# PROPOSED GUIDANCE ON RISK ANALYSIS APPROACHES FOR DIET RELATED NON-COMMUNICABLE DISEASES

## PROJECT DOCUMENT
## Proposed New Work for CCNFSDU

### 1. Purpose and Scope

**Purpose**

To evaluate the potential to create Codex guidance on the application of risk-analysis approaches for evaluating diet-related non-communicable disease (DRNCD) risk associated with the consumption of food categories in the context of overall dietary patterns and multidimensional factors.

**Scope**

The proposed work would:

- Evaluate whether existing Codex risk-analysis principles and methodologies could be adapted or extended to assess DRNCD risk associated with food categories, subcategories, and thereby patterns of consumption.
- Establish general scientific and methodological considerations for evaluating relationships between food categories and DRNCD outcomes within the context of the overall diet.
- Consider multidimensional factors that may influence DRNCD risk, including food composition and matrix characteristics, dietary patterns, consumption frequency and quantity, and population variability.
- Explore how existing Codex food-category systems and risk-analysis approaches may inform methodological development
- Support development of internationally harmonized science-based approaches that complement existing nutrient-based risk assessment frameworks
- Create a Codex framework for DRNCD risk assessment for use by Codex member countries and organizations in developing national regulations

**Out of Scope**

The proposed work would not:

- Establish a new food classification system.
- Classify foods as inherently “good” or “bad.”
- Replace existing nutrient-based risk assessment approaches or nutrient reference values.
- Address food safety hazards already covered under existing Codex frameworks.
- Address non-dietary determinants of non-communicable diseases.

## 2. Relevance and Timeliness

DRNCDs represent a significant and increasing global public health challenge as outlined in the accompanying Discussion Paper. There is growing evidence that DRNCD risk is influenced not only by individual nutrients, but also by broader dietary patterns, food groups, and characteristics of the food matrix within the context of the overall diet.

Current Codex approaches for nutritional risk assessment primarily focus on individual nutrients. However, national and regional authorities are developing food based dietary guidelines, nutrient profiling systems, and food classification approaches that incorporate broader food characteristics, such as formulation, processing, and dietary context. These approaches differ considerably in aspects of terminology, scientific rigor, and application, creating possible future challenges for international harmonization and trade. The development of a risk-analysis approach for evaluating DRNCD risk by food category and sub-categories by CCNFSDU would provide a mechanism to reduce the potential for DRNCD driven regulatory trade barriers, particularly for small and medium sized Food Business Operations (FBOs) by enabling a harmonized mechanism for member countries and organizations to assess the impact of DRNCD risk for the importation of those food categories.

Recent discussions within the Codex Alimentarius Commission and related Codex committees have addressed the growing international interest in science-based approaches to evaluate the relationship of food to DRNCD risk. Yet at present, there is no internationally harmonized framework for considering DRNCD risk at the level of food categories or dietary patterns.

There is a need for CCNFSDU to evaluate whether existing Codex risk analysis principles for nutrients have the potential to be adapted or expanded to support science-based and internationally harmonized approaches for assessing DRNCD risk associated with food categories and patterns of consumption.

## 3. Main Aspects to be Covered

The proposed work would evaluate current Codex risk analysis principles and CCNFSDU frameworks for nutrient-related risk analysis to determine their adaptability for DRNCD risk assessment within food categories and subcategories in the context of dietary patterns and multidimensional factors.

The work would include consideration of:

- Scientific evidence linking dietary patterns and food groups with DRNCD risk

- Methodological approaches for evaluating relationships between food categories and DRNCD risk in the context of the overall diet
- The role of multidimensional factors that may influence DRNCD risk, including:
    - Food composition and matrix
    - Food formulation and processing
    - Dietary patterns, frequency, and quantity of consumption
    - Population variability and susceptibility
    - Food environment, accessibility, and cultural practices.
- Potential applicability of existing Codex food category systems (i.e., GSFA/CXS 192-1995) to be adapted for DRNCD risk analysis as well as other risk analysis frameworks and tools used among Codex committees.
- Heterogeneity in food categories and the importance of avoiding assumptions of uniform health effects across all foods within a category
- Transparent, flexible, and adaptable approaches that can evolve with scientific evidence and different dietary contexts.

The proposed work would consider how existing Codex risk analysis approaches, including hazard identification, hazard characterization, exposure assessment, and risk characterization may provide a structured foundation for evaluating relationships among food categories, dietary patterns of consumption, and DRNCD outcomes.

The proposed CCNFSDU work output eventually would lead to guidance text to help member states and organizations apply the Codex DRNCD risk analysis approach within national regulatory frameworks, using the risk assessment and management considerations developed through this work. The guidance text would likely reside in the CCNFSDU Risk Analysis procedural section, with references to relevant appendices, and include a food category risk management tool. This tool could incorporate factors identified by the CCNFSDU and be utilized or referenced in other requirements or guidance from other Codex committees, such as the Codex Committee on Food Additives (CCFA) and/or the Codex Committee on Food Labeling (CCFL) or others as appropriate.

**4. Assessment Against Criteria for Establishment of Work Priorities**

*General criterion*

The proposed work would support consumer health protection and ensure fair practices in the food trade by exploring science-based and internationally harmonized approaches for evaluating DRNCD risk associated with food categories and subcategories.

