

1 **DISCUSSION DOCUMENT**

2 **Supporting Rationale for Proposed New Work**

3

4 **1. Introduction and Background**

5 Non-Communicable Diseases (NCDs) are a primary cause of early mortality globally, with Diet Related
6 Non-Communicable Diseases (DRNCDs) a leading risk factor contributing to them. Malnutrition in all its
7 forms, including excessive and imbalanced food intake, is a key modifiable risk factor underlying DRNCDs
8 such as obesity, cardiovascular disease (CVD), type 2 diabetes (T2D), and certain cancers. Recent global
9 estimates indicate that risk factors associated with diet, including high body mass index and elevated
10 blood glucose, have increased over the past decade, while other modifiable risk factors, such as smoking,
11 low birth weight, and environmental pollution, have declined [1]. These findings demonstrate the
12 growing importance of diet as a determinant of public health that needs to be addressed globally.

13

14 The Codex Alimentarius Commission has an important responsibility to protect consumer health and
15 safety while ensuring fair trade practices through the development of science-based standards and
16 guidelines. Within Codex, the Codex Committee on Nutrition and Foods for Special Dietary Uses
17 (CCNFSDU) is responsible for nutritional risk analysis and has established foundational approaches for
18 evaluating DRNCD risk associated with nutrient intakes, both inadequacy and excess [2]. These
19 recommendations are now part of the Guidelines for Nutrition Labeling [3].

20 However, the scientific understanding of diet and chronic disease risk has evolved beyond single-nutrient
21 paradigms. A considerable body of evidence demonstrates that dietary patterns and food groups and
22 categories are also associated with DRNCD risk. Additionally, many countries are adopting food-based
23 dietary guidelines and classification systems that incorporate broader food characteristics, including
24 formulation, processing, and the overall food matrix. This shift reflects a more integrated understanding
25 of how foods are consumed within dietary patterns and how they influence DRNCDs.

26 Despite these developments, there is no internationally harmonized framework within Codex to evaluate
27 DRNCD risk at the level of dietary patterns or food categories. This gap creates challenges for global
28 alignment, as national and regional approaches continue to progress, which could lead to consumer
29 confusion and unintended barriers to trade.

30 **Considering this context, this discussion document proposes that CCNFSDU consider new work to**
31 **evaluate whether existing Codex risk analysis principles could be extended to assess DRNCD risk**
32 **associated with the consumption of specific food categories given the complexity of foods and their**
33 **use in diets. The purpose is not to classify foods by DRNCD risk alone, but to evaluate how existing,**
34 **science-based, Codex tools and principles could provide a framework to assess food-related DRNCD**
35 **risk in a manner suitable for Codex purposes – to support public health, fair trade, and international**
36 **harmonization.**

37

38 2. Problem Statement and Policy Gap

39 Current Codex guidance for addressing DRNCD risk focuses primarily on the evaluation of individual
40 nutrients. While this approach has supported the development of nutrient reference values (NRVs) and
41 created risk management tools, it does not fully capture the broader factors needed to characterize risk
42 from intact foodstuffs or those being incorporated into national and regional dietary policy.

43

44 Governments and public health authorities are currently evaluating and adopting more food-based
45 dietary guidelines and classification systems that extend beyond nutrient composition to include
46 characteristics such as formulation, processing, and various components of the food matrix [4-7]. These
47 systems vary in their scientific foundations and application, resulting in increasing divergence in how
48 food-related health risks are defined and evaluated.

49

50 This issue was recently discussed at the 48th session of the Codex Alimentarius Commission [7] in the
51 context of ultra-processed foods (UPF). Members noted the lack of a clear, science-based, globally
52 harmonized definition, relevant to the work of Codex, and emphasized the importance of robust scientific
53 evidence, and the need for common reference points to support effective standards and guidelines
54 development. They also noted the relevance of this issue to multiple Codex committees, and members
55 were encouraged to bring forward proposals for future work.

56

57 In the absence of a harmonized Codex framework, continued divergence in national approaches may
58 lead to inconsistent regulatory interpretations, which could increase the complexity of international food
59 trade and create unintended barriers. However, the current lack of a structured, science-based approach
60 to evaluating diet and DRNCD risk beyond individual nutrients limits Codex's ability to provide relevant
61 harmonized, evidence-based guidance.

62

63 This represents a clear policy gap. While policy development has moved toward food-based approaches,
64 Codex risk analysis frameworks have not been extended to systematically evaluate DRNCD risk at the
65 level of food categories. Addressing this gap would enable Codex to provide internationally relevant,
66 science-based guidance that supports both public health and fair trade.

