Public consultation on the draft WHO Integrated food profiling model for regulatory measures

ISDI response

ISDI appreciates the opportunity to comment on the draft WHO integrated food profiling model for regulatory measures. ISDI shares WHO's objective of improving dietary patterns and preventing diet-related noncommunicable diseases. ISDI considers that measures pursuing this objective should be transparent, evidence-based and proportionate. However, ISDI does not support the draft integrated food profiling model in its current form, which raises significant concerns regarding scope, scientific validity, proportionality and regulatory application.

ISDI identifies four priority issues that should be addressed:

1. **Scope**: All Foods for Special Dietary Uses (FSDU) meeting the Codex CXS 146-1985 definition should be excluded consistently. This includes products covered by specific Codex commodity standards or guidelines and products meeting the general FSDU definition where no product-specific Codex standard has been established. Exclusions should be clarified by reference to relevant Codex categories and through illustrative examples for operational clarity.
2. **Scientific basis and proportionality of the criteria**: The translation of population-level dietary recommendations into product-level nutrient thresholds needs to be validated and WHO should provide evidence provided demonstrating the validity and incremental public health value of flavours, colours and sweeteners as standalone criteria. The Annex demonstrates that these ingredients increase classification coverage beyond the nutrient criteria, but increased coverage should not itself be treated as evidence of improved public health validity. Assessment should take account of the intended population, dietary role, ingredient function and product context.
3. **Validation and analytical methodology**: The integrated model should be clearly distinguished from the broader Nova-derived “UPF” classifier used in Annex 1. Concordance with that reference set should not be presented as independent validation. WHO should assess both the sensitivity and specificity of the model and demonstrate that the incremental products identified through the ingredient dimension advance its stated public health objective.
4. **Regulatory application and proportionality**: Classification by the draft model should be an input to, not a substitute for, application-specific assessment of evidence, proportionality, impacts and

ISDI AISBL. Registry No. 0798.133.816
Sq. de Meeûs 35, 1000 Brussels, Belgium
secretariat@isdi.org | **www.isdi.org**

legal context. Regulatory measures should be appropriate to the identified risk and no more restrictive than necessary to achieve their intended public health objective. WHO should also assess potential unintended consequences, including whether the draft model could obscure or discourage nutritionally beneficial reformulation.

ISDI recognises WHO's explicit statements that the draft model does not determine whether individual foods are healthy or unhealthy and that inclusion of flavours, colours or sweeteners does not imply that these ingredients are safe or unsafe. ISDI considers these qualifications as essential for the correct interpretation of the draft model and strongly encourages WHO to reflect them consistently throughout.

ISDI reiterates that all FSDU meeting the Codex definition should be explicitly excluded. The comments below follow the structure proposed by WHO for consultation responses. Where a priority issue recurs, the relevant section addresses a different aspect of that issue, including scientific rationale, operational application or drafting changes.

1. Purpose and intended use

ISDI supports the stated public health objective and recognises the WHO's distinction between the classification model and the regulatory instrument through which a classification may be applied. Any classification should be clearly presented as a potential input into regulatory decision-making that does not, without further assessment, determine whether or what regulatory action should apply.

Proportionality should be a fundamental element of the development and application of food-related health policy instruments. Measures pursuing legitimate public health objectives should be evidence-based, appropriate to the identified risk and no more restrictive than necessary to achieve the intended outcome. Given the diversity of food products, nutritional functions and target populations, policy interventions should be calibrated to the strength of the scientific evidence, the magnitude of the public health concern and the intended regulatory objective. Applying this principle would help ensure that measures are scientifically justified and effective while minimising unintended consequences for consumer access, nutrition, innovation and international trade.

Marketing restrictions, front-of-pack labelling, fiscal measures, procurement rules and reformulation policies pursue different objectives and have different legal, commercial and public health effects. Each application should therefore require a defined policy objective, application-specific evidence, proportionality and regulatory impact assessment, consideration of alternatives, and monitoring of intended and unintended effects.

