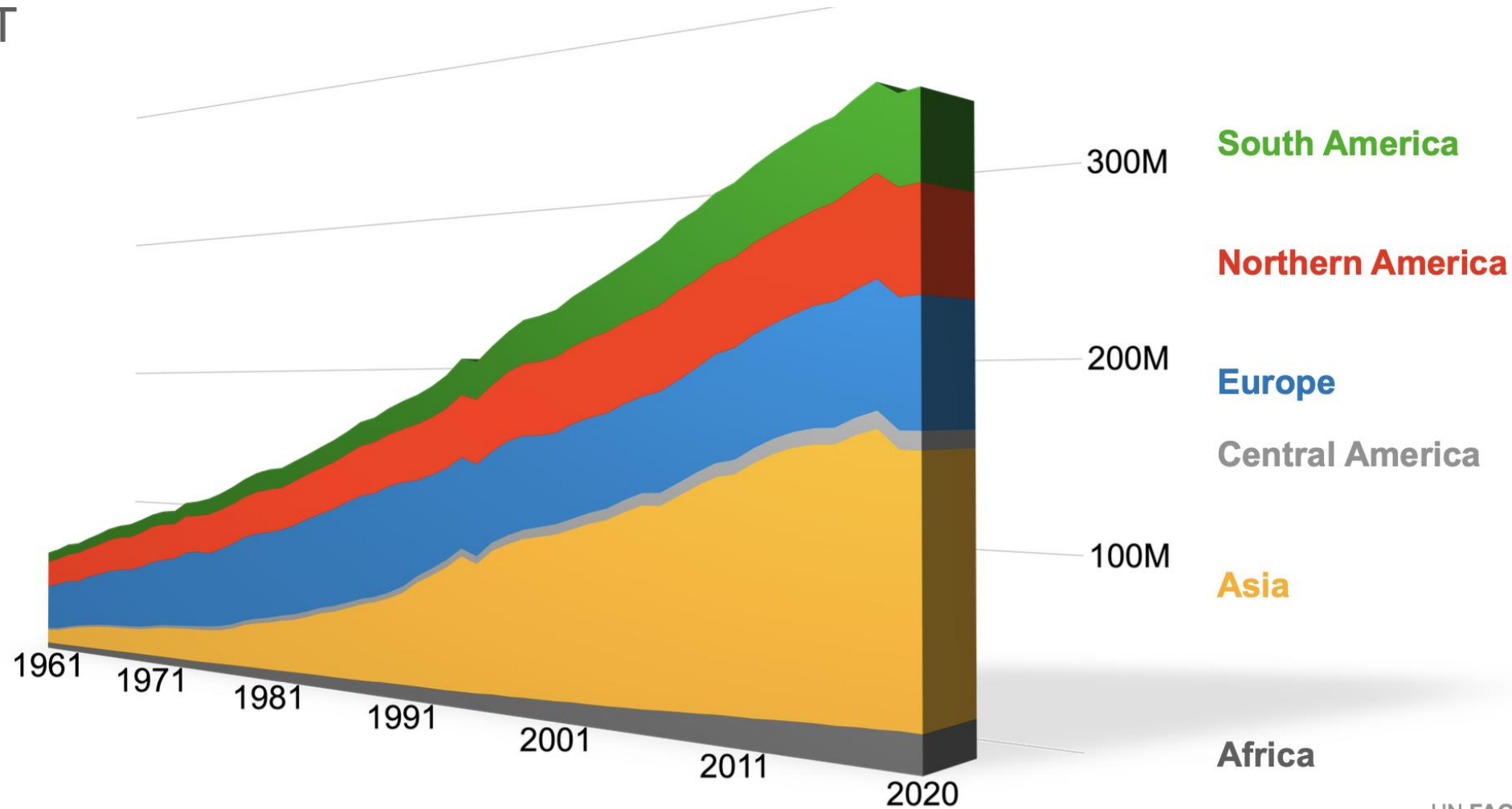


- +.5 degree warning
- Protein productions accounts for 50% of GHGE from the. Food system (17%)
- Most efficient solution for achieving 1,5°C goal

The land reclaimed through alternative protein utilization can be utilized for additional climate change mitigation, food security, and biodiversity conservation