67

68 3. Scientific Evidence for Diet-DRNCD Relationships

69 A substantial and consistent body of scientific evidence has demonstrated the relationship between
70 dietary patterns and food groups to DRNCDs, including obesity, T2D, CVD, and certain cancers [8-22].
71 While earlier approaches focused on individual nutrients, more recent evidence indicates that evaluating
72 foods as consumed within dietary patterns provides additional understanding of the complexity of the
73 diet-health relationship.

74

75 Across a range of populations, adherence to healthy dietary patterns, including the Mediterranean,
76 Dietary Approaches to Stop Hypertension (DASH), Nordic diet, and plant-based diets, has been
77 consistently associated with reduced risk of DRNCs and all-cause mortality [9-15]. Conversely, dietary
78 patterns characterized by high consumption of processed meats, sugar-sweetened beverages, and
79 refined grains have been associated with increased risk [16-18]. Specific food groups have also been
80 associated with risk of DRNCs: whole grains, fruits, vegetables, nuts, and legumes have been associated
81 with lower risk [19-22], while processed meats and sugar-sweetened beverages have been associated
82 with higher risk [16, 17].

83

84 Obesity

85 A body mass index (BMI) ≥ 30 kg/m² defines obesity for most countries and is a major independent risk
86 factor for CVD, T2D, certain cancers, and premature mortality [8, 13-15, 18]. Dietary patterns and specific
87 food groups play a role in energy balance and body weight regulation, with considerable evidence linking
88 specific dietary patterns to obesity risk in conjunction with other environmental and societal risk factors,
89 such as reduced physical activity, food insecurity, and urbanization [18].

90

91 Healthy dietary patterns, including the Mediterranean, DASH, vegetarian, vegan, and flexitarian, have
92 been associated with lower weight gain over time, reduced incidence of overweight or obesity, and
93 reduced waist circumference [10, 23-26]. Specific food groups have also been shown to impact obesity
94 risk. Higher intakes of whole grains, fruits, vegetables, legumes, and nuts have been associated with
95 lower risk of overweight and obesity, whereas higher intakes of processed meats and sugar-sweetened
96 beverages have been associated with increased risk of weight gain and adiposity [18, 22, 27-30]. Evidence
97 for dairy is mixed but generally indicates neutral or modestly protective associations, particularly for
98 yogurt [31].

99

100 Evidence from randomized controlled trials (RCT) provides support for causal effects for selected dietary
101 components within dietary patterns and certain food groups. Reduced intakes of dietary fat and added
102 sugars, along with increases in dietary fiber, have been shown to reduce body weight and improve
103 adiposity-related outcomes [32-34]. Increased consumption of pulses leads to modest weight loss even
104 in the absence of energy restriction [35]. However, interventions increasing fruits, vegetables, whole
105 grains, nuts, or dairy in isolation generally show neutral effects on body weight unless implemented
106 within an energy-restricted dietary pattern, suggesting that their primary role may be in supporting diet
107 quality and satiety rather than directly inducing weight loss [36, 37].

108

109 Type 2 Diabetes

110 Type 2 diabetes, characterized by insulin resistance and progressive beta-cell dysfunction, affects more
111 than 500 million adults worldwide and is a major risk factor for cardiovascular disease, kidney disease

112 and premature mortality [38]. Dietary patterns play a central role in T2D prevention and management by
113 impacting insulin sensitivity, glycemic control, bodyweight, and systemic inflammation [14, 16].

114

115 Prospective cohort studies support robust protective effects of the Mediterranean, DASH, and plant-
116 based diets for T2D risk [9, 10, 12, 39, 40]. Additionally, observational studies have shown higher intakes
117 of processed meat, added sugars, and saturated or trans fats are associated with increased incidence of
118 T2D, whereas diets rich in fruits, vegetables, whole grains, dietary fiber, nuts, legumes, and certain dairy
119 products show protective associations [14, 16, 21, 22]. While exact dietary patterns and macronutrient
120 proportions can vary, overall, the evidence supports a dietary pattern emphasizing fiber-rich plant foods
121 and unsaturated fats while limiting processed meats and added sugars, as a strategy for reducing T2D
122 incidence.

123

124 Randomized controlled trials examining the cause effect relationship of dietary components for T2D risk
125 factors report the strongest benefits for whole grains, nuts, legumes, and unsaturated fats replacing
126 saturated fat, whereas evidence for processed meat, added sugars, fruits and vegetables, and dairy is
127 either indirect, mixed, or largely neutral [41-47]. This is primarily attributed to dietary components in
128 these foods, such as dietary fiber, improving blood glucose control, and/or insulin sensitivity.
129 Demonstrating the importance of the food matrix, RCTs on added sugars suggest that adverse glycemic
130 effects are not uniform across all food sources and energy conditions, although sugar-sweetened
131 beverages and excess-energy mixed sugar sources have the largest number of scientific reports [48].

