PART 1: DISCUSSION PAPER FOR NEW WORK ON DEVELOPMENT OF PRINCIPLES FOR THE RISK ANALYSIS OF NEW FOOD SOURCES AND PRODUCTION SYSTEMS (NFPS)

(Prepared by the European Union)

Background

1. The transformation of food systems is associated with innovation and the rapid development of various new food sources and new production systems (NFPS). FAO and WHO have dedicated a number of studies, including foresight, that provide a vision on these ongoing developments, with more advancements expected in the future, as well as considerations on how to ensure food safety remains a priority in this time of continuous innovation. The FAO webpage "Food Safety Foresight – Staying prepared for a changing world"[1] provides an overview of these studies.

2. Governments need to ensure that their national regulatory frameworks are up to date to address these rapid developments. The experience of national competent authorities in the development of a risk analysis framework to ensure the safety in NFPS varies greatly. In this context, the development of a Codex text could provide a basis for follow-up action in supporting governments to further develop their national frameworks.

Discussions related to new food sources and new production systems (NFPS) at Codex

3. During CAC44 (2021), FAO and WHO drew the fast development of new food sources and new production systems (NFPS)[2] to the attention of the Codex membership and indicated that it was "critical to objectively assess the benefits they might bring as well as any risks associated with them - including food safety and quality concerns". It was also highlighted that food safety authorities should take the appropriate risk management actions to address these emerging risks and protect public health.

4. The topic of NFPS was subsequently discussed at CCEXEC82 (2021), CAC44 (2021), CCEXEC83 (2022), CAC45 (2022), and CAC46 (2023).

5. Two circular letters were issued to collect information from Codex Members and Observers on the topic. The outcome of this consultation is available in Appendix 2 of CX/EXEC 22/83/4[3].

6. This consultation highlighted the complexity of the topic. It also made apparent that while some Codex Members have experience with NFPS, this experience varies amongst them. The consultation also identified the need to learn more about the potential food safety, regulatory, labelling, nutritional, and quality issues associated with specific NFPS.

7. The following views were reported:

   - Most Members and Observers agreed that the modification of existing Codex standards or the development of new standards could reduce future trade barriers and provide a more harmonized global regulatory framework for these products.
   - There was no commonly accepted definition for "new food sources" and this should be further discussed and established by Codex. It was further noted that some foods could be considered as traditional in some countries/regions while being new in other countries/regions.
   - Various Members considered that the majority of the NFPS highlighted in the document were not foods *per se*, but rather non-traditional processes to produce food.
   - Some Members, especially from low- and middle-income countries, still lacked the knowledge and basic information on how to conduct safety assessments of alternative protein production processes.
   - Most Observers expressed concern about the labelling of these products, especially those intended to replace an existing product.

8. The consultation also collected information and views from Members and Observers on regulatory concerns, labelling aspects relevant to consumer protection and fair-trade practices, food safety and quality aspects as well as other matters relevant to the mission of Codex for the major types of NFPS[7].

9. NFPS were discussed extensively at CAC46 (2023). There was a general recognition on the importance and relevance of NFPS among Members and Observers. Amongst a range of ideas shared by Members and Observers on the types of work Codex may undertake, it was noted that general principles on risk analysis of NFPS could be developed to support national authorities in the management of NFPS.[4]

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[1] https://www.fao.org/food-safety/scientific-advice/foresight/en/
[2] CX/CAC 21/44/15 Add.1, New Food sources and production systems: need for attention and guidance?
[3] CX/EXEC 22/83/4
[4] REP23/CAC paragraph 198

10. In conclusion, CAC46 highlighted the importance of addressing challenges arising from NFPS and the important role Codex could play in this. Additionally, CAC46 encouraged Members to submit discussion papers or new work proposals either to active Codex Committees or to the Executive Committee through the Codex Secretariat.[5]

Importance of establishing risk analysis principles for NFPS

11. The rapid development of NFPS requires national legislative frameworks adapted to both enable innovation that contributes to the sustainability of food systems and protect public health from potential risks associated with NFPS. Shared principles will promote international cooperation, facilitate exchange of scientific and regulatory information, and help countries stay prepared as more NFPS continue to emerge.