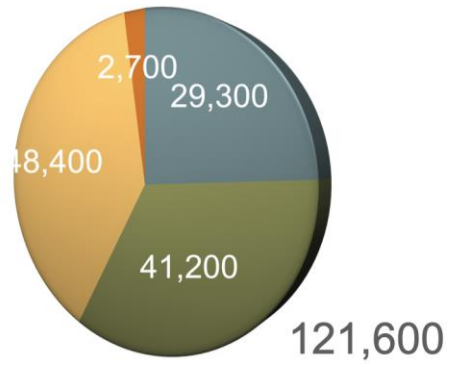
Meat Consumption by Country

MT

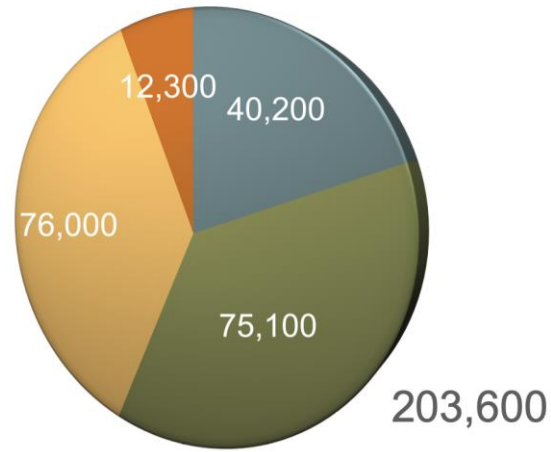


Meat Consumption

Developed countries

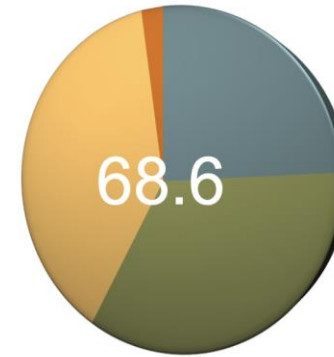


Developing countries



Developed countries

per capita



Developing countries

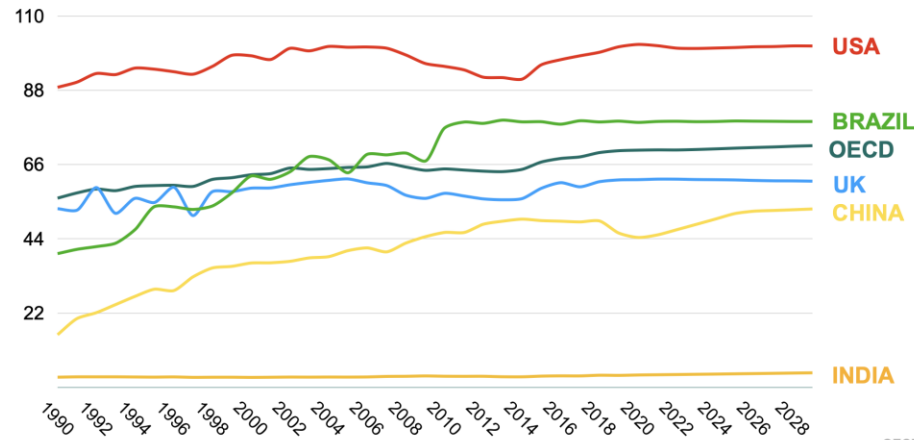


*according to current FAO categories, developed: Canada, USA, Europe, CIS, Japan, Israel, South Africa, Australia, New Zealand



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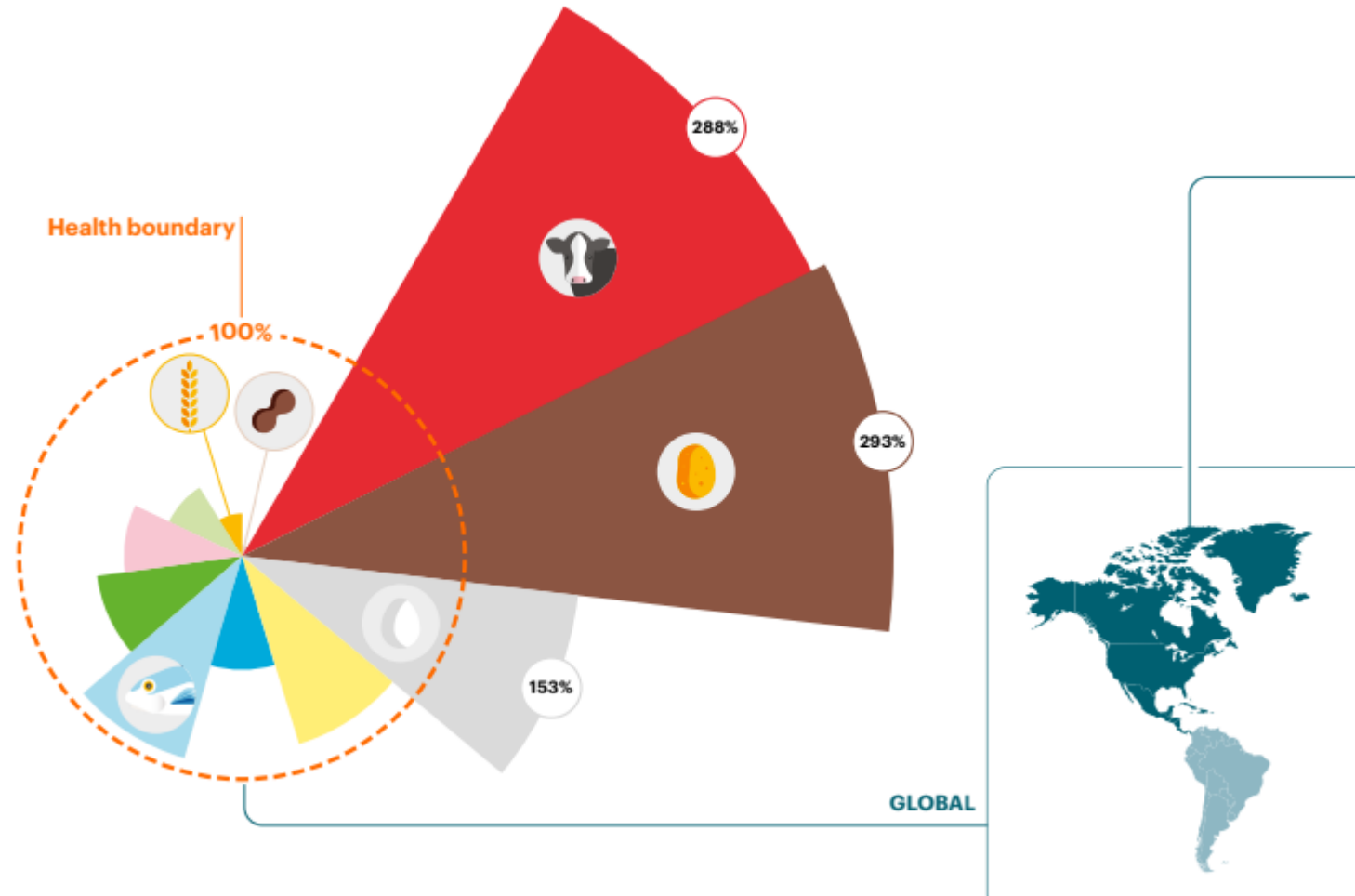
Kg, per capita