132

133 Cardiovascular disease

134 Cardiovascular disease encompasses coronary heart disease (CHD), stroke, heart failure, and peripheral
135 vascular disease, and remains the leading cause of death globally [49]. Dietary patterns and components
136 can impact multiple cardiovascular risk factors including blood pressure, lipid profiles, inflammation,
137 endothelial function, and thrombosis [50].

138

139 Observational evidence has demonstrated an association of diets such as the Mediterranean, DASH,
140 Nordic, and plant-based diets with lower risk of CVD, CHD, and stroke incidence, including some dose
141 response effects [10-12, 39]. Furthermore, evidence from prospective cohort studies and meta-analyses
142 have reported that dietary patterns characterized by higher intake of processed meat, added sugars, and
143 trans or saturated fats were associated with increased CVD risk, including CHD and stroke, whereas diets
144 rich in fruits, vegetables, whole grains, dietary fiber, nuts, legumes, and certain dairy products were
145 associated with reduced risk [13, 17, 20-22].

146

147 Randomized controlled trials examining the cause effect relationship of dietary components for CVD risk
148 factors report the strongest benefits for replacing saturated fat with unsaturated fat, increasing nuts,
149 legumes, whole grains, and dietary fiber, and limiting added sugars, whereas evidence for fruits and

150 vegetables, dairy, and red or processed meat is either smaller, inconsistent, or neutral over the short
151 durations typical of RCTs [51-61]. The primary mechanisms by which these are purported to reduce CVD
152 risk is by replacement of saturated fat with unsaturated fat, and inclusion of fiber-rich foods that help
153 reduce LDL-cholesterol, improve glycemic control, and minimize inflammation [56, 57, 62-70].

154

155 Cancer

156 The Global Burden of Disease study estimates that dietary risk factors account for approximately 5% of
157 cancer worldwide [71]. Furthermore, the World Cancer Research Fund (WCRF) and International Agency
158 for Research on Cancer (IARC) have identified evidence linking dietary patterns to certain cancer risks
159 [72]. Cancers of the digestive tract, particularly colorectal and gastric cancer, have shown the strongest
160 dietary associations [73-76]. WCRF estimates that improvements to diet could prevent approximately 30
161 – 40% of cancers in high income countries and 20 – 30% in low- and middle-income countries [72].

162

163 Evidence from prospective cohort studies and meta-analyses have shown plant-based diets, such as the
164 Mediterranean and DASH diet, to have an inverse association with cancer incidence and mortality across
165 several sites, including colorectal, gastric, liver, lung, and breast [76-86]. Alternatively, dietary patterns
166 rich in fat, sugar, energy-dense foods, red and processed meats, while being low in fiber and fresh fruits
167 and vegetables, has been associated with increased risk of colorectal cancer, pancreatic cancer, and
168 breast cancer [76, 80-82]. Specific food categories, such as processed meat and salt-preserved foods,
169 have demonstrated positive associations with cancer incidence and mortality, particularly cancers of the
170 digestive tract, while fruits, vegetables, whole grains, and dietary fiber have shown consistent protective
171 associations [22, 74, 80, 87-97]. Interestingly, dairy products have shown inconsistent associations with
172 cancer risk which are primarily site-specific and dairy product specific [98, 99]. A meta-analysis of
173 prospective cohort studies on colorectal cancer reported a 17% risk reduction per 400 g/day total dairy
174 products, but when types of dairy products were examined, a risk reduction only remained for milk
175 intake, but not cheese [98]. The opposite was observed for breast cancer where consumption of total
176 dairy food, but not milk, was associated with a reduced risk of breast cancer [99]. These findings suggest
177 a role of the food matrix in DRNCD risk, beyond the food group alone.

178

179 Across these DRNCDs, the direction of observational evidence demonstrated broad consistency even
180 with differences in study design, populations, and endpoints. Evidence from RCTs provides additional
181 support for causal relationships but also reveals the need for nuance in considering different food groups,
182 chronic disease outcomes, food composition, and effects of the food matrix.

