食 品 法 典 委 员 会

C

联合国粮食及农业组织

世界卫生组织

Viale delle Terme di Caracalla, 00153, 意大利罗马-电话: (+39) 06 57051-电子邮件: codex@fao.org-www.codexalimentarius.org

议题 4 **CX/EXEC 22/82/4**

2022 年 6 月

联合国粮农组织/世卫组织联合食品标准计划

食品法典委员会执行委员会

第八十二届会议

线上会议

2022 年 6 月 20-24 日和 6 月 30 日

执委会新食品来源和生产体系分委员会 — 临时报告

1. 引 言

1.1 在食品法典委员会执行委员会第八十一届会议上，粮农组织和世卫组织介绍了一份文件，概述了影响农业粮食体系、与食品安全和质量有关的新问题，其中包括新的食品来源和生产体系。会议同意设立一个分委员会，责成其研究潜在机制，应对食典中新出现的跨部门、总体性问题。

1.2 食品法典委员会第四十四届会议要求食典委秘书处发出一份通函，向各成员和观察员征集有关新食品来源和生产体系持续变化的信息，例如，为促进安全和公平贸易做法而采取的监管措施。食典委第四十四届会议还要求执委会第八十一届会议设立的分委员会审议收到的答复，并评估相关食典工具的范围和适宜性，即是否适用于推进与新食品来源和生产体系有关的安全、质量、标签、营养和/或公平贸易做法等工作。

1.3. 食典委第四十四届会议还要求该分委员会以包容的方式开展工作，确保采取有效举措（在可行的情况下，通过区域协调员）与所有希望做出贡献的成员和观察员保持接触，并编写一份报告，供执委会第八十三届会议审议，然后向食典委第四十五届会议建议下一步工作。

1.4. CL 2022/06/OCS-CCEXEC 号文件[1]已于 2022 年 3 月发布。此外，根据食典委第四十四届会议关于发扬包容精神的要求，向所有食典委成员和观察员发出了一封信函，请他们与食典委主席和副主席进行非正式交谈，以交流对该问题的看法。

1.5. 与六个区域协调员进行了非正式交谈：粮农组织/世卫组织非洲协调委员会（乌干达）、亚洲协调委员会（中国）、欧洲协调委员会（哈萨克斯坦）、拉美和加勒比协调委员会（厄瓜多尔）、北美和西南太平洋协调委员会（斐济），以及近东协调委员会（沙特阿拉伯）；并与要求举行会议的每个成员和观察员举行了讨论[2]。

1.6. 本临时报告的内容摘自对通函的答复以及所进行的非正式讨论。本临时报告旨在为审议是否需要对分委员会的职责范围或工作计划进行修订提供参考，以便其及时完成工作，供执委会第八十三届会议审议，进而向食典委第四十五届会议提出建议。

2. 对通函的答复及非正式讨论内容摘要

2.1. 在收到通函后，25 个成员和 10 个观察员提供了有关新食品来源和生产体系的答复[3]。这些答复广泛概述了世界不同地区如何看待、监管和发展新食品来源和生产体系的现状（附录 1）。

2.2. 对收到的答复和非正式磋商进行了初步分析，突出表明：

- 有必要对新食品来源和生产体系的定义或特征确立明确统一的认识，因为 CL 2022/06/OCS-CCEXEC 号文件中指出的各食品类别之间存在着显见差异，即养殖肉类、海产品和乳制品、发酵衍生成分、基于植物的蛋白质替代品、海藻、可食用昆虫、3D 打印食品和微藻。

- 在新食品来源和生产体系方面，一些成员已经积累了丰富的知识和经验，而其他成员和观察员则表示，需要获取更多信息，才能评价各种新食品来源和生产体系的食品安全和监管情况。

- 有必要确定食典委如何能够对这一主题做出有益的贡献，特别指出需要确定现有食典文本中的知识空白，并仔细评估制定标准/准则/行为守则的必要性，以便安全地消费并公平交易来自新食品来源和生产体系的食品。在这方面，有答复指出，食品行业的

[1] 载于：https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FCircular%252520Letters%252FCL%2525202022-06%252Fcl22_06e.pdf

[2] 与欧洲联盟、粮农组织、良好食品研究所、国际乳品联合会，以及美国进行了非正式讨论。

[3] 成员：阿根廷、澳大利亚、加拿大、智利、中国、哥斯达黎加、丹麦、厄瓜多尔、埃及、欧洲联盟、斐济、印度、印度尼西亚、日本、沙特阿拉伯王国、哈萨克斯坦、马来西亚、新西兰、挪威、大韩民国、泰国、乌干达、联合王国、乌拉圭和美国。观察员：消费品论坛、欧洲天然大豆食品制造商协会、欧盟特色食品原料行业联合会、欧洲植物蛋白协会、亚洲食品工业协会、良好食品研究所、原子能机构、国际统一食糖分析方法委员会、国际乳品联合会和国际肉类秘书处。

发展日新月异，同样重要的是，所考虑的任何方法或监管框架都不应扼杀食品部门的创新。

- 在新食品来源和生产体系方面经验较为丰富的成员可以助力制定国际标准草案，惠及经验较少的成员。
- 在启动这方面的新工作之前，应考虑以下主要食典程序：
  - 《食品法典通用原则》
    - 目的
    - 范围
    - 性质
    - 食典对“食品”的定义
  - 食典标准和相关文本的制定程序，特别强调严格审查。
  - 《确定工作重点标准的应用准则》。

2.3. 从收到的答复中确定了两大类方案，作为食典委开展新食品来源和生产体系工作的可能途径：

a. 一些答复认为，现有的食典结构足够灵活，可以开展有关新食品来源和生产体系的工作。在现有的食典结构和机制内，可以考虑以下措施：

- 根据《程序手册》规定，向食典委提出新的工作建议。
- 向现有附属机构下放更多的灵活性，以确保其能够处理新食品来源和生产体系的新情况。
- 责成附属机构，包括综合主题委员会和商品委员会，审查其现有的标准/准则/行为守则，以确定可能的差距，处理与新食品来源和生产体系有关的具体问题，并向食典委报告审查结果。
- 考虑重新启动已无限期休会的附属机构，以处理一些已确定的新食品来源和生产体系问题（如植物蛋白法典委员会）。

b. 其他答复意见指出，目前的食典结构尚不足以处理这方面新工作，或者尚未做好充分的准备，因此，有必要就此建立一个新的附属机构，例如：

- 设立一个新食品来源和生产体系委员会；或者
- 设立一个工作组。

2.4. 粮农组织和世卫组织内部继续就这一主题开展独立于食典委相关举措的工作。最近的一些相关出版物包括：

- 粮农组织，2022 年。《展望报告：思考食品安全的未来》[4]。
- 粮农组织，2021 年。《从食品安全角度审视食用昆虫》[5]。
- 粮农组织，2021 年。《水产养殖中基于基因组的生物技术》[6]

2.5. 此外，粮农组织正在开展工作，对一份海藻食品安全报告进行定稿。同时，粮农组织还计划于 2022 年底召开有关细胞培养食品的专家磋商会，目前在开展筹备工作。

3. 供执委会第八十二届会议审议的问题

3.1. 迄今收到的答复突出表明，新食品来源和生产体系覆盖面广泛，发展迅猛。

3.2. 有必要在着手开展任何新工作之前，明确确定食典委在这一领域应该/能够发挥的作用，以确保工作行之有效、高效推进，并对消费者保护和公平食品贸易做法作出重要贡献。

3.3. 为了便于分委员会持续开展工作，请执委会第八十二届会议：

i. 审议本文件中提出的关于新食品来源和生产体系的信息和初步评估；

ii. 确定可能需要执委会分委员会在推进工作的过程中特别考虑和分析的任何具体问题；

iii. 考虑是否需要对分委员会的职责范围或工作计划进行任何修正，以便其高效完成工作，及时供执委会第八十三届会议开展讨论，并向食典委第四十五届会议提出建议；

iv. 评价是否需要与成员和观察员进行新一轮磋商，以及如何开展这一磋商进程。

[4] https://www.fao.org/3/cb8667en/online/cb8667en.html
[5] https://www.fao.org/policy-support/tools-and-publications/resources-details/en/c/1394684/
[6] https://www.fao.org/3/cb7955en/cb7955en.pdf

附录 **1**

COMPILATION OF REPLIES TO CL 2022/06/OCS-CCEXEC - REQUEST FOR INFORMATION ON NEW FOOD SOURCES AND PRODUCTION SYSTEMS; NEED FOR CODEX GUIDANCE AND ATTENTION TO INFORM THE CCEXEC SUB-COMMITTEE ON WORKING ON THIS TOPIC

(In original language only)

Comments of Argentina, Australia, Canada, Chile ,China, Consumer Goods Forum, Costa Rica, Denmark, Ecuador, Egypt, ENSA, EU Specialty Food Ingredients, European Union, European Vegetable Protein Association, Fiji, Food Industry Asia, Good Food Institute, IAEA, ICUMSA, IDF/FIL, India, Indonesia, International Meat Secretariat, Japan, Kazakhstan, Kingdom of Saudi Arabia.Malaysia, New Zealand, Norway, Republic of Korea, Thailand, Uganda, United Kingdom , Uruguay, USA

GENERAL COMMENTS

Thank you for the opportunity to respond to circular letter CL 2022/06/OCS-CCEXEC. Australia's overarching view is that existing Codex procedures provide the necessary mechanisms to assess whether new work should be undertaken in Codex on issues related to new foods and production systems, including what scientific advice would be necessary for the new work. We think it may be premature to consider changing existing structures and processes when a specific issue to be addressed by Codex has not yet been identified by a committee or a member. In the Australian context, some of the new food sources and production systems listed in the CL have been used or sold for some time (e.g., plant-based protein alternatives, seaweed). For others (e.g., cultivated meats) the technology is newer and such foods are not yet on the market. However, we note the FAO/WHO expert bodies and ad hoc consultations have previously provided scientific advice on the types of food safety risks Australia has identified below (e.g. toxicological, microbiological, nutritional, allergens). Similarly, Codex has experience developing standards, guidelines and codes of practice to manage these types of risk. We outline in more detail in the tables below how the new food sources and production systems listed in the CL are regulated in Australia. To assist with understanding our responses, a short summary of the Australian system is provided here. The Joint Australia New Zealand Food Regulation System and the Australia New Zealand Food Standards Code are designed to accommodate new production technologies and new foods. The system has experience in assessing and managing the types of risks (e.g. toxicological, microbiological, nutritional, allergens) that may arise from new food sources and production systems. Where a food meets all the requirements in the Australia New Zealand Food Standards Code (the Code), the food does not require pre-market approval before it can be sold. A range of plant-based protein alternatives, edible insects, seaweeds and microalgae meet these	**Australia**

requirements and are already on the market. Where a food (or a process used to produce a food) does not comply with the current requirements of the Code, pre-market approval is required. An organisation can seek pre-market approval via an application to change the Code. The food regulation system has established processes for FSANZ to assess these applications and, where appropriate, to amend the Code to permit new foods or processes. In some instances, the new food sources and production systems listed in the CL are likely to require pre-market approval (e.g., some fermentation-derived ingredients may require pre-market approval as novel foods or GM foods). The FSANZ Application Handbook provides guidance on the types of information applicants must provide for different types of pre-market approvals. Other regulatory processes would apply to export to ensure that importing countries' requirements are met. In this respect it would be helpful to have harmonisation of approaches.	
Chile agradece la oportunidad de presentar observaciones sobre nuevas fuentes de alimentos y sistemas de producción. Antes de responder los cuadros y respectivas preguntas consultadas en la Circular CL 2022/06-EXEC, deseamos manifestar nuestra preocupación de no tener definiciones de los productos consultados, por lo que solicitamos en primera instancia para el trabajo propuesto establecer una denominación de uso común entre los países miembros para aquello productos alternativos a la carne, leche y otros, sin desmedro de las actuales definiciones con las que cuenta el Codex Alimentarius. Es importante establecer algunos elementos básicos sobre estos "nuevos alimentos" entre estos la definición o entendimiento que se va a tener de cada uno de ellos; las características propias de cada uno y los riesgos inherentes a cada producto, esto es calidad nutritiva o aporte nutricio; condición sanitaria, capacidad de transmitir enfermedades o plagas y zoonosis; posibles riesgos de los procesos de elaboración. Estos puntos no están considerados en la consulta de esta circular.	**Chile**
New foods and production systems (NFPS) is an area that is already growing fast and it is very likely to grow even more over time. China would like to submit the following comments replying to CL 2022/06/OCS-CCEXEC based on the current management on new foods in our country and experiences in participating in Codex work.	**China**
Global Food Safety Initiative www.mygfsi.com GFSI POSITION ON NEW FOOD SOURCES AND PRODUCTION SYMPTOMS; NEED FOR CODEX GUIDANCE AND ATTENTION TO INFORM THE CCEXEC SUB-COMMITTEE ON WORKING ON THIS TOPIC April 2022	**Consumer Goods Forum**

GFSI would like to thank Codex for the opportunity to comment on this emerging and challenging topic and is pleased to submit its comments below. GFSI is pleased that Codex is looking to undertake an assessment of the range and suitability of Codex tools that could be used to progress work on safety, quality, labeling, nutrition and/or fair trade practices related to new food sources and production systems as the lack of international guidelines has become a prevalent regulatory challenge in many countries while proposing many benefits to answer some of the food systems challenges. One of the biggest challenges facing food business operators (FBOs) is the absence of global standards that impact the production and trade of many of the categories listed in this circular letter (CL). However, GFSI is conscious that given the potential nature and extent of the issues raised in this CL, it is not possible, realistic or efficient for Codex to address the list of issues raised in a vertical manner. To progressively work through each of the topics in 'vertical' committees, would make the guidance obsolete due to the long working timeline when GFSI stresses the urgency to address those topics at CODEX and in an horizontal manner. Further, given that so many of the issues raised with these categories are cross cutting, GFSI has elected to provide overarching comments addressing the issues raised in this CL. GFSI believes that the categories raised should be addressed horizontally. GFSI also believes that the horizontal approach is the best way to ensure that a risk based approach is the overarching angle considered for this new food source work supported by a strong scientific based knowledge with the support of FAO and WHO. As a consequence, the proposals are the following - Codex should look to establish overarching guidance on new ingredients from a food safety perspective, for example, looking at how new ingredients are evaluated for allergens. - For new topics such as plant-based, cell-based, precision fermentation or edible packaging, there is a need to develop general guidance in terms of definition, scope, general requirements and labeling to ensure harmonisation and avoid fragmentation at the national level. - Global Food Safety Initiative – April 2022 |1 Global Food Safety Initiative www.mygfsi.com In cases where there is a need to develop specific vertical standards, then the existing procedure as outlined in the Codex Procedural Manual which provides guidance on the application of the criteria, including what information needs to be examined by Codex's Executive Committee when performing a Critical Review, in the criteria applicable to commodities' for the establishment of work priorities may be followed. On the question of how Codex may wish to tackle this work, GFSI believes that there are two options. One would be the establishment of a Task Force (similar to that for Antimicrobial Resistance). Should that not be feasible, establishing a Working Group at the Codex Alimentarius Commision level under the auspices that these issues meet Goal One in the Codex Strategic Plan 2020-2025 - Address current, emerging and critical issues in a timely manner is justified. GFSI is willing to bring its support to CODEX, for an horizontal approach, for this work. Global Food Safety Initiative – April 2022	

	Ecuador
En respuesta a la Carta Circular CL 2022/06/OCS-CCEXEC, La Región de América Latina y el Caribe agradece a la Secretaría de Codex por preparar y presentar el documento sobre la solicitud de información sobre nuevas fuentes de alimentos y sistemas de producción. Los diferentes países miembros que conforman la región de América Latina y el Caribe han realizado las observaciones a varios puntos de la carta para lo cual se puede mencionar que: Con respecto a la carne cultivada y otras proteínas alternativas creadas mediante nuevos sistemas de producción, el énfasis principal desde el punto de vista de la seguridad de los alimentos debería ser el análisis del producto final para confirmar la seguridad de los alimentos para el consumo. Algunos países, especialmente los de ingresos bajos y medios, aún carecen de conocimientos e información básicos para realizar evaluaciones de la seguridad de los procesos de producción de proteínas alternativas. Dado que la mayoría de los peligros asociados a la producción de carne cultivada no se espera que sean novedosos, pueden aplicarse los métodos de evaluación de la seguridad conocidos de otros campos, como los alimentos convencionales y los productos farmacéuticos. En el caso de las partes nuevas de los procesos de producción, puede ser útil desarrollar principios o directrices de aplicación general para la evaluación de la seguridad. La próxima consulta de expertos de la FAO puede proporcionar una plataforma fundamental para el desarrollo de tales directrices o principios. En el caso de los productos proteicos alternativos que aún no están ampliamente disponibles, especialmente los productos cárnicos cultivados, se recomienda al CCEXEC continuar recopilando información sobre el estado de la normativa y los impedimentos comerciales. En miras de iniciar un grupo de trabajo electrónico conjunto (J-EWG) en el que participen los comités pertinentes, como el Comité del Codex sobre Higiene de los Alimentos y el Comité del Codex sobre Aditivos Alimentarios, para abordar cuestiones horizontales relacionadas con estos productos, como la elaboración de principios o directrices para armonizar la normativa. Las normas horizontales y de productos del Codex existentes no parecen ser adecuadas para su aplicación directa a algunos productos proteínicos alternativos que ya se comercializan en ciertas jurisdicciones. Estos alimentos también están sujetos a diferentes procesos regulatorios en distintos países. Será útil revisar los códigos de productos existentes para evaluar la posibilidad de incluir estos alimentos. La modificación de las normas existentes del Codex o el desarrollo de nueva normas podría reducir las futuras barreras comerciales y proporcionar un marco normativo mundial más armonizado para estos productos. Las normas nuevas o modificadas también deberían ser lo suficientemente flexibles como para no ahogar la futura innovación tecnológica. En muchos países, los productos a base de plantas y otras proteínas alternativas no encajan en los códigos del SA existentes establecidos por la Organización Mundial de Aduana- OMA, una organización observadora del Codex. Los códigos del SA heredados de la OMA no recogen la gama de ingredientes que se utilizan actualmente en las proteínas alternativas de origen vegetal ni las diversas formulaciones que están evolucionando en esta categoría, lo que da lugar a ambigüedad y, en algunos casos, a tipos de derechos más elevados para los productores que exportan sus productos a otros mercados.	

The tables seem to be formatted with lines of different weight throughout all the versions. It would be best to standardise the formatting of the tables across the document and versions.	**ICUMSA**
The International Dairy Federation (IDF) is grateful for the opportunity to provide a response to the Request for Information on New Food Sources and production systems; Need for Codex guidance and attention to inform the CCEXEC sub-committee on working on this topic. In the context of this work on new food sources and production systems, we consider it essential to focus on and ground the work within the mandate of Codex of protecting public health via food safety and quality and ensuring fair practices in food trade. These new food technologies may raise significant challenges in terms of food safety, labelling, fair trade practices, and could have unknown impacts on human health over time. Currently, there is still the need to understand and learn about the impact of these “new foods” and innovative technologies at the different levels. Any work within Codex should be aligned with its mandate and its procedure manual (1). In addition, Codex must carefully avoid conflicts with any existing Codex Standards, Guidelines, or Codes of Practice when initiating new work. We would, therefore, specifically note the relevancy of the Codex General Standard for the Use of Dairy Terms (GSUDT) (CXS 206-1999) to many issues associated with some of the new food sources identified in the CL. Established in 1999, the GSUDT provides guidance on the correct use of terms which are universally identified with dairy products. The GSUDT defines milk as “the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or further processing.” If new work is initiated on these new food sources, this definition and other core principles of CXS 206-1999 must be considered and not undermined. Consistent with the Codex General Standard for the Labelling of Prepackaged Foods, a core principle of the GSUDT is that foods shall be described and presented in a manner that ensures consumers are not misled or confused (2). Labelling of dairy products or nondairy products using dairy terms shall not be false, misleading, deceptive, or create an erroneous impression regarding its character in any respect, including being suggestive of any other product with which the food might be confused. IDF would strongly oppose any attempt to define or label any finished products that do not contain dairy as milk or milk products as this would be inconsistent with both the spirit and terms of the GSUDT. We note the current challenges facing agri-food systems, and our sector is committed to nourishing the global population with safe and nutritious dairy foods produced through sustainable production systems. We would like to point out the complexity of food systems and the many drivers which impact them, as well as the need to take a holistic and evidence-based approach. Dairy foods are part of a healthy diet, a fact proven by decades of scientific research and evidence and reflected in food based dietary guidelines around the	**IDF/FIL**

world (3). Therefore, we urge caution with language or assertions that imply that these new technologies and “new foods” would be better than the foods they are seeking to replicate or replace, e.g., avoiding statements that promote them as “game-changing innovations” as indicated in the section 5 of the document. We consider that the existing Codex system is fully capable of incorporating these “new foods”, whether it is about food safety, food hygiene or labelling. It is our suggestion that Codex should begin any assessment of the need for new work on this subject by assigning all Codex Committees to review their body of documents to assess whether any Codex standards, guidelines, or codes of practice within their scope of responsibility need to be updated to address these “new foods”. Each Codex Committee should be requested to report back to the Codex Alimentarius Commission on their findings and recommendations for potential new work in this area. Only after this assessment is completed by the experts represented in Codex’s many subject matter committees and clear gaps or needs are identified should the Commission determine whether new work should commence. Since 1903, IDF has been setting standards to ensure the safety of milk and dairy products and to facilitate their trade. IDF has served as an essential technical advisor to Codex since Codex was established, providing technical support on all aspects related to milk and dairy products. We contribute to the work of several horizontal Codex committees, engaging Codex across more than a dozen committees on many topics. IDF is available for further consultations on the topic. (1) Codex procedure manual. Twenty-seventh edition. 2019. Criteria for the establishment of work priorities p43 (2) IDF Bulletin 507/2020 – The Codex General Standard for the Use of Dairy Terms. Its nature, intent and implications (accessed on 22 March ’22 Bulletin-of-the-IDF-507_2020_The-Codex-General-Standard-for-the-Use-of-Dairy-Terms.CAT_-snusw3.pdf (fil-idf.org) (3) Home | Food-based dietary guidelines | Food and Agriculture Organization of the United Nations (fao.org)	
Indonesia would like to thank for the opportunity to comment on the circular letter (CL) in the context of collecting information on New Food Sources and Production System. We noted that for the purpose of collecting this information, the term “new food” has been defined as specified in the para 6 of CL 2022/06/OCS-CCEXEC. However, for better clarity, the definition of “new food” should be further explained and discussed, because there are several cases that quite confusing, whether it fall within the definition of new food as intended by the CL, or not. For example: - If the food is already known, and have long history of consumption and/or traded in a particular country or region, is it still included in the category of “new food”? - If the food was previously known (or even already has CODEX standard), but now the products is formulated using different raw materials (for example using biological material of different type/genus; or even completely different material). Is it also included in the new food category?	**Indonesia**

Request for Information on New Food Sources and production systems; Need for Codex guidance and attention to inform the CCEXEC sub-committee on working on this topic New Zealand would like to thank the Codex Secretariat for inviting responses to this CL requesting information on new food sources and production systems to inform the work of the CCEXEC sub-committee. We look forward to having the opportunity to discuss this issue further at the next Commission meeting. Scope New Zealand is still exploring key issues/challenges relating to new food sources and production methods and implications for our food system. We note as we see globally there is an increased interest in traditional knowledge and consumption of indigenous foods in New Zealand along with a desire to export these foods products. It will be important to ensure indigenous voice is included in these discussions. Issues In the Codex framework the focus is on general or horizontal standards that apply to all foods. Therefore, such foods will already be subject to existing Codex standards and work by the relevant Committees. Unless a specific need is presented by a particular new food or new technology, we cannot see there would be justification for a new standard or a new approach within Codex. For example, • Labelling would be largely covered by existing general Codex labelling standards. Where specific labelling is needed for example where a new food may require consideration of allergen labelling requirements, as maybe the case with some insects, or naming issues of some of the plant-based protein alternatives, these could be developed in the Codex Committee for Food Labelling (CCFL). • Processed foods including, cultivated meats could be put to the Codex Committee on Food Hygiene (CCFH). • Nutrition issues – for example such as nutrient expectations of consumers with varied nutrient content of alternatives to milk, could be considered by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).	**New Zealand**

Way forward We agree that some work is needed to identify any gaps related to the emergence of agri-food technology on food safety and facilitating trade. Should gaps be identified, consideration could be given to why there are gaps and how these may be resolved. New Zealand would support a full discussion of the issues at CAC. If gaps are identified New Zealand could support consideration of the issue by a panel of experts to consider how the gaps can be resolved.	
De acuerdo con el Manual de Procedimiento, el fin del Codex es proteger la salud de los consumidores y asegurar prácticas equitativas en el comercio de los alimentos. Para la elaboración de las normas, se debe seguir el examen crítico, donde se establecen prioridades. Los alimentos nuevos mencionados en el documento, son alimentos para los cuales no existe comercio relevante, ni su consumo es difundido a nivel mundial ni regional, ni se han identificado temas relevantes que justifiquen actualmente la elaboración de normas al respecto, que es el fin del CODEX. Por lo tanto, entendemos que no se justifica destinar recursos ni priorizar este tema cuando el presupuesto es acotado, como se manifiesta anualmente, habiendo temas relevantes que impactan en el comercio actualmente. Estos nuevos temas, quizás deban ser tratados, en esta etapa, por organismos nacionales, regionales o internacionales cuya prioridad sea la investigación.	**Uruguay**
General U.S. Comments in Response to CL 2022/06/OCS-CCEXEC The United States appreciates the opportunity to offer comments and provide information to assist the sub-committee in carrying out its charge and support CCEXEC in developing recommendations for next steps. Identifying and addressing critical emerging issues is consistent with Goal 1 of the Codex Strategic Plan, and this horizon-scanning exercise will contribute to achievement of that goal. Detailed responses as to the status of specific new foods and production systems (NFPS) in the United States are provided below. A review of the issues in the Circular Letter suggests emphasis on the following general points: • It is essential to focus and ground any new work within the mandate of Codex to develop science-based standards and recommendations to protect consumer health and ensure fair trade practices. While the U.S. food system has some experience with many of the NFPS, there is currently still a need to understand and learn more about the impact of specific NFPS in terms of potential food safety, regulatory, labeling, nutritional, and quality issues. • In general, the majority of the “new foods” highlighted in the document are not foods themselves, but rather non-traditional mechanisms to produce food. The majority of issues for NFPS can be addressed by the standing general subject committees, who can develop appropriate approaches to deal with any identified unique food safety or fair trade considerations consistent with their mandates.	**USA**

• Codex should only develop vertical/commodity standards when existing standards exclude these new production processes for analogous foods. In some cases, it may be appropriate to modify existing Codex texts (standards, guidelines, or codes of practice) to accommodate new production processes (for example, it may be appropriate to develop a new food category in the General Standard for Food Additives). • One approach would be to recommend that the standing committees consider the issues raised in the collective response to this Circular Letter to identify issues that fall under their mandates that should be addressed, seek additional information as to which products/production methods are in use in international trade, and develop an approach for the management of the work on the issues identified by members, including requesting scientific advice from the FAO/WHO expert bodies and/or expert consultations as required. (This would be similar to the request by CCEXEC70 for committees to develop approaches for general management of their work.) • New work should proceed when it is supported by sufficient science and there is significant international trade, consistent with the Working Principles for Risk Analysis in Codex and an evaluation according to the Codex Criteria for the Establishment of Work Priorities.	

RANGE OF POTENTIAL ISSUES THAT CODEX NEEDS TO BE ABLE TO ADDRESS IN THE FUTURE

Egypt have a general concern in the case of cultivated meat, seafood, and dairy is that the cultured cell is derived from a halal animal and this is issue about labeling aspects.	**Egypt**
Novel foods are regulated in the EU by Regulation (EU) 2015/2283 (EU Novel Food Regulation). 'Novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997 (date of enter into force the former novel food regulation), and that falls under at least one of the 10 listed categories in the Regulation. The EU Novel Food Regulation requires that a novel food should be safe and that the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value. The 10 categories of the EU novel food definition include newly developed or newly produced foods originating from plants, animals, microorganisms, cell cultures, minerals, etc., specific categories of foods (insects, vitamins, minerals, etc.), foods resulting from new production processes and practices, and state of the art technologies (e.g. intentionally modified or new molecular structure, nanomaterials). It also includes the so called 'traditional foods from third countries' meaning foods that do not have a history of consumptions in the European Union but are consumed as part of the staple diet in other parts of the world (e.g. insects). Technologies and sources used for the production of new food may not necessarily by themselves be new and/or may not necessarily	**European Union**

produce a new food. The inverse can also be true in the sense that a traditional food technology can produce novel foods from a non-novel food.	
Food Industry Asia would like to thank the CCEXEC for initiating the discussion on these emerging issues in Codex. It is very important that Codex provides global guidance to help create a harmonised framework, safeguarding consumers and helping foster innovation. General guidance particularly in terms of safety evaluation, definition, scope, food additives and labelling would be of great benefit. Food Industry Asia views the below issues as pertinent, relevant and emerging within the Asia region. Please see some examples in the below table.	**Food Industry Asia**
Food sources identified below can be separated into two categories: the one which has been already eaten for long years among Japanese population, and the other which has been really emerging and not yet widely distributed in Japan. We would like to share available information on these food sources.	**Japan**
Currently In Kazakhstan there are sporadic cases of the development of new technologies and systems for the production of new food products. In Kazakhstan, there is food production based on the strong traditions of national cuisine. For example, lyophilized mare, camel milk, fermented dairy products. Use of new food sources such as crickets, fly larvae are commonly raised to feed animals, birds, fish (zoos, pet stores). In Kazakhstan, the consumption of meat and meat products is traditionally high, which leaves an imprint on the food culture of the entire population. Given the large areas (sown areas, pastures, etc.) for the volume of food production at a given low population density, Kazakhstan is able to cover the needs and be a net food exporter	**Kazakhstan**
The UK has a regulatory products framework in place that includes a process for authorising novel foods (products without a history of consumption in the UK or EU prior to 1997) which would include all of the food sources listed. We are aware of developments in all the areas listed above in the UK. At this stage the sectors and businesses involved are at different stages of product/process development with some at an early scoping phase and others gathering data/evidence to seek regulatory approval. • We are already considering applications for new protein rich extracts from a range of plant sources and microalgae. • We anticipate cultivated meat, dairy and seafood and plant-based proteins will likely start seeking approval in the next 2-3 years. • An approval for an edible insect product is underway, with more application expected in the coming 1-3 years. • We have been approached by innovators interested in developing more sustainable dual use products based around seaweed, e.g. food contact material pouches for condiments and water that can also be consumed after use to help reduce packaging waste. We have noted that any innovation would need to comply both with Food Contact Materials legislation, but also additives etc. There is also a	**United Kingdom**

question about hygiene given they are the packaging and thus in contact with the external environment. There are also hypersensitivity/allergen issues if not correctly processed as seaweed often have crustacea living on them. It may be helpful for Codex to consider distinguishing in the above list between biomass and precision-based fermented products, given the differences in the technologies and the resulting products, as well as their regulatory status (e.g. Quorn, a biomass fermented product, has been authorised in the UK for some time). Regarding 3D printing, it may also be worth considering the inclusion of 4D printing. The 4th Dimension is time and so something that is 4D printed has the ability to change characteristics over time or with addition of an external factor like temperature (e.g. changes shape).	