OECD Data

Alternative proteins: a need for the future?

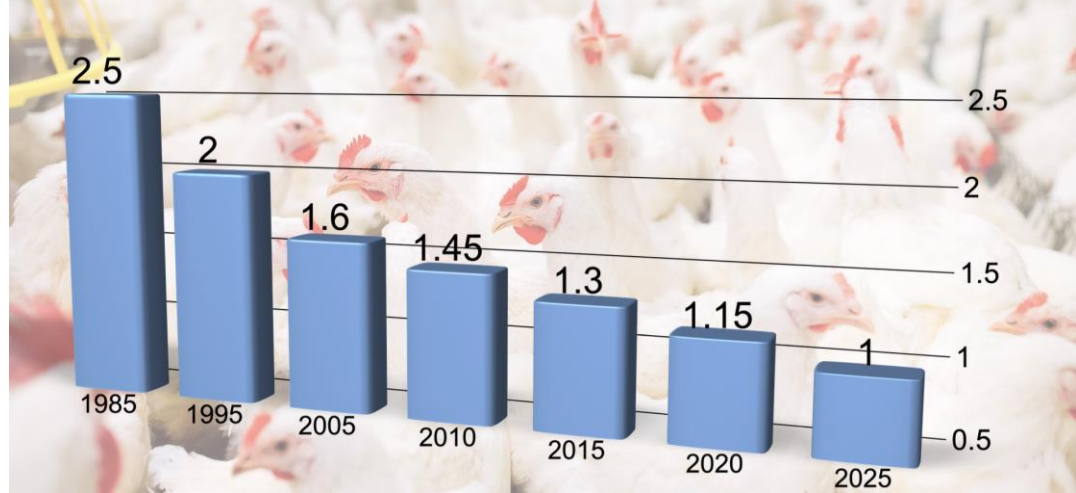
Transformation to healthy diets by 2050 will require substantial dietary shifts.



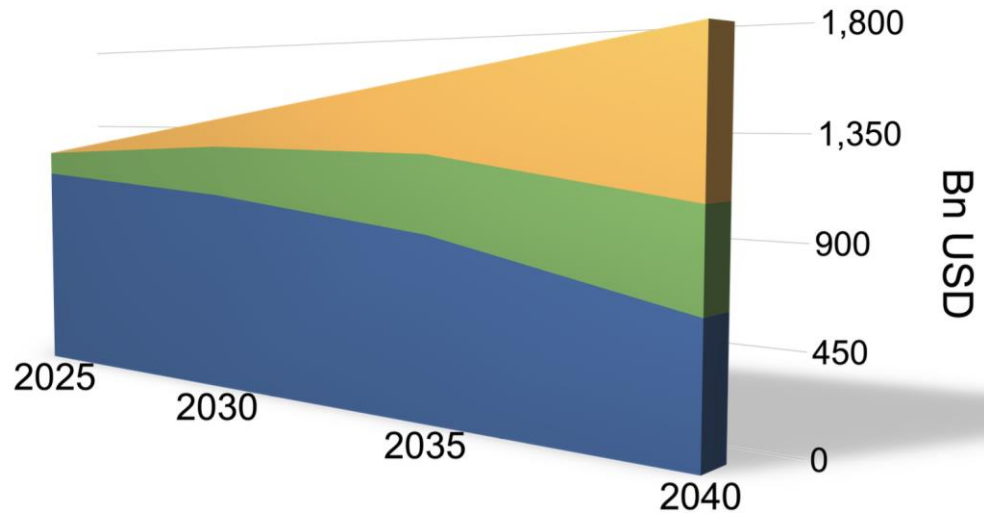
This includes a more than doubling in the consumption of healthy foods such as fruits, vegetables, legumes and nuts, and a greater than 50% reduction in global consumption of less healthy foods such as added sugars and red meat