183

184 **Taken together, the evidence supports Codex consideration to transition from exclusively individual**
185 **nutrient-based risk analysis approaches to more integrated frameworks that consider food categories**
186 **and dietary patterns. This does not replace nutrient-based risk assessment but complements it by**
187 **capturing additional dimensions of diet that are relevant to DRNCD risk.**

188

189 *NOTE: A distinction is warranted between terminology used in scientific literature and that which is*
190 *applied in Codex frameworks. Most of the available evidence linking DRNCD risk is generated at the level*
191 *of food groups which share nutritional or biological similarities. In contrast, Codex frameworks are*
192 *organized around food categories that reflect regulatory groupings based on product type, use, and*
193 *composition. While the constructs are similar, they are not equivalent, and translation of the scientific*
194 *groupings to regulatory groupings requires consideration of factors such as formulation, food matrix, and*
195 *consumption patterns. For clarity, the terminology used in this document is defined in section 10.*

196

197 **4. Translation of Evidence to Dietary Guidance and Policy**

198 Multiple authoritative scientific organizations have issued evidence-based dietary guidelines for diet-
199 related NCD prevention. Many of these guidelines emphasize food-based recommendations in addition
200 to nutrient-specific targets. For example, the World Health Organization (WHO) recommends limiting
201 free sugars to less than 10% of total energy intake [100], reducing sodium intake to less than 2 g/day
202 [101], replacing saturated fats with unsaturated fats [102], eliminating industrially produced trans fats
203 [102], and increasing consumption of fruits, vegetables, whole grains, legumes, and nuts [103, 104].
204 Similarly, the NHS Eatwell Guide recommends 5 servings of fruits and vegetables daily, choosing
205 unsaturated oils in small amounts and limiting foods high in fat, salt, and sugar [105]. For many years
206 the Dietary Guidelines for Americans has promoted healthy dietary patterns including the Mediterranean
207 diet, DASH diet, and plant-based diets, continually emphasizing nutrient-dense food choices that limit
208 added sugar, saturated fat, sodium and alcohol [106]. Argentina, Japan, and China dietary guidelines also
209 include an emphasis on fruits and vegetables, dairy, whole grains, and lean sources of protein, as well as
210 limiting foods higher in sugars, fats, and sodium [107-109]. The EAT-Lancet Commission proposed a
211 similar healthy diet that aligns with environmental sustainability [110]. These convergent
212 recommendations from the published literature and numerous scientific bodies demonstrate the
213 strength and consistency of the evidence linking dietary patterns to DRNCD.

214

215 In parallel, several regions are developing or applying food classification systems to inform policy
216 decisions and operationalize dietary guidance. These systems incorporate additional factors such as
217 nutrient composition, formulation, and processing. While there is a lack of consistency among the
218 different approaches, they reflect a broader shift toward evaluation of foods in the context of broader
219 dietary patterns.

220

221 **However, without a globally harmonized framework, the differences in approaches and classifications**
222 **may lead to inconsistent policy implementation and interpretation, which may have ramifications for**
223 **public health and trade. This reinforces the need for Codex to consider whether existing risk analysis**
224 **principles can be extended to support the evaluation of DRNCD risk at the level of food categories in a**
225 **way that can align scientific evidence with global policy.**

226

227 **5. Existing Approaches to Classification and Risk Assessment**228 *Nutrition Risk Analysis Within CCNFSDU*

229 The remit of CCNFSDU includes addressing nutritional issues, establishing NRVs, and managing
230 information for label inclusion for specialized nutrition products. As part of this work, the committee has
231 been proactive in its adaptation of risk analysis methods to address the complexity of nutritional risk
232 management.

233

234 In 1995 the Committee requested Australia to prepare a discussion paper on the “diet modelling”
235 approach, a form of risk-analysis intended to forecast the impact of changes in food composition on the
236 potential consumption of nutrients and non-nutrients in the diet (ALINORM 95/26 paragraph 91) [111].
237 At that time, other Codex Committees were already using risk analysis approaches to evaluate microbial
238 and chemical food safety.

239

240 CCNFSDU first considered the application of dietary modelling or nutrition-related risk assessment at its
241 20th session in 1996 [112]. Following discussion at the 22nd Session in 2000, the committee agreed to
242 proceed with the development of a methodology for applying risk assessment to relevant Codex
243 standards and related texts (ALINORM 01/26, paragraphs 128-131) [113]. The Committee noted that
244 nutrient intake assessments were necessary to provide a scientifically justified public health and safety
245 rationale for setting standards or measures more stringent than Codex standards.

246

247 At its 23rd Session in 2001, CCNFSDU concluded that implementation of a risk-based approach required
248 establishment, where possible, of upper limits (ULs) for vitamins and minerals and FAO/WHO agreed to
249 extend existing work on recommended nutrient intakes accordingly (ALINORM 03/26, paragraphs 138-
250 143) [114]. During the discussion of this item (CX/NFSDU 01/10), the committee noted that “a risk
251 assessment approach to setting standards for nutrients may be of increasing importance as all
252 governments and Codex address controversial topics such as the use of non-nutritive ingredients (fat, oil
253 and sugar replacements) and different dietary fibers in foods, increased use of novel foods or ingredients,
254 foods derived by biotechnology, dietary supplements and food fortification” as well as assessment and
255 scientific validation of nutrition and health claims [115].