RANGE OF POTENTIAL ISSUES THAT CODEX NEEDS TO BE ABLE TO ADDRESS IN THE FUTURE - <u>CULTIVATED MEAT, SEAFOOD, AND DAIRY</u>

-carnes	**Argentina**
There is significant research and development in this area in Australia and internationally. Commercial manufacturers may start applying in the next 12-24 months.	**Australia**
-Within Canada, these products are regulated under existing regulations pertaining to novel foods – as such no new regulatory approaches are being considered. Canada is in the process of developing guidance for food safety endpoints specific to this sector to provide transparency and encourage continuing dialogue. Canada is aware of a commercialized lab-grown meat product, chicken nuggets, approved in Singapore.	**Canada**
-En Chile, existe un desarrollo parcial para estas categorías.	**Chile**
-Regarding to cell culture-based food products, it is still under research in China and some academic institutions, universities and industries are engaged in the research. Although the commercial production of the products has been approved by some countries, it seems that there are still some safety issues need to been considered and solved, such as the safety of GMO, the safety of cell lines, purity and genetic stability of cell cultures during production, introducing pathogens using animal serum in the culture media and so on. A systematic evaluation of such products should be completed before a decision is made to develop Codex standards. Obviously, it is not an appropriate time to do this.	**China**

- Research in cultivated meat and milk is ongoing in Denmark.As part of a governmental strategy on ingredients we are in a working process to evaluate the possibilities for developing cultivated meat and dairy products. The focus at the moment is mostly concentrated on inputs from the Research and Innovation sectors.	**Denmark**
-Cultivated meat, seafood, and dairy x	**EU Specialty Food Ingredients**
-- SINGAPORE – Novel food regulatory framework with specific pre-market and labelling requirements for cultivated products already in place. - SINGAPORE – Standard(s) for novel and hybrid (e.g., mixture of plant-based and cultivated or traditional meat) alternative proteins currently under development- CHINA - In December 2021 China's 14th Five-Year (2021-2025) National Agricultural and Rural Science and Technology Development Plan was published, which highlighted for the first-time cell-cultured meat, synthetic egg analogues, and recombinant proteins as areas for R&D investment.- JAPAN - The Japanese Association for Cellular Agriculture (JACA) is a collaboration between industry, government, and academia organised by the Center for rulemaking strategies (CRS) Tama University, that is currently working to form regulations for the commercialisation of cell-based meat in Japan through round table discussions with stakeholders.	**Food Industry Asia**
-Cultivated meat is genuine animal meat (including seafood and organ meats) that is produced by cultivating animal cells directly, a production method that eliminates the need to raise and farm animals for food. Cultivated meat is arranged in the same or similar structure as animal tissues, thus replicating the sensory and nutritional profiles of conventional meat. Cultivated meat (specifically chicken) has been approved for sale in Singapore, and several countries have established or are in the process for establishing frameworks for assessing cultivated meat products. In addition, there are multiple cell culture technology companies utilizing cells to produce non-muscle products such as bovine or human milk, which may need to be considered differently for regulatory clearance. **Singapore**. The Singapore Food Agency (SFA) oversees cultivated meat. The agency published the world's first regulatory guidance on safety assessments for novel foods and ingredients in 2019, including specific requirements regarding the approval of cultivated meat products. It updated the regulatory guidance more comprehensively in December 2021 and again in April 2022. The agency currently assesses applications on a case-by-case basis and encourages companies to reach out to SFA early to clarify queries and has urged applicants seeking approval for their novel foods/ingredients to communicate with SFA throughout the application process. The approval process takes around nine-twelve months to complete if all required information for the dossiers have been submitted. SFA has already approved two cultivated chicken products produced by Eat Just, Inc. SFA also granted scientific manufacturing firm Esco Aster a license to manufacture cultivated meat products from cells that have gone through the safety assessment process and received SFA's approval.**United States**. Regulatory jurisdiction is shared between the Food and Drug Administration (FDA) and the Department of Agriculture (USDA) pursuant to a formal agreement between the agencies. The FDA will oversee cell collection and banking and all cultivation inputs and processes up through the moment of biomass "harvest" of the cultivated product from the bioreactors. FDA has significant experience overseeing cell cultivation, as this process has been used in biotechnology applications for many years. The USDA will regulate processing as well as packaging and labeling for terrestrial meats and catfish, while the FDA will have jurisdiction over all other seafood products during the processing, packaging, and labeling stages.FDA is in the process of creating guidance regarding premarket consultation during the preharvest phases and separate guidance regarding labeling for cultivated seafood	**Good Food Institute**

products. USDA is in the process of creating regulations on the labeling of cultivated terrestrial meats and catfish. The agencies have agreed to work together to develop harmonious labeling schemes. In the meantime, USDA has set forth an interim process for label preapproval. Cultivated meat companies seeking to sell their products before USDA finalizes its regulations can submit their labels to USDA for review and approval. **European Union**. Under the EU's novel foods regulation, cultivated meat products require pre-market authorization, although products developed using genetic engineering may instead fall under the regulation on genetically modified food and feed. Applications for new products must be made to the European Commission and its Directorate-General for Health and Food Safety. The European Food Safety Authority (EFSA) is responsible for conducting a risk assessment and providing a scientific opinion on the safety and nutritional aspects of the product. If that opinion is favorable, the European Commission along with representatives from the EU member states have the authority to grant final approval. Approvals apply across all member states. The process can take between about 18 months to 3 years to complete.**United Kingdom**. The UK Food Standards Agency (FSA) will regulate cultivated meat. Companies must apply to the agency for pre-market approval. The UK adopted the same approach as the EU with respect to risk assessments and authorizations for novel foods and genetically modified foods under which approved products are added to the country's list of authorized novel foods. The UK has indicated it may create a distinct regulatory framework for cultivated meat. **Canada**. The Food Directorate will oversee the regulation of cultivated meat, which is considered a "novel food." Producers must apply for premarket approval before selling their products. The approval process includes three parts: (i) a letter of no objection for human food use through the novel food assessment process, (ii) a premarket assessment for new animal feed (regardless of whether the product is intended for use as animal feed), and (iii) an environmental assessment.**Australia and New Zealand**. Food Standards Australia New Zealand (FSANZ) will oversee the regulation of cultivated meat. FSANZ has indicated that cultivated meat would be captured within existing standards in the Food Standards Code and require premarket approval. Depending on the composition of the cultivated meat product, these standards may include those for novel foods, processing aids, food additives, foods produced using gene technology, vitamins and minerals, labeling that indicates the true nature of the food, and food safety requirements.**Israel**. The National Food Control Service (FCS) at the Ministry of Health is responsible for food regulation. Cultivated meat is considered a novel food in Israel subject to its premarket authorization process. The agency has dedicated a team of experts to evaluate the safety assessments that will be required as part of a cultivated meat regulatory framework. **Japan**. Cultivated meat may already fall within the existing regulatory regime in Japan and might not require a premarket assessment or approval. But Japan has yet to create any regulations specific to cultivated meat. The Japan Association for Cellular Agriculture (JACA), a collaboration between industry, government, and academia, has been set up to create formal guidelines for cultivated meat safety assessments to ensure consumer acceptance and streamline commercialization in Japan. **Brazil**. The General Food Office at the National Health Agency (ANVISA) and the Animal Products Inspection Department within the Ministry of Agriculture will be responsible for reviewing for approving cultivated meat products. ANVISA is currently in the process of better understanding the food safety and labeling aspects of cultivated meat and developing a regulatory framework. It is likely that this framework will fall under the umbrella of Brazil's current novel foods regulatory scheme.**Thailand**. In 2016, Thailand published an informal notification and framework on novel foods. There have not been any known successful novel foods approvals. **China**. China has taken a number of steps to promote and fund cultivated meat research and development, including incorporating cultivated meat in its most recent national five-year agricultural plan. China has yet to announce how the country plans to regulate cultivated meat.	

-Incorrectly called "Cultivated meat" also called in vitro, cultured, artificial or lab-grown meat should be called "cultivated muscle cells"Meat is an incorrect term since it corresponds to a complex tissue which includes muscle cells, fat cells and blood vessels and which also undergoes a maturation (aging) process.	**International Meat Secretariat**
While cell-cultured food products have not yet been on the market in Japan, research and development are underway. For example, the private sector, partly in collaboration with research institutes, is carrying out research and development on cell-cultured food production technologies with the use of cattle cells and fish cells. In 2020, the Ministry of Agriculture, Forestry and Fisheries of Japan set up the FoodTech Public-Private Council which is a communication forum between the relevant private food industries and the government, for the purpose of exchanging opinions and information on research, development and utilization of new food technologies. The members are sharing views and current status on new food sources and production system through the council meetings.	**Japan**
The Kingdom of Saudi Arabia has standards and regulations for red meat, poultry and their products, as well as fish, marine products and dairy products.	**Kingdom of Saudi Arabia**
- There are currently demands for cultivated meat in Malaysia market. Currently Malaysia is in the process of reviewing the national policy and legislation of cultivated meat, seafood and dairy.	**Malaysia**
The Norwegian government has a goal to use more of the marine resources and in a sustainable way. Organisms on a low trophic level are of particular interest for use as both food and feed, like seaweed, krill, calanus, tunicates, sea cucumber, polycheata, gelly fish, starfish and low trophic mesopelagic fish. There is ongoing research on risk factors relevant for the food safety in several of these species. It is in general important to have international and harmonized standards/guidelines in place to support development of sustainable production systems and at the same time ensuring food safety. At present, seaweed has the highest priority.	**Norway**
-[Technology - currently in use]- Development of scaffolds for mass production of cultivated foods· Fiber anisotropy technology (technology to provide texture similar to traditional meat) to imitate traditional meat texture[Technology - in development]- Research on cell culture media without animal derived serum· Research on the development of non-animal components that can replace animal serum that acts as a nutrient and growth factor in the medium for ethical aspects[Regulatory approach - currently in use]- Food ingredients cultivated with microbial such as lactic acid bacteria listed in the food ingredient list of 'Korean Food Code' are included in ‘fermented beverages’ category- Standard for approval of ‘temporary standards and specification’ for cultivated meat, seafood and dairy[Regulatory approach - in development]- Safety assessment on cultivated food derived from livestock and aquatic organisms· Developing guideline for safety evaluation of cultivated foods for the definitions of terms, evaluation principles, procedures and standards related to cultivated foods	**Republic of Korea**
Technology currently not in use in the country	**Uganda**

-The United States recognizes the innovation of meat and poultry products produced using animal cell culture technology (i.e., “cultured” meat and poultry), a process that involves taking a small number of cells from living animals and growing them in a controlled environment to create food, among other things.	**USA**

RANGE OF POTENTIAL ISSUES THAT CODEX NEEDS TO BE ABLE TO ADDRESS IN THE FUTURE - <u>FERMENTATION-DERIVED INGREDIENTS</u>

-Si	**Argentina**
Australia is aware of research and development in this area in Australia and internationally. Precision fermentation can be used to create products (e.g. proteins, carbohydrates) that are equivalent to those from natural sources, such as meat, dairy and human milk. An example of research and development in this area is the start-up Eden Brew (https://www.edenbrew.com.au/), which is aiming to produce animal-free ‘dairy’ products using fermentation-derived proteins.The technology could also be used to develop substitutes for meat or dairy products that do not contain the proteins some consumers are allergic to. Precision fermentation could also be used to produce substances that enhance the sensory appeal of food (e.g. mouthfeel).	**Australia**
-There have been a variety of fermentation-derived ingredients and products on the market for many years, including those using precision fermentation. In Canada, products manufactured using fermentation that do not have a history of safe use are regulated under Canada’s regulations pertaining to novel foods. Fermentation-derived ingredients, such as enzymes and other substances with a technical purpose in the food, would be regulated as food additives under existing regulations. Some fermentation products may be not novel if they do not meet the regulatory definition, for example, protein extracted from Fusarium venenatum fungi. Some fermentation-derived ingredients are used in plant-based protein alternatives, such as soy leghemoglobin. Fermentation of yeast has been used to produce sweeteners.	**Canada**
-Para este punto Chile se refiere a los Ingredientes derivados de la fermentación de biomasa a partir principalmente de hongos y levaduras, la diferencia de la metodología de elaboración actual es que estos ingredientes derivados de la fermentación de biomasa son para el consumo del microorganismo en su totalidad o como mínimo procesamiento, basado en el contenido proteico de este y no con el objeto de modificar el alimento a través de la generación de distintos sabores o aromas.	**Chile**
-Fermentation-derived ingredients involve novel food (new ingredients) and new food additives, which can only be allowed to be used in food after pre-market approval to certify that there are no safety issues. For such products, the safety of GMM requires special attention. One example is Human milk oligosaccharides (HMOs), which has passed GMM and food safety assessment and has been officially announced for public hearing. In order to ensure the safety of the products, sensory, physical, chemical (total arsenic, lead) and microbiological (TPC, Enterobacteriaceae, Salmonella) requirements will also be specified. If approved, it could be allowed to be used in formulated milk powder, infant formula, follow-up formula and formula for special medical purposes for infants as nutrient fortifier substances.	**China**

- It is a trend to ferment new food stuffs e.g. fermented side streams.As part of a governmental strategy on ingredients we are in a working process to search for more and new possibilities for developing fermentation-derived ingredients for both feed and food purposes.	**Denmark**
-x	**EU Specialty Food Ingredients**
Fermentation-derived ingredients Clarification is need here if the proposed topic encompasses both biomass fermentation and precision fermentation or just the more "novel" precision fermentation process.	**Food Industry Asia**
-SINGAPORE – Novel food regulatory framework with specific pre-market and labelling requirements for protein products produced through fermentation already in place.	**Food Industry Asia**
- Within the alternative protein industry, fermentation is used in three primary ways: 1. Traditional fermentation uses intact live microorganisms to modulate and process plant-derived ingredients, resulting in products with unique flavor and nutritional profiles and modified texture.2. Biomass fermentation leverages the fast growth and high protein content of many microorganisms to efficiently produce large quantities of protein with the microbial biomass itself serving as an ingredient. The cells of the microbial biomass can be intact or minimally processed. 3. Precision fermentation uses microbial hosts as "cell factories" for producing specific functional ingredients such as enzymes, flavoring agents, vitamins, natural pigments, and fats. Where ingredients derived from fermentation meet a country's definition of a novel food, they may require premarket approval under the country's novel food regulations. Singapore, for example, has published regulatory guidance on safety assessments for novel foods, including specific requirements for foods produced by biomass fermentation and ingredients produced through precision fermentation. EFSA has also evaluated novel fermentation-derived ingredients under its novel foods regulation, and FSANZ has approved soy leghemeglobin, a plant-based protein derived from precision fermentation, as a genetically modified food and a nutritive substance. In the United States, fermentation-derived ingredients have come to market under the U.S. regulatory framework for ingredients and food additives. New ingredients and additives must be approved by the FDA unless they are "generally recognized as safe" (GRAS) under the conditions of intended use. A company may submit a notice to FDA that its ingredient is GRAS. FDA can respond in one of two ways: it may inform the company that there is not enough information available to determine that the ingredient is GRAS or it may issue a "no questions letter." Such a letter is not an explicit approval of the product but indicates that FDA does not question the company's conclusion that its ingredient is GRAS. Several companies that produce fermentation-derived products have received "no questions letters" from FDA in recent years. If a company does not believe its ingredient is already GRAS, it must submit a food additive petition to FDA for approval. If FDA approves the petition, it will add the ingredient to its food additive regulations.	**Good Food Institute**
Shrimp paste: fermented condiment made from finely crushed shrimp or krill.	**Indonesia**
The Kingdom of Saudi Arabia has a standards for residues of ethyl alcohol (ethanol) in food	**Kingdom of Saudi Arabia**

There is currently interest from the industries for fermented-derived ingredients such as fungi-based protein. Currently Malaysia is in the process of reviewing the national policy and legislation of these products.	**Malaysia**
Regulatory approaches - see below	**Norway**
-[Technology - currently in use]- Development of key yeast/fungi and complex spawning of Korea traditional fermented soybeans· Development of various high-functional complex spawn by conducting fermentation characteristics investigation and safety evaluation targeting fermentation core strains(yeast, mold)[Regulatory approach - currently in use]- Microorganisms listed in the food ingredient list of 'Korean Food Code' can be used for fermentation while ingredients that are not in the list should be approved in accordance with ‘temporary standards and specification' before being used	**Republic of Korea**
-In development	**Thailand**
Fermentation-derived ingredients Innovation in use	**Uganda**
The United States Food and Drug Administration (FDA) has reviewed the safety of fermentation derived ingredients including macroingredients (proteins (see “plant-based proteins” below), fats/oils, carbohydrates/fiber), nutritionally relevant biomass, reduced sugars, sweeteners, colors, and flavoring agents for use in food. This includes ingredients produced using microorganism production platforms produced through genetic engineering, including new technologies. FDA reviews the safety of uses of these food ingredients through existing regulatory mechanisms such as the Generally Recognized as Safety (GRAS) notification and Food Additive Petition (FAP) or Color Additive Petition (CAP) programs.”	**USA**

RANGE OF POTENTIAL ISSUES THAT CODEX NEEDS TO BE ABLE TO ADDRESS IN THE FUTURE - <u>PLANT-BASED PROTEIN ALTERNATIVES</u>

Sí	**Argentina**
-There are a wide range of plant-based protein alternatives on the market in Australia, which do not generally require pre-market approval. These are mostly based on soy or cereals and some pulses (chickpea, faba, pea). Additional crops (primarily pulses and some oilseeds) are being incorporated at increasing rates	**Australia**
-In recent years, there has been a proliferation of plant-based protein products on the market in Canada, and many more on the horizon. These include meat substitutes, milk alternatives, other dairy replacements (cheese, yogourt, ice cream, etc.), egg substitutes, and fish and seafood substitutes. New techniques for processing and manufacturing these products are also evolving (protein fractions, etc.).• In Canada, certain plant-based protein alternatives are regulated as simulated meat and poultry products. The simulated meat and poultry product regulations prescribe compositional requirements, including a minimum protein quality, and labelling requirements.• Plant-based beverages are regulated as general foods, and do not currently have a specific regulatory framework in Canada. The addition of vitamins	**Canada**

and minerals to plant-based beverages is permitted by policy. • Plant-based products which resemble cheese do not have a specific regulatory framework in Canada but the addition of certain nutrients to these products is permitted by policy.• Other plant-based protein alternatives are currently regulated as general foods, unless they are considered novel in which case they are regulated under existing Canadian regulations pertaining to novel foods. • Mycelium-derived products have also emerged on the market, some being marketed as plant-based protein alternatives. Depending on the processing, these could be regulated as general foods or as novel foods/ingredients. Some of these also fit the definition of simulated meat or poultry products and are regulated as such.	
-Existe un desarrollo parcial para esta categoría	**Chile**
-Plant-based protein alternatives are from protein-rich plants, including wheat, pea, soybean, mung bean and so on to substitute for meat protein. Since they have been consumed as food for a long history, they are not considered as new foods in our country. Many standards for food ingredients and products related to plant-based protein are issued, including mandatory food safety standards established by authority agency and voluntary food standards established by industry. Such as National food safety standard on plant protein for food processing, National food safety standard on soybean products. The requirements for sensory, contaminants, pathogens are specified in these standards.With the introduction of the concept of plant-based meat products, first voluntary standard established by industry for plant-based meat products came in effect in 2021. No animal protein source but 10% animal ingredients are allowed in the standard. For these products, there may be more concern associated with the labelling instead of food safety issues. Some confusions are from ambiguity regarding definition of “plant-based” and plant-based alternatives to dairy termed as beverages or as milk. In addition, for new food ingredients without long-term consumption history, pre-market approval is required to certify their safety, for example, rapeseed protein isolate, soy leghemoglobin.	**China**
- We are just on our way to form a governmental strategy to overcome the protein deficiency and to look for alternative proteins, including plant-based proteins, both for food and feed.Rape seed protein and mung bean protein are novel food approved in EU. In Denmark we experience an interest in grass protein as well but this is not yet approved.	**Denmark**
-Unlike the other categories of foods outlined in this table, most plant-based protein alternatives are not considered new/emerging food sources in Europe. The EU Novel Food Regulation defines novel foods as products that have not been consumed to a significant degree before 15 May 1997. Soy-based foods, which account by far for the largest share of plant-based protein alternatives in the EU market, have been on the EU market for over 40 years. At the international level, this is even more obvious, as soy products have been traditionally consumed in Asia in the form of tofu and soy-based drinks. Indeed, there is already a Codex standard for non-fermented soybean products in place. Therefore, we take the view that plant-based protein alternatives should not be in the scope of the CAC44 work on food sources and production systems.	**ENSA**
-X	**EU Specialty Food Ingredients**
-EUVEPRO does not have complete clarity on what falls within the concept of plant-based protein alternatives. For the purpose of this consultation, EUVEPRO’s focus will be on plant-based protein ingredients for human consumption. Our focus is on Europe, however some of our members operate globally.Most plant-based protein alternatives are not considered new/emerging food sources in Europe,	**European Vegetable Protein**

notably as soy-based and wheat-based protein foods have been consumed for decades. EUVEPRO considers the following protein types as emerging from a perspective of increasing use as ingredients in plant-based foods globally:- Pulses (e.g. pea, chickpea, lentils)- Potato- RiceAccording to a 2021 Innova Market Insights study, the following food categories represent the largest sectors of use for plant-based proteins in EU + UK: - Bakery & Cereals (bread, energy bars, cakes, biscuits/cookies)- Ready meals (pizza, sandwiches, main dishes)- Sports nutrition (ready-to-drink, bars, powders)- Meat, Fish & Eggs (meat alternatives, deli meat, fish & seafood, egg products)But they are used in many other market segments.Mycoproteins from fungi are not included in the scope of the EUVEPRO comments above on plant-based proteins.	**Association**
-- SINGAPORE – Novel food regulatory framework with specific pre-market and labelling requirements for plant-based protein products already in place.- SINGAPORE – Standard(s) for plant-based protein currently under development - CHINA - in June 2020 a government sponsored industry group, China Institute of Food Science and Technology (CIFST), issued for comment a draft of the first voluntary standard for plant-based meat products in China - The T /CIFST 001-2020 Group Standard for Plant-Based Meat Products	**Food Industry Asia**
-GFI understands this category to refer to products made from plants that are alternatives to animal-based products. This includes plant-based meat, seafood, eggs and dairy.Many ingredients in plant-based alternative proteins are whole foods or are ingredients that have a long history of use in food, and therefore do not require government approval. Certain novel plant-based ingredients may require regulatory assessment or approval, however.Where plant-based protein alternatives meet a country's definition of a novel food, they may require premarket approval under the country's novel food regulations. Singapore, for example, has published regulatory guidance on safety assessments for novel plant-based foods. EFSA has evaluated mung bean protein under the EU's novel foods regulation, leading to the approval of the ingredient by the European Commission. In the United States, certain plant-based ingredients, such as mung bean protein isolate and soy leghemoglobin, have come to market under the GRAS or food additive petition process. The GRAS notice and food additive petition processes work the same way for plant-based ingredients as for fermentation-derived ingredients. The Food Safety and Standards Authority of India (FSSAI) has issued draft rules for vegan food products seeking an endorsement under Food Safety and Standards (Vegan Foods) Regulations in 2021. The final regulation will be published following a review of public comments on the draft rules. In Brazil, The Department of Inspection of Plant Products at the Ministry of Agriculture and the General Food Office at the National Health Agency are co-leading a regulatory impact analysis on the regulation of plant-based proteins. The work is ongoing.	**Good Food Institute**
The Kingdom of Saudi Arabia is in the process of adopting a draft regulation on "Plant-based substitutes for meat and other products of animal origin".	**Kingdom of Saudi Arabia**
- Pea (or any other local legumes or pulses) protein isolate: extracted protein created through a specific process that separates/isolates protein from other elements of peas.- Mycoprotein from *Fusarium venenatum*: single cell protein made from a type of fungus, *Fusarium venenatum*.	**Indonesia**
-Processed plant products claiming to substitute for meat	**International Meat Secretariat**

This food category is not a new food source for Asian people. Soybean-based products are the most popular plant-based protein alternatives in the Asian region. Some relevant regional standards were developed by CCASIA, such as Regional Standard for Tempe (CXS 313R-2013), Regional Standard for Non-Fermented Soybean Products (CXS 322R-2015) and Regional Standard for Fermented Soybean Paste (CXS 298R-2009).Consumer needs for food are being more diversified around the world. This trend is increasing the distribution of “meat-like processed foods” which use soybean protein products and defatted soybeans as the main ingredients. In February 2022, the Ministry of Agriculture, Forestry and Fisheries of Japan established “the Japanese Agricultural Standard (JAS) for Textured soy protein products.” This Japanese national standard aims to help consumers correctly understand what ingredients are used in this type of processed foods and choose which products to buy. The standard covers scope, terms and definitions, requirements for production, labelling, and other necessary aspects for Textured soy protein products.	**Japan**
-Plant-based protein alternatives products such as soy-based culture meat and plant-based seafood products are currently available in Malaysian market.	**Malaysia**
Regulatory approaches - see below	**Norway**
-[Technology - currently in use]- Fiber anisotropy technology to imitate traditional meat texture· Technology to provide texture similar to traditional meat using plant based protein ingredients[Regulatory approach - currently in use]- Safety management according to the type of main raw material used in the product by classifying into processed beans and processed grain products[Regulatory approach - in development]- Review on the safety management standards for alternative protein products considering current market growth of various products	**Republic of Korea**
-In development and commercial product	**Thailand**
FDA has reviewed the safety of plant-based protein alternatives such as pea, potato, rice, shitake, sunflower, safflower, fava, and corn protein for use in food. FDA has also reviewed the safety of proteins produced by new technologies (such as fermentation) that historically have been obtained from animal sources, including beta lactoglobulin, myoglobin, soluble egg-white, and whey protein with higher alpha lactalbumin. FDA reviews the safety of these ingredients through existing regulatory mechanisms such as the Generally Recognized as Safety (GRAS) notification and Food Additive Petition (FAP) programs.”	**USA**

RANGE OF POTENTIAL ISSUES THAT CODEX NEEDS TO BE ABLE TO ADDRESS IN THE FUTURE - SEAWEED

Seaweed is already sold for human consumption in Australia and Zealand (i.e nori, wakame). The Australian seaweed industry is small, mostly relying on collection via beach cast and wild harvest. Australia is a net importer of seaweed.Some small manufacturers make seaweed extracts for the health and nutrition market.Research is exploring the potential for using specific seaweed species in feed for cattle and dairy cows to reduce methane emissions.2020 AgriFutures Australia report – the Australian Seaweed Industry Blueprint	**Australia**
-Many seaweed products can be shown to have an established history of safe as food. If not, they are regulated under existing Canadian regulations pertaining to novel foods.	**Canada**
-Existe un desarrollo parcial para esta categoría en el país	**Chile**
-There is a long history of consuming seaweed in our country. In order to ensure the safety of the seaweed, the national food safety standard for seaweed was established. The standard specified the requirements for sensory, contaminants, pathogen and food additives. The specific requirements for contaminants, pathogen and food additives refer to general standards.	**China**
- Growing interest in using seaweed for human consumption.As part of a governmental strategy on ingredients we are in a working process to search for new possibilities for using seaweed.	**Denmark**
-On seaweeds, several species have been found in Fiji which have economic potential based upon reports for the same genera in overseas countries. Some of these species are already used as food in Fiji and are a commodity traded in local municipal markets. The most common economic seaweeds are Gracilaria maramae, Gracilaria sp., Hypnea pannosa and Acanthophora spicifera.	**Fiji**
We understand that seaweed is consumed traditionally in countries, especially those in East and South-east Asian region. Therefore, clarification is needed here to confirm on the scope for this category.	**Food Industry Asia**
- *Caulerpa racemose* and *Caulerpa lentillifera* : Types of edible seaweed (types of seaweed that can be consumed as fresh food). - Nori/laver product made from edible seaweed other than genus *Pyropia* (*Ulva lactuca*, *Gracilaria sp*., *Caulerpa sp*.)	**Indonesia**
Seaweed has been eaten by Japanese people for a long time and is consumed commonly in East Asian countries. Laver product made from a type of seaweed was standardized into an Asian regional standard (CXS 323R-2017).The Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) conducted the surveillance for arsenic (total and inorganic), cadmium, mercury (total) and/or iodine in dried seaweed, and processed seaweed-based products from 2006 to 2008, and from 2014 to 2016. The surveyed seaweed includes Kombu (Saccharina spp.), hijiki (Sargassum fusiforme), and wakame (Undaria pinnatifida). MAFF submitted the relevant analytical results obtained from the surveillance to GEMS/Food database in response to the call for data by FAO/WHO. MAFF also issued advice for manufacturers and consumers to reduce inorganic arsenic in hijiki during processing/cooking.	**Japan**
In general, seaweed is not considered new food source in Malaysia, nevertheless seaweed covers wide range of products.	**Malaysia**
Production of seaweed for use as food and feed is increasing in Norway, with many producers on both wild harvest and aquaculture. This has a long history since decades and we are the third biggest harvester of seaweed in the world, but most of this is for industrial production of alginate. There is a lot of research on new food and feed products and processing methods to ensure food safety. We	**Norway**

consider lack of global harmonised guidance, in particular for the use as food, is an important obstacle to both trade and development of this production. Norway is at present in collaboration with other Nordic countries, developing guidelines on food based on seaweed, for the use for both producers and national food authorities. The most important risk factors in Nordic products are identified as iodine and inorganic arsenic, but also cadmium and other heavy metals may be a risk.	
-[Regulatory approach - currently in use]- Standards for heavy-metals in seaweed based on 'Food Code'· Setting the standard for heavy metal(lead, cadmium) only for laver and seasoned laver products in seaweed- Standard for products using seaweed according to food types	**Republic of Korea**
-In development and commercial product	**Thailand**
Product not currently consumed in the country	**Uganda**
Codex has already established a regional commodity standard for seaweed namely CXS 323R-2017 Regional Standard for Laver Products. Seaweed itself can be traded as a commodity or a food ingredient. FDA reviews the safety of uses of these ingredients through existing regulatory mechanisms. Examples include seaweed derived Calcium for use in fortification of food and Seaweed as a source of fucoidans (long chain polysaccharides) for addition to food.	**USA**