12. The *Working principles for risk analysis for food safety for application by governments* (CXG 62-2007) are designed for "conventional" foods with a history of safe use. NFPS often lack such history and may involve whole foods or novel production technologies, requiring adapted approaches.

13. There is precedent in Codex to develop a guidance for the risk analysis of specific categories of foods. For example, the *Principles for the risk analysis of foods derived from modern biotechnology* (CXG 44-2003) was developed for biotechnology-derived foods. There is therefore an opportunity for Codex to provide a trusted global reference for NFPS, ensuring consistent, proportionate and effective risk analysis worldwide.

14. Specific aspects of NFPS that need to be addressed in the three components of risk analysis include but are not limited to:

- **Distinct challenges of NFPS**: NFPS are characterised with an absence of history of safe use in a national or regional territory. NFPS innovations may introduce new food safety challenges. Therefore, the development of specific risk assessment approaches is imperative. By contrast with risk assessment related to specific substances used in the production of foods (food additives, contaminants, veterinary drugs, pesticides), the risk assessment of some types of NFPS (e.g. algae, seeds, berries) has to cover whole foods. In addition, the different types of NFPS are associated with various potential risks and therefore require different risk assessment approaches.
- **Regulatory requirements**: Depending on the types of NFPS, intended use of the NFPS and jurisdiction, governments may require pre-market authorisations by competent authorities or notifications which consist of informing the authorities without requiring their authorisation. Depending on the outcome of the risk assessment, NFPS may require conditions for their placing on the market or post-market monitoring. Specific labelling provisions may be required to provide, for example, information on the safe use, on nutritional characteristics or on the nature of the products or their production.
- **Production processes and technologies:** Other than the foods themselves, the production processes and technologies should be part of the risk assessment, as they have the potential of introducing new risks.
- **Monitoring and surveillance:** Due to the inherent novelty of NFPS and the absence of prior or limited knowledge about these products, monitoring and surveillance mechanisms may be considered as part of risk management.
- **One Health approach:** The application of a One Health approach in the risk analysis of NFPS. This would be, for example, the case for NFPS that are developed with the objective of a positive environmental impact.
- **Other legitimate factors:** Other legitimate factors relevant to health protection, ethical concerns and fair-trade practices may be identified in the risk management process for the safe integration of NFPS into food systems[6]. Principles on how to address these issues could be integrated in the Risk Management and Risk Communication.
- **International cooperation:** International cooperation and information exchange to leverage global expertise and data can play an important role in the risk analysis framework development by national authorities. This is especially the case in a rapidly evolving field like NFPS that require adapted risk assessment methodologies.

[5] REP23/CAC paragraph 206(i) and (iii)
[6] FAO. 2025. *Exploring the future landscape of new food sources and production systems – A foresight exercise*. Mukherjee, K., Trieb, J., Niegowska Conforti, M., Di Martino, M., Fattori, V. & Lipp, M. Rome. (https://doi.org/10.4060/cd4981en)

Conclusion

15. NFPS has been demonstrated to be increasingly important in the ongoing transformation of food systems. At the same time, Members have reported diverse experiences in the risk management of NFPS and expressed a sustained interest on this topic at various Codex platforms. Initiating new work to develop risk analysis principles for NFPS would mark an important step for Codex in addressing the emerging risks associated with NFPS, to protect public health while facilitating fair practices in NFPS trade.

16. A project document for the proposed new work is contained in Part 2 of this document.

PART 2: PROJECT DOCUMENT - NEW WORK PROPOSAL FOR THE DEVELOPMENT OF PRINCIPLES FOR THE RISK ANALYSIS OF NEW FOOD SOURCES AND PRODUCTION SYSTEMS (NFPS)

(Prepared by the European Union)

1. Introduction

Food systems are currently facing multiple challenges including environmental concerns, sustainability and nutritional issues. Addressing these challenges will require a comprehensive transformation of these food systems, with innovation playing a major role. This innovation is diverse and may take place at various stages of food production and processing. Additionally, exploring new sources of food represents another area of innovation.