256

257 At CCNFSDU’s 24th Session in 2002, FAO reported that a technical report on general principles for
258 establishing ULs for vitamins and minerals was in progress [116]. The work aligned with the broader
259 Codex “Draft Working Principles for Risk Analysis for Application in the Framework of Codex
260 Alimentarius”, which had already been adopted into the 12th edition of the Codex Alimentarius
261 Commission Procedural Manual (ALINORM 03/41, Appendix IV; and paragraphs 142-148) [117, 118]. Risk
262 assessment was the responsibility of the FAO/WHO expert bodies and other Recognized Authoritative
263 Scientific Bodies (RASBs) (risk assessors). CCNFSDU, working in concert with CCFL, subsequently

264 implemented two nutrient-specific DRNCD NRV standards for intake levels not-to-exceed for saturated
265 fatty acids and sodium (CAC/GL-1985 3.4.4.3) [119]. **These nutrient-specific NRV standards have been**
266 **in place for over a decade and demonstrate that Codex has already incorporated DRNCD considerations**
267 **into existing nutrient-based risk-management approaches.** A summary of CCNFSDU work on guidelines
268 and standards related to DRNCD considerations is provided in Appendix III.

269
270 Other Existing Codex Risk Analysis Frameworks Relevant to DRNCDs

271 Beyond the work of CCNFSDU, several other Codex committees routinely apply risk-analysis frameworks
272 in collaboration with FAO/WHO expert bodies, including the Codex Committee on Contaminants in Foods
273 (CCCF), the Codex Committee on Food Additives (CCFA), the Codex Committee on Pesticide Residues
274 (CCPR), and the Codex Committee on Food Hygiene (CCFH). While these committees primarily address
275 toxicological, microbiological, additive, or residue related risks, their methodological approaches may
276 have relevance to DRNCD risk analysis. Newer considerations in food qualities that could affect DRNCD
277 risk may require different methods of analysis to create metrics suitable for use in risk analysis. Such
278 methods require evaluation and grading by the Committee on Methods of Analysis and Sampling
279 (CCMAS).

280
281 For example, the CCFA, in coordination with JECFA, uses the Food Category System within the General
282 Standard for Food Additives (GFS) to organize and evaluate additive use by food categories or sub-
283 categories [120]. Likewise, CCCF applies risk assessment methodologies involving the establishment of
284 Maximum Limits (MLs) for contaminants within specific food categories traded globally. While these
285 approaches were developed for evaluation of additives and contaminants, they demonstrated that Codex
286 already applies food category-specific risk assessments and risk management approaches across the
287 global food system. **These existing frameworks may provide useful methodological foundations for**
288 **considering DRNCD risk for dietary patterns, food groups, or food categories.**

289
290 Contemporary Approaches to Diet Quality and Food Classification

291 As previously discussed, scientific approaches to evaluating diet quality and DRNCD risk have evolved
292 from nutrient-based systems toward broader models of dietary patterns and dietary context. Some of
293 these approaches include nutrient profiling systems, dietary pattern indices, and food classification
294 systems intended to capture multidimensional aspects of diet quality and health risk (Table 1) [121]. A
295 recent article proposed guiding principles for science-based food classification systems that may be of
296 interest to the committee [122].

297

298 **Table 1. Approaches to Diet Evaluation**

Paradigm	Key concept	Example metrics	Limitations
Nutrient reductionism	Individual nutrient adequacy	Dietary Reference Intakes: (EAR, RDA, AI, UL, EER, and AMDR), Mean Adequacy Ratio, and Nutrient Rich Foods Index	Ignore food synergies and diet context
Pattern-based assessment	Overall eating pattern predicts health outcomes	Guideline-based: Healthy Eating Index and Alternative Healthy Eating Index Specific patterns: Healthy Eating Index and Alternative Healthy Eating Index	Ability to distinguish quality within food groups and matrix
Mechanistic proxies	Diet quality captured through specific biological pathways	Inflammatory: Dietary Inflammatory Potential and Empirical Dietary Inflammatory Pattern Glycemic: Index and Glycemic Load Oxidative/acid-base: Dietary Total Antioxidant Capacity and Potential Renal Acid Load	Focus on single mechanisms lack consideration of processing and bioavailability
Processing-based classification	Degree/type of food matrix industrial processing alters health effects independent from nutrients	Processing based: NOVA, IARC/EPIC, IFPRI, IFIC, UNC, and Siga score	Standardization, mechanistic understanding, and flawed equation of level of processing with healthfulness
Integrated systems (emerging)	Multi-dimensional quality (nutrients, patterns, processing, and sustainability)	Multi-variable: Planetary Health Diet Index, EAT-Lancet index, and World Index for Sustainability and Health	Standardization and validation Lack of common computational method of analysis including weighting factors and variable inclusion