RANGE OF POTENTIAL ISSUES THAT CODEX NEEDS TO BE ABLE TO ADDRESS IN THE FUTURE - EDIBLE INSECTS

Some edible insects (e.g. whole insects or mixed products) and insect products (e.g. 'flour') are already on the market. Crickets and mealworms are currently commercially produced in Australia for human consumption, but in small quantities.A significant focus for Australian insect farming is the production of feed for livestock and aquaculture.Research on insects as food for humans in Australia is currently minimal.2022 CSIRO report - Australia's Protein Roadmap	**Australia**
Several Insects in form of commodities and products consumed in significant quantities in the country	**Uganda**
Edible insects are consumed as ethnic food in Malaysia but not for commercial purposes.	**Malaysia**
FDA has had discussions with food technologists about edible insects as food ingredients. Concerns for this use of edible insects would be potential cross-reactivity with known allergens. FDA would review such requests through existing regulatory mechanisms, such as the Food Additive Petition (FAP) program.	**USA**
-There is a habit of eating edible insects in some areas of China. Some of them are commercialized, such as fried grasshopper, grasshopper paste (one of composite seasoning made with grasshopper as main raw material). For such products, the main focus should be on the species of insects, the control of the hygiene and sanitation during breeding and allergies to insect protein. At present, enterprise usually develops the standard which apply to their own business. Food safety indicators have been established in the standard. Moreover, some studies on insect protein are going on by academic institute and universities.	**China**

-While most of the popular insects used as food around the world have a history of safe use for human consumption (e.g. dried whole or ground crickets), certain edible insect species and products may be considered a novel food (e.g. black solider fly larvae, insect protein concentrates from various species) as defined under Canadian regulations. In Canada, those edible insect products with an established history of safe use as food would not be novel, while those edible insect products that are new as food would be subject to Canadian regulations pertaining to novel foods.	**Canada**
-[Technology - in development]- Development of protein extraction technology with improved essential amino-acid index in edible insects· Developing technology to remove chitin, which has poor processing aptitude, improve the essential amino acid index, and process the mass production to utilize edible insects as a future protein source- Development of food for patients using edible insects and health functional food· Development of patient food menu using edible insects and clinical trials· Functional study using edible insects: improvement of blood circulation, obesity, osteoporosis, etc- Development of safe breeding technology for edible insects· Development of safe breeding technology for edible insects that can be used for various purposes(Edible insect Safety Breeding Manual)· Standardization of edible insect breeding technology· Development of mass production system (ICT integration automation, scale-up)[Regulatory approach - currently in use]- Raw materials for edible insects: Only edible insects listed in the raw material list of food code can be used as raw materials for food· Standard for heavy metal in edible insects based on 'Food Code'· Establishment of integrated standards for heavy metals(lead, cadmium, inorganic arsenic) in edible insects- Edible insects: Standards on food type of 'processed insect food' for the food manufactured using edible insects· Definition, specifications(acid value, peroxide value, coliform group, number of bacteria, E.coli) and test method of processed insect food- Regulation related to insect production system: Act on the promotion and support of insect industry· Definition of edible insects, breeding standards and specifications, risk assessment, etc.	**Republic of Korea**
- Insects are seen as a potential new feed, food or product for technical use (oil of insects as fuel). A few establishments are under development for big scale production of protein consisting of insects and oil of insects for feed purposes and technical use (fuel). There is much research focus on providing new feed sources for insects.Some small-scale companies in Denmark.	**Denmark**
Cricket (and any other edible insect) flour/ powder: new source of protein (in the form of flour/powder) made from crickets (or other insect) using various processes.	**Indonesia**
-In development and commercial product	**Thailand**
Insects such as Inago locusts, bee larvae, silkworms, larvae of some aquatic insects have been traditionally consumed in certain regions in Japan. Currently, there is a growing interest in the use of insects for food and feed, and new products are under development. Some products, for example, crackers using powders prepared from certain species of edible crickets, are on sale. In 2020, the Ministry of Agriculture, Forestry and Fisheries of Japan set up the FoodTech Public-Private Council, which is a communication forum between the relevant private food industries and the government, for the purpose of exchanging opinions and information on research, development and utilization of new food technologies. Taking into consideration the fact that there are some challenges for consumers to widely accept insects and insect-based food products, the members are discussing developing quality standards and management systems on the use of insects for food and feed.	**Japan**

Regulatory approaches - see below	**Norway**
-Sí	**Argentina**
-X	**Argentina**
-Hermetia illucens; Acheta domesticus; Tenebrio molitor.	**Chile**
Costa Rica considera que, los insectos comestibles son un producto con gran potencial porque responde a las macrotendencias relacionadas a la búsqueda de fuentes de proteína alternativas producidas de una manera sostenible. De igual manera, es un tema en el que cada vez hay mayor interés no sólo por el comercio local sino también el intercambio comercial de este nuevo tipo de proteína.En Costa Rica se han identificado al menos 6 empresas que se dedican a la cría de insectos para consumo humano y actualmente se comercializan algunos productos elaborados a base de grillo (barras de proteína y harina de grillo), los cuales se encuentran debidamente registrados.El Centro Nacional de Ciencia y Tecnología de Alimentos (CITA) de la Universidad de Costa Rica está desarrollando un proyecto denominado: "Consumo de insectos y su aplicación en matrices alimentarias en Costa Rica: retos y oportunidades de una estrategia potencial para el fortalecimiento de la seguridad alimentaria nacional" (http://www.cita.ucr.ac.cr/insectos).	**Costa Rica**
Australia is aware of only limited research in Australia in this area. The research is focused on developing 3D printed foods for people with problems swallowing.An example is work by researchers at Edith Cowan University developing 3D printed foods for residents in aged care facilities who have problems chewing or swallowing. Link to article on research: https://www.ecu.edu.au/newsroom/articles/research/3d-printed-meals-could-help-us-make-better-food-choices	**Australia**

RANGE OF POTENTIAL ISSUES THAT CODEX NEEDS TO BE ABLE TO ADDRESS IN THE FUTURE - 3-D PRINTED FOODS

-If any food does not have a history of safe use, or if the process is novel and caused the food to undergo a major change, they are regulated under Canadian regulations pertaining to novel foods.	**Canada**
-3-D printed foods are under research in our countries. Many universities and academic institutions are keen on this research, involving various of food such as biscuit, fruit and vegetable purees and so on. 3-D printed foods are characterized by personalization, but this	**China**

technology will take some food safety problem, such as potential migration of chemicals from the 3D printer to food, inability to clean all surfaces that come in contact with the food “ink”. Moreover, due to the relatively high cost of this technology, its commercialization will take some time.	
- Not on the market, only R&D-scale.	**Denmark**
None identified	**Malaysia**
Regulatory approaches - see below	**Norway**
-[Regulatory approach - currently in use]- Final food product : Safety management through 「Food Code」 and 「Food Additives Code」- Production process and 3D printers : 「Food Sanitation Act」 and 「Standards and Specifications for Utensils, Containers and Packaging」	**Republic of Korea**
-In development	**Thailand**
Technology currently not in use in the country	**Uganda**
This production process is in current use in the USA for a number of different product applications and will likely be used for additional applications over time, including assembly of plant-based, animal cell materials, and microbial ingredients. If new food ingredients were to be used in 3-D printed foods, we would examine those ingredients via our existing regulatory mechanisms	**USA**

RANGE OF POTENTIAL ISSUES THAT CODEX NEEDS TO BE ABLE TO ADDRESS IN THE FUTURE – MICROALGAE

A few types of microalgae (e.g. chlorella, spirulina) are used in food products in Australia. In addition, products derived from microalgae (e.g. natural food colourings, omega-3 fatty acids, nutritional supplements) are also available.2021 AgriFutures Australia report – The algae and seaweed opportunity: An Australian prospect	**Australia**
-Those algal-derived products with an established history of safe use as food would not be novel, while those that have no history of safe use as food are subject to Canadian regulations pertaining to novel foods.	**Canada**
-Existe un desarrollo parcial para esta categoría.	**Chile**
-Microalgae as novel food is required to pre-market approval. It can’t be consumed until it is proved that there is no food safety issue after risk assessment. Nannochloropsisgaditana is an approved one of microalgae. Food containing it are sold in the United States, Chile, Canada and other countries. Nannochloropsisgaditana contains protein, EPA and other nutrients. The announcement also mentioned that its safety should meet the national food safety standards for algae and their products.	**China**
- Growing interest in microalgae for food use.	**Denmark**

-x	**EU Specialty Food Ingredients**
- Spirulina powder: products made from dried *Spirulina spp*. biomass.- Read algae (*Lithothamnion sp*.): used as raw material in producing natural mineral source such as Aquamin F.- Brown algae (*Sargassum fusiforme*) and many more	**Indonesia**
None identified	**Malaysia**
There is ongoing development in Norway on production of certain species of microalgae for the use in both food and feed. Regulatory approaches - see below	**Norway**
-[Technology - currently in use]- Technology to secure a stable mass of microalgae- Stable mass production, long-term preservation, and safety of microalgae that can be used for various industries[Technology - in development]- Development of functional food using microalgae· Research on the development of functional food(health-promoting tofu products using microalgae extract, etc)- Development of technology using microalgae to improve water quality· To promote the use of microalgae for improvement and purification of water quality and environmental pollution(Research on the development of microalgae culture and integrated process using industrial wastewater, development of a water purification system that simulates the microalgae and microbe community in a heavy metal-contaminated environment, etc.)[Regulatory approach - currently in use]- Regulation on safety of microalgae based on 'Food Code' and 'Functional Ingredients And Standards And Specifications For Health Functional Foods' · Management of minimum microalgae content and sampling method in food using functional microalgae- Quality control by acquiring international certification for the quality control field of microalgae materials· Regulation to obtain ISO international certification in the field of material quality management from organizations that sell or use useful materials extracted from microalgae (such as the National Marine and Biological Resources Center)-Production system safety and quality management· Regulates to allow the use of internationally recognized test methods such as codex regulations, aoac, and pam, and to present the test methods and sources	**Republic of Korea**
-In development	**Thailand**
Technology currently not in use in the country	**Uganda**
Microalgae is used as an alternative method in largescale production of different food ingredients such as nutritionally 'beneficial' biomass, as a source of macroingredients, and color. We have seen a growing interest for use of this approach for new applications. FDA has reviewed the safety of food uses of ingredients produced using this production method through existing regulatory mechanisms such as the GRAS notification program.	**USA**

RANGE OF POTENTIAL ISSUES THAT CODEX NEEDS TO BE ABLE TO ADDRESS IN THE FUTURE - OTHER

~~Otros (especifique)~~Preparados vegetales bebibles	**Argentina**
Australia is aware of technological innovations such as fractionation, concentration and protein isolation that enable concentration of substances. Another innovation is microencapsulation to protect ingredients.	**Australia**

The use of conventional food waste products, such as pomace for use as an ingredient, may be an emerging new food. If these products do not have a history of safe use they would be regulated under Canadian regulations pertaining to novel foods.	**Canada**
-Extractos vegetales obtenidos por diversas formas e incluidos en productos calificados como suplementos o complementos alimentarios. Estos extractos se comercializan entre países sin que exista una clara identificación de las sustancias extractadas y de los efectos que puedan tener en el metabolismo del ser humano o respecto de las propiedades saludables que se les declara.	**Chile**
- Interest in using different side streams for food use, e.g. spent coffee grain, potato peel etc.	**Denmark**
-Plant cell cultures	**EU Specialty Food Ingredients**
-New meat product with a blend of 2 or more meat types (Codex has standard on luncheon), but more so on mixture of meat, vegetables, sauces and spices which are mostly researched and developed by food research institutions and food industries.	**Fiji**
No such categories are there as mentioned above. However to encourage innovation/ new technologies and regulate the same, the approaches being followed are: 1. Non-specified food including Novel food: any food other than proprietary food or food ingredients, including additives, processing aids and enzymes for which standards have not been specified in any regulation made under the Food Safety and Standards Act. Novel food would cover all above mentioned categories. 2. Proprietary food: an article of food that contain only those ingredients other than additives which are either standardized or permitted for use in the preparation of food products under the Food Safety and Standards Regulations and those food or ingredients mentioned in the Indian Food Composition Tables (IFCT), 2017, National Institute of Nutrition, except the ingredients which may be specified by the Food Safety and Standards Authority of India (National Food Regulatory Body) from time to time.	**India**
- Banana (hump, peel, flower/ blossom/ heart/ inflorescence)- Seed of Snake fruit (*Salacca edulis*), seed of Sengon (*Falcataria moluccana*), etc- Tempe (as currently described at CXS 313R-2013) made from legumes other than soybean	**Indonesia**
There is technical Regulation No. SFDA.FD 5013 and are accompanied by a guideline for novel foods.	**Kingdom of Saudi Arabia**
-Insects for feed	**Thailand**
In the context of this work on new food sources and production systems, we consider it essential to focus on and ground the work within the mandate of Codex of protecting consumer health via food safety and quality and ensuring fair practices in the food trade. Currently, there is still the need to understand and learn about the impact of these “new foods” and innovative technologies in terms of the	**USA**

regulatory, labelling, nutritional, and food safety aspects outlined below.. Any work within Codex should be aligned with its mandate and its Procedural Manual.	

What are the main issues/concerns on trade and/or safety of any of the innovations, new technologies or new/emerging food sources or production systems you have identified that could productively be addressed by Codex? Please provide information/data if available for each of the types of innovations, new technologies or new/emerging[7] food sources or production systems on the following aspects: regulatory matters; labelling aspects; nutritional aspects; fair trade practices; quality aspects; environmental or sustainability aspects and any other relevant matters in the tables below.

REGULATORY MATTERS

Cultivated meat, seafood and dairy products are likely to require pre-market approval as 'GM foods' if the foods are produced using GM technology or where a GM constituent is present in the final food for retail sale (Australia New Zealand Food Standards Code – Standard 1.5.2 – Food produced using gene technology (legislation.gov.au)).Where GM technology is not used, products are likely to require pre-market approval as 'novel foods' under the Novel Foods Standard (Australia New Zealand Food Standards Code – Standard 1.5.1 – Novel foods (legislation.gov.au)).FSANZ has not yet received any applications for such foods. Additional or alternative pre-market approvals may be required depending on: if production requires the use of processing aids, food additives, or fortification with vitamins or minerals; the purpose of the final food (e.g. pre-market approval as a nutritive substance may be required).	**Australia**
General comment: Canada is of the view that there are many challenges regarding new food sources and production systems. Some potential challenges are: (1) the composition of these new foods as the definition or description of these new foods can vary broadly from one manufacturer to another; (2) the production of these new foods; (3) the possible lack of regulations in current frameworks to regulate these new foods (i.e. no compositional standard); (4) the possible discordance of these new foods with existing food standards in regulations; (5) the current regulatory definitions, prohibitions and/or requirements for some foods, including certain simulated meat or poultry products, and whether these also apply to new foods; (6) the lack of guidance for industry and consumers to better understand what these new foods are or should be; and (7) specific microbiological and chemical contaminant criteria for these new foods would be useful to develop to ensure the safety of these products.	**Canada**
There are countries, e.g., Singapore, Australia, New Zealand, India, that are using their existing novel food regulatory frameworks, which differ from country to country e.g., regarding the definition of what is deemed novel, to assess the below foods; this can provide a good basis for the risk assessment of these foods, however information pertaining to specific safety considerations e.g.. allergenicity, new technology, and optimal labelling requirements may be lacking.	**Food Industry Asia**

[25][7] Some food sources and production systems may not be new to all jurisdictions but may be expanding to new geographical areas that have not managed such food sources/systems previously

Having said this, many countries, e.g., Philippines, Vietnam, Indonesia, lack a specific regulatory framework for assessing the below food types, with these foods currently being assessed on a case-by-case basis. Codex standards and/or guidelines could help fill the gaps in the currently adopted regulations for these foods, and help guide countries who currently do not have a regulatory framework and possibly have little information regarding the status of their alternative protein market.	
Currently, all food products permitted to be traded in Indonesia must comply with the food regulations, especially related to maximum limits of chemical and microbiological contaminants.	**Indonesia**
Undoubtedly, Kazakhstan, as a participant in international trade, will certainly be involved in "new production systems". This will require the provision of guarantees that the products were obtained in compliance with the technologies, are safe and of high quality. In light of these circumstances, Codex will play an indispensable role in setting standards based on risk assessment. There is no regulation in the country on new food sources	**Kazakhstan**
Confidence and capacity of national food control systems to manage risks associated with new foods sources, from authorisation through to verification to protect consumer health and facilitate trade. Consideration of the regulatory management of these new technologies and how consumer confidence can be maintained by ensuring food innovations are safe are a key consideration. In the UK this is managed through our novel food framework. However, it is already clear that some of these sectors will provide challenges in new operating models and the importance of mechanisms to allow the sharing of data between companies that will need to be coordinated to provide a basis for assessment and effective regulatory oversight. -We have considered the development in these technologies and the data available to understand the hazard that the unique aspects of the production process could pose from a food safety perspective.	**United Kingdom**

REGULATORY MATTERS - <u>CULTIVATED MEAT, SEAFOOD, AND DAIRY</u>

-At this time, Canada does not have any specific microbiological criteria in place for these products. We anticipate the need to develop and support post-market tools as needed (microbiological and chemical contaminant criteria) before these products begin to reach the marketplace.	**Canada**
- The Danish Veterinary and Food Administration is in a working process to evaluate the possible legal barriers for developing and using cultivated meat and dairy products for food and feed.	**Denmark**

-● Definitions of meat in various jurisdictions and technical definitions for cultured meat does not align. A common accepted definition for novel tissue engineered foods is needed. ● It stays unclear to which food category cultured meat would/can belong or if a new food category needs to be established to cover the needs for this new technology.● Conventional meat is regulated at almost all level of production. which can be applied to cultured meat and for which additional adaptions are needed (e.g., safety and quality conditions of the in vitro growing process).● Labelling of cultured meat would have a profound impact on the take-up of the products in the market & acceptance of the consumer. Labelling approaches are not harmonised resp. not established yet in several jurisdictions – a common approach would be needed to provide also transparency to the consumers.● The labelling of plant-based meat is already a contentious issue between conventional meat producers and cultivated meat producers and so regulators will need to steer a course based on fairness and science.● Safety- Points addresses already in chapter 4.5 of the FAO report “Thinking about the future of food safety” for Cell-based food production- A Guideline for the conduct for a safety assessment for cultured meat is required, which should address also aspects like zoonosis/pathogens originating from origin organism; safety of selected / immortalised cells / re-programmed or modified cells, genetically drift, in case Serum is used aspects like: bacteria, viruses, prions.- Another aspect is the safety of the Scaffolding materials, which requires a harmonized approach.	**EU Specialty Food Ingredients**
-Cell-based agriculture would in principle fall within the scope of the EU Novel Food Regulation unless the technique used to culture meat, seafood or milk falls under the scope of Regulation (EC) No 1829/2003 (GMO Regulation)	**European Union**
-Some countries may still lack core information pertaining to the food production process for cultivated meat, in-house expertise in how to assess the related food safety issues, or both, limiting their ability to establish appropriate review mechanisms for these foods.	**Good Food Institute**
-Should it be called meat? No. Actions have been engaged by the meat industry to ban the use of the term meat."meat" is defined by Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin as "the edible parts of animals referred to in points 1.2 to 1.8, including blood. " and by Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (INCO) as "Skeletal muscle of mammalian and avian species, which is recognised as fit for human consumption, together with tissues that are naturally embedded or adherent".Is it possible to harmonize the definition of meat internationally?Should cultivated muscle cells be regulated in the same way as meat?	**International Meat Secretariat**
Currently there is no national standard on cultivated meat, seafood and dairy products. The safety aspect and halal status of cultivated meat, seafood and dairy (i.e. source of stem cell) are our main concerns.	**Malaysia**
-Novel foods are subject to a pre-market authorisation procedure in the European Economic Area (EEA), which includes Norway, and are regulated by Regulation (EU) 2015/2283 on novel foods.Novel Food is defined as food that has not been consumed to a significant degree by humans in the EU/EEA before 15 May 1997, when the first Regulation on novel food came into force, and that falls under at least one of 10 categories (article 3(2)a)). In order to be granted a pre-market authorisation, novel foods must, on basis of available scientific evidence be evaluated as:Safe for consumersProperly labelled, so as not to mislead consumersIf novel food is intended to replace another food, it must not differ in a way that the consumption of the Novel Food would be nutritionally disadvantageous for the	**Norway**

consumer.Cultivated meat, seafood and dairy would be a novel food, according to the novel food definition in Regulation (EU) 2015/2283 on novel foods, as “food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae”; is one of the novel food categories.Additionally, foods in the other indicated foods sources below in the table, could probably fall under the novel food definition in the EEA if not consumed to a significant degree before 1997. For example, insects are novel foods in the EU/EEA. Novel food authorisations have been granted for several insect species.	
-- International standards for safety assessment of 'cultivated food'· Guidelines for disease infection, genetic equivalence, expression of hazardous substances, scope of available substances, toxicity evaluation, etc. of cell donor animals if genetic differences exist · Regulations and guidelines for comparative analysis and allergy assessment of tissue cells, genomes, proteins, and metabolites before in vitro culture, which secure the first cells by manufacturing process· Manufacturing and processing standards through safety evaluation methods and regulations for substances (cellular separation reagents, nutritional additives, non-nutritive additives, and other supports) added during the production stage of cultured food· Safety management scope of the production process (manufacturing, processing stage/ production stage) is required for safety management of cultivated food production facilities (cell banks, bioreactor, animal cell treatment facilities, etc.) using various production methods- Need to review on ethical issues for ingredients used in production system	**Republic of Korea**
On March 7, 2019, the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) signed a formal agreement to jointly oversee the production of human food products comprised of or containing cultured cells derived from cell lines of those species covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act. The agreement describes each agency's intended role with respect to the oversight of such products. In summary, FDA will oversee the collection, growth, and differentiation of livestock and poultry cells until cell harvest. A transition from FDA to FSIS oversight will occur during the cell harvest stage. FSIS will then oversee the processing, packaging, and labeling of the resulting meat and poultry products made using animal cell culture technology. More information on this agreement can be found at: https://www.fda.gov/news-events/press-announcements/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food-products-cell-lines-livestock-and.The USDA Agricultural Marketing Service (AMS) Dairy Program notes that for cell culture-based food products, there seems to not be a consensus on the consumer acceptance and regulatory transparency of these foods. From a AMS perspective, it may mean that bringing this topic into Codex potentially raises issues for which the U.S. has no clearly defined position	**USA**

REGULATORY MATTERS - <u>FERMENTATION-DERIVED INGREDIENTS</u>

Fermentation-derived ingredients are likely to require pre-market approval as GM foods if they are produced using GM technology. FSANZ has assessed applications for a number of products produced using genetically modified bacteria. A recent example is Application A1186 – Soy leghemoglobin in meat analogue products. Soy leghemoglobin is produced by a GM yeast, Pichia pastoris. FSANZ assessed soy leghemoglobin as a nutritive substance (for the purpose of providing a source of iron to meat analogue products) and as a GM food.	**Australia**

Fermentation ingredients may also require pre-market approval based on their purpose or technological function (e.g. food additive, nutritive substances).	
-En Chile la Ley 21.179 del Ministerio de Salud prohíbe catalogar y etiquetar como leche a un producto que no sea de origen animal. No existe regulación en este ámbito para la industria cárnica.Importante definir un proceso de trazabilidad en la producción de productos que contengan carne cultivada (estándares GMP). Existe sólo legislación general, no se tratan en forma especificas “nuevos alimentos” por lo tanto se adecua a lo existente y no se representa legalmente lo necesario para su desarrollo y comercialización.	**Chile**
- The Danish Veterinary and Food Administration is in a working process to evaluate the possible legal barriers for developing and using fermentation-derived ingredients for food and feed.	**Denmark**
● Safety of used microorganism: Several microorganisms are in the focus to be used for novel food ingredients, which also do include the use of engineered Microorganism. It needs to be assured that non-pathogenic strains which do not produce harmful metabolites are used. ● Standardization and harmonization of safety risk assessment of microorganisms with focus on the safety risks rather than hazards is deemed necessary. A Guidance on how to assess safety of microorganism resp. engineered microorganism is seen beneficial. Furthermore, a System equivalent to the QPS approach in Europe would be supportive. an approach similar to the QPS approach by EFSA would be desirable, both at the level of safe species (e.g. Kluyveromyces lactis) and at the level of safe strain lineages (e.g. Escherichia coli K12) as also formalized by JECFA by the “presumed safe progeny” concept in its new enzyme evaluation guidelines (see:https://www.who.int/docs/default-source/food-safety/publications/section9-1-4-2-enzymes.pdf?sfvrsn=e238e86e_2) , to streamline safety assessment and to reduce the need for animal experimentation. ● Development of standardises analytical methods is seen.	**EU Specialty Food Ingredients**
Fermentation-derived ingredients are already widely used across the food industry in the EU. A key decision element of novelty is a case-by-case assessment to determine whether emerging/novel innovative fermentation technologies (e.g. precision fermentation) used in foods result in significant changes in their composition or structure, affecting their nutritional value, metabolism or level of undesirable substances. Additionally, the EUMS note that the development of standard(s) on yeast would allow comparison between products made with traditional yeast and products made with fermentation involving yeast from more innovative technologies.	**European Union**
Existing Codex commodity and horizontal standards do not appear to apply directly to some alternative protein products that are already on the market in certain jurisdictions, including, for example, products containing ingredients produced through biomass fermentation techniques. These foods are subject to different types of regulatory approval processes in different countries. Amending existing Codex standards or developing new Codex standards could reduce future trade barriers and provide a more harmonized global regulatory framework for such products. New or amended standards should be flexible enough to avoid stifling innovation and allow for maximum flexibility in the technology used to produce foods.	**Good Food Institute**

Alcohol residues in fermented food and beverages are required for religious opinion.	**Kingdom of Saudi Arabia.**
Currently there is no national standard on fermentation-derived ingredients.	**Malaysia**
Guidelines for safety assessment of foods manufactured using fermentation-derived ingredients· Terms and definitions for microorganisms (bacteria, yeast, mold, etc.) used in the production of fermentation-derived foods· Guidelines for safety evaluation, such as toxicity, antibiotic resistance, etc., depending on whether the microorganism is for direct ingestion or removing after use in the production of fermented foods· Guidelines for safety evaluation of gene extraction and recombination process, mold culture process, etc. are required when cultivating protein-producing genes in existing foods such as milk and eggs in mold	**Republic of Korea**
Enabling policy and regulatory frameworks for adequate control	**Uganda**
Applications are being received for products in this space with the focus of the work being the food safety risks. Considerations of factors beyond safety, the potential to nutritionally disadvantage consumers and the potential for consumers to be misled is outside the scope of the current regulatory framework in the UK.	**United Kingdom**
Food ingredients produced using new fermentation technologies have been reviewed by FDA within existing regulatory frameworks, and with the safety standard of a reasonable certainty of no harm to consumers. The main considerations for safety include the safety of the production organism and its metabolites, the manufacturing, the products of manufacturing (including the main ingredient and co-fermenting components, if any), identity, stability, dietary exposure, and the intended use.	**USA**