By embracing innovative approaches, food systems can be modified to meet the emerging demands. New food sources and new production systems (NFPS) are rapidly evolving and require appropriate regulatory oversight. However, there are currently no internationally agreed principles dedicated to the development of national regulatory frameworks for NFPS.

While there are no international definitions of NFPS, FAO uses the term “new food sources” to refer to any food sources not yet widely consumed globally, either because their consumption has historically been limited to specific regions of the world, or because only recent technological innovations have made it possible to produce or process them. “New food production systems”, on the other hand, refer to new technological innovations or advancements in pre-existing food technologies involved in new production systems[7].

2. Purposes and scope of the standard

The experience of national competent authorities in developing risk analysis frameworks to ensure food safety in NFPS is disparate. The purpose of the new work is to support governments in the development or adaptation of their national frameworks to regulate NFPS. It is similar to the purpose of the *Principles for the risk analysis of foods derived from modern biotechnology* (CXG 44-2003) that was adopted to support national regulatory frameworks for foods derived from modern biotechnology.

The scope of the new work will involve the development of general principles for risk analysis related to NFPS. It will provide core principles for the three components of risk analysis: risk assessment, risk management and risk communication. Furthermore, the document will include key definitions, such as definitions of “new foods” or “new food sources” or “new production systems” depending on the terminology that will be approved during the work.

3. Relevance and timeliness

At CAC44, FAO and WHO called for Codex to recognise food system innovations that seek to address challenges related to feeding a growing global population, whilst producing food more sustainably. CAC46 extensively discussed and underscored the importance of addressing the challenges related to NFPS and encouraged the submission of new work proposals pertaining to NFPS. These developments reflect the growing recognition of the need for Codex to establish international frameworks and guidelines to ensure the safety and regulation of NFPS on a global scale.

A Codex text that sets the basic principles to carry out risk analysis on NFPS is therefore essential and timely to harmonise upcoming regulations at national level in this field and to ensure that food safety aspects are properly addressed.

4. Main aspects to be covered

The document will cover the three components of risk analysis: risk assessment, risk management and risk communication and how these components should be adapted to NFPS. It will provide regulators with a reference for the development of their national regulatory frameworks. It will provide information to stakeholders on the various aspects that should be considered when developing and considering the placing on the market of NFPS.

Moreover, the document will provide clear and precise definitions for key terms and will propose mechanisms for reviewing the effectiveness of the risk assessment given the dynamic nature of NFPS.

The document will also set the foundation for information exchange amongst regulators on both risk assessment and risk management aspects, including decisions regarding the placing on the market of NFPS. This aspect will support regulators and risk assessors to keep pace with latest developments in a field that is in rapid evolution.

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[7] FAO. 2022. *Thinking about the future of food safety*. Rome. (https://doi.org/10.4060/cb8667en)

Other specific aspects of NFPS that would need to be addressed in the three components of risk analysis include but are not limited to:

- **Distinct challenges of NFPS**: NFPS are characterised with an absence of history of safe use in a national or regional territory. This absence requires the development of specific risk assessment approaches. By contrast with risk assessment related to specific substances used in the production of foods (food additives, contaminants, veterinary drugs, pesticides), the risk assessment of some types of NFPS (e.g. algae, seeds, berries) has to cover whole foods or food ingredients. In addition, the different types of NFPS are associated with various potential risks and therefore require different risk assessment approaches.
- **Regulatory requirements**: Key areas of risk management, such as pre-marketing approvals, labelling and post-market surveillance will be addressed. For example, depending on the types of NFPS, governments may require pre-market authorisations by competent authorities or notifications which consist of informing the authorities without requiring their authorisation. NFPS may also, on the basis of the outcome of the risk assessment, require conditions for their placing on the market or post-market monitoring. Specific labelling provisions may also be required to provide, for example, information on the safe use, on nutritional characteristics or on the nature of the products or their production.
- **Monitoring and surveillance:** Due to the inherent novelty of NFPS and the absence of prior or limited knowledge about these products, monitoring and surveillance mechanisms may be considered as part of risk management.
- **Production processes and technologies:** Production processes and technologies should be part of the risk analysis, as they have the potential of introducing new risks.
- **One Health approach:** The application of a One Health approach in the risk analysis of NFPS. This would be, for example, the case for NFPS that are developed with the objective of a positive environmental impact.
- **Other legitimate factors:** Other legitimate factors relevant to health protection, ethical concerns and fair-trade practices may be identified in the risk management process for the safe integration NFPS into food systems[8]. Principles on how to address these issues would be integrated in the risk management and risk communication.
- **International cooperation:** International cooperation and information exchange to leverage global expertise and data, can play an important role in the risk analysis framework developed by national authorities. This is especially the case in a rapidly evolving field like NFPS that require adapted risk assessment methodologies.