Table adapted from Krenek A, and Gardner CD. [121]

300 Many of the tools and approaches continue to evolve and also differ in their intended use, scientific
301 assumptions, and applicability to regulatory risk analysis. Many of these tools were also developed for
302 different purposes, including consumer guidance, dietary assessment, or research purposes rather than
303 regulatory risk analysis. Nevertheless, they illustrate increasing scientific interest in approaches that
304 extend beyond nutrient assessments to broader consideration of foods, dietary patterns, and dietary
305 context.

306

307 Implications for Future CCFSDU Work

308 Taken together, these examples demonstrate that Codex has long incorporated risk-analysis principles
309 into nutrition and food standard development. Currently, existing Codex frameworks apply food category
310 specific approaches for contaminants, additives, and other food-related risks, while CCFSDU has
311 established individual nutrient-based approaches to address DRNCD risk management. Because
312 CCFSDU's approach is individual nutrient-based, it does not provide guidance on DRNCD risk profiles
313 based on food groups and dietary patterns. Existing diet quality frameworks and food classification
314 systems contribute useful perspectives, but none fully address the multidimensional nature of DRNCD
315 risk with a regulatory lens. **These considerations support the need for further evaluation of whether
316 existing Codex risk-analysis principles and methodologies could be adapted or expanded to address
317 DRNCD risk associated with food categories and patterns of consumption.**

318

319 **6. Conceptual Framework and Methodological Considerations for Food Category-Based Risk** 320 **Assessment**

321 Purpose and Conceptual Basis

322 The proposed new work would explore whether and how existing Codex risk-analysis principles could be
323 applied to DRNCD associated with food categories. Such an approach should recognize the complexity of
324 the total diet and dietary patterns, including frequency and quantity of consumption, bioavailability,
325 nutrient/energy density, food matrix effects, and population variability in susceptibility and exposure.

326

327 Given Codex's mandate in food safety and nutrition, CCFSDU is well positioned to explore science-based
328 methodologies for evaluating relationships between food categories and DRNCD risk. The proposed work
329 would build upon existing Codex risk-analysis principles while considering emerging scientific
330 understanding related to foods, dietary patterns, and the broader dietary context. The framework
331 presented in the following sections is intended solely as a conceptual illustration of how
332 multidimensional factors could potentially be considered within a structured risk-analysis approach.

333

334

335 Multidimensional nature of DRNCD risk assessment

336 Assessment of DRNCD risk at the food category level presents several methodological challenges due to
337 the myriad factors beyond individual nutrient influence on DRNCD risk. However, advances in dietary
338 assessment, data analysis, and scientific understanding of dietary patterns and food matrix effects
339 support more integrated approaches to dietary risk analysis.

340

341 One example of a potential framework organizes relevant considerations into three complementary
342 domains:

343

344 Group 1: Food matrix and composition

- 345 • Nutritional composition (macro and micronutrients, energy density, dietary fiber)
- 346 • Food formulation (ingredients and additives)
- 347 • Food structure and matrix effects impact on bioavailability, satiety, or palatability
- 348 • Food preparation and processing methods
- 349 • Potential contaminants or other food-related exposures

350

351 Group 2: Human factors

- 352 • Dietary patterns including frequency and quantity of consumption
- 353 • Population variability (demographics and health status)
- 354 • Bioavailability and metabolic variability
- 355 • Potential genetic- and microbiome-related interactions

356

357 Group 3: Food environment, economic and social context

- 358 • Availability and accessibility of foods
- 359 • Cultural and behavioral dietary practices
- 360 • Socioeconomic influences on consumption patterns
- 361 • Broader food-system considerations (e.g., sustainability) relevant to population exposure

362

363 These domains provide an example of a multidisciplinary and overall diet approach to DRNCD related risk
364 analysis while recognizing the interactions among foods, populations, and dietary context that can
365 influence health outcomes.

366

367 Integration with Existing Codex Risk Analysis Principles

368 The Codex risk assessment framework provides a structured, science-based, and transparent process
369 that includes hazard identification, hazard characterization, exposure assessment, and risk
370 characterization [123]. Within the example framework, food matrix and composition factors may

371 contribute primarily to hazard identification and characterization, while human and contextual factors
372 may contribute more to exposure assessment and characterization of population variability.