All FSDU shall be excluded from the scope of this and any other general model. FSDU are specifically formulated to meet particular nutritional requirements arising from physiological conditions, life stages or specific dietary needs. Their composition, intended use and dietary role differ from those of

foods intended for the general population and should be assessed through the dedicated nutritional, compositional, safety and marketing frameworks applicable to them.

This is particularly relevant to foods specifically formulated for infants and young children. Infants and young children have distinct nutritional requirements, consumption patterns and dietary roles. Products intended for these populations should be assessed through dedicated, age-appropriate nutritional and regulatory frameworks.

These products are already subject to dedicated composition, safety and labelling requirements, including the relevant Codex standards (CXS 146-1985, CXS 72-1981, CXS 156-1987, CAC/GL8-1991, CXS 74-1981, CXS 73-1981, CXS 180-1991, CXS 181-1991, CXS 203-1995, CXS 118-1979 and CXS 53-1981) and corresponding national and regional legislation. Applying a general profiling model designed to identify foods to be consumed in moderation to these products could be misinterpreted by parents and caregivers as advice to limit or avoid them and could lead some to replace them with nutritionally inappropriate alternatives. This would be contrary to the intended public health objectives.

The exclusion should apply on the basis of the nature, intended use and specialised nutritional purpose of the product, in addition to whether a product is covered by a product-specific Codex commodity standard or guideline. It should therefore encompass: products meeting the general Codex definition of FSDU, including products for infants and young children[1]; products covered by relevant Codex standards and guidelines; and products meeting the FSDU definition for which no product-specific Codex standard has yet been established.

The absence of a product-specific Codex standard or guideline does not mean that a product lacks a specialised nutritional purpose. For example:

- Products formulated for use in relation to intense muscular effort, including sports foods and sports drinks, may provide carbohydrates, fluids and electrolytes for defined physiological functions such as hydration and endurance performance.
- A product formulated specifically without lactose for lactose intolerant individuals clearly meets the definition of FSDU

Where such products meet the Codex definition of FSDU, they should be covered by the general FSDU exclusion and assessed through their relevant category-specific framework rather than a general model.

ISDI therefore calls on WHO to:

[1] Within Codex, an infant means a person of not more than 12 months of age and a young child means a person from the age of more than 12 months up to the age of three years, so products intended for these age groups are clearly defined as FSDU.

- Define the exclusion by reference to the Codex CXS 146-1985 definition of FSDU and apply it consistently to all products meeting that definition;
- Clarify that the exclusion encompasses both products covered by specific Codex FSDU commodity standards and guidelines and products meeting the general FSDU definition for which no product-specific Codex standard or guideline has been established[2];
- Clarify exclusions by reference to the relevant Codex Alimentarius categories, rather than only selected examples. In particular, consideration should be given to Category 13 foods under the General Standard for Food Additives (CXS 192-1995), including Category 13.4 (Formula Foods for Weight Control Diets), Category 13.5 (Foods for Special Medical Purposes), and other Foods for Special Dietary Uses. This additional approach would improve consistency across jurisdictions and reduce ambiguity regarding products with specialised nutritional purposes;
- Avoid using breast-milk substitutes (BMS) as a separate operative product-category boundary, since products considered BMS would be covered by the general FSDU exclusion and illustrative examples; and
- Ensure that products designed to meet specific nutritional requirements are addressed within the relevant dedicated nutritional, compositional and regulatory frameworks rather than through a general food profiling model.

2. Rationale

ISDI supports the principle that measures intended to prevent diet-related NCDs should reflect established dietary recommendations and the contribution of nutrients of public health concern. The evidence required should, however, be appropriate to the purpose and consequences of the measure. Evidence sufficient for research, surveillance or initial classification is not necessarily sufficient for regulatory measures with legal, commercial or financial consequences.