*Criteria applicable to general subjects*

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

National and regional authorities are developing food based dietary guidelines, nutrient profiling systems, healthy diet indices, and food classification approaches aimed at assessing DRNCD risk. These approaches differ in terminology, scientific rigor, and application. In the absence of internationally harmonized approaches, increasing divergence in national and regional approaches may contribute to inconsistent regulatory interpretations and possible barriers to food trade. The outcomes from the proposed work would support greater scientific consistency and transparency in any subsequent work to develop relevant frameworks, guidelines or tools, developed based on existing Codex risk analysis principles, methods or frameworks, that could be adapted to assess DRNCD risk associated with food categories used by Codex.

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

The scope of the proposed work is limited to the evaluation of methodologies and potential development of a framework which could be used by CCNFSDU and member countries and organizations to consider DRNCD risk associated with food categories and subcategories in the context of overall dietary patterns and multidimensional factors.

*c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental bodies.*

Multiple international organizations and national authorities are evaluating food-based approaches to DRNCD prevention, including nutrient profiling systems, dietary health indices, dietary pattern guidance, and food classification systems. Recent discussions in the Codex Alimentarius Commission also noted increasing international interest in science-based, harmonized approaches related to DRNCD risk.

The proposed work differs from existing approaches by focusing on whether the existing Codex risk analysis and food category approaches and methodologies could be adapted to support

transparent, science-based, and internationally harmonized assessment of food-related DRNCD risk.

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

The proposed work is amenable to standardization because it focuses on adapting and integrating previously established Codex methodologies, principles, and scientific approaches for risk analysis for the purpose of DRNCD risk analysis at the level of food categories. Codex frameworks already exist to apply risk analysis approaches within the food-related domain, including contaminants, additives, and nutrient-based DRNCD risk assessments.

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

DRNCDs are among the leading causes of morbidity and mortality globally, with dietary factors representing a major contributor to disease burden. As a result, DRNCD risk within the context of foods and dietary patterns is a key public health issue that needs to be addressed globally. It is particularly important to develop globally harmonized guidance that provides flexibility to consider factors such as regional and cultural dietary differences in food category consumption.

**5. Relevance to Codex Strategic Objectives**

The proposed work supports Codex objectives related to consumer health protection, science-based standards, and international harmonization. The proposed work is aligned with the following key 2026-2031 Codex Strategic Objectives:

**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.

The proposed work addresses the growing global burden of DRNCDs and increasing international interest in food-based dietary approaches. The proposed work could also ensure fair trade by setting harmonized standards rather than a myriad of national and regional regulations that could limit trade.

**Strategic Goal 2:** Enhance Codex work management systems and practices that support the effective and efficient development of standards and related texts.

The proposed work would build upon existing Codex risk analysis principles and frameworks currently being applied across nutrition, contaminants, additives, and food hygiene committees to explore more aligned methodological approaches for DRNCD risk assessment related to foods.

**Strategic Goal 3:** Strengthen relationships with relevant international organizations, promoting a coordinated approach to address global challenges. Specifically, goal 3.2: Gaps in approaches to addressing global challenges that Codex could contribute to are identified through targeted engagement with relevant international organizations, by identifying a major gap around Codex's ability to address a significant global challenge around food drivers of DRNCDs.

The proposed work is aligned with ongoing international efforts related to dietary guidance, nutrient profiling, and food classification systems relevant to DRNCD prevention. It would support internationally harmonized principles while still recognizing different regional dietary contexts and public health priorities.

**Strategic Goal 4:** Maximize the impact of Codex by increasing the visibility and use of standards. Specifically goals 4.1 and 4.3: 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; harmonization through the increased use of Codex texts in establishing national food control systems and regulations.

Development of internationally recognized methodological approaches for evaluating DRNCD risk associated with food categories and dietary patterns could elevate science and promote harmonization across member countries and international food systems. The work may also inform DNRCD research efforts going forward.

**6. Relationship to Existing Codex Texts**

The proposed work would complement and extend existing Codex texts on dietary risk assessment and management.

CCNFSDU, working in concert with the Codex Committee for Food Labeling (CCFL), incorporated risk analysis principles into the development of two nutrient-specific DRNCD risk nutrient reference values for intake levels not-to-exceed for Saturated Fatty Acids and Sodium (CAC/GL-1985 3.4.4.2). The proposed work would not replace these nutrient-based approaches but rather explore opportunities to expand or adapt this approach to food categories and subcategories and dietary patterns. The proposed work encompassing food category definition for DRNCD risk could be integrated into the planned CCFA revision of the Food Categories tied to GSFA/CXS 192-1995.

**7. Requirement for Expert Scientific Advice**

The development of the proposed work may require expertise from multiple disciplines including, but not limited to:

- food science
- nutrition science
- agriculture
- public health
- epidemiology
- clinical research
- biostatistics
- behavioral science
- food analysis

**8. Proposed Timeline**

Start date and Scoping Phase 2026-2027

Codex Step 1: 2027-2028

Adoption: Codex Step 5/8: 2032-2033

**9. Resource Implications**

The proposed work will require contributions from:

- FAO/WHO (existing data collation and feedback)
- FAO/WHO convening of a joint expert consultation on DRNCD Risk Analysis leveraging JEMNU or a special scientific consultation body such as recent ones on Food Allergens or Antimicrobial Resistance.
- Member countries, organizations, and observers (information and scientific/technical resources)
- Codex Secretariat support (coordination and documentation).