REGULATORY MATTERS - <u>PLANT-BASED PROTEIN ALTERNATIVES</u>

As noted above, many plant-based protein alternatives do not require pre-market approval.Australia New Zealand Food Standards Code – Schedule 17 – Vitamins and Minerals contains permissions for the use of vitamins and minerals in particular foods, including 'analogues derived from legumes' (e.g. analogues of meat and dairy products) and 'analogues derived from cereals, nuts, seeds, or a combination of those ingredients'.If new sources of protein are used or different parts of existing plants without a history of consumption as foods are used, then pre-market approval may be required – these would most likely be regulated as a novel foods. A recent example is the approval of rapeseed protein isolate - A1175 – Rapeseed protein isolate as a novel food (foodstandards.gov.au)	**Australia**
-Canada has an existing specific regulatory framework for simulated meat and poultry products. However, with the rapidly evolving plant-based protein alternative market, there have been issues identified recently including the fortification requirements, minimum protein quality, and certain labelling requirements. Terminology that is/isn't permitted for these products has also been raised as an issue. Canada is in the process of updating guidance for these products with the aims to provide greater clarity about the application and	**Canada**

interpretation of the regulations. Canada restricts the addition of vitamins, mineral nutrients and amino acids to foods. While simulated meat and poultry products are permitted to contain prescribed amount of certain added nutrients, no such permission exists in Canadian regulations for other plant-based protein products such as plant-based beverages, cheeses, egg and fish substitutes. Requests for fortification of plant-based products has created issues. The addition of certain nutrients to plant-based beverages and cheeses is temporarily permitted through policy.	
-● Is there a need to have a harmonized definition resp. food category? Plant based meat alternatives (does not cover the whole product category of “plant-based protein alternatives) ● See chapter 4.3 of the FAO report “Thinking about the future of food safety” for plant-based protein alternatives**Pathogenic microorganisms originating from raw ingredients require validated heat treatments and re-contamination during processing must be avoided. Spoilage bacteria do also play an important role. Depending on growing and harvesting conditions of plant materials, residues of pesticides or traces of heavy metals may be present. Allergic reactions may be expected for soy and lupins; individuals that are allergic to peanuts may cross-react to pea protein.	**EU Specialty Food Ingredients**
-There is an increased demand for plant-based alternatives to meat in Europe due to growing awareness of health and environmental matters. The qualification as a new protein from the regulatory perspective will depend on a number of elements, such as the production process, the processing technology used, the source, the history of consumption of that protein, composition, etc.	**European Union**
-EUVEPRO believes that innovation in the development of plant-based proteins is crucial to provide high quality and versatile plant-based proteins. Plant-based proteins have a big potential in the shift to more balanced diets and to secure sufficient food for the growing world population. However, regulations are still an obstacle for new protein development and market access in Europe.	**European Vegetable Protein Association**
-Some countries require that meat alternatives be nutritionally equivalent to their conventional counterparts or meet certain set nutritional standards. While some alternative proteins are meant to directly mimic conventional meat, others are not and have different nutritional profiles. Requiring nutritional equivalence for all alternative proteins stifles innovation and reduces options available in the marketplace, including, for example, those with more fiber or less saturated fat. Differing nutritional standards in various countries can also create barriers to trade.	**Good Food Institute**
-Processed plant product is preferable to to the term "plant-based protein alternative"These products are highly processed.These products should not be named with reference to animal species or using butcher's, delicatessen or fish trade terminology.	**International Meat Secretariat**
There’s no specific standard for the plant-based protein, however specific provision on labeling can cover plant-based protein product.	**Malaysia**
Regulatory approaches - see above	**Norway**
-Guideline for new technology for plant-based protein alternatives including gene editing technology	**Republic of Korea**
-There is still no standard for plant-based protein alternative. Plant based protein and components should be defined clearly.	**Thailand**

-The scope of this category is hugely diverse. It may be more helpful to provide examples of products being referred to guide work in this area.	**United Kingdom**
Food uses of these ingredients have been reviewed by FDA within existing regulatory frameworks, and with the safety standard of reasonable certainty of no harm. The main considerations for safety include the production system (fermentation, mechanical processing, chemical extraction etc), the products (protein of interest) and by-products (antinutrients, toxicants, if any), amino acid profile (protein digestibility corrected amino acid /PDCAAS score, for example), stability, dietary exposure, and their safety in the intended use.	**USA**

REGULATORY MATTERS – <u>SEAWEED</u>

New species of seaweed may require pre-market approval as novel foods. In addition, the selective extraction or purification of constituents into more refined products may require pre-market approval.Levels of iodine managed through a Maximum Level (ML). Australia tests imports of some varieties of seaweed for levels of iodine and inorganic arsenic:https://www.awe.gov.au/biosecurity-trade/import/goods/food/type/brown-seaweed	**Australia**
-Existe sólo legislación general, no se tratan en forma especificas “nuevos alimentos” por lo tanto se adecua a lo existente y no se representa legalmente lo necesario para su desarrollo y comercialización.Dependiendo del Uso: consumo animal, consumo humano, uso en la agricultura.Nuestro Reglamento Sanitario de los Alimentos (RSA), establece:RSA: De los aceites y mantecas o grasas comestibles de origen animalARTÍCULO 255.- Aceites comestibles de origen marino son los obtenidos de animales marinos y algas, con exclusión de anfibios y reptiles, de consistencia fluida a 15ºC, que no han sido sometidos a proceso de hidrogenación. Los aceites de algas deberán ser autorizados por el Ministerio de SaludDS N°2/2016 SAG Insumos visados para uso en agricultura orgánica· Extractos de algas· Algas marinas Resolución 1992/2006 SAG ESTABLECE NOMINA DE ADITIVOS AUTORIZADOS PARA LA ELABORACION Y FABRICACION DE ALIMENTOS Y SUPLEMENTOS PARA ANIMALESSustancias naturales usadas con especies y otros condimentos y saborizantes:1 Laminaria spp. Y Nereocystis spp. Algas pardas (Kelp)2 Porphyra spp. y Rhodymenia palmata (L.) Grev. Algas rojas3 Rhodymenia palmata Alga DulceExtractos naturales (libre de solventes) usados en conjunto con especias, condimentos y saborizantes:1 Laminaria spp. Y Nereocystis spp., Algas pardas (Kelp)2 Porphyra spp. y Rhodymenia palmata (L.) Grev. Algas rojas	**Chile**
- The Danish Veterinary and Food Administration is in a working process to evaluate the possible legal barriers for developing and using seaweed products for food and feed.	**Denmark**
-Besides their uses in other sectors, algae are also becoming an important source of alternative protein food source in the drive for sustainable food systems and global food security. From the regulatory perspective, in the EU, a number of macroalgae species (e.g. Hizikia fusiforme, Laminaria digitata), are not considered novel food as they have a documented history of consumption before 15 May	**European Union**

1997. Other seaweeds may be novel. There are provisions in the EU Novel Food Regulation to determine the novel food status of a food if food business operators are unsure.	
-A Preliminary Study on Farming Potential of Seaweed Species Present in Fiji – FAO). Most of this edible seaweed are often sold in municipal markets as raw and have not been value added to new products. Supply can be from small outer islands or coastal areas of the main islands of Viti-Levu & Vanua-Levu. The only seaweed that has been value added and has reached international markets is 'Nama' (Caulerpa racemosa), not as a food product but as a beauty therapeutic product. Apart from this product, edible seaweeds are consumed locally and value addition is still at its initial stage.	**Fiji**
We are facing challenges to classify seaweed in the right commodity as it is neither an animal nor a plant. However, there are safety limit for heavy metals (arsenic, lead and cadmium) in seaweed established in the regulations (Table 1A, 1B and 1E of the Fourteenth Schedule, Regulation 38, Food Regulations 1985)	**Malaysia**
There is no specific Norwegian legislation on food safety on seaweed. Seaweed species and products which are defined as novel foods are subject to a pre-market authorisation procedure in the EEA – see above.	**Norway**
-- Guideline for risk assessment on the seaweed and products with seaweed	**Republic of Korea**
The ingredients that have been reviewed by FDA have fallen within existing regulatory frameworks, and with the safety standard of a reasonable certainty of no harm to consumers. A seaweed food ingredient can be the biomass or as a source of an ingredient that would be added to food. The safety issues for such an ingredient would include the safety of the source (including identity, composition), the process scale up (specifications, manufacturing controls, Good Manufacturing Practices (GMP), raw materials used etc.), article of commerce (biomass, ingredient produced by the microalgae), dietary exposure and safety (anticoagulant activity, immunomodulatory effects) of the article of commerce for its intended use(s).	**USA**

REGULATORY MATTERS - <u>EDIBLE INSECTS</u>

Respecto a antecedentes normativos internacionales, se cuenta con documentación y normativa de referencia de la FAO ("Insectos comestibles. Perspectivas de futuro para la alimentación y la seguridad alimentaria" - 2013), Australia / Nueva Zelanda, Unión Europea, Dinamarca, Suiza, Bélgica y Estados Unidos. A modo de resumen, se presentan los puntos más relevantes:	**Argentina**
Edible insects are considered on a case-by-case basis to determine whether pre-market approval is necessary.Several species of insects have been considered by the Advisory Committee on Novel Foods as either traditional foods (e.g. green tree ants which have a history of safe consumption by First Nations communities in Australia) or non-traditional but not novel foods (e.g. super mealworm, house crickets and mealworm beetle, which have a history of safe consumption in other countries). For these particular edible insects, no pre-market approval was required.	**Australia**

Insectos ~~comestibles~~comestibles (no permite dejar comentarios en la casilla correspondiente) Existe sólo legislación general, no se tratan en forma especificas “nuevos alimentos” por lo tanto se adecua a lo existente y no se representa legalmente lo necesario para su desarrollo y comercialización.	**Chile**
A nivel nacional aún no se ha emitido un marco normativo estandarizado sobre temas relevantes como: residuos permisibles en este alimento, etiquetado, prácticas productivas entre otras.	**Costa Rica**
Since insects are new farmed animals, there is a need for new feed for insects. The Danish Veterinary and Food Administration is working with the Research and Innovation sector to explore if it can be safe and sustainable to open some of the EU feed bans to use this subset as feed for insects.	**Denmark**
–Edible insects have the potential to become an additional source of alternative protein in the drive for sustainable food systems and global food security. They are considered novel foods under the EU Novel Food Regulation.	**European Union**
The Kingdom of Saudi Arabia follows the Islamic approach in regulating some food products, and the technical regulation SFDA/FD/GSO 2055-1 stipulates “HALAL FOOD - Part 1 : General Requirements” has stated Scorpions and all types of insects, worms and animals prohibited to be killed by Islamic Rules and the like such as ants, bees, woodpeckers and hoopoes are non-halal, except locusts and unavoidable bee parts falling in honey.	**Kingdom of Saudi Arabia**
Currently there is no specific national standard for edible insect.	**Malaysia**
–Regulatory approaches - see above	**Norway**
–- Guideline for safety assessment of edible insects· Definition and scope of edible insects· Criteria for residual veterinary drugs and pesticide residues· Management measures for allergy caused by edible insects· Guidelines for food insect breeding facilities and storage facilities before processing· Standard manufacturing process, storage method, etc. to prevent the possibility of rancidity due to high fat content, etc	**Republic of Korea**
Enabling policy and regulatory frameworks for adequate control	**Uganda**
One application currently progressing in the UK, with more expected to be submitted.	**United Kingdom**
– These ingredients could be regulated as food additives to assure that they meet the safety standard for their intended use(s) in the United States. One major safety issue for edible insects is cross-reactive allergenicity with known allergens (shellfish), which would have to be addressed through labeling statements, demonstrated to be protective of sensitive consumers (see below).	**USA**

REGULATORY MATTERS - <u>3-D PRINTED FOODS</u>

It is likely these will be made up of many ingredients, which may or may not require pre-market approval. Food produced via a printing process may require pre-market approval as a novel food.FSANZ has not received any applications for pre-market approval for 3D printed foods.	**Australia**
–There are many regulatory questions associated with 3-D printed foods: who is responsible for the food, for example, for compliance (who is the regulated party – the printer company?); is it safe, is it nutritionally equivalent, is it authentic? What do you call it? Do you have to identify it as such on the label?	**Canada**
Alimentos impresos en ~~3-D~~3-D (no permite dejar comentario en la casilla correspondiente) Existe sólo legislación general, no se tratan en forma especificas “nuevos alimentos” por lo tanto se adecua a lo existente y no se representa legalmente lo necesario para su desarrollo y comercialización	**Chile**
–To our knowledge, the foods that can be 3D printed are limited to the processes available. Material extrusion is by far the most common process for 3D printing food, and requires paste-like inputs like purées, mousses, and other viscous foods. The use of 3D technology per se may not be a sufficient criterion to automatically classify a 3D produced food as being novel as additional elements (e.g. composition, changes in structure, nutritional value, etc.) will need to be considered.	**European Union**
No information.	**Malaysia**
Regulatory approaches - see above	**Norway**
–- Guidelines for safety assessment of 3-D Printed for food production· Hazards for 3-D printing used in food production and provide guidelines for safety evaluation· Standards regarding to the absorption rate of powders, pastes, particles, etc., which are possible as cartridge materials· Stability and safety after and before being cooked	**Republic of Korea**
No applications yet received for authorisation as a novel food. Novel status of products is likely to be assessed on a case-by-case basis, depending on whether there have been significant changes to the composition or structure of the food.	**United Kingdom**
– The use of already authorized ingredients in 3-D printed foods would not require additional review by FDA unless the printed use is significantly different than those uses already allowed for the ingredient. In those instances, the safety of the expanded use would be considered via existing regulatory mechanisms for ingredients.	**USA**

REGULATORY MATTERS – <u>MICROALGAE</u>

In some cases, pre-market approval may be required as a novel food. Depending on the intended use of microalgae (or products derived from microalgae), it may require pre-market approval as a nutritive substance.	**Australia**

Existe sólo legislación general, no se tratan en forma especificas “nuevos alimentos” por lo tanto se adecua a lo existente y no se representa legalmente lo necesario para su desarrollo y comercialización. Dependiendo del Uso: consumo animal, consumo humano, uso en la agricultura RSA: De los aceites y mantecas o grasas comestibles de origen animal ARTÍCULO 255.- Aceites comestibles de origen marino son los obtenidos de animales marinos y algas, con exclusión de anfibios y reptiles, de consistencia fuida a 15ºC, que no han sido sometidos a proceso de hidrogenación. Los aceites de algas deberán ser autorizados por el Ministerio de Salud DS N°2/2016 SAG Insumos visados para uso en agricultura orgánica · Extractos de algas · Algas marinas Resolución 1992/2006 SAG ESTABLECE NOMINA DE ADITIVOS AUTORIZADOS PARA LA ELABORACION Y FABRICACION DE ALIMENTOS Y SUPLEMENTOS PARA ANIMALES Sustancias naturales usadas con especies y otros condimentos y saborizantes: 1 Laminaria spp. Y Nereocystis spp. Algas pardas (Kelp) 2 Porphyra spp. y Rhodymenia palmata (L.) Grev. Algas rojas 3 Rhodymenia palmata Alga Dulce Extractos naturales (libre de solventes) usados en conjunto con especias, condimentos y saborizantes: 1 Laminaria spp. Y Nereocystis spp., Algas pardas (Kelp) 2 Porphyra spp. y Rhodymenia palmata (L.) Grev. Algas rojas	**Chile**
● Lacking of a clear and common agreed definition of microalgae. ● Safety on species level is crucial for safety review (toxin producer versus non-toxin producer in the same family) – a list of known microalgae qualified as safe resp. a taxonomic guidance would be helpful. ● Safety aspect to be addressed:● Quality of growing substrate; ● Microbial contamination due to open air production (pathogens, viruses); ● Contamination with heavy metals and phycotoxins (microcystin); ● Allergic reactions to some microalgae products have been reported. ● Analytical method description resp. method validation e.g., microcystin.	**EU Specialty Food Ingredients**

–Similar to seaweed, in the EU there are novel microalgae species which have been authorised under the EU Novel Food Regulation and listed in the Union list of authorised novel foods	**European Union**
Limited information	**Malaysia**
– There is no specific Norwegian legislation on food safety on microalgae. Microalgae which are defined as novel foods are subject to a pre-market authorisation procedure in the EEA – see above.	**Norway**
- Guidelines for safety evaluation of microalgae· Systematic standardization, standardization and certification system required to secure the safety of raw materials and extracted substances (toxicity evaluation, prevention of rancidity, etc.)· Production process management standards for storage methods and hygiene and safety management of production facilities (photobiological incubator, fermenter, open culture facility, etc.)	**Republic of Korea**
– Food uses of the ingredients that have been reviewed by FDA have fallen within existing regulatory frameworks, and with the safety standard of reasonable certainty of no harm. FDA has received a few Generally Recognized as Safety (GRAS) notices for food uses of ingredients sourced from microalgae (biomass).	**USA**

REGULATORY MATTERS – <u>OTHER</u>

~~Otros (especifique)~~Preparados vegetales bebibles	**Argentina**
~~Otros~~ Bebidas vegetalesOtros (especifique)	**Argentina**
En cuanto a las representaciones gráficas y/o leyendas, a nivel nacional durante el debate técnico se acordó que no deben existir leyendas o alegaciones que relacionen estos productos con la leche (ni que se refiera a que la reemplaza o sustituye o bien que sean productos de una calidad nutricional superior a la misma) y que se debe contemplar la utilización de representaciones gráficas de los ingredientes distintivos, así como la declaración del contenido porcentual de dichos ingredientes. Se continúa evaluando la posibilidad de representaciones gráficas en relación a los ingredientes facultativos. Por el momento no se avanzó en otros aspectos.	**Argentina**
Actualmente, sólo se cuenta con normativa internacional de referencia de Codex para productos/bebidas a base de soja.	**Argentina**
Argentina se encuentra trabajando en el desarrollo de una propuesta para la incorporación al Código Alimentario Argentino de nuevas categorías de alimentos en relación a los preparados vegetales bebibles a base de algún ingrediente distintivo (maní, soja, frutos secos, cereales, semillas oleaginosas, coco, pseudocereales, entre otros). Dado el emergente mercado que ofrece este tipo de alimentos, la amplia variedad que se encuentra disponible y el crecimiento de la adopción de dietas vegetarianas y veganas por parte de la población a nivel mundial, se considera que es un tema que el Codex podría abordar. Las propuestas que están tratándose a nivel nacional se basan en la evaluación de los siguientes ejes: establecer cuáles son los ingredientes que le aportan la identidad a estos productos, fijar lineamientos en cuanto a su rotulado y a la cantidad mínima en la que	**Argentina**

deben estar presentes dichos componentes a fin de otorgar un aporte nutricional distintivo respecto de otras bebidas y generar una denominación	
-El Ministerio de Salud de Chile, cuenta con antecedentes generales, en las resoluciones del Instituto de Salud Pública (ISP) de las sustancias incluidas como extractos vegetales en alimentos que tienen o se les declara efectos farmacológicos.	**Chile**
- Many of the above products need a novel food approval in EU. We don't know to which degree that is also the case in other parts of the world. Definitions should maybe be harmonized worldwide.	**Denmark**
-Plant cell cultures● Consumer acceptance can be a challenging factor. ● In contrast to animal cell cultures, there is a long history of plant cell cultures for the production of secondary metabolites and food ingredients.● How to deal with engineered cell cultures and derivate produced from them.	**EU Specialty Food Ingredients**
-Food consisting of engineered nanomaterials; food consisting of, isolated from or produced from material of mineral origin, bioactive substances, vitamin metabolites.	**European Union**
-With respect to food standards, if a guideline or SOP could be develop for mix food products. It is often quite difficult to confirm which Food Safety Standards do we have to comply with when interpreting laboratory results of mixed/blended food products, especially when individual commodity have their own set of standards. (In the case of mixed spices, e.g. chilli powder & turmeric powder) as 1 product. And if it could be raised with relevant Codex commodity committee to develop a guideline or SOP regarding mixed/blended food products.	**Fiji**
1. Non-specified food including Novel food: No person shall manufacture or import any non-specified food or food ingredient, as the case may be, except with the prior approval of the Food Safety and Standards Authority of India (National Food Regulatory Body). 2. Proprietary food: The Food Business Operator (FBO) shall be fully responsible for safety of the proprietary food in respect of human consumption.	**India**
-Codex should establish novel food standard because each national regulation of novel food is different and inconsistent. Particularly, the definition of novel food and new food source should be clarified.	**Thailand**

LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES

General Comment – For the most part, Canada does not believe there would be any specific requirements for the labelling for these products, outside of what is identified below. There may be specifics about how they are classified and how to name them.	**Canada**
In the EU, there are clear horizontal rules on the labelling of food set out under the Food Information to Consumer Regulation (EU) No 1169/2011.	**European Union**

In addition, a novel food may have additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population. The EU and its Member States (EUMS) are of the view that a clear labelling requirement is needed to ensure that consumers are not misled and are well informed to make informed, healthy and sustainable food choices. Labelling and providing clear and factual information to consumers might be particularly challenging in situations like cultured meat or alternative proteins sourced via novel/innovative methodologies which although somehow linked to traditional food sources (animals and plants) are considerably different.	
Provisions regarding labelling are regulated by government under regulation on labelling of processed food. Information on the processing technology for certain food such as genetically modified food or irradiated food must be stated on the label.	**Indonesia**
Labeling on "new products" should clearly inform the consumer of what raw materials, what technology was used to produce the "new food". This will allow the consumer to follow not only their consumer possibilities and preferences, but also to prevent certain health risks (for example, an allergic reaction).	**Kazakhstan**

LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES - <u>CULTIVATED MEAT, SEAFOOD, AND DAIRY</u>

Labelling requirements for all domestic and imported food for sale in Australia and New Zealand are contained in the Australia New Zealand Food Standards Code (the Code). Generic labelling requirements are based on the protection of public health and safety, provision of adequate information relating to food to enable consumers to make informed choices and prevention of misleading or deceptive conduct and include:· Food identification: a name or description sufficient to indicate the true nature of the food, unless the food has a prescribed name· Labelling of ingredients: a common or descriptive name to indicate the true nature of the ingredient· Nutrition information· Lot identification· Name and business address of the supplier· Allergen declarations and other warning and advisory statements· Date marking· Directions for use and storage· Conditions for voluntary nutrition content claims and health claims.Cultivated meat, seafood, and dairy does not currently have regulatory approval to be sold in Australia. A pre-market assessment of these foods would consider the application of existing generic labelling requirements and whether any additional, specific labelling requirements are warranted. However as noted above, labelling requirements apply to the food as sold. The Code does not usually require labelling that refers to specific production systems that are used in the manufacture of food.The Code can be accessed from https://www.foodstandards.gov.au/code/Pages/default.aspx	**Australia**
En términos generales para toda la tabla, es emitir directrices de uso común entre los países miembros para regular el etiquetado de los productos alternativos a la carne, leche y mariscos. De esta forma se protege al consumidor y se evitan prácticas comerciales poco	**Chile**

equitativas o desleales. Sobre este punto es importante señalar que se debe rotular la verdadera naturaleza de los productos y de los ingredientes que los componen, por lo que Chile sugiera que se debería hacer un trabajo relacionado con la determinación de dicha naturaleza.	
- The horizontal food labelling regulation applies for these foodstuffs. Marketing standards and specific labelling regulation for milk, milk products, fish and aquaculture products have to be taken under consideration.	**Denmark**
-Clear and accurate labeling is essential to consumer protection and fair practices in trade. Codex labeling standards and guidelines should not mandate the use of inaccurate terms, disparaging terms, or terms that consumers do not understand on the labels of alternative protein products. They should allow the use of words that are commonly used to describe products well-known by consumers (e.g., burger, sausage, chicken, milk) so long as clear qualifying language is used where necessary to avoid confusion. Moreover, in the case of cultivated meat products that would have the same physiological effects as conventional products, labeling guidelines must consider proper allergen labeling including the prominent declaration of ingredients that may cause hypersensitivities (such as egg, crustaceans, fish, and bovine milk) using terms that are fully understood by consumers.	**Good Food Institute**
-Accurate, truthful representation. Verifiable, transparent standards in production and supply.The term "cultivated muscles cells" should be used instead of "cultivated meat". The term "meat" refers to all parts of an animal that are intended for human consumption or have been found to be safe and suitable for human consumption. This is not the case of the new food source, which comes from stem cells, cultivated to replicate and differentiate into muscle cells.	**International Meat Secretariat**
When labeling these products it must be emphasized that they are produced in laboratories by culture, for example: "synthetic protein product made from beef cells".	**Kingdom of Saudi Arabia**
Currently there is no national standard on cultivated meat, seafood and dairy, including on labelling requirement.	**Malaysia**
In the EEA (European Economic Area), which includes Norway, novel foods are subject to the general labelling requirements. For novel foods it may be necessary to provide for additional labelling information, regarding the description of the food, its source, its composition or its conditions of intended use - to ensure that consumers are sufficiently informed of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population.	**Norway**
-- Guidelines for terms related to 'cultivated food'· Need to prevent misunderstanding and confusion between consumers and manufacturers by establishing labelling regulations that can be distinguished from conventional livestock products for the definition of cultivated food, product names, and components labelling	**Republic of Korea**
-The production technology should be displayed on the label.Rationale: It is the new and unfamiliar technology to consumer.	**Thailand**
It may be necessary to allow for the clear distinction between ‘natural’ meat, seafood and dairy products and those derived from artificial cultivation in order to ensure consumer choice and avoid misleading information. It may also be necessary to think about how information such as country of origin and method of farming might be used to describe cultivated products.	**United Kingdom**

FSIS will develop regulatory requirements to ensure the truthful and not-misleading labeling of food products derived from the cultured cells of livestock and poultry. On September 3, 2021, FSIS published an advance notice of proposed rulemaking (ANPR) to request comments pertaining to the labeling of meat and poultry products comprised of or containing cultured cells derived from animals subject to the Federal Meat Inspection Act or the Poultry Products Inspection Act. Issues raised in the comments submitted in response to this ANPR will inform future rulemaking to establish labeling requirements for these products. More information can be found in FSIS' ANPR (86 FR 49491, https://www.federalregister.gov/documents/2021/09/03/2021-19057/labeling-of-meat-or-poultry-products-comprised-of-or-containing-cultured-animal-cells) and on FSIS' website at https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/foods-made-cultured-animal-cells. FSIS extended the comment period by 30 days, and the ANPR comment period closed on December 2, 2021. FDA published on October 7, 2020, a similar Request for Information on labeling of foods comprised of or containing cultured seafood cells (85 FR 63277, https://www.federalregister.gov/documents/2020/10/07/2020-22140/labeling-of-foods-comprised-of-or-containing-cultured-seafood-cells-request-for-information). Accordingly, FSIS is working with FDA to develop joint principles for the labeling of cell-cultured food products under their respective jurisdictions. FSIS will preapprove all labeling of human food products derived from the cultured cells of livestock and poultry, including labeling claims and FSIS inspectors will verify labeling accuracy during inspection.With regard to dairy the United States is concerned about the potential impact of work on labelling of ingredients already defined in other standards – e.g., milk is defined as "the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or further processing.". Since these definitions exist already in Codex standards (in particular, the General Standard for the Use of Dairy Terms CXS206-1999), it would be best to understand the scope of this work prior to commencing. Any work should not conflict with existing standards such as GSUDT and should seek to prevent consumer confusion with appropriate labelling.	**USA**

LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES - <u>FERMENTATION-DERIVED INGREDIENTS</u>

Generic labelling requirements noted above apply to these ingredients. As noted above, labelling requirements apply to the food as sold. The Code does not usually require labelling that refers to specific production systems that are used in the manufacture of food. GM foods and ingredients (including food additives and processing aids) that contain novel DNA or novel protein must be labelled with the words 'genetically modified'. This means that where GM bacteria are used to produce the ingredient, but there is no novel protein or DNA present in the ingredient, it will not be required to be labelled as GM. As noted above, precision fermentation can generate substances identical to those in human milk. When approving Application A1155 – 2'-FL and LNnT in infant formula and other products, FSANZ prohibited infant formula products containing 2'FL or LNnt from carrying references to 'human milk identical oligosaccharide', 'human milk oligosaccharide', 'HiMO' or 'HMO' (or words or abbreviations of similar effect).	**Australia**
-En el caso de carne cultivada en laboratorio es importante destacar el origen de la carne, es decir, que proviene de un cultivo celular en lugar de un animal sacrificado.	**Chile**

Some fermentation processes involve the use of GM microorganisms, which depending on the process used are present or absent from the final product. There is lack of clarity regarding the labelling of such products, particularly if the GM microorganism is not present in the final product.	**Food Industry Asia**
Clear and accurate labeling is essential to consumer protection and fair practices in trade. Codex labeling standards and guidelines should not mandate the use of inaccurate terms, disparaging terms, or terms that consumers do not understand on the labels of alternative protein products. They should allow the use of words that are commonly used to describe products well-known by consumers (e.g., burger, sausage, chicken, milk) so long as clear qualifying language is used where necessary to avoid confusion. Moreover, in the case of fermentation-derived ingredients that would have the same physiological effects as conventional products, labeling guidelines must consider proper allergen labeling including the prominent declaration of ingredients that may cause hypersensitivities (such as egg, crustaceans, fish, and bovine milk) using terms that are fully understood by consumers.	**Good Food Institute**
Saudi Arabia has national legislations that are based on religious grounds, all products must not be alcohol-free, unless the standard for ethyl alcohol residues in foods stipulates that.	**Kingdom of Saudi Arabia**
Currently there is no national standard on fermented-derived ingredients.	**Malaysia**
Fermentation-derived ingredients- Guidelines for product names related to 'fermented-derived ingredients'· Guidelines for product names are needed so that consumers can identify the purpose of using raw materials (direct consumption/ improvement of functionality in food)- Regulations on indication of completion of relevant evaluations taking into account consumer concerns about antibiotic resistance and virulence genes	**Republic of Korea**
Provision of appropriate information about the products	**Uganda**
Fermentation-derived food ingredients that are allergenic proteins or are proteins from known allergenic sources may require consideration for labeling as containing an allergen (e.g., beta-lactoglobulin produced by fermentation used in foods that do not contain milk). Allergenic fermentation media and formulation components may also require labeling in the United States.	**USA**

LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES - PLANT-BASED PROTEIN ALTERNATIVES

Generic labelling (FSANZ code -https://www.foodstandards.gov.au/code/Pages/default.aspx) requirements apply to plant-based protein alternatives. Some foods, including milk and some meat products, are defined in the Code and can only be sold using a specific name or representation if they meet the definition and any composition requirements.Allergen labelling may be required where appropriate	**Australia**