The nutrient criteria and specified sensory-ingredient criteria represent analytically distinct dimensions. The first identifies composition associated with established dietary recommendations. The second seeks to identify formulation characteristics hypothesised to increase sensory appeal and

[2] FSDU include infant formula (CXS 72-1981), formulas for special medical purposes for infants (CXS 72-1981), follow-up formula for older infants (CXS 156-1987), product for young children (CXS 156-1987), formulated foods for older infants and young children (CXG 8-1991), cereal-based foods for infants and young children (CXS 74-2981), canned baby foods (CXS 73-1981), ready-to-use therapeutic foods (CXG 95-2022), foods for special medical purposes (CXS 180-1991), formula foods for use in weight control diets (CXS 181-2991), formula foods for use in very low energy diets for weight reduction (CXS 203-1995), special dietary foods with low-sodium content (CXS 53-1981), gluten-free foods (CXS 118-1979) and sports foods and drinks. It may also be noted that Codex is currently preparing a standard for foods for older infants and young children.

consumption. Treating either dimension as an independent trigger for the same IFM classification inappropriately assumes that both validly identify the same public health target.

WHO should therefore distinguish clearly between attributes directly measured by the draft model and behavioural or health effects inferred from them. In particular, WHO should provide evidence showing that the sensory ingredient dimension adds relevant predictive value beyond the nutrient criteria alone.

WHO should also acknowledge that population dietary recommendations concern overall intake, whereas the model translates them into thresholds applied to individual products. Actual dietary contribution depends on the amount and frequency of consumption. A food may exceed a diet-level threshold when assessed as an individual product while nevertheless forming part of a healthy dietary pattern when consumed in an appropriate quantity and context. If the same principle were extended beyond industrially produced, pre-packaged foods, a range of fresh, minimally processed or whole foods could also exceed one or more diet-level thresholds when assessed in isolation. WHO should therefore validate that the translation of population-level recommendations into product-level thresholds reliably distinguishes the products relevant to the model's stated purpose.

3. Overall structure

The distinction between the integrated model and the Nova-derived "UPF" classifier used in Annex 1 requires considerable clarification. Annex 1 uses 23 broader "UPF" markers in addition to flavours, colours and sweeteners, including modified starch, added fibre, glucose or dextrose, maltodextrin or dextrin, lactose, isolated protein sources, whey, casein, emulsifiers, gelling agents and thickeners.

WHO should make explicit throughout the document that:

- Classification as "UPF" in Annex 1 does not mean that a product is identified as an IFM by the draft integrated model;
- The broader "UPF" markers are analytical variables used to construct a comparator, not proposed or prospective regulatory criteria;
- Agreement with the "UPF" reference set demonstrates classification concordance, not independent validation against dietary, behavioural or health outcomes; and
- Failure to identify a product included in the "UPF" reference set should not automatically be interpreted as a deficiency or false negative requiring additional ingredient markers.

The draft model's output should be described neutrally as "identified by the model" or "not identified by the model". Neither outcome should be presented as a conclusion about overall healthiness, ingredient safety or the appropriateness of a particular regulatory intervention.

The dual nutrient and ingredient-based approach may also create unintended reformulation disincentives. A product remains identified by the model if it contains a specified flavour, colour or sweetener, even where reformulation has materially reduced sodium, sugars or saturated fatty acids below the applicable thresholds. Conversely, the use of flavours or sweeteners may enable reductions in nutrients of public health concern while maintaining product acceptability. Treating either dimension as an independent trigger for the same undifferentiated classification may therefore obscure beneficial reformulation and weaken incentives to improve nutrient composition.

4. Public health principles

ISDI supports the principles of alignment with dietary guidance, scientific evidence, transparency, proportionality and contextual relevance. The principles should also expressly include classification validity, evidence appropriate to the intended regulatory use, and proportionality between the strength of the evidence and the consequences of the measure.

The scientific evidence presented for the sensory-ingredient dimension is insufficient, and concordance with Nova group 4 does not provide independent validation. WHO should distinguish evidence that an ingredient:

- Is prevalent among products classified as “UPF”;
- Is useful for reproducing that classification;
- Independently affects consumption behaviour; and
- Predicts relevant dietary or health outcomes.

Evidence supporting one of these propositions should not be treated as establishing the others. Prevalence, administrative detectability and concordance with Nova do not, individually or collectively, establish that the presence of an ingredient is a valid standalone predictor of the dietary or regulatory outcome the model is intended to address.

