29/04/2022

CODEX EXECUTIVE COMMITTEE

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

CL 2022/06-CCEXEC

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

a. Please identify the innovations, new technologies or new/emerging food sources or production systems that are currently in use, in development, or for which regulatory approaches have been or are being developed in the jurisdictions in which you operate.

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 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.

Cultivated meat, seafood, and dairy	
Fermentation-derived ingredients	
Plant-based protein alternatives	
Seaweed	
Edible insects	
3-D printed foods	
Microalgae	
Other (please specify)	

[1] 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

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[2] 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.

II. REGULATORY MATTERS

Cultivated meat, seafood, and dairy	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)
Fermentation-derived 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.
Plant-based protein alternatives	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.
Seaweed	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 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.
Edible insects	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.
3-D printed foods	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.
Microalgae	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

[2] 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

Other (please specify)	Food consisting of engineered nanomaterials; food consisting of, isolated from or produced from material of mineral origin, bioactive substances, vitamin metabolites.

III. LABELLING ASPECTS RELEVANT TO CONSUMER PROTECTION AND FAIR-TRADE PRACTICES

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.

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.

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IV. 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.

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

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.

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

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.

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VII. 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.

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b. Do existing Codex standards cover the issues(s) identified?

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).

c. If not, what would be the need for and benefit of a Codex Standard in the areas you have identified?

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.

d. How would you recommend the issues you have identified as needing a Codex Standard be prioritized?

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.

e. What is your assessment of the scientific basis needed to work on the issues identified?

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.

f. 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.?

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.

VIII. APPROACHES TO DEVELOPING CODEX STANDARDS

g. In instances where the need for and benefit of a Codex standard or other text is identified, Codex could use different approaches depending on the issue. Please give examples of what you think should be addressed: (1) vertically (i.e., commodity standard or text); (2) horizontally (i.e., general standard or text); (3) a combination of both. Please indicate how each of the issues you have identified above might be addressed by one or more of these means

See reply in point d.

IX. USE OF CODEX WORKING MECHANISMS

h. 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).

i. Do these mechanisms provide Codex with sufficient tools to address the issues you have identified?

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.

ii. 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?)

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.

iii. 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?

See reply to i and ii. The establishment of new working mechanisms should be duly considered at a later stage.