373

374 Risk characterization would integrate evidence across these domains to evaluate potential relationships
375 between food categories, patterns of consumption, and DRNCD outcomes within the context of the
376 overall diet. This approach is expected to complement rather than replace nutrient-based risk
377 assessment methodologies. Additionally, the impact of food composition and matrix would encompass
378 compositional and process interactions, such as how food additive mixtures and processing interact in
379 the context of DRNCD risk, a risk analysis separate from the toxicological risk evaluations currently
380 conducted by CCFA on stand-alone food additive ingredients.

381

382 To identify food categories, the Food Category System and Food Category Descriptors (Appendix IV)
383 established in CXS 192-1995 General Standard for Food Additives by CODEX CCFA could be used as
384 examples for applying a DRNCDs risk assessment methodological framework [120]. The following
385 example is presented solely to illustrate how this framework could be applied within a food category-
386 based risk analysis.

387

388 *Fine Bakery Wares (CXS 192-1995, Category 07.2)*

389 Fine bakery wares (Category 07.2), as defined in the General Standard for Food Additives (CXS
390 192-1995) [120], include ready-to-eat products such as cakes, cookies, pies, doughnuts, sweet
391 rolls, muffins, and mixes for their preparation. These products are widely consumed across
392 different populations and are commonly characterized by formulations varying in combinations
393 of refined/whole grains, added sugars, fats, and differing levels of dietary fiber and
394 micronutrients. An example framework for conducting an assessment on this category is provided
395 in Appendix II.

396

397 Within a conceptual risk-analysis framework:

- 398 • Hazard identification could be informed by food composition and matrix, including energy
399 density, added sugar, sodium and saturated fat content, formulation, and structural
400 impacts on palatability and/or satiety.
- 401 • Hazard characterization could evaluate the relationship between the hazards identified
402 and DRNCD-related outcomes.
- 403 • Exposure assessment could consider the frequency and quantity of consumption, portion
404 sizes, cultural dietary patterns, and population-specific intake variability.
- 405 • Risk characterization could integrate these factors within the context of the overall diet
406 while accounting for variability in formulation, processing, and population susceptibility.

407

408 This example illustrates how food matrix, human factors, and contextual factors could potentially be
409 evaluated within a structured risk-analysis framework.

410

411 *Key methodological considerations*

412 An important consideration of this framework is the heterogeneity that exists within food categories and
413 subcategories. Foods classified within the same Codex category may differ considerably in nutritional
414 composition, formulation, preparation methods, structural characteristics, and contributions to health.
415 As a result, category-level assessments should recognize the importance of sufficient granularity to avoid
416 assuming uniform effects of all foods within a category. For example, in the “fine bakery wares” category,
417 a chocolate chip muffin and a low-fat bran muffin would both fall in the same category, but have
418 substantially different nutritional profiles, implications for DRNCD risk, and variability in intake levels in
419 the overall diet. Other variations, such as cooking temperature and time, ingredient interactions,
420 viscosity, density, and fiber content, are just a few other characteristics that would need consideration
421 within individual food categories.

422

423 The proposed framework is not intended to establish a new food classification system or classify foods
424 as inherently “good” or “bad.” Rather, it is to provide a structured and science-based approach for
425 evaluating factors that may contribute, positively or negatively, to DRNCD risk within the context of the
426 overall diet. Foods can simultaneously contain both beneficial and less desirable attributes, so any
427 developed framework should support balanced evaluation to support continuous improvement and
428 innovation, rather than binary classification. The framework should also remain flexible and adaptable
429 to evolving scientific understanding and regional dietary contexts.

430

431 **7. Relevance to Codex and International Trade**

432 Codex Alimentarius’s tagline of “safe, good food for everyone - everywhere” highlights its unique role in
433 global food trade to set international food standards that protect consumer health and ensure fair
434 practices in the food trade through science-based guidelines. As global food systems evolve, many
435 countries and regions are developing dietary guidance intended to address DRNCDs, including policies
436 related to nutrient profiling, front-of-pack labeling, and food classification systems.

437

438 These approaches can often differ substantially in aspects of terminology, methodology, scope, and
439 scientific rigor. Increasing divergence has the potential to impact international trade harmonization,
440 particularly if food categories or dietary risk concepts are defined or applied differently across regions
441 [124].