Flavours, colours and sweeteners are also subject to established regulatory frameworks governing their safety and conditions of use. International standards developed through the Codex Alimentarius system and, in many jurisdictions, dedicated regulatory frameworks provide for the assessment and authorisation of food additives and establish conditions for their use. The fact that an authorised ingredient is present in a food should therefore not, without additional evidence relevant to the draft model's stated public health objective, be treated as establishing that the ingredient causes an adverse health effect or that the food containing it should be identified as one to be consumed in moderation.

The model should recognise certain alternative sugars that have been developed specifically to provide nutritional or metabolic benefits. For example, isomaltulose has an authorised European Union health claim relating to lower post-prandial glycaemic responses, while D-tagatose has an authorised health

claim relating to maintenance of tooth mineralisation. Such ingredients, when authorised for the corresponding products, should not automatically be treated identically to conventional sugars without considering their demonstrated physiological properties.

More generally, the assessment of an ingredient should take account of its composition, function, demonstrated physiological properties and the product context in which it is used.

A principle that ingredient-based criteria should be introduced only where evidence connects the ingredient's function in the product to the specific public health objective is missing from the draft model. A processing-based classification should not itself be treated as evidence that every classified product or ingredient causes the same health outcome.

5. Clarity/application of the approach

Greater clarity is required in the following areas.

Baby foods

WHO should resolve the apparent inconsistency between excluding FSDU while including baby foods and products for young children in the analytical dataset. Under Codex CXS 146-1985, FSDU includes foods for infants and young children, so baby foods and products for young children should be covered by the exemption for FSDU.

Sports foods and sports drinks

Sports foods and drinks are specifically formulated to support physiological functions such as hydration and endurance performance. Carbohydrates and electrolytes contained in these products serve recognised functional roles during prolonged physical activity. Application of the proposed profiling criteria may inadvertently classify products designed for exercise performance as less healthy despite their intended nutritional purpose. Sports foods and drinks meet the Codex definition of FSDU, irrespective of whether a product-specific Codex standard has been established, so they should be excluded from the scope of the model.

IFM classification and the Annex 1 “UPF” comparator

The proposed integrated model and the Annex 1 “UPF” classifier are analytically distinct and should not be conflated. Classification as “UPF” within the Annex 1 analytical framework should not imply that a product should be identified by the integrated model, and a product not identified by the integrated criteria should not be treated as a false negative because it is included in the “UPF” reference set. Concordance with the selected comparator does not establish the public health validity of the integrated model.

Ingredient function

The presence of an ingredient should not, in itself, be used as an automatic standalone marker for identifying a food as one to be consumed in moderation, or as a direct trigger for regulatory restrictions. Such an approach does not establish that the ingredient's presence is relevant to the public health outcome the model is intended to address and does not adequately account for ingredient function or product context. Specified sensory ingredients may serve materially different functions in specialised nutrition products. In foods for special medical purposes, for example, sensory characteristics may affect whether a nutritionally necessary product is acceptable and usable by a patient. Colours, flavours or sweeteners may also serve formulation or identification purposes permitted within the relevant regulatory framework.

Irrespective of this broader concern with standalone ingredient-based triggers, a comprehensive Codex-based FSDU exclusion must be applied before any profiling criteria are assessed. Otherwise, products may be captured for reasons unrelated to the model's stated rationale despite their specialised nutritional purpose.

6. Decision tree/usability

Scope determination must be explicit at the first step and classification must be separated from subsequent regulatory assessment.

Step 1: Determine whether the product is within scope.

Identify excluded categories before applying any profiling criteria. The exclusion should cover all products meeting the Codex CXS 146-1985 definition of FSDU, including products covered by specific Codex standards or guidelines and products meeting the definition for which no product-specific Codex standard has been established. It should be accompanied by illustrative examples and reference to relevant Codex Alimentarius categories, including additional consideration for Category 13 under CXS 192-1995. A separate BMS exclusion would then be unnecessary as an operative product-category boundary.

Step 2: Assess nutrient criteria.