An outline of the draft document is included in the **Annex**.

5. Assessment against Section 2: Criteria for establishment of work priorities

General criterion: Consumer protection from the point-of-view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed new work will support the development of national regulatory frameworks for NFPS. It will support the adoption of measures that ensure that safe NFPS are placed on the market and that consumers are informed on the safe use, nutritional characteristics and nature of the products. Principles of risk analysis that are adapted to these types of products and processes will also ensure transparency in the adoption of risk management measures and thus fair practices in food trade.

These types of products are expected to be increasingly present in trade and thus also on global markets. Not all countries have adopted regulatory frameworks for NFPS yet. Countries, including developing countries, may be producers of some types of products that may be considered as NFPS in other countries or regions. This is, for example, the case for products that are considered traditional in some countries (e.g. plants or plant extracts) but have not been traded globally, making them new in other countries.

[8] FAO. 2025. *Exploring the future landscape of new food sources and production systems – A foresight exercise*. Mukherjee, K., Trieb, J., Niegowska Conforti, M., Di Martino, M., Fattori, V. & Lipp, M. Rome. (https://doi.org/10.4060/cd4981en)

Criteria applicable to general subjects

a) Diversification of national legislations and apparent resultant or potential impediments to international trade.

National legislations on NFPS currently vary widely, from having specific legislation dedicated to NFPS to the total absence of specific legislation on the subject. The efforts by Codex can play a crucial role in assisting countries in developing national frameworks for the regulation of NFPS that are grounded on the same risk analysis principles, thereby facilitating smoother trade and market access for these products.

b) Scope of work and establishment of priorities between the various sections of the work.

The scope of the work would be dedicated to principles of risk analysis for NFPS.

The document intends to provide overarching general principles for the risk analysis for all types of NFPS. The different sections of the work (definitions, risk assessment, risk management and risk communication) being closely inter-related, they should be developed in close conjunction.

The priority of this work is to align risk analysis principles for NFPS. This effort, coupled with the clarification of key terms will contribute to consistent global regulation of NFPS.

c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

FAO and WHO have carried out extensive work on the ongoing and possible future developments of NFPS, including in the context of foresight studies. The FAO webpage "Food Safety Foresight – Staying prepared for a changing world[9]" provides an overview of this work.

The Novel Food and Feed Working Party of the Organisation for Economic Co-operation and Development (OECD) serves as a forum for exchanging information on novel foods and feeds derived from modern biotechnology as well as other novel foods and feeds. Developments on the safety assessment of novel foods are currently published on a yearly basis[10].

d) Amenability of the subject of the proposal to standardization.

The subject of the proposal is amenable to standardization as the principles would be grounded on the risk analysis paradigm that is a core element of Codex work.

CAC has in the past successfully developed texts with a similar purpose. It is the case of the *Principles for the risk analysis of foods derived from modern biotechnology* (CXG 44-2003) which support national regulatory frameworks for foods derived from modern biotechnology.

e) Consideration of the global magnitude of the problem or issue

A number of new food sources and new production technologies are identified (FAO report "*Exploring the future landscape of new food sources and production systems – A foresight exercise")*[11] as both highly feasible and impactful, with a high likelihood to emerge either within the next five years or in the intermediate future (5-15 years).