442

443 CCNFSDU is uniquely positioned within Codex to explore if existing risk-analysis principles could support
444 more consistent and scientifically based approaches for evaluating DRNCD-related risks associated with
445 dietary patterns and food categories. Development of internationally recognized methodological

446 principles could help support transparency, improve scientific consistency, and enable greater alignment
447 across member countries while respecting national public health priorities and regulations.
448

449 **Given the global burden of DRNCDs and the growth of food-based dietary policies, consideration of**
450 **the food category related risk assessment approaches is highly relevant to the ongoing work of Codex**
451 **and CCNFSDU.**

452

453 **8. Key Questions for Committee Discussion**

- 454 • To what extent could existing risk-analysis principles and approaches within Codex be adapted to
455 address DRNCD risk associated with food categories, food groups, or dietary patterns?
- 456 • Is the development of a food category-based method within the remit and expertise of CCNFSDU?
457 What other stakeholders may need to be involved? How could such work align with existing Codex
458 activities and systems?
- 459 • What scientific criteria and types of evidence would be appropriate for evaluating relationships
460 between food categories, patterns of consumption, and DRNCD risk?
- 461 • How should the overall diet context, population variability, frequency, and quantity of
462 consumption be considered within a food category-based risk assessment framework?
- 463 • How might food matrix characteristics, formulation, and processing methods be appropriately
464 incorporated into DRNCD risk analysis?
- 465 • What methodological approaches could support flexibility to consider heterogeneity within food
466 categories and regional dietary differences?
- 467 • How could Codex work in this area move forward to both support international harmonization
468 while respecting national public health priorities and regulations?

469

470 **9. Conclusion and Recommendation**

471 Diet-related non-communicable diseases continue to represent a major global public health challenge,
472 with growing scientific evidence suggesting that DRNCD risk is influenced not only by individual nutrients,
473 but also by broader dietary patterns, food groups, food categories, and characteristics of the food matrix
474 within the context of the total diet.

475

476 CCNFSDU and other Codex committees have extensive experience applying science-based risk-analysis
477 principles to nutrition, food safety, additives, contaminants, and related food-category approaches. At
478 the same time, increasing development of national and regional frameworks related to DRNCD risk
479 demonstrates the need for internationally harmonized methodological principles that are transparent,
480 evidence-based, and adaptable to differing dietary contexts and public health priorities.

481

482 The proposed new work would enable CCNFSDU to explore whether existing Codex risk-analysis
483 principles and methodologies could be adapted or expanded to address DRNCD-related risks associated

484 with patterns of food consumption and food categories. Such work is not intended to create a new
485 regulated food classification system or classify foods as inherently “good” or “bad,” but rather would
486 support structured scientific evaluation within the context of the total diet. CCNFSDU is invited to
487 consider whether new work in this area would be appropriate and beneficial to support future Codex
488 guidance related to DRNCD risk assessment and risk management.

489

490

491 **10. Terms and Definitions**

492 The following working definitions are provided solely for the purposes of this discussion paper and do
493 not represent formal Codex definitions unless otherwise specified.

494

495 Bioavailability

496 The extent to which nutrients or other food components are released from the food matrix, absorbed,
497 and utilized by the body.

498

499 Dietary pattern

500 The quantities, proportions, variety, combinations, and frequency of foods and beverages that are
501 habitually consumed over time.

502

503 Diet-Related Non-Communicable Diseases (DRNCDs)

504 Chronic non-communicable diseases for which dietary intake and dietary patterns are recognized as
505 contributors to risk, including but not limited to obesity, cardiovascular disease, type 2 diabetes,
506 hypertension, and certain cancers.

507

508 Energy density

509 The amount of energy provided per unit of weight or volume of food or beverage, typically expressed as
510 kilocalories or kilojoules per gram or milliliter.

511

512 Food category

513 A grouping of foods that share common characteristics based on composition, intended use, processing,
514 preparation, or regulatory classification

515

516 Food environment

517 The physical, economic, policy, and sociocultural conditions that influence food availability, accessibility,
518 affordability, marketing, selection, and consumption.

519

520

521 Food formulation

522 The composition and combination of ingredients, additives, and processing inputs used in the
523 manufacture or preparation of a food product.

524

525 Food group

526 A collection of foods categorized primarily according to shared nutritional characteristics or common
527 dietary guidance usage, such as fruits, vegetables, dairy, grains, or meats.

528

529 Food matrix

530 The physical and chemical structure of a food, including the interactions among nutrients and non-
531 nutrient components, which may influence digestion, bioavailability, satiety, metabolic responses, and
532 health effects.

533

534 Food processing

535 Physical, chemical, biological, or technological methods applied to foods during manufacturing,
536 preparation, preservation, packaging, or storage to improve safety, stability, quality, functionality, or
537 convenience.

538

539 Food subcategory

540 A more specific subdivision within a broader food category that groups foods with additional shared
541 characteristics related to composition, formulation, preparation, or use.

542

543 Nutrient Profiling

544 The classification or ranking of foods according to their nutritional composition using predefined criteria
545 or algorithms intended to support dietary guidance, policy, labeling, or related applications.

546

547 Palatability

548 The sensory acceptability and perceived pleasantness of a food that may influence consumer food
549 preference and consumption behavior.

550

551

552

553

554 **11. REFERENCES**

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