Overcoming Possibilities through Technological Development

Feed conversion ratio evolution of broilers from 1985 to 2025



Animal Protein Market Projection

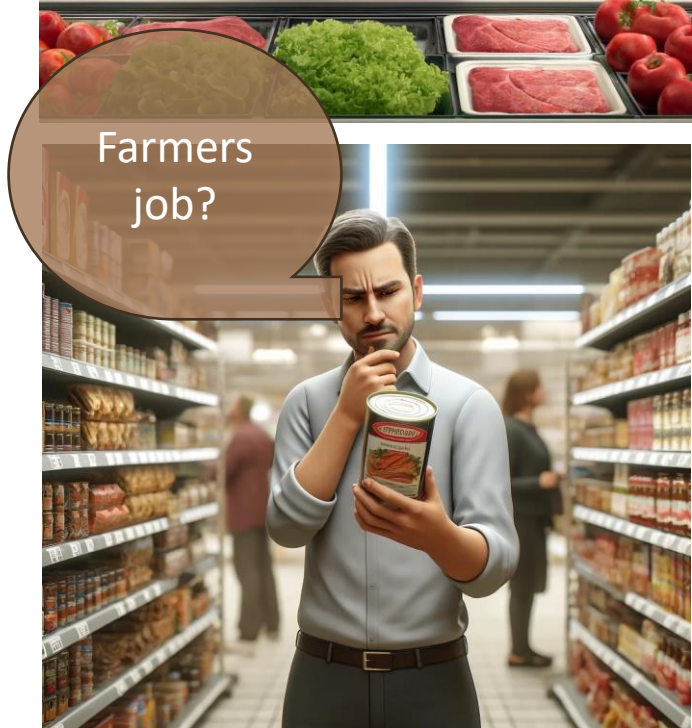


- Conventional meat
- Novel vegan meat replacement
- Cultured meat





Halal?
Safe to
eat?



Farmers
job?



Food
from lab?



Taste, cost,
good as real
meat?

Initiatives to address the Food Safety and Regulatory framework



Food safety



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Expert consultation on food safety hazard
identification specific to the cell-based food
production

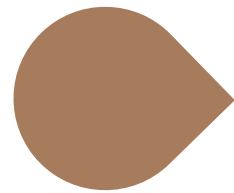
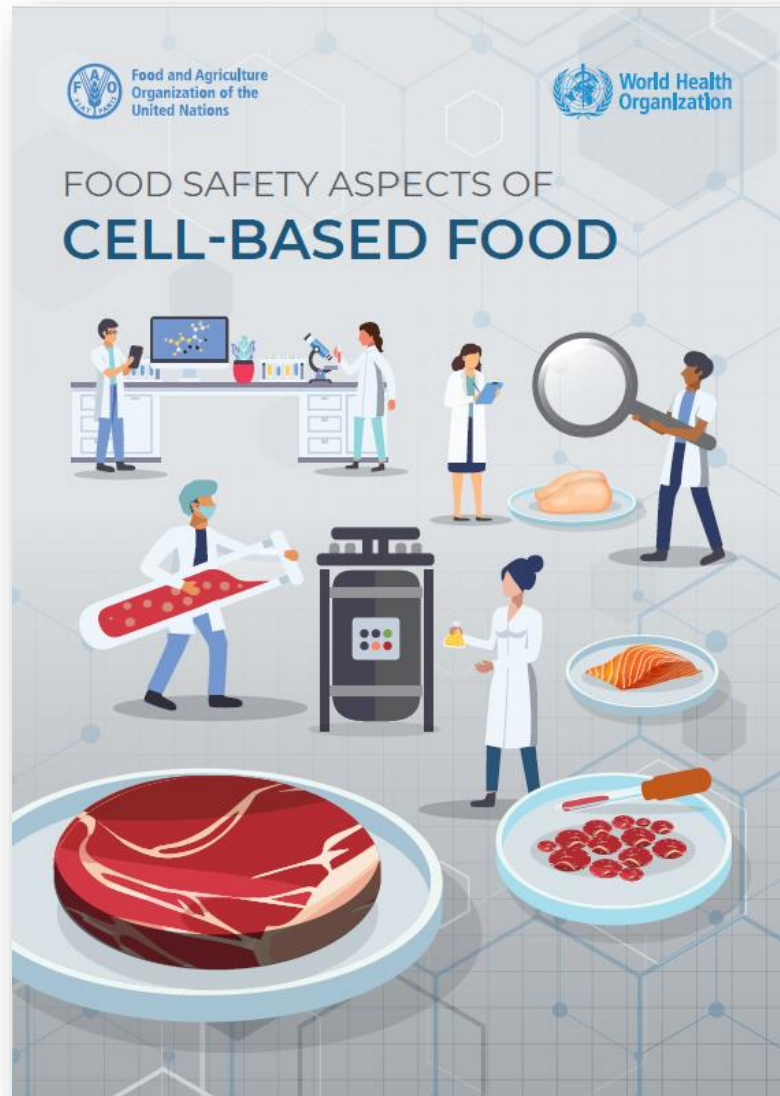
1-4 November 2022 in Singapore



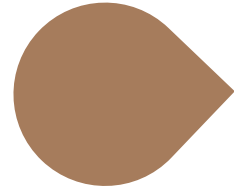
EFSA's Scientific Colloquium 27 "Cell culture-
derived foods and food ingredients"