The report of the CCEXEC sub-committee on NFPS[12] outlined various aspects concerning NFPS, including regulatory concerns, the labelling considerations relevant to consumer protection and fair-trade practices, nutritional aspects, food safety and quality. It also addressed other matters expressed by Codex members on different types of NFPS.

6. Relevance to Codex strategic objectives

The proposed work aligns with the direction provided by the Codex Strategic Plan 2026-2031.

The drivers for change**,** including FAO and WHO strategic directions and the 2020-2026 One Health joint action plan of the quadripartite, identified the need to integrate foresight and preparedness for the emerging issues to come. NFPS are a large part of emerging issues and may play a major contribution to the transformation of food systems.

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[9] https://www.fao.org/food-safety/scientific-advice/foresight/en/

[10] https://www.oecd.org/en/topics/sub-issues/biosafety-novel-food-and-feed-safety/consensus-documents-on-the-safety-of-novel-foods-and-feeds.html

[11] FAO. 2025. *Exploring the future landscape of new food sources and production systems – A foresight exercise*. Mukherjee, K., Trieb, J., Niegowska Conforti, M., Di Martino, M., Fattori, V. & Lipp, M. Rome. (https://doi.org/10.4060/cd4981en)

[12] CX/EXEC 22/83/4

Within the role of Codex, Codex texts can provide an enabling environment which facilitates the uptake and implementation of policies and programs to address global challenges around areas such as climate change, environment, sustainability, and trade. In doing so, Codex recognizes that the inherent international diversity of food systems means that, different values or solutions may be relevant in different national or regional situations or contexts." The proposed work will support the development of national or regional regulatory frameworks for NFPS, considering national or regional contexts. This includes the possible development and adoption of different NFPS in various parts of the world or the fact that some products may be considered as NFPS in some parts of the world while being regarded as "conventional or traditional" foods in other parts of the world.

The proposed work will contribute to the following Strategic Goals:

Strategic Goal 1: Respond to Members' needs for protecting the health of consumers and ensuring fair practices in the food trade in an evolving global landscape by developing science-based standards and related texts

- Foresight and horizon-scanning activities are used to support the identification of issues likely to impact food safety, quality and trade.

The objective of the proposed work is to support Codex Members to address the issues identified by the foresight activities of WHO and FAO. FAO and WHO drew the attention of Codex Members on this matter in 2021 in the document "New Food sources and production systems: need for attention and guidance?"[13]. Members indicated interest for Codex work in this area in subsequent meetings[14].

Strategic Goal 3: Strengthen relationships with relevant international organizations, promoting a coordinated approach to address global challenges

- The contribution of CAC to the transition towards sustainable and resilient food systems, is identified and considered.
- Contributions from relevant international organizations throughout the development of Codex texts are encouraged.

NFPS are currently being developed and have the potential to contribute to the improvement of the sustainability of food systems. This contribution is extremely varied and depends on the type of NFPS. For instance, the use of new food sources may enable the use of abundant natural resources and thereby improve food security and nutrition. Meanwhile developing new production methods may lead to more efficient use of energy, water and land thereby positively contributing to environmental protection and efforts in the context of climate change.

Strategic Goal 4: Maximize the impact of Codex by increasing the visibility and use of standards

- The profile and recognition of Codex as the international food standards setting body for protecting consumer health and ensuring fair practices in food trade is enhanced.
- The use of Codex texts in the context of integrative approaches such as One Health is promoted.
- Harmonization through the increased use of Codex texts in establishing national food control systems and regulations is advocated for.

The development of NFPS is an area that currently receives major attention from national governments. This new proposal will enable Codex to provide a systemic contribution to the national and regional regulation of NFPS. It will hence both enhance the profile and recognition of Codex and directly meet the needs of numerous governments who wish to ensure that their regulatory systems are fit for these new developments.