-Claims and terminology:• Terminology that is and is not permitted for certain plant-based protein alternatives has been a topic of increasing interest. Some foods, such as milk and certain meat preparations have prescribed compositional standards in national regulations. The ability for plant-based protein foods and beverages which do not meet these compositional standards to use standardized food terminology as part of their common names and branding on labels is a point of contention. • Nutrition and health-related statements and claims (e.g. nutrient content claims, health claims) that are or are not permitted for certain plant-based protein alternatives. • Permitted protein claims include both protein content and protein quality factors. Several plant-based protein alternatives may not qualify for protein claims.	**Canada**
-EUVEPRO has noticed that the current labelling provisions across the Standard for Vegetable Protein Products (CXS 174-1989) and the Standard for Soy Protein Products (CXS 175-1989) reflect different degrees of provisions.The VPP Standard describes the protein product based on the protein (N x 6.25) content of 40% or more (dry weight). However, the Standard for Soy Protein Products (CXS 175-1989) does distinguish between protein flour, concentrate and isolate products based on protein content. It could be considered whether more detailed descriptions of plant protein products would be needed in the VPP Standard also.	**European Vegetable Protein Association**
-- The definition of “plant-based” and “100% plant-based” has yet to be clearly defined in the majority of countries worldwide, which is creating consumer confusion in terms of if the products labelled as such are vegan, vegetarian, contain animal-derived ingredients, or have been produced using animal or microbial genes. Varied certification schemes by NGOs and civil society groups have attempted to fill this regulatory void, however this has exacerbated consumer confusion as different schemes have differing criteria. It may therefore be beneficial to employ a standard of identity and define characterising ingredients for these products. - Consideration needs to be given to how non-animal and non-plant ingredients (such as water, gasses, minerals, salt etc.) should be treated.	**Food Industry Asia**
-Clear and accurate labeling is essential to consumer protection and fair practices in trade. Codex labeling standards and guidelines should not mandate the use of inaccurate terms, disparaging terms, or terms that consumers do not understand on the labels of alternative protein products. They should allow the use of words that are commonly used to describe products well-known by consumers (e.g., burger, sausage, chicken, milk) so long as clear qualifying language is used where necessary to avoid confusion.	**Good Food Institute**
-Accurate, truthful representation. Nomenclature (what can be associated with terms like meat, burger, steak, sausage, etc.).There is a need to regulate the use of traditional animal food names in the description, marketing or promotion of manufactured and marketed plant protein products in order to enhance consumer protection against the use of inappropriate terms on food.The following names should not be used to describe a processed plant-based food:1) a legal name for which no addition of vegetable proteins is provided for by the rules defining the composition of the foodstuff concerned2) a name referring to the names of animal species and groups of species, to morphology or to animal anatomy 3) a name using the specific terminology of the butcher's, delicatessen or fish trade; 4) a name of a foodstuff of animal origin representative of commercial usage.	**International Meat Secretariat**
There are specific provisions on labeling that can cover plant-based protein product	**Malaysia**
Regulatory approaches - see above	**Norway**

-- Establishment of product name and type classification criteria for vegetable alternative protein food· Need to establish regarding to mark other food types such as sausage, ham, milk, etc. on the product name of plant-based protein alternatives to prevent misconceptions or confusion· Need to be labelled with clearly different with traditional livestock products	**Republic of Korea**
-Label should consist of ingredient and nutritional value Rationale: 1. There is some plant based protein product mixed with animal protein and claim it to be plant-based protein product.2. The nutritional value profile of protein, especially essential amino acid from plant is different from the protein from meat.	**Thailand**
There is an ongoing discussion on these foods, especially where they 'mimic' some properties (usually only visual and some organoleptic) of the original meat and dairy product. Whether they should be allowed to use marketing terms and imagery otherwise either reserved for, or taken by consumers to mean, the original meat or dairy product is a key question.	**United Kingdom**
Labeling aspects to be considered would include potential allergenicity as well as identity to differentiate between plant-based alternatives and traditional protein food ingredients including areas of nutrition	**USA**

LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES – SEAWEED

Generic labelling (FSANZ code -https://www.foodstandards.gov.au/code/Pages/default.aspx) requirements apply.	**Australia**
-There's no specific standard for the seaweed, however specific provision on labeling can cover seaweed product.	**Malaysia**
Labelling of seaweed products regarding information of use to ensure protection of the consumers is an important aspect, as there is not much tradition for using such products in the diet in Norway and Europe. There is no specific Norwegian or EU/EEA legislation on labelling of seaweed for the use as food, but Norwegian producers have established a voluntary labelling system for products with high iodine content, to inform consumers on a possible risk by eating too much, particularly for vulnerable groups. Seaweed defined as novel foods in the EEA could be subject to specific labelling requirements – see above.	**Norway**
-- Guidelines for labelling the product name, protein content, and components of seaweed	**Republic of Korea**
Codex has already established a regional standard for seaweed, CXS 323R-2017 Regional Standard for Laver Products. This regional standard addresses the labeling needs for this product using the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985).	**USA**

LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES - EDIBLE INSECTS

Respecto al etiquetado de los productos, es importante mencionar que los productos para consumo humano a base de insectos y que se comercializan en la actualidad en los países contienen en su rótulo la leyenda de advertencia en cuanto a su alergenicidad, similar a la de los crustáceos.	**Argentina**
Generic labelling (FSANZ code -https://www.foodstandards.gov.au/code/Pages/default.aspx) requirements apply. No edible insects have required pre-market approval in Australia and New Zealand, so any need for additional specific labelling requirements have not been considered.Potential for cross-reactivity with shellfish/crustacea allergy, hence allergen labelling may need to be considered.	**Australia**
Además de la información que debe estar disponible para cualquier producto alimenticio, para este producto en particular los consumidores requieren evidencia de la cantidad de proteína en el producto final, información sobre la especie del insecto y cualquier otro dato respcto a la calidad e inocuidad del alimento.	**Costa Rica**
–No information	**Malaysia**
The European Food Safety Authority (EFSA) has conducted a risk profile related to production and consumption of insects as food and feed (EFSA 2015). The opinion presents potential biological and chemical hazards as well as allergenicity and environmental hazards associated with farmed insects used as food and feed taking into account the entire chain, from farming to the final product. The opinion also addresses the occurrence of these hazards in non-processed insects, grown on different substrate categories, in comparison to the occurrence of these hazards in other non-processed sources of protein of animal origin.	**Norway**
- Guidelines for labelling the product name, protein content, and components of edible insects· Guidelines on the ingredients to be indicated, such as the agreed product name, protein content, allergies, etc., for edible insects itself or the food containing the same food are required(protein content labelling required for each products since the protein content of each insect species are different)	**Republic of Korea**
Allergens should be declared on the label.	**Thailand**
Presentation of adequate information about the products	**Uganda**
With seaweed and edible insects, there are potential food safety and allergen issues which would be dealt with under ‘novel food’ processes as set out above. Otherwise normal food information requirements would apply.	**United Kingdom**
– Edible insects would likely require special labeling statements to alert shellfish allergic consumers. The labeling statements would be a condition of safe use, and it would need to be demonstrated that the statement was sufficiently protective. There are potential concerns in particular about cross-reactivity for shrimp and shellfish-allergic individuals, based on data in the literature.	**USA**

LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES - 3-D PRINTED FOODS

Generic labelling (FSANZ code -https://www.foodstandards.gov.au/code/Pages/default.aspx) requirements apply. Information on label regarding storage conditions for printed foods may be required.	**Australia**
–No information	**Malaysia**
Regulatory approaches - see above	**Norway**
- Guidelines and standards for definition of food ink used in 3-D printed food, product name, and type classification display· When manufacturing 3-D printed foods, pre-treated food ink is absolutely necessary, and since specific nutrients and functional ingredients are pre-packed or distributed in cartridge form as food ink, the food ink should be marked as “Ink for 3-D printed foods” so that it can be distinguished from general food ingredients	**Republic of Korea**
As above, once novel foods requirements are met and the food determined as safe, normal food (in particular ingredient) labelling rules would apply.	**United Kingdom**
– It is not clear whether there is any intrinsic aspect of this production process that would result in the need to communicate additional information to consumers other than that already provided under existing labeling requirements.	**USA**

LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES – MICROALGAE

Generic labelling (labelling (FSANZ code -https://www.foodstandards.gov.au/code/Pages/default.aspx) requirements apply.	**Australia**
–Limited information	**Malaysia**
Regulatory approaches - see above	**Norway**
- Guidelines for labelling on product name, nutrient components, method of production	**Republic of Korea**

LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES - OTHER

~~Otros (especifique)~~Preparados vegetales bebibles En cuanto a las representaciones gráficas y/o leyendas, a nivel nacional durante el debate técnico se acordó que no deben existir leyendas o alegaciones que relacionen estos productos con la leche (ni que se refiera a que la reemplaza o sustituye o bien que sean productos de una calidad nutricional superior a la misma) y que se debe contemplar la utilización de representaciones gráficas de los ingredientes	**Argentina**

distintivos, así como la declaración del contenido porcentual de dichos ingredientes. Se continúa evaluando la posibilidad de representaciones gráficas en relación a los ingredientes facultativos. Por el momento no se avanzó en otros aspectos.	
¿Cuenta con información sobre aspectos del etiquetado pertinentes para la protección del consumidor y las prácticas comerciales equitativas? En cuanto a las representaciones gráficas y/o leyendas, a nivel nacional durante el debate técnico se acordó que no deben existir leyendas o alegaciones que relacionen estos productos con la leche (ni que se refiera a que la reemplaza o sustituye o bien que sean productos de una calidad nutricional superior a la misma) y que se debe contemplar la utilización de representaciones gráficas de los ingredientes distintivos, así como la declaración del contenido porcentual de dichos ingredientes. Se continúa evaluando la posibilidad de representaciones gráficas en relación a los ingredientes facultativos. Por el momento no se avanzó en otros aspectos.	**Argentina**
-Labelling aspects relevant to consumer protection and fair-trade practices:- Labelling to represent the true content of the product, as per labelling requirements in Codex Standards. Ingredients, additives to be specified whether added or not.- In case of blended/mixed products, a ratio of individual products should be clearly specified. - Foreign labelling on certain food products that is hard to read and understand – if there is a guideline developed that such product should be for local market only and if it is to be exported, then a common language that is understood by the majority should be used in its label. - Product that was destined to a specific country ends up in another country. - Production & Best before/Expiry date should be clearly stated on the label.- Origin, manufacturers, distributors, etc. should be clearly stated.	**Fiji**
-*For all alternative protein products:*- Use of the animal related terms e.g., meat, fish, milk, and use of language used traditionally to describe animal-based food e.g., sausage, burger, fillet is claimed by some to result in consumer confusion and unfair competition with traditional animal (meat and dairy) sectors. The need for the use of appropriate qualifying terms to prevent consumers being misled e.g., “imitation”, “plant-based” cell-cultured”, “cell-based” etc. has been adopted by some countries, such as Singapore and Japan.*For hybrid products:*- Clarity regarding the composition and content of hybrid products must be provided to prevent consumers being misled	**Food Industry Asia**
1. Non-specified food including Novel food: Based on approval given by the Food Safety and Standards Authority of India (National Food Regulatory Body). 2. Proprietary food: Proprietary food shall use only such additives and at such levels, as specified for the Category or Sub-category under the Regulations, to which the food belongs. Such Category or Sub-category shall be clearly mentioned on the label along with the generic name, nature and composition of the proprietary food. No health claims shall be made in respect of proprietary foods either on the product label or otherwise, unless it is substantiated by adequate and scientific evidence.	**India**
Any new work must be consistent with the Codex General Standard for the Labelling of Pre-packaged Foods (GSLPF).A core principle of the GSLPF is that foods shall be described and presented in a manner that ensures consumers are not misled or confused. We urge caution with language or assertions that imply that these new technologies and “new foods” would be better than the foods they are seeking to replicate or replace, e.g., avoiding statements that promote them as “game-changing innovations” as indicated in paragraph 5 of the background section of the circular letter.	**USA**

NUTRITIONAL ASPECTS

The EU Novel Food Regulation also requires that where the novel food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer. The EUMS are of the view that the nutritional aspects should be evaluated as part of the risk assessment.	**European Union**
It is very important that the nutritional value of a new food product is not lower than the value of the product that it is intended to be replaced. The assessment of the nutritional value of a new food product should include the risks assessment of the food's ingredients impact on human body as a whole, storage conditions and shelf life.	**Kazakhstan**
Under the UK's regulatory framework for novel foods the potential for consumers to suffer nutritional disadvantage by selecting a novel product over a counterpart is a cornerstone of the review process. It is recognised for many alternative protein sources there will be wider implications from changing patterns in the diet and differences in protein quality. Further consideration is needed on to what extent that could be assessed and addressed.	**United Kingdom**

NUTRITIONAL ASPECTS - <u>CULTIVATED MEAT, SEAFOOD, AND DAIRY</u>

FSANZ has not received any applications to permit cell-based meat, seafood or dairy as a GM food or a novel food. A pre-market assessment would consider the nutritional profile of the food. When applying for pre-market approval, applicants may also seek permissions for the fortification of cell-based meat, seafood or dairy with vitamins and minerals to align the nutritional profile with traditional foods.Some manufacturers may create cell-based meats, seafood or dairy products with a 'healthier' nutritional profile (e.g. lower saturated fat, higher fibre) than traditional foods	**Australia**
-Cell line, media, equivalency and finding the right comparator	**Canada**
En términos generales y aplica para toda esta tabla es que realizadas las definiciones generales o entendimiento transversal de lo que significa cada uno de los nuevos alimentos definidos en las casilla de esta tabla y de las anteriores, es necesario generar un Grupo de trabajo para determinar tanto en base a las recomendaciones de Codex como aquella que surjan para esta nueva "categoría" de alimentos (nuevos alimentos) los requerimientos nutricionales mínimos a informar. Por otra parte, se debe salvaguardar la información nutricional básica que determina cada país, y la información nutricional complementaria que se debe rotular cuando se hace declaración de nutricional específica, como pudiera ser el caso de la vitaminas y minerales.	**Chile**
-Need to study long-term impacts on health.No current evidence, and no data available, on nutritional composition. Currently lacking certain micronutrients specific to animal products (such as vitamin B12 and iron) and which contribute to good health. The positive effect of any (micro)nutrient can be enhanced if it is introduced in an appropriate matrix. In the case of in vitro meat, it is not certain that the other	**International Meat**

biological compounds and the way they are organized in cultured cells could potentiate the positive effects of micronutrients on human health. Uptake of micronutrients (such as iron) by cultured cells has thus to be well understood. Cannot exclude hypothesis of a reduction in the health benefits of micronutrients due to the culture medium, depending on its composition.	**Secretariat**
There is no established requirements and standards for these products.	**Malaysia**
-- Establishment of expected nutrient standards for cultivated foods· Need to set the minimum amount of major nutrients that can be expected when consumed for each source of cultivated food	**Republic of Korea**
FSIS is considering nutritional aspects of cultured meat and poultry within the context of the advance notice of proposed rulemaking (ANPR) referenced above. Caution should also be taken regarding assertations that cultivated foods are nutritionally equivalent or better than foods they are seeking to replace.	**USA**

NUTRITIONAL ASPECTS - <u>FERMENTATION-DERIVED INGREDIENTS</u>

As noted above, a recent example is Application A1186 – Soy leghemoglobin in meat analogue products. FSANZ assessed soy leghemoglobin as a nutritive substance (for the purpose of providing a source of iron to meat analogue products) and as a GM food. As noted above, precision fermentation can be used to produce substances identical to those in human milk. A recent example is Application A1155 – 2'-FL and LNnT in infant formula and other products. 2′-O-Fucosyllactose (2′-FL) and Lacto-N-neotetraose (LNnT) are oligosaccharides that naturally occur in human milk. FSANZ assessed these as GM foods (produced by GM Escherichia coli strains) and as nutritive substances. They are now permitted in infant formula products. The majority of micronutrients in nutritional supplements and fortified processed foods, such as B12 and riboflavin, are produced through fermentation, as are many flavouring components (The Good Food Institute (GFI), 2020).	**Australia**
Equivalency	**Canada**
-Contenido de vitaminas - Ácidos grasos saturados e insaturados.En términos nutricionales es importante establecer cuál es el contenido proteico, grasas, aminoácidos y otros compuestos. Como también es relevante la digestibilidad de este contenido nutricional. Analizar también el aporte nutricional de este tipo de productos.	**Chile**
No information	**Malaysia**
Establishment of nutritional quality standards for fermentation-derived ingredients· Need to set the minimum amount of major nutrients that can be expected when consumed	**Republic of Korea**
Ability for full understanding of the nutritional benefits	**Uganda**
Nutritional equivalency. For example, with respect to protein (should have similar protein digestibility corrected amino acid (PDCAAS) scores to commonly consumed proteins), fatty acid profile (algal oil as a source of DHA/EPA found in fish), substitutional use, depends on use and use level (for example, use in infant formula)	**USA**

NUTRITIONAL ASPECTS - PLANT-BASED PROTEIN ALTERNATIVES

Plant-based meat and dairy substitutes may have nutritional profiles that differ from traditional foods. For example, one study (Curtain et al. 2019) found differences in energy, fat, saturated fat and sodium levels between plant-based meat analogues and traditional meat products. As noted above, the Code provides permissions for the addition of some vitamins and minerals to meat and dairy analogues.If there are significant differences between the nutritional profile of these foods and beverages compared to traditional versions (e.g. between plant-based beverages and cows milk), may need to consider whether consumers understand these differences and whether nutrition labelling is sufficient to manage this.Infant FormulaFSANZ has identified emerging formulations based on non-traditional protein sources including pea, rice, almond, and buckwheat protein. Nutritionally infant formula must comply with the essential composition prescribed in Standard 2.9.1 of the Australia New Zealand Food Standards Code (the Code) be safe and suitable for use as sole source of nutrition and ensure that there are no anti-nutritive effects. Infant formula based on alternate proteins are required to undergo pre-market assessment and are considered novel within the infant population. Use in general foods· Pea and rice protein fermented by shiitake mycelia, not considered novel but was considered non-traditional by the Advisory Committee on Novel Foods (ACNF). FSANZ is yet to assess this substance.· ACNF considered potato protein isolate to be traditional and not novel when used in general foods as it is equivalent to potato protein consumed in the diet of general population. Similar, in principle, to other fractions of foods, such as whey from milk.Rapeseed protein isolate was considered to be a novel and non-traditional source of protein. FSANZ assessed rapeseed protein isolate through Application A1175 - Rapeseed protein isolate as a novel food.	**Australia**
-Some plant-based protein alternatives are considered simulated meat and poultry products. These products must contain certain nutrients and have a minimum protein quality, as they are considered a replacement for an animal-based food in the diet. A concern with some plant-based alternatives is the bioavailability and quality of the plant proteins, as well as other nutrients. In recent years issues have arisen regarding high levels of sodium, saturated fat, and sugar in some plant-based protein alternatives. This is a potential public health concern as consumers increasingly introduce these products to their diets.	**Canada**
- Eating less or no meat, and replacing animal foods with plant-based proteins is becoming more popular. However, as WHO also points towards*, some plant-based meat and dairy substitutes may not be better for people's health. Many of these plant-based substitutes can be defined as ultra-processed foods, which means they have a high energy density and tend to be high in sodium, saturated fat and free sugars, and lacking in dietary fibre and in vitamins and minerals found in unprocessed foods (including animal-based foods) and minimally processed plant-based foods. To assist policy-makers with developing evidence-based dietary guidelines, food policy and general health advice, more studies are need to provide better information about what kinds of foods can replace animal foods – with whole foods or minimally processed foods as a priority.This specifically concerns the opportunities and challenges to achieve adequate nutrition (adequate amounts of vitamins, minerals and macronutrients) when replacing animal foods with plant-based foods, including adequate amounts of for example proteins, omega-3 fatty acids, vitamin B12, iron etc. *https://www.who.int/europe/news/item/22-12-2021-new-who-factsheet-how-can-we-tell-if-plant-based-products-are-healthy	**Denmark**

-EUVEPRO would like to raise that the General Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods might no longer reflect the reality of the market for foods containing VPP and are not sufficiently clear when it comes to the nutritional adequacy requirements.	**European Vegetable Protein Association**
-The reproducibility in terms of nutritional content of a finished products can be difficult due to crop variation. Increased macro and micronutrient testing may be required to ensure products contain what they state they contain. Tolerance limits for nutrition labelling need to be considered.	**Food Industry Asia**
-Need to study long-term impacts on health.Standards to regulate health and nutrition claims	**International Meat Secretariat**
The nutritional value of plant-based protein alternatives may be low compare to animal sources, as some plant products contain high percentage of fat, salt, sodium and saturated fats.	**Kingdom of Saudi Arabia**
There is no established requirements and standards for these products. However, there are specific provision on labeling that may cover plant-based protein product.	**Malaysia**
-- Establishment of nutritional quality standards for plant-based protein alternatives· Need to set the minimum amount of major nutrients that can be expected when consumed	**Republic of Korea**
Recommended Dietary Allowance levels, composition, antinutrients/toxicants may need to be considered. As noted above caution should also be taken regarding assertations that cultivated foods are nutritionally equivalent or better than foods they are seeking to replace.	**USA**

NUTRITIONAL ASPECTS – SEAWEED

-Limited information	**Malaysia**
Norwegian food safety authorities focus at present mainly on food safety aspects, but there are a lot of reported nutritional benefits in the literature on the use for both food and feed. There are however no authorised health claims that can be used for seaweed for use as food in Norway or in the EU/EEA.	**Norway**
-- Establishment of nutritional quality standards for seaweed· Need to set the minimum amount of major nutrients that can be expected when consumed	**Republic of Korea**
This will depend on the intended use.	**USA**

NUTRITIONAL ASPECTS - EDIBLE INSECTS

Los insectos representan una alternativa sostenible para abordar la seguridad de los alimentos y piensos al contener niveles elevados de proteínas. La composición nutricional de los insectos comestibles es difícil de generalizar, debido al gran número de especies consumidas. Se han realizado numerosas publicaciones científicas sobre el contenido y calidad nutricional en insectos y se afirma que, dependiendo de la especie, método de crianza y alimentación, pueden presentarse diferencias significativas en el contenido nutricional. En general, el contenido de proteínas se encuentra entre un 40-60% en base seca, ricas en aminoácidos esenciales, y ácidos grasos insaturados, fibra y micronutrientes. El consumo de insectos enteros, o en polvo como ingrediente, puede considerarse como una fuente alternativa prometedora de proteína que puede utilizarse para desarrollar alimentos con un alto perfil nutricional	**Argentina**
¿Cuenta con información sobre aspectos nutricionales? Los insectos representan una alternativa sostenible para abordar la seguridad de los alimentos y piensos al contener niveles elevados de proteínas. La composición nutricional de los insectos comestibles es difícil de generalizar, debido al gran número de especies consumidas. Se han realizado numerosas publicaciones científicas sobre el contenido y calidad nutricional en insectos y se afirma que, dependiendo de la especie, método de crianza y alimentación, pueden presentarse diferencias significativas en el contenido nutricional. En general, el contenido de proteínas se encuentra entre un 40-60% en base seca, ricas en aminoácidos esenciales, y ácidos grasos insaturados, fibra y micronutrientes. El consumo de insectos enteros, o en polvo como ingrediente, puede considerarse como una fuente alternativa prometedora de proteína que puede utilizarse para desarrollar alimentos con un alto perfil nutricional.	**Argentina**
FSANZ recognises the risk of food allergy including anaphylaxis from consuming insects in crustacean-allergic individuals is evolving and has been considered in a number of recent international reports (EFSA 2015; EFSA 2019; EFSA 2021; FAO 2021). The Advisory Committee on Novel Foods (ACNF) had previously considered that the edible insects super mealworm (Zophobas morio), house crickets (Achaeta domestica), and mealworm beetle (Tenebrio molitor) were not traditional but not novel foods, with no safety concerns identified at intended levels of use. Currently there is no specific food standard that relates to edible insects in Australia and New Zealand.Relatively little information is currently available on levels of antinutrients and heavy metals in insects	**Australia**
Los insectos pueden complementar las fuentes tradicionales de piensos como la soja, el maíz, los cereales y la harina de pescado. Contienen niveles elevados de proteínas y grasas. También son ricos en fibra y micronutrientes como cobre, hierro, magnesio, fósforo, manganeso, selenio y cinc. Pueden criarse aprovechando diversos flujos de residuos, como los residuos de alimentos. Además, pueden consumirse enteros o molidos, en forma de polvo o pasta, e incorporarse a otros alimentos.	**Costa Rica**
–Limited information	**Malaysia**
- Establishment of nutritional quality standards for edible insects· Establishment of minimum protein content that can be absorbed through ingestion of edible insects	**Republic of Korea**

Nutritional benefits associated with the products	**Uganda**
– This will depend on the intended use.	**USA**

NUTRITIONAL ASPECTS - <u>3-D PRINTED FOODS</u>

FSANZ has yet to receive an application relating to 3-D printed foods. Given the significant degree of processing involved in producing 3D printed foods, fortification with vitamins or minerals may be needed to make up for processing losses.3D printed foods may help provide nutrition to people with digestive disorders, such as problems with swallowing. Currently, most scientific research focuses on structure and composition of 3-D printed foods. There is limited evidence regarding the digestibility and bioavailability of 3-D printed foods; more research is needed to confirm the 3D-printed food safety and other biological and nutritional aspects.	**Australia**
High degree of processing involved	**Kingdom of Saudi Arabia**
–No information	**Malaysia**
- Establishment of minimum standards for nutritional quality of 3-D printed foods· Since -3-D printed foods which is differentiated from general foods in the regard to focus on specific nutritional components and functions such as digestion and absorption, it is necessary to set the minimum nutrient content for each type of food to minimize the nutritional imbalance problem	**Republic of Korea**
– It is not clear that this production process would have any significant relationship to nutrition	**USA**

NUTRITIONAL ASPECTS – MICROALGAE

FSANZ notes an increased use of oil derived from marine micro-algae (Schizochytrium sp.) as a source of DHA in infant formula. There are nutritional concerns related to other micro-algae strains and their (potential) future use in infant formula	**Australia**
–Limited information	**Malaysia**
- Establishment of nutritional quality standards for microalgae· Setting on the minimum content of major nutrients that can be expected when consumed	**Republic of Korea**
– This will depend on the intended use.	**USA**

NUTRITIONAL ASPECTS – OTHER

~~Otros (especifique)~~Preparados vegetales bebibles Durante los debates que están teniendo lugar a nivel técnico entre los reguladores sobre este tema, se pretende definir un punto de corte tal que el componente representativo del producto (soja, avena, almendras, arroz, etc.) esté presente en una proporción mínima y suficiente que logre el aporte de un % mínimo del VD del nutriente característico que aporta dicho componente. Sin embargo, dada la variabilidad que existe de aportes nutricionales (derivada de las diferencias en los ingredientes característicos), es que se continúa analizando cual sería la forma más adecuada de agrupar los productos según sus ingredientes característicos y aportes nutricionales. Se está analizando también cómo abordar la cuestión de los productos que tienen mezclas de componentes representativos.	**Argentina**
-Pre-assessment of nutritional information through laboratory testing protocols should be confirmed by relevant certified laboratories for labelling purpose.	**Fiji**
-*For all alternative protein products:*- Some alternative protein products contain high levels of sodium, fat, and sugar, as well as lower micronutrient levels compared to the animal-derived products they aim to mimic. Industry should aim to match or improve the nutritional quality of alternative proteins compared to the products they aim to mimic, to match the perception of many consumers that these products are healthier versus their animal-based counterparts. - Protein quality in terms of the amino acid profile, digestibility and bioavailability must be considered.- The presence and effect of anti-nutritional factors must be taken into account.	**Food Industry Asia**
1. Non-specified food including Novel food: Based on approval given by the Food Safety and Standards Authority of India (National Food Regulatory Body). 2. Proprietary food: A proprietary food may also contain vitamins and minerals in quantities not exceeding one Recommended Dietary Allowance of the respective micronutrients.	**India**

FOOD SAFETY ASPECTS (E.G. PHYSICAL, CHEMICAL AND/OR MICROBIOLOGICAL RISKS)

General Comments: Canada believes that there are food allergen related concerns when it comes to new food sources. It is difficult to put these in one category, because they are a food safety issue but also a labelling issue (in many cases safety issues related to food allergens can be mitigated or managed by appropriate labelling that warns/informs affected consumers). In particular when the new food source is/or contains protein, there is the potential for the food to become a food allergen, or to be similar enough to an existing food allergen that it will trigger allergic reactions in people with already existing allergies, both of which are a concern.	**Canada**

In the EU, one of the objectives of the Novel Food Regulation is to provide a high level of protection of human health and consumers' interests. In order to be authorised to be placed on the European Union market, a novel food has to undergo a safety evaluation by the independent experts of the European Food Safety Authority (EFSA) who must conclude that the inclusion of a novel food in the Union list of novel foods is not liable to have an effect on human health. In case EFSA cannot conclude on the safety of a novel food or concludes that the consumption of the novel food is liable to have an effect on human health, the novel food is not authorised and is not included in the Union list of authorised novel foods. EFSA has published guidance on both novel and traditional foods. Besides the general safety requirement for all novel foods, there may be additional safety considerations for specific new foods. In the case of seaweeds for example, special attention should be paid to the presence/content of heavy metals and iodine as available occurrence data shows that seaweeds contain significant concentrations of arsenic, cadmium, iodine, lead and mercury. In the case of insects, the feed used for the rearing of insects may play a role in the presence of contaminants or allergens in the final food.	**European Union**
In general, food safety aspects are regulated by competent authorities through ministerial/agency decrees, including declaration of allergen profile in the label.	**Indonesia**
Since this is a new food product, it is necessary to conduct a thorough study of all risks (physical, chemical, microbiological) in order to avoid possible harmful effects on the human body at various stages - cultivation /growing/ production / storage of "new food product".	**Kazakhstan**
At this stage for many of the innovations identified the data on which to assess if there was a risk from the food innovation is small (e.g. for 3-D/4-D printed foods and cultivated products). However, for some of the technologies consideration could be made of the hazards the food could pose and to what extent they are managed.	**United Kingdom**