11-12 May 2023 in Belgium

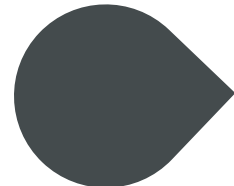
Food safety aspects of cell-based food



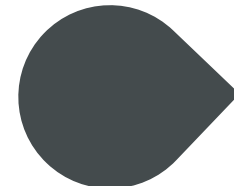
Terminologies



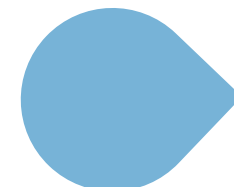
Production process



Regulatory framework as June 2022



Case studies from Qatar and Singapore



Expert consultation on Hazard Identification



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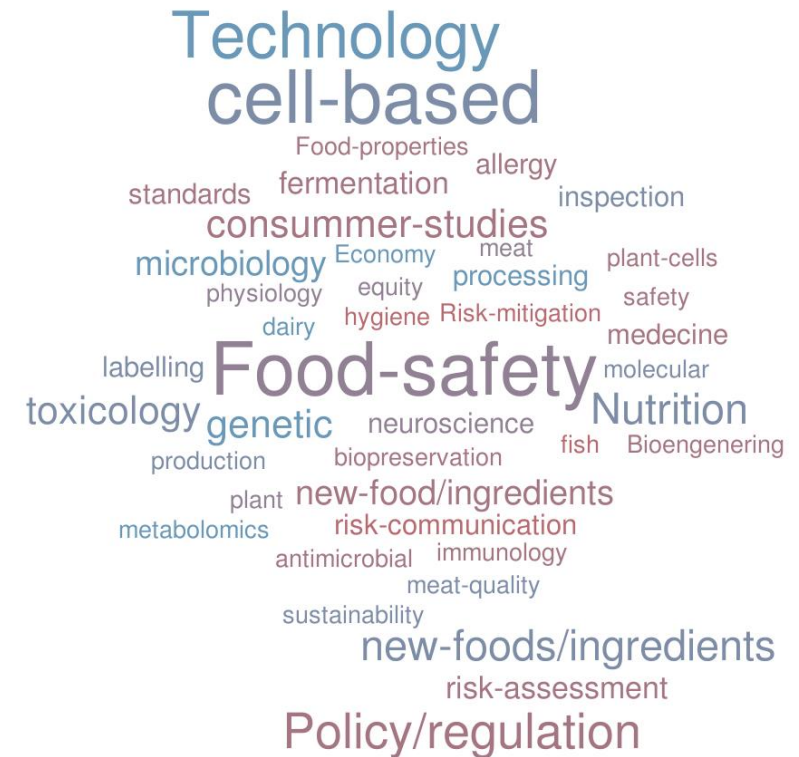


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Food safety aspects of cell-based food

Hazard identification is the first step of Risk Assessment

- Expert consultation on food safety hazard identification specific to the cell-based food production
1-4 November 2022 in Singapore
- 23 experts from academic and industrial field