7. Information on the relationship between the proposal and other existing Codex documents, as well as other ongoing work

The proposed work will consider the principles and guidelines on risk analysis as provided in the following Codex documents:

- Section 4.1 of the Procedural Manual: Working principles for risk analysis for application in the framework of the Codex Alimentarius;
- Section 4.2 of the Procedural Manual: Definitions of risk analysis terms related to food safety;
- *Working principles for risk analysis for food safety for application by governments* (CXG 62-2007); and

[13] CX/CAC 21/44/15 Add.1, New Food sources and production systems: need for attention and guidance?
[14] The topic of NFPS was discussed at EXEC82 (2021) and CAC44 (2001), EXEC83 (2022), CAC45 (2022), and CAC46 (2023).

- *Principles for the risk analysis of foods derived from modern biotechnology* (CXG 44-2003)

8. Identification of any requirement for and availability of expert scientific advice

The development of the document will consider the following reports:

FAO. 2021. *Looking at edible insects from a food safety perspective. Challenges and opportunities for the sector.* Rome. (https://doi.org/10.4060/cb4094en)

FAO. 2022. *Thinking about the future of food safety - A foresight report.* Rome. (https://doi.org/10.4060/cb8667en)

FAO and WHO. 2022. *Report of the expert meeting on food safety for seaweed – Current status and future perspectives. Rome, 28–29 0ctober 2021.* Food Safety and Quality Series No. 13. Rome. (https://doi.org/10.4060/cc0846en)

FAO. 2024. *Plant-based food products, precision fermentation and 3D food printing – Food Safety Foresight Technical Meeting Report, 13–17 November 2023*. Rome. (https://doi.org/10.4060/cd2430en)

FAO. 2025. Food Safety Foresight Framework Meeting. Summary report. 1–3 April 2025. Rome. (https://openknowledge.fao.org/handle/20.500.14283/cd5135en)

FAO. 2025. *Exploring the future landscape of new food sources and production systems – A foresight exercise*. Mukherjee, K., Trieb, J., Niegowska Conforti, M., Di Martino, M., Fattori, V. & Lipp, M. Rome. (https://doi.org/10.4060/cd4981en)

9. Identification of any need for technical input to the standard from external bodies, for planning purposes

The documents reported under point 8 provide substantial considerations on the different aspects of risk analysis of NFPS, including risk assessment. While it is not anticipated that expert scientific advice will be needed, discussions could lead to an identification on the need for targeted requests for FAO/WHO expert advice on specific aspects of risk assessment or risk communication of NFPS.

10. Proposed timeline for completion of new work, including the start date, proposed date for adoption at Step 5, proposed date for adoption by the Commission

Subject to the agreement of the relevant body and Codex Alimentarius Commission’s approval, it is anticipated that the proposed work can be completed in three sessions of the designated Codex body.

ANNEX

PRINCIPLES FOR THE RISK ANALYSIS OF NEW FOOD SOURCES AND PRODUCTION SYSTEMS (NFPS)

DRAFT OUTLINE

1. **Introduction**

   This section would introduce the specific features of NFPS and the need to consider tailored principles of risk analysis.

2. **Scope**

   This section would outline the different types of NFPS and indicate the extent to which the principles of risk analysis are intended to regulatory authorities and food business operators placing NFPS on the market.

3. **Definitions**

   This section would include definitions related to NFPS such as “new foods” or “new food sources” or “new production systems” depending on the terminology agreed during the work. It would also define the different types of NFPS including foods that may be considered as traditional in some countries or regions and new in other parts of the world. It could include definitions of other terms that will be used in the document.

4. **Principles**

4.1. Risk Assessment

4.2. Risk Management

4.3. Risk Communication

5. **Capacity building and information exchange**

   This section would include:

- considerations on the gradual implementation of the risk analysis principles on NFPS in countries that do not have regulatory frameworks in place.
- considerations on the importance of exchange of information on NFPS as it relates to innovation. This information exchange may cover: developments of risk assessment methodologies, outcome of risk assessments on NFPS, exchange of information on risk management decisions such as authorisations or restrictions on certain types of NFPS.

6. **Review process**

   This section would underline that since NFPS are deeply associated with innovation, the risk analysis components should be regularly reviewed to consider emerging risks, emerging scientific information but also experience acquired thanks to products that are on the market.