FOOD SAFETY ASPECTS - <u>CULTIVATED MEAT, SEAFOOD, AND DAIRY</u>

The Code currently has definitions for meat, seafood and dairy which would not capture cultivated versions.Meat, seafood and dairy have primary production standards that require businesses to identify potential safety hazards and put controls in place to manage the risk. Similar requirements for the safe production of cultivated versions may be necessary.Prevention of introducing pathogens at early culture stages would be required, given likely production method in culture media presents prime growth conditions (i.e. growth media such as animal serum).Microbiological limits may need to be applied. This may include consideration of processing criteria.	**Australia**
-There is the possibility to develop post-market risk management based on the microbiological or chemical risks that arise along the continuum from manufacturing to sale.	**Canada**

-The implications of the use of antibiotics, certain types of scaffolding material, and foetal bovine serum must be considered	**Food Industry Asia**
-For alternative proteins created in new ways, the primary emphasis from a food safety perspective should be on testing the end product to confirm the safety of the foods for consumption. Food safety authorities should also ensure that production facilities are hygienic and free from contamination and that good manufacturing practices are followed. Most hazards associated with the production of cultivated meat are not expected to be novel, and known safety assessments from a variety of fields (including conventional foods and pharmaceuticals) are thus applicable. For novel parts of the process, it may be helpful to develop generally applicable principles or guidelines for food safety assessments. The Food and Agriculture Organization's (FAO) upcoming expert consultation on food safety aspects for cultivated food products may provide a further basis for the development of such Codex principles or guidelines. See FAO, Thinking About the Future of Food Safety (2022), p. 54; FAO, Scientific Advice on Cell-Based Food Products and Food Safety Considerations - Call for Experts (2022).	**Good Food Institute**
-Control of residues of chemicals used in cultivation	**IAEA**
-Risks of contamination due to nature of production systems. Given the great number of cell multiplications taking place, some dysregulation of cell lines is likely to occur as happens in cancer cells. High-rate cell proliferation of industrial-scale production is likely to accumulate genetic alterations … There is also concern around developing cancerous and other undesirable cells from genomic alterations. As a result, regular monitoring of genetic stability is necessary for quality assurance" (Ong et al., 2021. Comprehensive Reviews in Food Science and Food Safety 20:5421–5448. Chen et al., 2022. Biomaterials, 280, 121274).Unknown potential effects on the muscle structure and possibly on human metabolism and health when in vitro meat is consumed.Risks of contamination due to nature of production systems. Given the great number of cell multiplications taking place, some dysregulation of cell lines is likely to occur as happens in cancer cells. "High-rate cell proliferation of industrial-scale production is likely to accumulate genetic alterations … There is also concern around developing cancerous and other undesirable cells from genomic alterations. As a result, regular monitoring of genetic stability is necessary for quality assurance" (Ong et al., 2021. Comprehensive Reviews in Food Science and Food Safety 20:5421–5448. Chen et al., 2022. Biomaterials, 280, 121274).Unknown potential effects on the muscle structure and possibly on human metabolism and health when in vitro meat is consumed.INDUSTRY-RANKED RESEARCH PRIORITIES (by start-ups themselves, Ong et al. Compr Rev Food Sci Food Saf. 2021;20:5421–5448. https://doi.org/10.1111/1541-4337.12853The research topics highlighted in this review were shared with industry experts during the third workshop to identify their priorities for future research. Participants were asked to vote on the five topics they deemed most relevant and important to address from their perspective as industry leaders. Votes were tallied in real time, and the top seven areas voted as most relevant (with percentages) were as follows:- Develop industry-wide standards for safe residue levels of relevant inputs (68%);- Identify the concentration of inputs (e.g., growth factors, antibiotics, scaffold, novel inputs) in the product, as a function of where in the process used and thoroughness of removal steps (60%);- Assess whether media recycling concentrates hazardous inputs/residues (44%);- Assess the range of geneticmodification approaches and outcomes that affect safety (40%);- Evaluate the comparative approach for the safety assessment of the final product (36%);- Identify novel metabolites or expression products (36%); - Evaluate whether specific food processing techniques affect safety of specific process inputs (36%).	**International Meat Secretariat**
-Limited information	**Malaysia**

-- Guidelines for risk assessment on each production step of cultivated food· Standards for the presence or absence of disease infection in the carcass of the originating organism, the presence of contamination with pathogenic microorganisms, residual substances (antibiotics, hormones, pesticides), the number of total bacteria and E. coli· Toxicity evaluation of substances without specifications (genotoxicity, metal contamination during carcinogenicity tests, microbial contamination, etc.) and the setting of standards are required when producing cultivated foods · Genetic stability and if genetic differences exist, whether hazardous substances are expressed	**Republic of Korea**
FSIS implements a HACCP based regulatory infrastructure to ensure regulated food products are produced safely and these products would also be required to meet HACCP regulations. FSIS is considering the food safety hazards associated with cultured meat and poultry, including organoleptic (e.g., appearance, odor, taste), biological, chemical, or other characteristics, within the context of the advance notice of proposed rulemaking (ANPR) referenced above.	**USA**

FOOD SAFETY ASPECTS - <u>FERMENTATION-DERIVED INGREDIENTS</u>

New microbes may requirement pre-market approval to assess the safety of ingredients they produce.	**Australia**
-Realizar las consultas pertinentes a los órganos científicos para analizar si las metodologías utilizadas actualmente son válidas o no para estos productos nuevos en términos de inocuidad.Realizada la denominación de uso común entre los países miembros para cada categoría de nuevo alimento e identificados los distintos procesos para la generación de cada uno de estos, identificar en base a la metodología de Análisis de Riesgo los peligros químicos, físicos o microbiológicos, para determinar si los controles requeridos y evaluar el efecto de cada uno de los procesos identificados sobre los riesgos definidos.	**Chile**
Realizada la denominación de uso común entre los países miembros para cada categoría de nuevo alimento e identificados los distintos procesos para la generación de cada uno de estos, identificar en base a la metodología de Análisis de Riesgo los peligros químicos, físicos o microbiológicos, para determinar si los controles requeridos y evaluar el efecto de cada uno de los procesos identificados sobre los riesgos definidos.	**Chile**
The culture medium used and where it is derived from must be considered carefully	**Food Industry Asia**
For alternative proteins created in new ways, the primary emphasis from a food safety perspective should be on testing the end product to confirm the safety of the foods for consumption and ensuring good manufacturing practices. Food safety authorities should also ensure that production facilities are hygienic and free from contamination and that good manufacturing practices are followed.	**Good Food Institute**
LImited information	**Malaysia**
Guidelines for risk assessment of fermentation-derived ingredients· Guidelines for evaluating whether fermented ingredients contain antibiotic resistance or toxic genes	**Republic of Korea**

Potential physical, chemical and microbiological related risks	**Uganda**
The majority of fermentation derived ingredients would likely fit within the current Codex system. As an example, the Joint Expert Committee on Food Additives (JECFA) recently reviewed Steviol glycosides from fermentation (INS 960b). The additive was considered by the Codex Committee on Food Additives, forwarded to the Commission for adoption, and included in the General Standard for Food Additives. Some of the food safety aspects for such ingredients include a thorough understanding of the genetic construction of the production system (pathogenicity and toxigenicity of the source; genetic modification of the production organism; generational stability; inability to produce antibiotics, toxins, allergens etc). Potential allergenicity of the components of the fermentation media, safety studies with article of commerce. GMP, specifications, etc.	**USA**

FOOD SAFETY ASPECTS - <u>PLANT-BASED PROTEIN ALTERNATIVES</u>

Microbiological and chemical hazards during production may have to be considered.	**Australia**
-EUVEPRO considers that any food safety aspects related to plant-based proteins are adequately regulated within the existing frameworks in the EU.	**European Vegetable Protein Association**
-The allergenicity of non-traditional plant-based proteins must be assessed	**Food Industry Asia**
-For alternative proteins created in new ways, the primary emphasis from a food safety perspective should be on testing the end product to confirm the safety of the foods for consumption. Food safety authorities should also ensure that production facilities are hygienic and free from contamination and that good manufacturing practices are followed.	**Good Food Institute**
There are safety limits for contaminant in plant-based protein established in the regulations (Fourteenth A Schedule of Regulations 38A, Food Regulations 1985)There are also specific provisions on labeling that may cover plant-based protein product.	**Malaysia**
-- Guidelines for microbiological hazard assessment of plant-based protein alternative foods· Standards for heat resistance, residual amount of endospore-forming bacteria (Bacillus spp, Clostridium spp) and possible fungal toxins during processing	**Republic of Korea**
The majority of such ingredients would likely fit within the current Codex system. Some aspects would include allergenicity, dietary exposure (including cumulative), presence/absence of process- related contaminants and toxicants, appropriate safety studies, GMP, specifications for minor components	**USA**

FOOD SAFETY ASPECTS – SEAWEED

Food Standards Australia New Zealand (FSANZ) Vigilance & Intelligence Before food issues Emerge (VIBE) has identified changes in consumption patterns of seaweed in the Australian and New Zealand (ANZ) population which may raise concerns regarding iodine intake and accumulation of other contaminants such as cadmium, methylmercury and inorganic arsenicDue to the possibility of heavy metal presence guidance on a safe portion size to prevent excess intake may be required.	**Australia**
-The chemical safety of seaweed (marine biotoxins, heavy metals) was raised at CCCF14 as captured in paragraph 37 of CX/CF 21/14/3. CX/CF 21/14/3 indicates that the FAO is developing background documents on each edible seaweed and edible insects that were slated for publication in 2021.	**Canada**
-Realizada la denominación de uso común entre los países miembros para cada categoría de nuevo alimento e identificados los distintos procesos para la generación de cada uno de estos, identificar en base a la metodología de Análisis de Riesgo los peligros químicos, físicos o microbiológicos, para determinar si los controles requeridos y evaluar el efecto de cada uno de los procesos identificados sobre los riesgos definidos.	**Chile**
Bioaccumulation of heavy metals, pesticides and other pollutant can occur in seaweed and present a health risk	**Food Industry Asia**
Some of the risks associated with seaweed, such as heavy metals that can bind to proteins and interfere with their physiological activity. Other elements such as iodine, although necessary for humans and animals, can cause adverse health effects if consumption is excessive.	**Kingdom of Saudi Arabia**
There are safety limits for heavy metals (arsenic, lead and cadmium) in seaweed established in the regulations (Table 1A, 1B and 1E of the Fourteenth Schedule, Regulation 38, Food Regulations 1985).There are 2 standards related to seaweed that deals with hygiene, and to a certain extent food safety aspect, of seaweed production i.e., MS 1998:2007 –Good Aquaculture Practice (GAqP) – Aquaculture Farm General Guidelines and MS 2467:2012 – Code of Practice for Seaweed Cultivation.	**Malaysia**
In certain species of seaweed there are risk factors as too high iodine content, inorganic arsenic, cadmium, lead, and mercury. These factors are identified as important and are monitored. The data base is increasing considerably on these parameters. Particular regulations on these are under discussion. Nickel is also a possible risk factor. In addition, possible microbiological risks regarding seaweed as use for food should be more evaluated, even though there are reported quite few outbreaks from consumption of seaweed both in Europe and globally.	**Norway**
-· Standards for heavy metals and marine toxins in seaweed· Setting on the residual amount standard for marine toxins such as Palytoxin· Setting the standard based on the intake history of some residual heavy metals such as arsenic and cadmium	**Republic of Korea**
Codex has already established a regional standard for seaweed, CXS 323R-2017 Regional Standard for Laver Products. This regional standard addresses the food safety aspects using general references to the General Standard forContaminants and Toxins in Food and Feed (CXS 193-1995) and the General Principles of Food Hygiene (CXC 1-1969). It is assumed that future standards for seaweed can do the same.	**USA**

FOOD SAFETY ASPECTS - EDIBLE INSECTS

¿Cuenta con información sobre aspectos de la inocuidad de los alimentos (por ejemplo, riesgos físicos, químicos o microbiológicos)? Principales riesgos microbiológicos del consumo de insectos Según trabajos científicos realizados en los últimos años, se han identificado diversos microorganismos presentes en insectos y que pueden ser transmitidos por ellos. La flora microbiana de los insectos está compuesta por bacterias de diferentes géneros como Clostridium, Staphylococcus, Streptococcus, Bacillus, Proteus, Pseudomonas, Escherichia, Micrococcus, Lactobacillus y Acinetobacter, y bacterias patógenas tales como Listeria, Salmonella, Campylobacter y E. coli verotoxigénica. Estos microorganismos pueden estar presentes en insectos no procesados, dependiendo del sustrato utilizado para su alimentación y de las condiciones de cría. También indica que la prevalencia de algunos de estos patógenos, por ejemplo Campylobacter spp., es menor en comparación con otras fuentes no procesadas de proteína animal, ya que la replicación activa de los patógenos en el intestino no parece ocurrir en los insectos. Además, el riesgo de transmisión de estas bacterias podría mitigarse mediante un procesamiento efectivo. Las bacterias patógenas de los insectos (entomopatógenos) son consideradas inofensivas para animales y humanos. Por lo tanto, los peligros microbiológicos provenientes del consumo de insectos se originarán principalmente a partir de una microbiota residencial (natural o accidental) relacionada a las condiciones de cría: alimentación, manipulación, procesamiento y conservación (EFSA, 2015). El Comité Científico de la Agencia Federal para la Seguridad de la Cadena Alimentaria (Federal Agency for the Safety of the Food Chain - FASFC) emitió un reporte (SciCom 14-2014 and SHC Nr. 9160) sobre potenciales riesgos microbiológicos, químicos y físicos asociados al consumo de insectos. En cuanto a los riesgos microbiológicos, debido a que los insectos están taxonómicamente mucho más alejados de los humanos que el ganado convencional, hay razones para suponer que el riesgo de infecciones zoonóticas es bajo (pero no inexistente) (FAO, 2013). Es por ello que se indican una serie de pautas a considerar acerca de los piensos o nutrientes utilizados en la alimentación de los insectos, condiciones de cría y cultivo, faena, el procesamiento posterior y la comercialización y criterios de higiene y seguridad alimentaria de los alimentos. Principales riesgos toxicológicos asociados al consumo de insectos En cuanto a la evaluación toxicológica y los riesgos potenciales relacionados con el consumo de insectos, es sabido que algunas especies pueden contener sustancias tóxicas presentes de forma natural, como es el caso de los glucósidos cianogénicos (sustancias capaces de producir ácido cianhídrico en condiciones específicas de acidez y presencia de enzimas específicas). (Zagrobelny et al., 2009). Sin embargo, el mayor impacto sobre los aspectos toxicológicos estará relacionado con los métodos de producción específicos, el sustrato utilizado, la etapa de recolección, la especie de insecto y la etapa de desarrollo. Asimismo, los métodos para el procesado posterior tendrán también un impacto en la incidencia y los niveles de contaminantes químicos y biológicos en los alimentos y piensos derivados de insectos (EFSA, 2015). En consecuencia, la principal recomendación general es limitar el consumo de insectos a aquellos que hayan sido criados en granjas en condiciones controladas (Kourimská &Adámková, 2016). La Autoridad Europea de Seguridad Alimentaria (EFSA) ha publicado un documento sobre los riesgos relacionados con la producción y el consumo de insectos como alimentos y piensos (EFSA, 2015). En esta publicación, se revisan los pros y contras del consumo de los	**Argentina**

insectos. En cuanto a la valoración de los riesgos de origen químico en insectos con destino de alimentación, se concluye que están influidos por factores como métodos de producción, sustratos, fase larvaria y especie de insecto. Los contaminantes químicos pueden originarse a partir de fuentes naturales o artificiales, o bien ser producidos por el propio metabolismo de los insectos. Se han encontrado en casos puntuales metales pesados, dioxinas, micotoxinas, pesticidas, biocidas para higienización de instalaciones y equipos y medicamentos veterinarios. Acumulación potencial de micotoxinas Según la literatura disponible, las micotoxinas afectan, de por sí, y sobre todo si están presentes en altas concentraciones, a la supervivencia misma de los insectos. A bajas concentraciones, el efecto observado es la reducción de su performance de crecimiento. Sin embargo, al administrar estos compuestos con la dieta en ensayos experimentales con varias especies de insectos, no se observó acumulación de micotoxinas, incluso a concentraciones de hasta 25 veces los límites máximos o valores de referencia. (Camenzuli et al., 2018) Algunos autores recomiendan un período de ayuno de 24 hs antes de la cosecha o una purga dentro de los 1 a 3 días previos a la cosecha con frutas o verduras frescas. Dado que el contenido intestinal tiene un gran impacto en la concentración total de micotoxinas (Bosch et al, 2017), se recomienda un período de ayuno de 24 hs antes de la cosecha, lo cual debería transformarse en una práctica habitual en el contexto de la producción comercial (Bosch et al, 2017 Camenzuli et al., 2018). Es necesario realizar estudios adicionales para develar el destino y las vías metabólicas de estas micotoxinas. Acumulación potencial de metales Los estudios realizados hasta la fecha revelan que los metales esenciales pueden ser adecuadamente regulados por el propio metabolismo luego de la ingestión por las larvas de insectos. Contrariamente, la capacidad de regular metales no esenciales fue bastante menor, llevando a su bioacumulación, con consecuencias importantes sobre la supervivencia y el potencial de desarrollo. Sin embargo, existirían distintos patrones de acumulación, dependiendo de la especie de insecto y del estadio de desarrollo. Hasta ahora, solo han sido publicados unos pocos datos sobre contaminantes detectados e identificados en insectos o productos derivados destinados al consumo humano o animal.	
–Unknown potential as a host to microbiological pathogens, contain toxins and or allergens. Processed products (flour) subject to provisions of the Code.Allergen labelling may be required.	**Australia**
Some insects used as food contain protein that could trigger allergic reactions, particularly in consumers with allergies to crustaceans.The chemical safety of edible insects (pesticides, toxic metals, flame retardants) was raised at CCCF14 as captured in paragraph 22 of CX/CF 21/14/3. CX/CF 21/14/3 indicates that the FAO is developing background documents on each edible seaweed and edible insects that were slated for publication in 2021.	**Canada**
Realizada la denominación de uso común entre los países miembros para cada categoría de nuevo alimento e identificados los distintos procesos para la generación de cada uno de estos, identificar en base a la metodología de Análisis de Riesgo los peligros químicos, físicos o microbiológicos, para determinar si los controles requeridos y evaluar el efecto de cada uno de los procesos identificados sobre los riesgos definidos. Entre las principales preocupaciones desde el punto de vista de la inocuidad de los productos se relacionan con las prácticas productivas	**Chile**

relacionadas con la alimentación, condiciones de crianza y manejos generales de insectos que puedan determinar la contaminación de los mismos con contaminantes microbiológicos como L. monocytogenes, Salmonella spp, entre otros; residuos de plaguicidas; residuos de medicamentos veterinarios; contaminación con metales pesados; presencia de micotoxina; dioxinas, furanos y PCBs. No contamos con datos sistemáticos sobre los aspectos relacionados con la inocuidad de los productos derivados de insectos.	
No se conocen casos de transmisión de enfermedades o parasitoides a humanos derivados del consumo de insectos (siempre que los insectos hayan sido manipulados en las mismas condiciones de higiene que cualquier otro alimento). Se ha estudiado que pueden producirse alergias comparables a las alergias a los crustáceos, que también son invertebrados. En comparación con los mamíferos y las aves, los insectos pueden plantear un riesgo menor de transmisión de infecciones zoonóticas a los humanos, el ganado y la fauna, aunque este tema debe investigarse más a fondo. FUENTE: Organización de las Naciones Unidas para la Alimentación y la Agricultura (FAO) 2013. Guía informativa: “La contribución de los insectos a la seguridad alimentaria, los medios de vida y el medio ambiente”. Según el documento “Looking at edible insects from a food safety perspective” de FAO con respecto a la inocuidad de los insectos se requiere: -investigación y análisis sobre cómo producir, procesar, almacenar y transportar insectos y alimentos derivados de insectos de forma inocua -establecer las buenas prácticas de manufactura en la producción de insectos y reforzar su aplicación -realizar un análisis de riesgos de la aplicación de la economía circular en la producción de insectos, considerando que se utilizan residuos como alimento -evaluar el riesgo de alergenicidad de los insectos FUENTE: Organización de las Naciones Unidas para la Alimentación y la Agricultura (FAO) 2021. Looking at edible insects from a food safety perspective. https://www.fao.org/3/cb4094en/cb4094en.pdf	**Costa Rica**
- There is a need to carry out thorough allergenic risk assessments for insect and insect-based products, particularly due to insects and crustaceans belonging to the same arthropod family and in turn there being a degree of allergenicity cross over - The feed substrate used has to be carefully considered, as waste and animal-based substrates can introduce e.g., zoonoses risk - The risk of toxins (e.g., heavy metals and mycotoxins) and microbial contamination risk of insect and insect-based products must be assessed and tested	**Food Industry Asia**
Control of residues of chemicals used to control disease and optimize output in insect production facilities.	**IAEA**
Potential food safety hazards for edible insects, including bacteria, viruses, fungi, and parasites, chemical hazards including mycotoxins, pesticides, heavy metals, antimicrobials, and physical hazards.	**Kingdom of Saudi Arabia**
–Limited information	**Malaysia**

The European Food Safety Authority (EFSA) has conducted a risk profile related to production and consumption of insects as food and feed (EFSA 2015). The opinion presents potential biological and chemical hazards as well as allergenicity and environmental hazards associated with farmed insects used as food and feed taking into account of the entire chain, from farming to the final product. The opinion also addresses the occurrence of these hazards in non-processed insects, grown on different substrate categories, in comparison to the occurrence of these hazards in other non-processed sources of protein of animal origin.	**Norway**
- Standards for pesticide residues and residual veterinary drugs in edible insects- Guidelines for microbiological hazard assessment of edible insects· Standard for heat resistance, residual amount of bacteria forming endospores, and fungal toxins that may occur during the food processing · Criteria and evaluation guidelines for allergen content	**Republic of Korea**
Potential physical, chemical and microbiological related risks	**Uganda**
– The raising of insects has been demonstrated to have potential for microbial hazards. Lack of controls on environmental hazards have led to chemical hazards such as pesticides and heavy metals. Some insects contain hard or sharp parts such as spines, stings, or chinbones (rostrum) which may constitute a physical hazard if consumed as whole.	**USA**

FOOD SAFETY ASPECTS - <u>3-D PRINTED FOODS</u>

Provisions of the Code apply to processed new foods: contains requirements for the safe food processing. These will be important for managing microbial risks.Chemical and other residues may need regulation (new or existing ML/Maximum Residue Limits) depending on process and media.May require pre-market approval for food additives (e.g. ink materials) to assess safety.Allergen labelling may be required.	**Australia**
Realizada la denominación de uso común entre los países miembros para cada categoría de nuevo alimento e identificados los distintos procesos para la generación de cada uno de estos, identificar en base a la metodología de Análisis de Riesgo los peligros químicos, físicos o microbiológicos, para determinar si los controles requeridos y evaluar el efecto de cada uno de los procesos identificados sobre los riesgos definidos.	**Chile**
–No information	**Malaysia**
- Sanitary management guidelines for 3-D printed foods· Safety management guidelines for sanitary management of food contact surfaces such as nozzles, containers, ink jetting and stacking parts of -3-D food printers are required· Setting the standard for Microbial treatment of food ink material (powder material sterilization process, cartridge sterilization process, etc.)	**Republic of Korea**

– It may be helpful to consider whether there are any broad commonalities in potential sources of microbial hazards associated with this production process that could be a useful focus for development of broadly applicable GMP beyond those already in use in food production.	**USA**

FOOD SAFETY ASPECTS – <u>MICROALGAE</u>

Provisions of the Code apply to processed foods and contains requirements for the safe food processing.Presence of toxins naturally found in microalgae.Chemical and heavy metals contaminants should be considered.	**Australia**
Realizada la denominación de uso común entre los países miembros para cada categoría de nuevo alimento e identificados los distintos procesos para la generación de cada uno de estos, identificar en base a la metodología de Análisis de Riesgo los peligros químicos, físicos o microbiológicos, para determinar si los controles requeridos y evaluar el efecto de cada uno de los procesos identificados sobre los riesgos definidos.	**Chile**
- Bioaccumulation of heavy metals, pesticides and other pollutant can occur in microalgae and present a health risk	**Food Industry Asia**
–Limited information	**Malaysia**
- Guidelines for risk assessment on each production process· Need standards for contamination of the microalgae culture medium and residual substances (heavy metals, toxic substances)· Need to test for microbial contamination (total number of bacteria, types of bacteria, protozoa, etc.) in the culture medium and set the permissible limit standards· Whether or not hazardous substances are expressed when genetic stability and genetic differences exist· Need for criteria and evaluation guidelines for allergen content	**Republic of Korea**
– As with any plant used for food, it is important to consider whether there are toxins and antinutrients produced either constitutively or in response to certain growth conditions that could raise safety concerns. This question is readily addressed given currently available genomic, molecular, and biochemical tools and methods.	**USA**

FOOD SAFETY ASPECTS – <u>OTHER</u>

-Realizada la denominación de uso común entre los países miembros para cada categoría de nuevo alimento e identificados los distintos procesos para la generación de cada uno de estos, identificar en base a la metodología de Análisis de Riesgo los peligros químicos, físicos o microbiológicos, para determinar si los controles requeridos y evaluar el efecto de cada uno de los procesos identificados sobre los riesgos definidos.	**Chile**
- Food safety aspects will be addressed in relation with the novel food approval.	**Denmark**

-Product should have completed food safety protocols checking such as; HACCP and Preventative Controls plus Prerequisite Programs, Microbiology Testing, Foreign Material Testing, Process Checks, Incoming ingredient and packaging safety checks.	**Fiji**
1. Non-specified food including Novel food: Based on approval given by the Food Safety and Standards Authority of India (National Food Regulatory Body). 2. Proprietary food: A proprietary food shall comply with the microbiological requirements as specified in the Regulations. If no microbiological standards are specified for any foods or food categories in the regulations, proprietary foods falling under such food categories shall not contain any pathogenic microorganism at a level that may render the food product unsafe. The physico-chemical aspect of a proprietary food is based on the Certificate of Analysis (CoA) given by the Food Business Operator (FBO).	**India**

QUALITY ASPECTS (E.G. ESSENTIAL COMPOSITION AND QUALITY FACTORS, WEIGHTS AND MEASURES, METHODS OF ANALYSIS AND SAMPLING)

As noted above, a pre-market assessment of cultivated meat, seafood or dairy would consider the nutritional profile (compared to the natural equivalent).	**Australia**
The EU Novel Food Regulation clearly prescribes that the novel food application should contain, among other things, detailed specifications reflecting the identity and composition and the safety and quality attributes of the novel food. The specifications are part of the authorisation of a novel food and are set on the basis of the detailed analytical composition information of the novel food that is part of the risk assessment. Validated methods should be used for the analyses, preferably nationally or internationally recognised methods. Certificates of analyses and information on the accreditation of laboratories should be provided. In addition, a key quality attribute of a novel food is its stability over time, which needs to be documented by extensive stability testing covering both the novel food itself and in the foods in which it is used in. The EUMS are of the view that a new product should be fully characterized, including a detailed description of the manufacturing process and composition of the food and safety and quality (where appropriate) driven end points should be part of the specifications.	**European Union**
-Mechanisms to ensure authenticity of the product and appropriate labeling, to guarantee that quality and safety measures have been applied in production.	**IAEA**
In general, for quality aspect of food products are specified in the Indonesian National Standards and also in the regulation on food category system. For example, Indonesia has established National Standard on shrimp paste and spirulina powder which covered quality and safety aspects of the products.	**Indonesia**

-Several unsubstantiated claims on environmental impact of production. Claimed benefits for climate change questionable (very CO2 intensive production system, as opposed to methane from livestock).Only 4 scientific publications on impacts of “cultured meat” on the environment, “due to the limited data, the studies … are scarce and based on hypothetical production processes” (Rodríguez Escobar et al. (2021). Foods 2021, 10, 2941. https://doi.org/10.3390/foods10122941).Still far away from real muscle, which is made up of organized fibers, blood vessels, nerves, connective tissue and fat cells	**International Meat Secretariat**
Risk assessment system should be established in the production of "new food product " and its use in a product consumed directly by the consumer, detailed analytical data should be compiled, and international research methods should be used as a priority. In this case, accredited laboratories should be involved.	**Kazakhstan**
Not specified	**Malaysia**
-- Selection of quality factors and establishment of standards for cultivated food · Standard for the minimum moisture content, crude protein, fat, and additional ingredients that can ensure microbial safety· Type and purity of support used in culture	**Republic of Korea**
FSIS is considering certain compositional factors of cultured meat and poultry within the context of the ANPR referenced above.	**USA**

QUALITY ASPECTS - <u>FERMENTATION-DERIVED INGREDIENTS</u>

Not specified	**Malaysia**
Establishment of the minimum content standard for fermentation-derived ingredients in food· Setting the minimum content of fermentation-derived ingredients in food manufactured using fermentation-derived ingredients	**Republic of Korea**
Composition and quality factors	**Uganda**
Fermentation process related quality. Validated methods in place to characterize the products of fermentation and the article of commerce.	**USA**

QUALITY ASPECTS - <u>PLANT-BASED PROTEIN ALTERNATIVES</u>

-EUVEPRO considers that the determination of protein content/quantity and quality should be harmonized for plant-based protein products.The nitrogen-to-protein conversion factor (NCF) of 6.25 is the generally accepted reference used by regulatory authorities globally to ensure accurate protein intake, notably for plant-protein based products. This was recently addressed by CCNFSDU in relation to the Standard for Follow-up Formula for older infants and ‘Drink/Product for young children with added nutrients’ and ‘Drink for young children’.	**European Vegetable Protein Association**

Not specified	**Malaysia**
-- Establishment of the minimum essential components standard· Setting the minimum content of crude protein, fat, and additional ingredients to secure quality of products	**Republic of Korea**
Sensitive methods to detect process-related impurities and antinutritional components that might be present.	**USA**