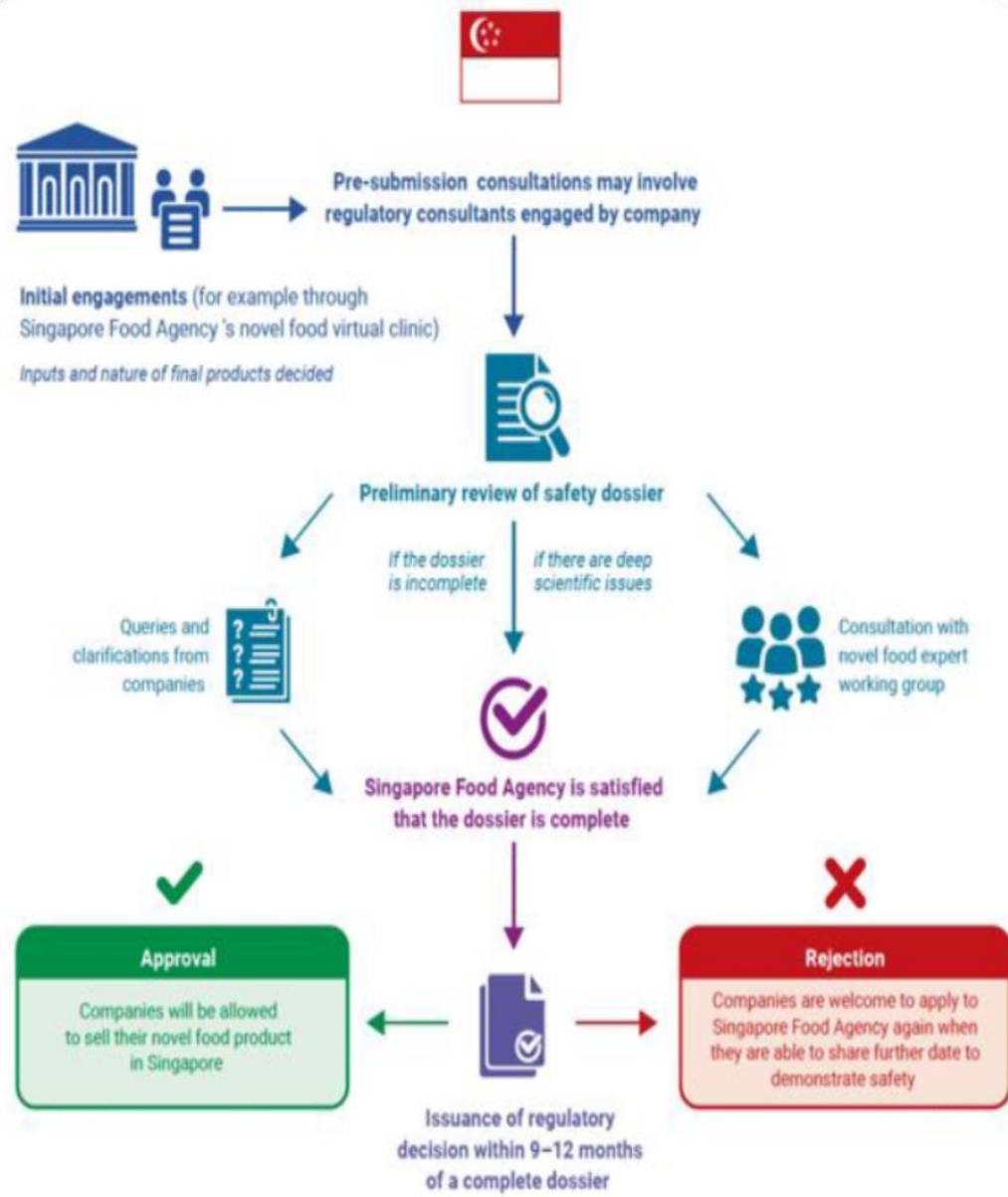
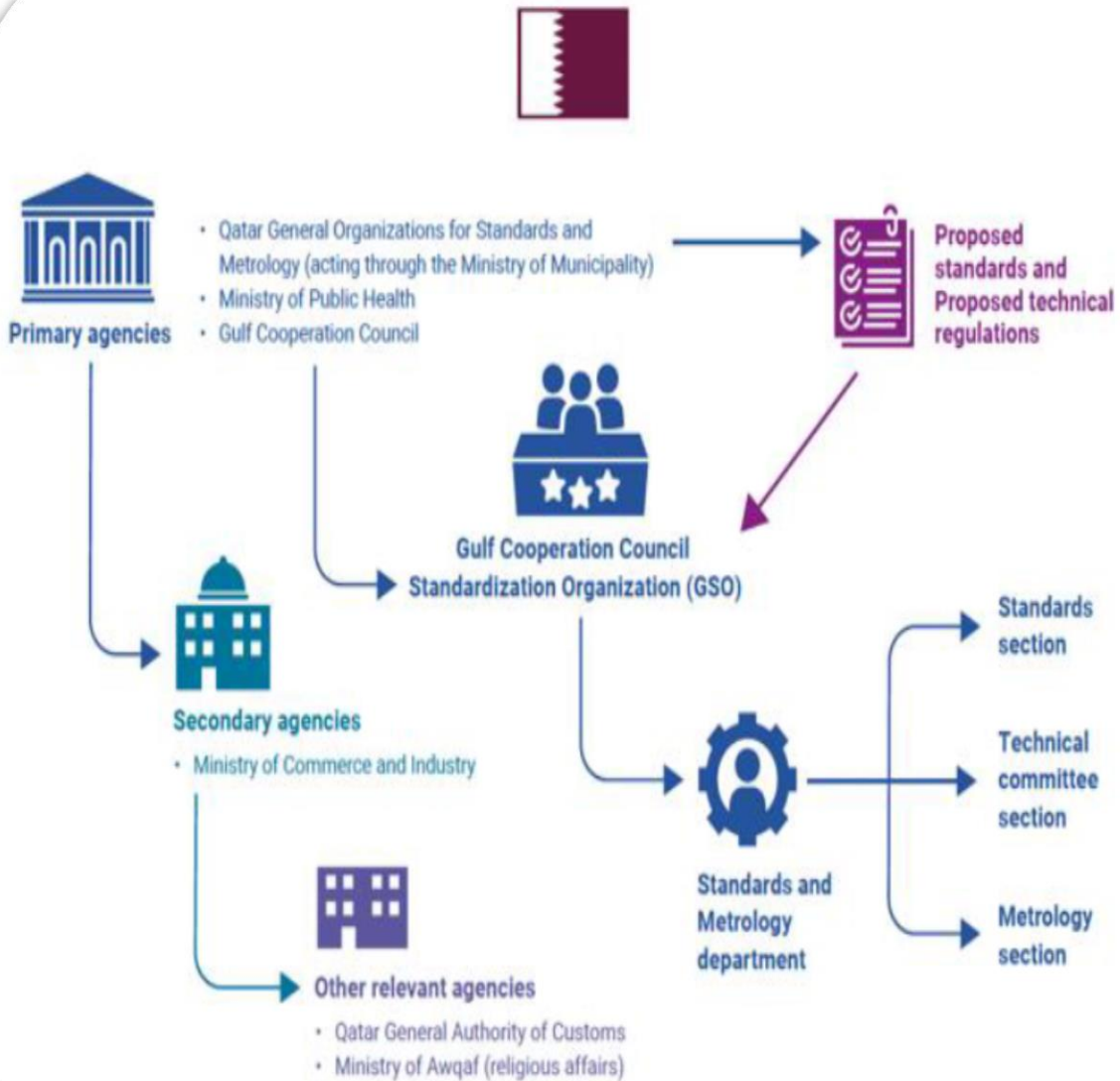
Word



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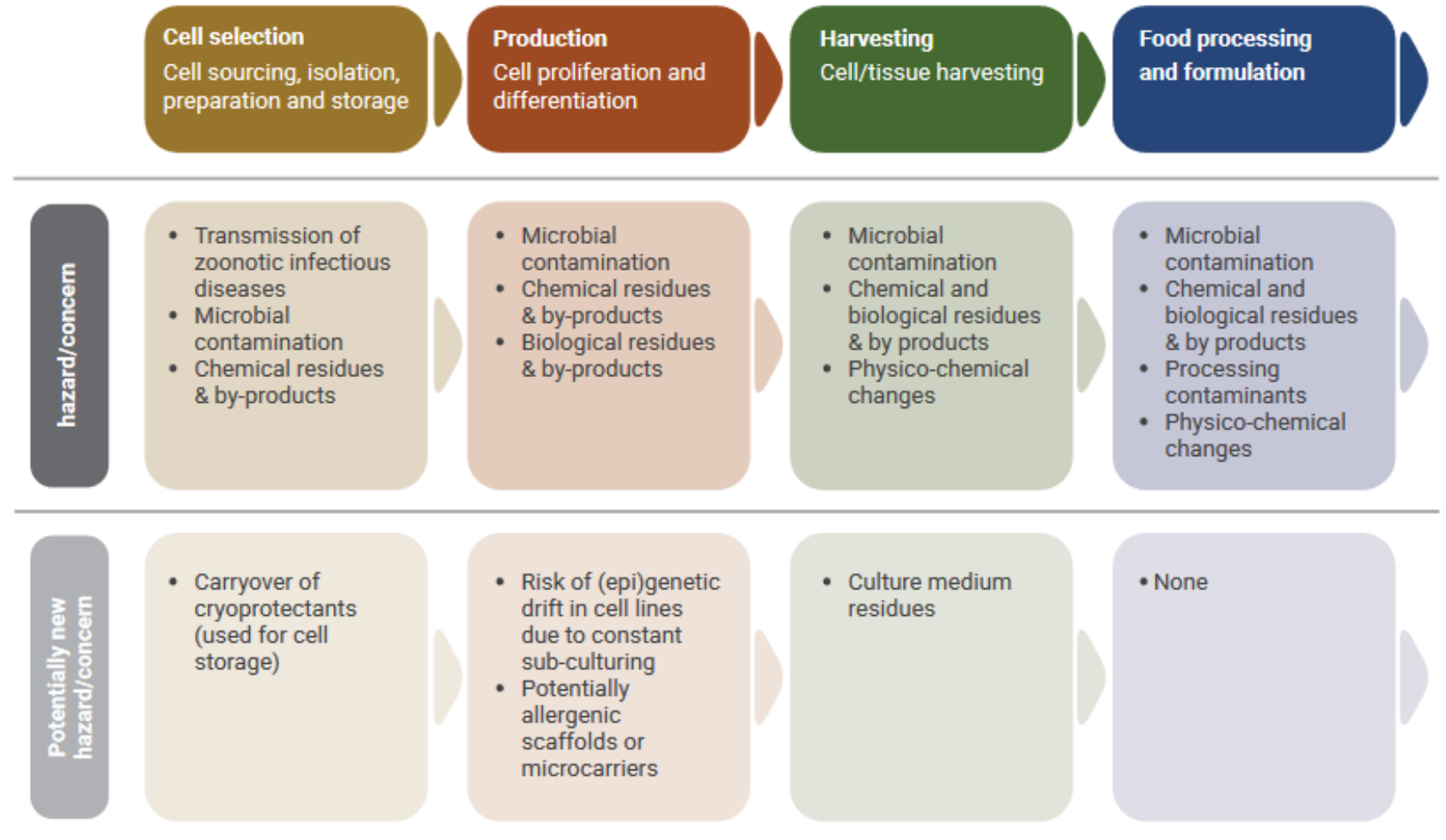


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Food safety aspects of cell-based food

Example of potential hazards during the production of cell-based food



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Main results from hazard identification

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Food hazards identified and ways to control

- Most of the hazards are well-known and exist in conventional food
- Microbial contamination during the cell growth and production stages mostly inhibit cell growth
- Post harvest contamination may occur but existing control measures and good manufacturing and hygiene practices, and Hazard Identification and Critical Control Points (HACCP), can ensure food safety



Importance of effective communication

- The trust can be strengthened by the proactive and transparent communication by regulators and stakeholders' involvement
- Terminology is important to not mislead the consumer. It depends on the language of each country



Challenges for a full risk assessment

Only few products has been commercialized

- Not scaled up production
- Few people consumed the products: niche
- Not affordable for a lot of people: cost of production estimated up to 437,000\$/kg in 2020 (Risner et al. 2020)

Not yet scaled up

=

Lack of (relevant) data and knowledge about production steps for a full risk assessment including microbiological, toxicological and nutritional aspects (+ sustainable aspects)

Next steps for Risk Assessment

- Need to identify other relevant **hazards** in a scaled-up hypothesis ?
- To increase knowledge about the interaction between the **hazards** and the **matrix** specially in a scaled-up hypothesis
 - New material/technology = new contaminants, toxins ?
 - New recombined product = allergenicity ? Microorganisms' adaptation/survival/ growth? Toxicity?
- Evaluate the **probability of occurrence** of the hazards: **Risk assessment**
- **Evaluate the nutritional profile of alternative protein**
 - ▷ Protein digestibility? Aminoacid profile ? Antinutrients?
 - ▷ Need to determine the type of data to collect
 - ▷ Active engagement of stakeholders essential
- **Evaluate the toxic profile of alternative protein**
 - ▷ e.g. Tiered Toxicity Testing Approach by EFSA

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Alternative proteins: how to assessing nutritional composition of cell-based foods?