QUALITY ASPECTS – <u>SEAWEED</u>

Not specified	**Malaysia**
In developing legislation, standards and guidelines, it is very important to be aware of the great differences between different species of seaweed as regards their constituents including content of risk factors as iodine and metals and also other hazards as biotoxins.	**Norway**
-- Establishment of quality factors and preparation of standards for cultivated food· Setting the standard for acid value, peroxide value, etc. to secure quality of products	**Republic of Korea**
Codex has already established a regional standard for seaweed, CXS 323R-2017 Regional Standard for Laver Products. This regional standard addresses the essential composition and quality factors, weights, and measures. methods of analysis and sampling are covered within the regional standard by a reference to theRecommended Methods of Analysis and Sampling (CXS 234-1999).	**USA**

QUALITY ASPECTS - <u>EDIBLE INSECTS</u>

Alergenicidad A pesar del interés nutricional que despierta este tipo de producto, uno de los principales problemas que presenta el consumo de insectos es el riesgo de reacciones alérgicas por parte de personas sensibles a crustáceos, moluscos, o incluso a alérgenos ambientales como los ácaros. Se ha demostrado que este problema está asociado a reactividad cruzada de varios de los denominados panalergenos, que son familias de proteínas presentes tanto en crustáceos como insectos. Además, otros alérgenos asociados más específicamente a insectos podrían estar también involucrados. Muchos de estos no han sido todavía identificados y caracterizados. En función de esto, la práctica que están adoptando algunos países es aconsejar a las personas alérgicas a crustáceos o moluscos que simplemente eviten el consumo de insectos (EFSA, 2015; Barre et al, 2014). A pesar del riesgo reconocido de que las proteínas de insectos podrían causar reacciones alérgicas, son muy limitados los estudios en donde se haya constatado fehacientemente que sean consecuencia directa de la ingesta de insectos. Sin embargo, las evidencias indicarían una alta probabilidad de que pueda producirse este tipo de reacciones cruzadas, por lo que el riesgo de reacciones alérgicas y las medidas de comunicación adecuadas deben ser específicamente considerados en la reglamentación.	**Argentina**
No tenemos mayor información al respecto por el momento debido a que no se han presentado casos concretos de alimentos a base de insectos o insectos para consumo.	**Argentina**

Alergenicidad A pesar del interés nutricional que despierta este tipo de producto, uno de los principales problemas que presenta el consumo de insectos es el riesgo de reacciones alérgicas por parte de personas sensibles a crustáceos, moluscos, o incluso a alérgenos ambientales como los ácaros. Se ha demostrado que este problema está asociado a reactividad cruzada de varios de los denominados panalergenos, que son familias de proteínas presentes tanto en crustáceos como insectos. Además, otros alérgenos asociados más específicamente a insectos podrían estar también involucrados. Muchos de estos no han sido todavía identificados y caracterizados. En función de esto, la práctica que están adoptando algunos países es aconsejar a las personas alérgicas a crustáceos o moluscos que simplemente eviten el consumo de insectos (EFSA, 2015; Barre et al, 2014). A pesar del riesgo reconocido de que las proteínas de insectos podrían causar reacciones alérgicas, son muy limitados los estudios en donde se haya constatado fehacientemente que sean consecuencia directa de la ingesta de insectos. Sin embargo, las evidencias indicarían una alta probabilidad de que pueda producirse este tipo de reacciones cruzadas, por lo que el riesgo de reacciones alérgicas y las medidas de comunicación adecuadas deben ser específicamente considerados en la reglamentación.	
Medición de la cantidad de proteína en el producto final. Definición de especie de insecto a utilizar y características. Los factores críticos para optimizar la producción son la temperatura y la humedad ambiental, así como el desarrollo de un alimento idóneo para los insectos. Se debe verificar el método de análisis de proteína de los insectos para que no se sobreestime con el contenido de nitrógeno de otras fuentes no proteicas.	**Costa Rica**
Mechanisms to ensure authenticity of the product and appropriate labeling, to guarantee that quality and safety measures have been applied in production.	**IAEA**
Not specified	**Malaysia**
- Establishment of quality factors and preparation of standards for edible insects· Standard for the minimum moisture content, crude protein, fat, and additional raw materials that can ensure microbial safety	**Republic of Korea**
Composition and quality factors	**Uganda**

QUALITY ASPECTS - <u>3-D PRINTED FOODS</u>

Foods for dysphagia – validation required for printed food texture/rheology to meet IDSSI guidelines upon production/storage	**Australia**
-Consumer preference is priority to ensure consumer expectations are met. Sensory and Quality attributes are tested to make sure the product meets specifications	**Fiji**
1. Non-specified food including Novel food: Based on approval given by the Food Safety and Standards Authority of India (National Food Regulatory Body).	**India**

2. Proprietary food: The quality aspects of a proprietary food is based on the Certificate of Analysis (CoA) given by the Food Business Operator (FBO).	
–No information Not specified	**Malaysia** **Malaysia**
- Establishment of quality factor standards for 3-D printed food ink· Due to the nature of ink containing a large amount of nutrients and functional ingredients, it is necessary to set standards for quality assurance - Establishment of minimum protein content, vitamins content, and essential fatty acid content standards in microalgae· Due to the characteristics of microalgae with high protein, vitamins and essential fatty acids, it is necessary to set standards to ensure quality- Standard for the minimum microalgae content in food made with microalgae· Due to the characteristics of microalgae mainly used as functional food, it is necessary to establish a standard for the minimum content	**Republic of Korea**

QUALITY ASPECTS – <u>OTHER</u>

On quality aspects the UK is committed to working towards agreeing informative food labelling and promoting robust science-based food standards internationally, whatever the production methods.	**United Kingdom**

ANY OTHER MATTERS RELEVANT TO THE MISSION OF CODEX TO PROTECT THE HEALTH OF CONSUMERS, ENSURE FAIR PRACTICES IN THE FOOD TRADE AND PROMOTE CO-ORDINATION OF ALL FOOD STANDARDS WORK UNDERTAKEN BY INTERNATIONAL GOVERNMENTAL AND NON-GOVERNMENTAL ORGANIZATION

Consumer acceptance of new foods and new food sources might prove to be a big challenge/obstacle for the development and deployment in particular in areas of the world with strongly embedded food cultures.	**European Union**
It is important for Codex to set international standards for these foods (being categorized as “new food”) because in fact, some of them are already known and traded (some are even internationally). The absence of international standard has potential to create trade barriers, hence it is important for Codex to develop the standard.	**Indonesia**
The introduction of "new food products" should not affect to the established tradition, the culture of consumption. Consumers should not be misled about its identity to traditional products.	**Kazakhstan**

ANY OTHER MATTERS - CULTIVATED MEAT, SEAFOOD, AND DAIRY

Concerns may come up for labelling requirements needed to differentiate the growing source, e.g., cell-based.	**Australia**
Limited information related to safety assessment, technical aspect and trade data on cultivated meat, seafood and dairy is available to regulators in order to establish standards.	**Malaysia**
Provide a dual perspective of cultivated food providing differentiated and clear guidelines within CODEX to avoid impeding the traditional livestock food market	**Republic of Korea**

ANY OTHER MATTERS - FERMENTATION-DERIVED INGREDIENTS

Limited information related to safety assessment, technical aspect and trade data on fermentation-derived ingredients is available to regulators in order to establish standards.	**Malaysia**
Need clear safety management guidelines depending on whether it is for ingestion or whether it is used only for manufacturing and processing and then removed	**Republic of Korea**

ANY OTHER MATTERS - - PLANT-BASED PROTEIN ALTERNATIVES

-In many countries, plant-based and other alternative protein products do not fit within existing Harmonized System (HS) codes established by the World Customs Organization (WCO), an observer organization to Codex. Legacy WCO HS codes do not capture the range of ingredients currently used in plant-based alternative proteins or the diverse formulations that are evolving in this category, resulting in ambiguity and in some cases higher rates of duty for producers exporting their products to other markets. That issue is not specific to plant-based and other alternative protein products as it also raises the broader issue of the compatibility of the various food categorization systems used by Codex Committees, such as the ones used for food additives, contaminants, and other chemical residues, with the WCO HS codes.	**Good Food Institute**
Limited information related safety assessment and technical aspect of plant-based protein alternatives is available to regulators in order to establish standards.	**Malaysia**
-Need to revise the existing standards and guidelines for plant-based alternative protein foods in consideration of various manufacturing processes and plant-based protein alternatives according to the development of the latest technology	**Republic of Korea**

ANY OTHER MATTERS - SEAWEED

As new types of seaweeds are consumed more widely, there may be a need to consider additional or amended MLs for heavy metals	**Australia**
Limited information related to safety assessment and technical aspect on seaweed is available to regulators in order to establish standards.	**Malaysia**
-Demonstration of harmlessness to the human body of seaweed ingestion containing some heavy metals	**Republic of Korea**

ANY OTHER MATTERS - EDIBLE INSECTS

El aporte del Codex resulta fundamental para apoyar a los gobiernos y las empresas que inician actividades productivas con insectos comestibles, con la mira de asegurar una producción eficiente, inocua y sostenible.	**Costa Rica**
Limited information related to safety assessment, technical aspect and trade data of edible insect is available to regulators in order to establish standards.	**Malaysia**
–The new classification of edible insects in HS code according to the increment in trade volume indicates further expansion of the market size in the future, and it is necessary to prepare an internationally agreed standard	**Republic of Korea**

ANY OTHER MATTERS - 3-D PRINTED FOODS

–No information	**Malaysia**
–Need to secure consumer trust on the products	**Republic of Korea**

ANY OTHER MATTERS – MICROALGAE

Limited information related to safety assessment, technical aspect and trade data of microalgae is available to regulators in order to establish standards.	**Malaysia**
Discussion for mutual understanding and standard agreement between countries with different food culture	**Republic of Korea**

ANY OTHER MATTERS – <u>OTHER</u>

-*For all alternative protein products:*Consumers tend to assume alternative protein sources are more sustainable and environmentally friendly, and the industry needs to work to not mislead the consumer and create products that are in line with this perception. Sustainability or environmental claims should however be covered in a standard/guidelines which is/are applicable to all food and beverages in order to create a level playing field.	**Food Industry Asia**

DO EXISTING CODEX STANDARDS COVER THE ISSUES(S) IDENTIFIED?

Creemos que en materia de insectos comestibles, no. y en el caso de Productos vegetales bebibles solamente los productos a base de soja.	**Argentina**
Australia's view is that this needs to be considered on a case-by-case basis, as issues are identified by existing committees or by members, as would be the usual process. This CL may assist to identify potential issues that Codex may need to address in the future. However, if and when those issues arise, the existing processes set out in the Procedural Manual will allow the Commission to consider fully if and how the issue should be addressed in Codex. Specifically, the PM sets out what information is required from a committee or a member who proposes new work or revision of a standard, which includes amongst other things: • information on the relation between the proposal and other existing Codex documents as well as other ongoing work; • its relevance and timeliness; • its relevance to the Codex strategic objectives; • an assessment against the Criteria for the Establishment of Work Priorities; • identification of any requirement for and availability of expert scientific advice; • and identification of any need for technical input to the standard from external bodies so that this can be planned for	**Australia**
Canada is of the view that general Codex texts on food hygiene, labelling, contaminants, etc. are written to apply to all foods. The mechanism or method of production of a food is not the defining feature on whether a Codex standard is needed. Canada does not believe that commodity standards are needed for every type of food, rather, when it is recognized a Codex standard is required to protect consumer health and promote fair trade practices. The existing guidance for microbiological risk analysis are helpful. For plant-based protein alternatives: Canada and the United States submitted a joint proposal for new work in April 2021 to the CCNFSDU to conduct a scoping exercise of plant-based alternatives. The objective of this proposed work is to compile a stock-take document on the global market, composition, regulation and consumer understanding of these products, which may help in determining the need for future	**Canada**

criteria or guidelines for plant-based alternatives. Food Allergens - When the new food source is/or contains protein, there is the potential for the food to become a food allergen, or to be similar enough to an existing food allergen that it will trigger allergic reactions in people with already existing allergies, both of which are a public health concern. It can be challenging to determine whether a protein from a new food source has the potential to become a food allergen or to cross react with existing food allergens. Codex developed some guidance related to allergenicity assessment for proteins being introduced into novel foods, which has also been used to assess potential allergenicity of novel proteins. This guidance dates back to the early 2000's and it would be useful for Codex to develop updated guidance on allergenicity assessment for proteins from new food sources. Areas where this type of guidance would be useful include: Plant-based protein alternatives and edible insects as well as possibly fermentation-derived ingredients and cultivated meat and dairy.	
Las normas existentes actuales del Codex no tratan en forma específica el abordaje de materias nuevas de alimentación y/o nuevos sistemas de evaluación para la inocuidad de productos, debido a que estos no cuentan con información e historial de uso alimentario seguro e inocuo para el consumo humano.	**Chile**
-It seems that new foods mentioned above haven't been covered by current Codex standards yet, but some new foods had been mentioned before, such as edible insects and seaweed. •Insects: The proposal on edible crickets and the products was proposed by Lao People's Democratic Republic and discussed during the 18th and 19th session of CCASIA in 2012 and 2014. In view of the insufficient availability of data to support new work, the coordinating committee agreed to discontinue consideration of this matter. •Seaweed: The safety of seaweed has been concerned by FAO and WHO recently. At the 35th session of CCFFP last year, the information relevant to food safety hazards linked to the consumption of seaweed was introduced by FAO and WHO. Furthermore, it is recalled that Regional standard for laver products (CXS 323R-2017) was approved in 2017. It should be concerned when considering to establish Codex standard on seaweed.	**China**
No existe en el Codex, disposiciones sobre insectos comestibles.	**Costa Rica**
Horizontal Codex standards partly cover food safety and labelling issues also with new foods. Some of the current vertical standards may also be applicable to new foods if they are related to a standardised product. However, the extent to which existing Codex standards cover all relevant health and safety, labelling or trade concerns would require further assessment. For example, the CCPFV CXS38-1981 (Standard for Edible Fungi and Fungus Products) may require revision to include new products derived through fungi fermentation).	**European Union**
EUVEPRO considers the following Codex texts to be relevant to plant-based protein products: - General Standard For Vegetable Protein Products (VPP) - CXS 174-1989 - General Standard For Soy Protein Products (SPP) - CXS 175-1989 - Standard for Wheat Protein Products Including Wheat Gluten – CXS 163-1987 - Regional Standard for Fermented Soybean Paste (Asia) - CXS 298R-2009 - Regional Standard for Non-Fermented Soybean Products - CXS 322R-2015	**European Vegetable Protein Association**

- General Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods (CXG 4-1989) However, most of these documents were developed three decades ago and consideration could be given on whether these are still fit-for-purpose in the context of new/emerging plant-based ingredient sources and applications in foods.	
-Codex texts such as the General Standard for the Labelling of pre-packaged Foods, General Principles of Food Hygiene etc. are applicable to these new emerging topics. There are however many gaps in existing Codex standards in terms of the products referenced above.	**Food Industry Asia**
-As noted in the “Regulatory Matters” section, some alternative protein products in the market do not appear to be covered by existing Codex standards.	**Good Food Institute**
No	**India**
No. Some issues, however, have been covered in the Codex standard especially regional standards. Furthermore, in the case of the use of new raw materials (ingredients), will this be considered a new food (for which there is no standard) or is it considered as a modified old/conventional/known food that have already been standardized, so the only thing needed is a revision of the original standard.	**Indonesia**
-No, this is a new product not yet widely marketed (with exception of "cultured chicken" in Singapore)	**International Meat Secretariat**
“New food product” risk analysis needs to be done to gain a better understanding of how much current codex standards cover safety and labeling issues.	**Kazakhstan**
It does not cover all issues.	**Kingdom of Saudi Arabia**
Existing Codex standards and related texts do not specifically applied to new food source or novel food such as cultivated meat, seafood, and dairy, fermentation-derived ingredient, plant-based proteins alternatives, and edible insects, and their labelling. However, the safety aspects of these products could generally be addressed through Codex general standards and guidelines such as:i. The General Principles of Food Hygieneii. Code of Practice for the management of allergens in food iii. General Standard for Contaminants and Toxins in Food and Feed	**Malaysia**
For seaweed, there are no particular standard relevant for food safety and seaweed is not covered in existing standards.	**Norway**
-Currently, There is no CODEX standard for ensuring the quality and safety of new food sources mentioned above. However, standards for scope, essential ingredients, quality, and nutritional factors for a plant-based alternative protein food have already been established through the Codex Committee on Vegetable Proteins (CCVP) under the "General Standards for Vegetable Protein Products" and "General Guidelines for the Use of Vegetable Protein Products in Food". However, this is limited to refined plant-derived protein products from plants and seeds because plant-derived proteins originating from single-cell proteins are not applicable.In addition, Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology (TFFBT) established in 1999 set standards on safety It does not cover all issues. and risk	**Republic of Korea**

analysis of genetically modified food (GMO) derived from biotechnology. However, this is limited only to genetically modified foods, excluding other food sources or production systems.Therefore, the demand of establishing guidelines and standards that applies to various new food sources and production systems is high.	
-The horizontal standards from general subject committees cover the food safety aspects such as good hygiene practices, maximum level or maximum residue limits. However, some standard such as food additive for novel food or ML for contaminants in insect may be required. Thus, the related standard should be amended to cover the novel food requirement.	**Thailand**
No	**Uganda**
In our view only partially, though the tools to assess risks and food safety exist, e.g. the risk analysis framework. It is possible to apply some Codex standards for some of the categories, for example international standards on protein ingredients for alternative proteins. However, these are likely to be partial and not address the wider context in which the food innovations are developing.	**United Kingdom**
The United States believes the existing Codex committees can consider the topics suggested by FAO and WHO and request support in the form of scientific advice, safety evaluations, or risk assessments in areas Codex members consider appropriate for new work within the mandate of Codex. Specific committees can use existing mechanisms to assess whether current standards sufficiently address the issues identified in this Circular Letter. For example, the General Principles of Food Hygiene and HACCP could be applied to cultivated meat, seafood, and dairy products in order to produce them safely. Codex experts such as the Joint Expert Meetings on Microbiological Risk Assessment (JEMRA) could help member countries to better understand food safety hazards associated with these products to facilitate applying the existing food hygiene framework. This information can be communicated through regular updates under standing committee agenda items on matters of interest from FAO and WHO, or through side events and special presentations by experts on issues of interest to the committees. As demonstrated by, CXS 323R-2017 Regional Standard for Laver Products, a type of seaweed, this is already taking place within Codex.	**USA**

IF NOT, WHAT WOULD BE THE NEED FOR AND BENEFIT OF A CODEX STANDARD IN THE AREAS YOU HAVE IDENTIFIED?

orientación a los gobiernos. Normas de referencia sobre base científica y acordadas multilateralmente que permitan proteger al consumidor y garantizar prácticas equitativas al comercio en el marco de los objetivos de Codex, a la vez que provean una base sobre la cual armonizar y evitar restricciones encubiertas al comercio internacional	**Argentina**
At this stage, Australia has not identified a need for a new Codex standard. The existing process for a committee or a member to propose new work or revision of a standard would need to be followed to allow Codex to determine if there is a need and benefit.	**Australia**
For cellular agriculture: There is a need for a new Codex standard for cellular agriculture and the development of premarket guidance for the safety assessment of these products would be useful.	**Canada**

For plant-based protein alternatives - Develop guidelines for nutritional safety and quality specific for each new food source/ system Food Allergens: see Canada's comment in Question (b) above.	
Una de las principales barreras son comerciales debido a que existe un desconocimiento por parte de las autoridades sanitarias nacionales al no tener definiciones claras en estas categorías de nuevos alimentos, lo que trae como consecuencia problemas en el ingreso de este tipo de productos a los diferentes mercados. Por otr parte, junto con identificar las barreras comerciales por no existir normativa de referencia, creemos importante además señalar que contar con normas de referencia establece una base común para los distintos miembros del Codex, es permitir que a nivel nacional se establezca una base sobre la cual desarrollar la innovación para la elaboración de nuevas fuentes de alimentos o proteínas, y su uso y comercialización.	**Chile**
-Codex standards are very important reference standards, which will guide member countries to establish national standards based on the results of risk assessment. It is also useful for ensuring the fair practices in food trade among member countries.	**China**
R/. El Codex es el ente de referencia en materia de inocuidad y comercio equitativo, por ende, el Codex es el organismo idóneo para abordar esta cuestión, en cumplimiento con los objetivos mencionados y su plan estratégico.	**Costa Rica**
The setting of Codex standards for new foods/new food sources would help to enhance human health protection at global level, fair trade practices and provide useful tools for control and enforcement authorities.	**European Union**
-There is a need for a clear and consistent/harmonised regulatory approach for new food sources and production systems in order to safe guard the consumer whilst not hampering innovation, as well as to help facilitate market access and trade through harmonisation internationally and at a national level (This is in line with Goal 1 – "Address current, emerging and critical issues in a timely manner" of Codex Strategic Plan 2020–2025). Many developed countries have developed and adopted their own novel food frameworks, however there are many countries that still lack a structured way of assessing new foods and new production methods. Standards specifically pertaining to certain new foods would be of great benefit, such as for plant-based food products which are increasingly being developed and consumed all across the globe.	**Food Industry Asia**
-Codex standards could reduce future trade barriers and provide a more harmonized global regulatory framework for such products, but new or amended standards should be flexible enough to avoid stifling innovation and allow for maximum flexibility in the technology used to produce foods.	**Good Food Institute**
A general guideline may be framed by the Codex and specific issues may be in accordance with the National Regulatory agencies.	**India**
Codex standards should cover all food products consumed and traded around the world, including new food sources, to ensure the quality and safety aspect and also to facilitate fair practices in the food trade.	**Indonesia**

-Need for international standard providing full transparency for nutritional, environmental, and food safety impact	**International Meat Secretariat**
Codex standards would allow for an international, independent and comprehensive assessment of the safety of “new food products”.	**Kazakhstan**
For plant-based protein alternatives, there is standard (GENERAL STANDARD FOR VEGETABLE PROTEIN PRODUCTS (VPP) CXS 174-1989). Preparing standard for the above-mentioned products to help in many ways such as r regulate them to ensure the safety of these products, to facilitate international trade, to ensure fair trade through a international mechanism for dealing with these food.	**Kingdom of Saudi Arabia**
Codex can explore and develop standards or review its text (e.g. safety requirements, labelling) to include provisions related to these new food sources/ novel foods, as appropriate, and can serve as guidance for countries to make decision on their national legislation regarding new food sources/ novel foods. Nevertheless, there are obvious needs for more information exchanged on the safety and quality aspect of these novel foods, related technology and innovations.	**Malaysia**
Yes, particularly for seaweed.	**Norway**
-As a way to address food insecurity, resource usage, and environmental pollution caused by growing global population, interest and development of new food sources and production systems have continued steadily. It is only natural that the market size grows as the need for sustainable food sources and production systems increases. However, there is no standards and guidelines yet worldwide that are consistent and clear. Every countries have different intake histories and definitions of new food sources. Some developing countries may not even be able to identify them due to a lack of technological advancement. These facts does not satisfy CODEX objectives for consumer protection and the integration of various related specifications.There are the following advantages in preparing internationally integrated standards for food sources and production systems for CODEX purposes:· The establishment of CODEX standards enables the harmonization of regulations regarding new food resource and production systems that differ from country to country· Avoid consumer and producer confusion by creating internationally integrated standards· It is possible to prepare CODEX standards in which both producers and consumers participate· Eliminating non-tariff barriers by promoting fair trade practices· Reduce associated unnecessary costs through internationally agreed standards· Improve technical skills in building capacity to meet CODEX standards· Promote consumer protection by improving food quality· Ensure marketability and fair pricing by identifying unidentified food sources and production systems	**Republic of Korea**
The need for the codex standard would propel the products in international trade while addressing underlying food quality and safety issues	**Uganda**
Food systems are complex and the use of Codex standards as the basis for national rules can help provide consumers and trading partners with the necessary food safety and quality assurances.	**United Kingdom**

We would recommend that individual Codex Committees review these new food or production methods and request comment from their members as to which foods or processes are currently utilized and in international trade to an extent where work at the Codex level is necessary.. Specific committees can use existing mechanisms to assess whether current standards sufficiently address the issues identified in this Circular Letter. For example, the Principles of Food Hygiene and HACCP could be applied to cultivated meat, seafood, and dairy products in order to produce them safely. As noted above, Codex experts such as JEMRA could help member countries to better understand the food safety hazards associated with these products to facilitate applying the existing food hygiene framework. As demonstrated by, CXS 323R-2017 Regional Standard for Laver Products, a type of seaweed, this is already taking place within Codex.	**USA**

HOW WOULD YOU RECOMMEND THE ISSUES YOU HAVE IDENTIFIED AS NEEDING A CODEX STANDARD BE PRIORITIZED?

creemos que lo importante es realizar las evaluaciones de riesgos, las cuestiones higienico sanitarias que se requieran y luego los aspectos nutricionales si correspondiera, y definir las cuestiones regulatorias y de etiquetado que deberían abordar las norma codex para estos productos	**Argentina**
By following the PM procedures for the elaboration of Codex standards and related texts.	**Australia**
Many committees have prioritization mechanisms to aid work management and we see prioritization for these products to fall into that process. In addition, we believe it is within the purview of CCEXEC to provide advice to the Commission on prioritization of issues affecting multiple Committees. The Commission then takes a decision on how Committees should prioritize. This is in line with the current Codex procedures, which appear to be working effectively.	**Canada**
En base a las definiciones consensuadas de los productos con que se trabajan, se recomienda: 1.- La priorización de la definición de análogos de alimentos. 2.- El trabajo específico que puede realizar Codex en lo que respecta a los insectos comestibles, para que estos puedan definirse como fuentes de alimentos. 3.- Microalgas. 4.- Cultivos cárnicos y productos fermentados de biomasa.	**Chile**
-When considering the necessary and feasibility of establishing Codex standards, it is very important to apply the principles mentioned in the Guideline on the application of the criteria for the establishment of work priorities. Include but not limited to the following aspects:1. To identify whether food safety hazards exist.2. To identify whether risk assessment has been carried out by FAO/WHO expert body or expert consultant panel.3. To identify whether there is an international trade and the trade volume. 4. To identify whether the product has been commoditized and the possibility of standardization. According to the circular letter, new foods denote those that have not been widely consumed either because they have recently emerged into global retail space thanks to technological innovation, or because their consumption has been historically restricted to specific populations or regions in the world. Considering the limited resources of Codex,	**China**

priorities should be given the foods that have been consumed for a long time in some regions and the safety have been assessed by FAO and WHO, such as seaweed, edible insects.	
R/. Costa Rica considera que debería realizarse una consulta a los miembros del Codex para identificar aquellas cuestiones que requieren una acción en el corto o mediano plazo. De igual manera, si surgieran una numerosa cantidad de temas emergentes, podría implementarse una herramienta de priorización a nivel de la CAC, tal y como ya lo han trabajado varios Comités del Codex como el CCFICS o el CCFL.	**Costa Rica**
A first priority would be the development of food safety standards in key areas, such as contaminants in seaweed or hygiene in insect production that could be addressed by existing general subject committees on the basis of FAO/WHO scientific advice. Section 4 of the FAO publication 'Thinking about the future of food safety – A foresight report' provides a useful basis to identify key food safety issues in different categories of novel foods. As a second priority, standards on nutritional aspects and labelling of the new foods should be developed, where appropriate. Ensuring proper and factual information to consumers would address the consumer acceptance challenge for these foods and facilitate their trade. Moreover, Codex standards on nutritional aspects and labelling of alternative proteins could assist Members in their implementation efforts with respect to the SDGs and transition towards more sustainable food systems. Thirdly, it should be considered if there is a need for developing commodity specific standards for certain categories of new foods setting specifications reflecting the identity and composition and quality attributes of the new food and ensuring proper and factual information to consumers thus addressing the consumer acceptance challenge for these foods and facilitating trade. Lastly, it could be further considered if Codex should develop a more holistic approach on new foods/new food sources, such as risk analysis principles. The EUMS are willing to share their experience and knowledge with new food sources, new foods and new production technologies with other Codex members and to explore how Codex could effectively contribute to the protection of consumer health and fair trade practices in this emerging area. We acknowledge that other regulators have similar experience with dedicated legislative frameworks on "novel foods" while other regulators may have experience on some types of food that would be considered as "novel" in the EU but that are traditional in their countries.	**European Union**
-Prioritisation for standard creation should be made based on the severity of the safety concerns raised for particular products and the current and predicted near future adoption of consumption of particular products; under this reasoning, Food Industry Asia proposes the development of horizontal guidance for plant based and cultivated products first. Food Industry Asia proposes focusing on the development of guidance for evaluation of ingredients, rather than focusing on vertical/commodity standard for ingredients. At a later stage work on commodity standards can be prioritised, depending upon the evaluation based upon criteria established in the Codex Procedural Manual.	**Food Industry Asia**

It should follow Criteria for the establishment of work priorities under Codex Procedural Manual, with specific consideration related to climate change and SDGs.	**Indonesia**
-1. Food Safety, 2. Environment, 3. Nutrition Research by Mancini and Antionoli, 2022 https://ift.onlinelibrary.wiley.com/doi/10.1111/1541-4337.12853	**International Meat Secretariat**
For each category of foods, it is necessary to determine the degree of novelty of the receiving / production processes and the raw materials used. Then, using the One Health approach, identify key areas in which it is necessary to ensure an adequate level of safety.	**Kazakhstan**
The technology and innovation for new food source is continuously moving and advancing to cater to current global needs and growing consumer demand. We believe that there is a need for Codex to consider this development and to conduct safety assessment on these products. In addition, Codex guidance is important to establish identity and classification of these novel food e.g. commodity or technology-based product.	**Malaysia**
We would suggest first prioritizing seaweed.	**Norway**
-The preparation of 'Guidelines for Identification of New Food Sources and Production Systems' should be given top priority. Different national definitions of new food sources, production systems and food intake history can confuse consumers, especially in developing countries with little experience with these foods. The WHO's workshop on "Regulatory and Food Safety Aspects of Alternative Proteins for Conventional Animal Products" (`21.5) and the 44th General Assembly (`21.11) hosted by the WHO Western Pacific Office confirmed the importance of a robust regulatory framework internationally agreed upon.In the future, science and technology will emerge to innovate sustainable food sources to cope with global population growth. In addition to the seven foods presented in the circular letter, more diverse and new food sources and production systems will surface. Strategic Objective 1 of the CODEX strategic plan 2020-2025 is to identify emerging issues and develop appropriate international guidelines. To present guidelines for identifying new food sources and production systems that we do not currently anticipate will provide a preemptive foundation for consumer and fair trade growth.After Codex set the basic framework including definitions and scope for new food sources and production systems, the designated committee will continue developing individual guidelines and specifications (including matters on food safety, labelling, quality criteria, nutritional aspects, etc.) for new food sources. The work will be prioritized based on global consumption and trade volume through relevant circular letters. For example, in South Korea, Korean food manufacturers focus on developing livestock- and aquatic life-derived culture meat among the above seven food sources, followed by edible insects. When the demands are identified, standards and guidelines are installed according to the understanding of consumer needs.	**Republic of Korea**
-We recommend the prioritized issues as follows: edible insect, insect for feed, plant-based protein alternatives, seaweed, microalgae, fermentation-derived ingredients and 3-D printed foods.	**Thailand**
At this point in time we have not identified specific issues though trust members would bring forward new work proposals in the normal way and for proposals to be considered in the context of the critical review but also: • Strategic Goal 1: Address current, emerging and critical issues in timely manner, and	**United Kingdom**

• Criteria for the Establishment of Work Priorities alongside Strategic Goal 1 to address new and emerging issues in a timely manner on the basis of need. However, given the diversity and pace of change we recognise the need to be agile in dealing with the issues and suggest an enhanced role for the Executive Committee in deciding how best to manage associated work.	
Any work on new foods or production methods at the Codex level should be prioritized on whether such products exist and are in international trade. Prioritization could also be considered based on the areas in which information is most readily available and jurisdictions have regulatory approaches for use and implementation. Little or no priority should be given to products or production methods that are not in use internationally.	**USA**

WHAT IS YOUR ASSESSMENT OF THE SCIENTIFIC BASIS NEEDED TO WORK ON THE ISSUES IDENTIFIED?

This is difficult to assess as a specific issue has not yet been raised in Codex. In accordance with the process in the PM for proposing new work or revision of a standard, a proposal would need to identify any requirement for and availability of expert scientific advice. Through this process, it could be assessed whether the existing expert bodies are placed to provide the necessary advice, and if not, explore additional options. If through this CL, there are key emerging issues identified related to new foods and production systems, then relevant Codex committees could possibly be asked to consider if scientific advice from the existing FAO and WHO expert bodies would be sufficient or if additional expert advice is likely to be needed.	**Australia**
For cellular agriculture: The development of premarket guidance for the safety assessment of products of cellular agriculture would be useful For plant-based protein products - Interpretation of the data from different technologies used; what is the comparator to evaluate safety; existing knowledge of the new area; how are these analysed to identify hazard due to genetic changes; long-term implication of the consumption of these foods.	**Canada**
Se requieren datos sobre: • Información nutricional. • Efectos de los procesos productivos sobre el alimento nuevo. • Antecedentes de historia alimentaria de la fuente de origen del alimento nuevo • Uso previsto del alimento nuevo y la cantidad prevista de consumo • Información de consumo humano previo del alimento nuevo • Información microbiológica relevante del alimento nuevo	**Chile**

• Toxicidad del alimento o de sus componentes • Alergenicidad del producto nuevo o de algunos de sus componentes.	
-A systematic and comprehensive risk assessment is essential for making appropriate risk management decision. For example, for 3-D print foods, potential migration of chemicals from the 3D printer to food and the resulting hazards need to be assessed. For seaweed, microbial risks from marine foodborne pathogens, heavy metal accumulation (e.g. As and Cd) and marine toxins such as palytoxin, domoic acid and analogs, ciguatoxins, and cyclic imines should be considered.	**China**
R/. Respecto al tema de insectos comestibles, cada vez hay más evidencia científica sobre los métodos de producción y beneficios del consumo de insectos. Por su parte, la FAO ha trabajado y apoyado ampliamente el tema. A nivel internacional diferentes empresas ya han iniciado la producción industrial de insectos para consumo humano. En Estados Unidos en el año 2011 no existían empresas oficialmente inscritas para la producción de insectos y en el año 2016 existían más de 25. Empresas como Protifarm en Europa y Aspire Food Group en Norteamérica son ejemplos de empresas que cultivan y procesan insectos a escala industrial. Por lo expuesto, Costa Rica considera que se cuenta con suficiente sustento técnico y científico para iniciar las discusiones en esta área.	**Costa Rica**
Advice from the FAO/WHO scientific bodies would be necessary taking on board a One Health approach to food safety risk assessment. As indicated earlier, EFSA as well as other risk assessment agencies have experience in assessing novel foods and this could be shared as necessary to facilitate the work of FAO/WHO bodies and Codex.	**European Union**
-Please see response to section (g).	**Good Food Institute**
Guidelines documents should contain general principles that may be adhered by the member countries.	**India**
The basis of Codex standard should always be based on science. With that, scientific information regarding the historical safe use of such food products, need also be considered.	**Indonesia**
-Very little scientific literature. Much hype, but little progress to date (https://doi.org/10.3389/fnut.2020.00007)	**International Meat Secretariat**
Need to use resources from OIE, IPPC and scientific advices of the Codex Expert Committees	**Kazakhstan**
Malaysia is of the view that there are insufficient data and information on these products to establish scientific basis to work on them. Nevertheless, it is important for Codex to conduct safety assessments on these products.	**Malaysia**
The knowledge and data base on risk factors on seaweed in increasing, in particularly on iodine and metals. A new report from WHO/FAO on food safety in seaweed will soon be published and can be a good background for development of Codex standards on seaweed.	**Norway**

-· Allergic safety assessment data/assessment method for food sources (food insects, vegetable alternative protein foods, cultured foods) that are highly likable to cause allergies· Safety assessment of residual animal drugs, pesticide residues, and other additives in food sources· Safety assessment related to the accumulation of heavy metals, antibiotic resistance, and toxicity assessment for food sources· Data collection and safety assessment of heavy metals and other hazardous substances that may be exposed to food through the cultivation process of new production systems, including precision agriculture and indoor vertical hydroponics	**Republic of Korea**
There is already substantial scientific research and assessment undertaken on the products that is available	**Uganda**
The UK Food Standards Agency is an evidence-based organisation. Initial consideration of development in areas such as cultured meat suggest that the data on safety of the product of these technologies may be limited. Work may be needed to support the development of geographically representative data that will be needed to consider risks in the developing sectors across the globe.	**United Kingdom**
Consistent engagement with the FAO/WHO scientific bodies such as JECFA (and potential convening of the Joint Expert Meetings on Nutrition (JEMNU) if nutritional aspects are to be considered) would be necessary to foster global agreement on the safety of new food sources and their corresponding production technology.	**USA**

WHAT ADDITIONAL INFORMATION, EVIDENCE OR ANALYSIS WOULD BE REQUIRED FOR NEW WORK PROPOSALS TO BE DEVELOPED FOR ANY OF THE ISSUES YOU HAVE IDENTIFIED IN YOUR ANSWER TO QUESTION A.?

As above, this would need to be considered on a case-by-case basis, for each particular issue identified by a Codex committee or member.	**Australia**
Análisis de idoneidad, Análisis nutricionales de los productos con los que se está trabajando, información sobre la inocuidad de estos productos, durabilidad de los productos. Es posible trabajar las pruebas y análisis desde una matriz troncal que se desglose en los requerimientos para cada tipo de productos descritos en el cuadro de la respuesta “a”.	**Chile**
-According to the requirement of PM, the proposal for new work should include the following points:•The purposes and the scope of the standard;•The relevance and timeliness;• The main aspects to be covered;•An assessment against the Criteria for the establishment of work priorities;•Relevance the Codex strategic objectives;•Information on the relation between the proposal and other existing Codex documents as well as other ongoing work;• Identification of any requirement for and availability of expert scientific advice;•Identification of any need for technical input to the standard from external bodies so that this can be planned for;•The proposed time-line for completion of the new work.It is believed if above information could be provided and fully considered, it is enough.	**China**
R/. Para el establecimiento de los factores esenciales de composición y calidad, se requieren datos de producción industrial de insectos para consumo humano.	**Costa Rica**
Once their safety is established, consumer information, perception and acceptance of the new foods and new food sources are key determinants for their successful contribution to healthy diets from sustainable food systems. This objective will invariably necessitate changes in consumer behavior.	**European Union**

-Please see response to section (g).	**Good Food Institute**
The issues identified may vary in each country/region. Therefore, in addition of trade data, it might be necessary to consider other factors such as its relevance to SDGs goals that Codex can contribute to it, etc.	**Indonesia**
This information will be determined as research progresses.	**Kazakhstan**
i. Detail process of the production of cultivated meat, seafood, and dairy.ii. Existing country's legislation and control mechanism of market access on novel foodiii. For cultivated meat, seafood, and dairy: a. Information on the nutrient used to feed the cell. b. The use of stem cell e.g. its source and process. c. Available DNA analysis between cultivated meat, seafood, and dairy with conventional meat, seafood, and dairy. d. Comparison nutrient profile between cultivated meat, seafood, and dairy with conventional meat, seafood, and dairy. iv. Long-term health effect of new food sources'/novel foods' consumption.	**Malaysia**
-In order to prepare standards and/or guidelines for new food sources and production systems, it is necessary to collect consumption-related data from members because they may have different definitions of "new food" as well as food intake history. It will be possible to form a definition(s) and related criteria for new food sources and production systems based on the data collected.	**Republic of Korea**
Input with regard to analysis may be required	**Uganda**
The need for new work will also depend on the specific nature of the foods, and should take into consideration the purpose of the foods (e.g., foods meant to serve as a substitute/replacement for other foods vs. "new" foods).	**USA**

APPROACHES TO DEVELOPING CODEX STANDARDS

No tenemos claridad por el momento, aunque consideramos que en esta instancia quizás la combinación propuesta en el 3 podría ser más adecuada.	**Argentina**
Australia's view is that consideration of the approaches for developing additional standards is premature. The information received through this CL might help determine whether there are key emerging issues that relevant Codex committees could provide further advice on. Otherwise, the existing process for proposing new work, provides the necessary mechanism to assess which committee/s are best placed to address the particular issue identified.	**Australia**
Chile cree que la forma de trabajo que se debiera adoptar es en el siguiente orden: 1) Abordarlo de manera vertical, para productos específicos, agrupados o no, realizando las respectivas normas. es decir, texto o norma de producto; 2) Abordarlo de forma horizontal (es decir, textos o normas generales).	**Chile**

-For edible insects, FAO had published a comprehensive paper entitled "Edible insects: future prospects for food and feed security" which covered a variety of issues including production and processing practices, food safety and preservation, possible contribution to food and feed security. It is suggested to consider possibility to establish the guidance on feeding edible insects. The guidance can include the requirement on the hygiene and sanitation of housing and facility, quality of sanitizers used, feed and water quality, nutrient supplementation quality, quality of ice used for cooling and quality of packaging material. It could be considered by CCFH.For some fermentation-derive ingredients, such as HMO, could be consider by CCFA.For seaweed, CCFFP is a possible choice to lead this work.	**China**
R/. En caso de emprenderse una nueva norma sobre insectos para consumo humano, al tratarse de un producto específico, debería abordarse a través de una norma de producto. En caso de identificarse otras cuestiones relativas a métodos de análisis, residuos de plaguicidas, contaminantes, aditivos o etiquetado entonces deberá analizarse cada caso por separado en el Comité correspondiente. Costa Rica considera que, al no existir un Comité específico para tratar esta cuestión, correspondería a la CAC definir el modo en el que se llevaría a cabo el trabajo, por ejemplo, por medio de un grupo de trabajo por correspondencia.	**Costa Rica**
See reply in point d.	**European Union**
-(3) a combination of both.It would be beneficial to have a general standard for novel foods, as well as specific standards pertaining to specific product groups. As innovation is occurring at a rapid pace the novel standard could provide a framework that is flexible enough to capture new foods and new processes, whilst the vertical standards could provide a greater degree of detail for more established but still “new” product groups such as “plant-based” products.	**Food Industry Asia**
-With respect to the HS code issue identified in response to section (a), it may be useful for the Codex Secretariat and the WCO Secretariat to prepare a background discussion paper exploring whether any coordination between WCO HS codes and Codex’s categorization systems covering semi-processed and processed foods and food ingredients would be appropriate and helpful to reduce barriers to international trade for plant-based alternative proteins as well as other foods currently covered by “Other” subtypes of HS codes.With respect to the apparent lack of applicable commodity or horizontal standards or guidelines for some alternative proteins, it may be useful for the Codex Secretariat, with the assistance of FAO and WHO, to prepare a discussion paper exploring whether new commodity standards, guidelines, or codes of practice are needed for certain plant-based proteins and/or foods created through microbial fermentation, or whether existing Codex commodity standards, guidelines, or codes of practice could in some cases be amended to include such foods. For example, the discussion paper could address whether the Codex standard for edible fungi and fungus products, first adopted in 1981 (CXS 38) by CCPFV, could be amended to include newer fungi-based fermentation-derived products. It could further address whether standards or guidelines under committees such as the CCFA and CCFH should be amended to clarify applicability to plant-based proteins and/or foods created through microbial fermentation. The discussion paper could be submitted for the review of the subcommittee of the CCEXEC for further recommendations to CCEXEC/CAC and then the assignment of the work or works identified to the relevant Codex Committees for their consideration.With respect to food safety considerations, as cultivated meat products and new fermentation-derived ingredients begin to enter the market, the CCEXEC should continue to collect information relating to the regulatory approval and trade of these products. Should the need arise in the future, it may be advisable to initiate a joint electronic working group (J-EWG) involving relevant committees, such as CCFH and CCFA, to address horizontal issues relevant to these products, such as whether	**Good Food Institute**

principles or guidelines relating to food safety assessments are needed. The J-EWG could be modeled after the one recently created between CCPR and CCRVDF. For cultivated meat, the FAO's upcoming expert consultation on food safety aspects for cultivated food products may provide a further basis for the development of such Codex principles or guidelines.	
Third option, a combination of both to ensure availability of safe and wholesome food for human consumption.	**India**
It depends on the issues, Codex should identify relevance subsidiary bodies (this may require modification/expansion of the scope of TOR for certain subsidiary bodies), established task force, or assign Regional Coordinating Committee if the product only traded in specific region.	**Indonesia**
-Codex may establish a general standards and general texts on new food source/novel foods. It may be difficult to develop based on commodity as these products are not commodity-specific but rather as a result of new technology or innovation.	**Malaysia**
-Combination of both approach- As new food sources and production systems will continue to emerge in the future for a sustainable food system, it is necessary to establish a basic framework for consistent safety management. Therefore, the CODEX Committee on New Food Sources and Production systems should be established to prepare unified commodity standard to prevent confusion among consumers and producers around the world by establishing term definitions, evaluation principles, procedures and standards through 'Safety evaluation guidelines for new food sources' and 'Safety evaluation guidelines for new production systems'.Afterwards, if the work of establishing the necessary standards for microorganisms, pesticide residues, and residues of veterinary drugs in new food sources according to the amount of high production, consumption, and trade, it will be possible to effectively establish a safety management system for new food sources and production systems that are emerging quickly.	**Republic of Korea**
-In principle, the existing general standard can still address the issues according to their respective mandates. It is unnecessary to address the issue by vertical standard. However, if it is needed to establish novel food standard, relevant committees (e.g. CCFICS, CCFL) may consider the issue. In case there is no relevant committee, the new taskforce may be established to consider the issues. For example, Code of Practice for edible insect may be established by this new taskforce.	**Thailand**
The horizontal approach would serve the purpose considering the wide coverage of the issues	**Uganda**
In general we believe the issues for Codex arising from food innovation could be managed within the existing subsidiary body structure, though we acknowledge that due to the cross-cutting nature of the issues closer cross-committee working may be needed. It is also important to ensure there is the necessary capacity and skills to provide timely expert scientific advice. However, we also recognise there may be a desire to explore other options that might facilitate a holistic approach to the management of work related to the "novel foods" category. If there is wider support for a discussion with the wider membership we would suggest tasking the Codex Committee on General Principles.	**United Kingdom**
In general, the majority of the "new foods" considered in this document are not foods themselves, but rather non-traditional mechanisms to produce food. Therefore, the appropriate mechanism to address any unique food safety or fair-trade considerations for these production processes is through the horizontal general subject committees, which can consider specific issues for the new production methods that fall under their existing mandates as they see necessary (e.g., through draft guidelines or codes of practice). New foods by their very	**USA**

definition are not limited to traditional production processes or strict traditional parameters of identity. Therefore, Codex should only develop vertical commodity standards for new foods when existing commodity standards exclude these new production processes for analogous foods. In some cases, it may be appropriate to modify existing commodity standards or horizontal standards to accommodate new production processes (for example, it may be appropriate to develop a new food category in the General Standard for Food Additives).	

CODEX ALREADY HAS A RANGE OF WORKING MECHANISMS (E.G., COMMITTEES (SOME ADJOURNED SINE DIE WITH POTENTIAL TO REACTIVATE), TASK FORCES, WORKING GROUPS, MATTERS REFERRED, CROSS-COMMITTEE WORKING GROUPS).

Australia's view is that existing mechanisms are sufficient to assess issues as they emerge and determine the best way of addressing in Codex. New work proposals can be brought to the CAC by member countries in accordance with existing processes in the Procedural Manual. This provides a mechanism when there is no obvious committee entry point.	**Australia**
Canada believes the current mechanisms provide Codex with sufficient tools for managing these issues. The mechanism for sharing information from FAO/WHO to committees using "Matters of interest from FAO/WHO" may be a starting point, then, each relevant committee may need to evaluate whether they have a role and if existing standards and guidelines apply or if there are gaps. We believe any adjustments or flexibility can be dealt with on a case-by-case basis as they arise. An example of when Codex has made an adjustment to address cross-cutting issues is the recent efforts to coordinate work at CCPR and CCRVDF. A joint working group could report to relevant committees, and work coordinated based on session dates.	**Canada**
Please see response to section (g).	**Good Food Institute**

DO THESE MECHANISMS PROVIDE CODEX WITH SUFFICIENT TOOLS TO ADDRESS THE ISSUES YOU HAVE IDENTIFIED?

Si	**Chile**
Yes, these mechanisms provide Codex with sufficient tools to address the issues. No need to establish additional tools.	**China**
Si	**Costa Rica**
Yes. The diversity of the working mechanisms that are available should in principle allow addressing most issues that have been identified. However, what is lacking is a mechanism that ensures that Codex is aware of ongoing innovation in order to promptly inform its establishment of work priorities. None of the existing committees appears to have such mechanism. Committees and CAC rather rely on proactivity of FAO/WHO and observer organizations.	**European Union**

EUVEPRO considers that the Codex Committee on Vegetable Proteins (CCVP), which is currently adjourned, would be the appropriate mechanism to address future issues in relation to plant-based protein ingredients. As a general approach, any assessment for the need of new work and/or revisions should be assessed by the relevant Codex Committees for the standards and guidelines within their scope. Each Codex Committee could then report back to the Codex Alimentarius Commission.	**European Vegetable Protein Association**
Yes	**Food Industry Asia**
Yes	**India**
It is enough. It is necessary to unite the efforts of all countries and observers in order to cover all possible data on “new food products”	**Kazakhstan**
Yes	**Kingdom of Saudi Arabia**
Yes	**Malaysia**
Do these mechanisms provide Codex with sufficient tools to address the issues you have identified?New food sources and production systems will continuously be developed in the future, and a CODEX committee will be need to carry out the related work in a very elaborated and professional manner.However, It is difficult to carry out work that encompasses both the new food supply and production system identified through the existing CODEX system and the supply and system that will emerge in the future. In the case of the Ad hoc Intergovernmental Task Force on Food Derived from Biotechnology(TFFBT), established in 1999 with Japan as the host, there are only standards centered on safety management and risk analysis of recombinant DNA-foods. Therefore, other new food sources and production systems cannot be included to standards or guidelines related to TFFBT. There is also the CODEX Committee on Vegetable Proteins(CCVP), established in 1989 with Canada as the host, has established General Standard for Vegetable Protein Products and Guidelines for the utilization of Vegetable Protein Products in Foods. However, these documents do not apply to plant-derived proteins derived from single cell proteins, and limited protein products derived from plant seeds.Since the task of identifying the risk factors at the processing stage and various production systems on each new food sources will be an enormous work with different forms and characteristics depending on manufacturing and processing technology, the establishment of sub-committee which will be in charge of this work is very needed. For this reason, Korea would like to propose the establishment of the CODEX Committee on New Food Sources and Production systems.Some of the new food sources, such as edible insects and seaweed, have been consumed for a long time in Asian countries, including South Korea, Thailand, China and Vietnam. Therefore, various databases closely related to safety management have been already established, which will be of great help in developing the CODEX standard. In addition, since Korea has always worked hard to preemptively respond to important issues of CODEX, Korea took the lead in coordinating opinions among Asian countries on 'new food supply sources and production systems', which will be constantly raised internationally now and in the future. We would like to address the issue by mediating communication with the Codex Presidency and Member States.	**Republic of Korea**
They do. The mechanism through task forces provides an excellent pathway with clear ToR and deliverables	**Uganda**

In our view yes, using the existing work management practices and subsidiary body structures is preferable to creating new ones.	**United Kingdom**
Yes, the majority of issues for new foods or production methods can be addressed by the standing general subject committees and fall within the existing mandates of those committees. The main aspects of safety for these would be additives used in their production or to make the final product (CCFA), hygienic practices in production (CCFH), nutritional aspects for current food replacements (CCNFSDU), and labeling for fair trade and safety aspects such as allergenicity (CCFL). Codex has already successfully accomplished this in CXS 323R-2017 Regional Standard for Laver Products, a type of seaweed, using existing tools. CCNFSDU may also consider new work proposals under development for plant-based protein alternatives	**USA**

IF SO, HOW CAN THEY BE BEST USED TO DO THAT? (E.G., IF THERE IS NO OBVIOUS COMMITTEE ENTRY POINT FOR A NEW WORK PROPOSAL, HOW COULD THIS BE CONSIDERED WITHIN THE CURRENT STRUCTURE?)

El trabajo propuesto podría comenzar realizando la consulta a expertos de la FAO para que ellos puedan proporcionar una base/lineamiento para el desarrollo de las normas o directrices que se elaboren con estos temas. Se sugiere que este trabajo sea realizado a través de equipos transversales de Comités idóneos del Codex Alimentarius mediante la modalidad de Grupos de Trabajos Electrónicos, considerando también la participación de los Comités Expertos Científicos del Codex (Órganos de expertos: JECFA, JMPR, JEMRA, JEMNU).	**Chile**
It should consider this matter in current Codex committees first. If necessary, the TOR of current committees could be broadened or revised to adapt the new needs. With regard to some adjourned sine die committees, it could be reactivated. If it is failed to find the proper committee to do this work, it could consider to establish working group or task forces to do it.	**China**
R/. Costa Rica considera que podría ser bajo un grupo de trabajo por correspondencia bajo la dirección de la Comisión del Codex.	**Costa Rica**
See reply to point d. A fully informed reply to this question needs further reflection that should build on the identification of the objectives of standardisation. The establishment of a task force or another type of subsidiary body should be duly considered at a later stage.	**European Union**
As the raised topics are cross-cutting and are not within the mandate of one committee, it would be preferable for CAC to either establish an ad hoc intergovernmental task force with a specific mandate to work on these emerging topics or to establish working group (which would be a quicker option and hence enable these emerging matters to be dealt with at a faster pace). An overarching framework is needed that describes how to assess new food sources and manufacturing processes.	**Food Industry Asia**
By means of adhoc Task Forces and Working Groups.	**India**

To be determined as the need for a particular Codex standard is identified	**Kazakhstan**
A new committee is created that includes specialist members from several other committees to discuss each product separately. For example, the Intergovernmental Task Force on Foods Derived from Biotechnology: Codex Intergovernmental Task Force on Antimicrobial Resistance (TFAMR)	**Kingdom of Saudi Arabia**
Codex may consider establishing a task force (TF) with terms of reference to develop a general standard on novel food. It could take similar approach with the principles and guidelines on food derived from modern biotechnology which provide overarching principles on the risk analysis of foods derived from modern biotechnology and food safety assessment of foods derived from recombinant-DNA plants and microorganisms. It could also include, for example, the definition of novel food, its classification (e.g. commodity based or technology based) and categorization according to Codex GSFA category and GSCTF classification. The TF can include members from Intergovernmental organisation (IGO) to enable information exchanged with interested parties (e.g. research institute and industries). At the same time, existing committees on general subject can consider addressing the cross cutting issues such as food additives, contaminants, allergens, microbial contamination, and labelling.	**Malaysia**
If so, how can they be best used to do that? (e.g., if there is no obvious committee entry point for a new work proposal, how could this be considered within the current structure?)The establishment of a new sub-committee, so called the CODEX Committee on New Food Sources and Production systems, is necessary to manage works systematically and professionally regarding to all new food sources and systems that are identified and will emerge according to technological development. By establishing a subcommittee that can review and take charge of the categories of new food and production systems as a whole, it will be possible to correct the confusion about new food sources that are constantly being raised. In this regard, the Republic of Korea, which has been continuously interested in and supporting CODEX, would like to propose the establishment and chair of the CODEX Committee on New Food Sources and Production systems.	**Republic of Korea**
Deployment through a task force with specified timeline	**Uganda**
In our view this should be considered by the Executive Committee in the context of the critical review in consultation with relevant subsidiary body chairs.	**United Kingdom**
One approach would be to task the standing general subject committees to examine these issues to determine what issues should be addressed pertaining to new foods and production processes that fall within their existing mandates – this would be similar to the request by the 70th CCEXEC that all committees develop an approach for the general management of their work. For example, CCEXEC could recommend that all committees consider the issues raised in the collective response to this Circular Letter and 1) identify issues that fall under their existing mandates that should be addressed; 2) request additional comment from their members as to which products/production processes are in use in international trade; and 3) develop an approach for the management of the work of their specific committee on the identified issues.	**USA**

DO YOU THINK EXISTING CODEX TOOLS NEED TO BE ADAPTED TO ENSURE THEY ARE SUFFICIENTLY FLEXIBLE TO ADDRESS THESE ISSUES AND IF SO HOW (E.G., BROADENING/REVISING TERMS OF REFERENCE OF COMMITTEES) OR DO WE NEED TO CONSIDER ANY NEW/ADDITIONAL WORKING MECHANISMS?

Current Codex working mechanisms are enough to address the emerging issues. It is suggested that more flexibility should be given to existing Codex committees to ensure that some new issues could be considered or addressed in Codex, such as seaweed. Many factors can affect the presence of hazards in seaweed. Several hazards, among them heavy metals and marine biotoxins, have been reported to be associated with seaweed. It is necessary to establish the guidance documents on seaweed production and utilization. Considering the mandate of current Codex committees, the proper way is to broaden the mandate of CCFFP to cover more fisheries and aquaculture products, not only limited to fish, crustaceans and mollusc.	**China**
See reply to i and ii. The establishment of new working mechanisms should be duly considered at a later stage.	**European Union**
As innovation continues to take place in the industry, we believe that there needs to be flexibility in the way the tools or mechanisms are structured. We view that the issues that are covered are broad and could cut across the remit of a few Committees. Therefore, we suggest a task force to address these issues.	**Food Industry Asia**
Existing Codex system is capable of discussing these “new foods” with respect to food safety, food hygiene or labelling. All Codex Committees need to review and assess whether any Codex standards, guidelines, or codes of practice within their scope need to be updated to address these “new foods” and report back to the Codex Alimentarius Commission on their findings and recommendations for potential new work in this area. This will result in identification of gaps or needs and help the Commission determine objectively whether this new work needs to be taken up.	**India**
To be determined as the need for a particular Codex standard is identified	**Kazakhstan**
It is possible to establish a committee of experts in the foundations of biotechnology and related food products.	**Kingdom of Saudi Arabia**
Existing Codex tools can be adapted to address these issues with sufficient flexibility. A task force (TF) can be established to develop standards and related text on new food source. It may be difficult to develop standards for new food produce using unconventional/ innovative technology such as 3D printed food as it is technology that could be used across all food. Therefore, the TF could be useful to address these cross-cutting issues.	**Malaysia**
Considering that new food sources and production system are being developed and expand rapidly with the development of food tech, the establishment of new CODEX Committee is necessary for preemptive safety management and risk communication on these issues. When discussing through existing sub-committee, it will lead to inefficiencies, such as taking a long time to set up the scope of discussion and to decide which committee is in charge of these works. Furthermore, blind spots may occur since the committee in charge is not clear. Therefore, it is absolutely necessary to establish a new sub-committee to deal with the issues related to new food sources and production systems effectively and in-depth. In this regard, Korea is actively working on the development of new technology for foods and regulations,	**Republic of Korea**

so we would like to express our will to lead a new working mechanisms, the CODEX Committee on New Food Sources and Production systems.	
Possibility on new working mechanisms may provide the best value	**Uganda**
It may be prudent for existing subsidiary bodies to review their terms of reference to confirm that existing remits are flexibly enough to cover relevant work relating to food innovation/new food sources. Subsidiary bodies should propose amendments to their terms of reference if/where necessary.	**United Kingdom**
This question is best answered by the various standing general subject committees, which would have the expertise to examine if responsibilities under their mandates need revision to address specific issues related to new food and production processes.	**USA**