Integrative Risk-Benefit assessment for healthy and sustainable diet

Protein quality

Fatty acid composition

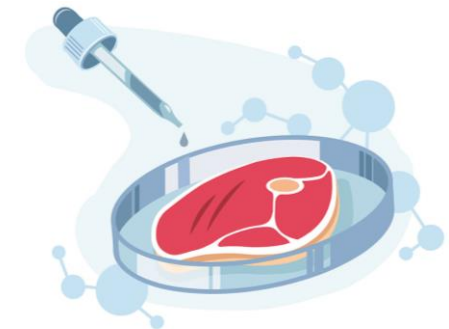
Carbohydrate composition

Vitamins and minerals

Others bioactive compounds

Addition or supplementation of nutrients and/or compounds could change growth characteristics and overall nutritional composition in unanticipated ways;

Numerous manipulations required to generate cell-based food should be viewed in the context of discussing processed foods



Challenges for scale up



Cell lines selection

Need to select lines that will be able to growth and differentiate after ~30-40 doublings

- If adult stem cells → limited expandability
- If genetically modified cells → consumer acceptance?
- If pluripotent stem cells → need long process

Long term growth and differentiation unexplored
Need cell banks adapted to this type of production



Cell media

Fetal Bovine Serum is the more efficient media, but others exists without FBS

- Expensive (~50% of the operating cost in 2020) FBS is a source of microbiological contaminants

+ Regulatory framework, market demand, public concerned, consumer acceptance...



Structure of the product

If product aim to look like a conventional food commodity: need to assembly the different cells lines by bioprinting or electrospinning for example

Even if visual aspect imitates a conventional food, what about the taste and texture?

Scaffold-based and Scaffold-free methods to structure the product ongoing

Engineered muscle is still small



Bioprocess scale up and design

Need high-capacity bioreactors (200k L) which is 10 times, or more than the current used

Responses of mammalian cells to hydrodynamic stresses and nutrient/toxin transport unknown

Challenges in the bioprocess in the bioreactor:

- nutrient input throughout the production process (preparation and sterilization)
- equipment used (bioreactor, scaffold, etc.)
- waste disposal
- control of environmental growing conditions (heat, gas, etc.)
- cleaning and disinfection

9. بعض الخطوات التالية التي يمكن للسلطات المختصة النظر في اتخاذها:

1.

Consider holding stakeholder meetings with cell-based food developers. First-hand information will always help in developing a good understanding of the "in-country" situation, especially as such information may not be readily available publicly.



2.

It may be useful to actively listen to consumers to understand what they want to know.



3.

To avoid confusion in the future, it may help to establish and use consistent terminology that is understandable to the public.



5.

A review of existing national regulatory frameworks may reveal that it is not needed to establish new regulations. There will most likely be multiple units, agencies, departments or even ministries responsible for relevant regulatory actions. Multisectoral engagements is critical.

4.

A review of other countries' regulatory situations may be useful to identify both good practices and lessons-learned. Informal technical network that FAO maintains to exchange information among regulators can further aid in such experience sharing.



6.

Consider simulating possible scenarios such as, what are the regulatory options if a cell-based food product arrived tomorrow at the border? How could a start-up company be supported if asked for guidance to conduct a food safety assessment?



2.

قد يكون من المفيد الاستماع بفعالية إلى المستهلكين من أجل فهم ما يريدون معرفته.



4.

قد يكون من المفيد إجراء استعراض للأوضاع التنظيمية في بلدان أخرى من أجل تحديد الممارسات الجيدة والدروس المستفادة على السواء. ويمكن للشبكة التقنية غير الرسمية التي تعدها منظمات الأغذية والزراعة للأمم المتحدة لتبادل المعلومات بين المنظمين أن تساعد أيضاً في تبادل الخبرات.



6.

النظر في محاكاة سيناريوهات محتملة من قبيل ما يلي: إذا وصل غداً إلى الحدود منتج غذائي تم إنتاجه من الخلايا، ما هي الخيارات التنظيمية؟ كيف يمكن دعم شركة ناشئة إذا طلبت التوجيه من أجل إجراء تقييم لسلامة الأغذية؟

1.

النظر في عقد اجتماعات لأصحاب المصلحة مع مطوري الأغذية المنتجة من الخلايا. وستساعد المعلومات المستمدة من مصادر مباشرة دائماً في تكوين فهم جيد للحالة "داخل البلد"، لا سيما وأن هذه المعلومات قد لا تكون متاحة بسهولة للجمهور.



3.

بغية تجنب اللاتباس في المستقبل، قد يكون من المفيد إنشاء واستخدام مصطلحات متسقة ومفهومة لدى الجمهور.



5.

قد يكشف استعراض الأطر التنظيمية الوطنية القائمة عن عدم الحاجة إلى وضع لوائح جديدة. ومن المرجح أن تكون هناك وحدات أو وكالات أو إدارات أو حتى وزارات متعددة مسؤولة عن الإجراءات التنظيمية ذات الصلة والمشاركة المتعددة القطاعات أمر بالغ الأهمية.



Thank you

? Questions ?



WHO

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