The proposed nutrient criteria should not be applied on the assumption that population-level dietary recommendations can be translated directly into thresholds for individual foods. WHO dietary recommendations concern overall dietary intake, in which different foods and food categories make different contributions to energy, nutrients of public health concern and nutritional adequacy. Exceeding a diet-level threshold when assessed at the level of an individual food does not, in itself, establish that the food should be identified as one to be consumed in moderation. This step should

therefore require that any product-level nutrient criteria are scientifically valid and appropriate for the intended regulatory purpose before they are incorporated into the classification process.

In addition, there is no internationally harmonised Codex definition of free or added sugars. The definitions selected for the draft model therefore require explicit justification, particularly where they differ from definitions used in national regulatory frameworks.

Step 3: Assess specified sensory ingredients.

The evidence presented does not establish a scientifically valid basis for using flavours, colours or sweeteners as independent standalone triggers. On the evidence presented, the sensory-ingredient dimension should not be retained as a standalone classification criterion. WHO's own analysis should nevertheless be reported transparently, including the product categories comprising the incremental set captured only by these ingredients.

Step 4: Record the classification result neutrally.

Use the endpoints “identified by the model” and “not identified by the model”. The outcome should not imply that a product is healthy or unhealthy, that an ingredient is safe or unsafe, or that a particular regulatory consequence is warranted.

Step 5: If regulatory action is contemplated, conduct a policy-specific assessment.

Assess the regulatory objective, supporting evidence, legal basis, proportionality, impacts, alternatives, interaction with existing category-specific regulation and monitoring requirements. Classification should be a potential input into this process, not its conclusion.

Since the draft model is not intended to identify whether an individual food is healthy or unhealthy, or whether an ingredient is safe or unsafe, products identified by the model should be treated neutrally in the same way as WHO proposes products not identified by the model should be treated neutrally.

7. Examples

Before the proposed model can be considered for regulatory use, WHO should demonstrate its operation and potential unintended classifications through worked examples. These should include products forming part of healthy dietary patterns as well as products intended to be captured by the model. This should also provide examples of products that are excluded from the scope, which should include all products meeting the Codex definition of FSDU.

8. Annexes

The terminology and interpretation of the analysis should distinguish clearly between comparison, concordance and independent validation.

A Nova-derived “UPF” classification should not be treated as a validated reference standard merely because the draft integrated model achieves high concordance with it. High agreement does not establish that the draft model is valid or predicts dietary exposure, excessive consumption or adverse health outcomes. Because the reference classifications and proposed model share some underlying characteristics, the analysis may also be affected by incorporation bias.

WHO should demonstrate the incremental validity of the ingredient dimension by comparing: nutrient criteria alone; specified sensory ingredients alone; and the integrated criteria. These alternatives should be evaluated against independent dietary, behavioural and health-related outcomes relevant to the model's purpose. Increased coverage of a Nova-derived reference set should not, by itself, be interpreted as an improvement in public health validity.

WHO should assess not only the model's sensitivity against its constructed reference set, but also its specificity, including the extent to which foods outside the intended target of the model are identified by the criteria. WHO's analysis indicates that nutrient thresholds alone capture nearly 92% of the regulatory reference set, while flavours, colours and sweeteners add approximately 6.0 percentage points, increasing overall capture to 97.92%. The incremental contribution also varies materially by region, from 2.7 percentage points in Europe to more than 14 percentage points in the Western Pacific Region. WHO should therefore report the product categories comprising this incremental set and evaluate whether the additional products identified through flavours, colours or sweeteners advance the model's stated public health objective against independent dietary, behavioural or health-related outcomes.

The findings concerning products not identified by the integrated criteria require neutral interpretation. These products tend to contain other “UPF” markers while having substantially lower median saturated fat, sugar and sodium levels than products identified by the draft model. This indicates that the two approaches classify products according to different characteristics. It does not establish that the draft integrated model has failed to identify products that should be consumed in moderation.

The analysis should also distinguish product prevalence from dietary exposure. Product-count analysis gives equal weight to products irrespective of sales, purchase frequency, customary portion or contribution to dietary intake. WHO should, where feasible, supplement product-level analysis with consumption-, purchase- or sales-weighted evaluation and state the limitations of extrapolating from listed-product counts to population dietary risk.

Given the reliance on automated ingredient classification, WHO should report validation against an independently annotated and representative sample, including sensitivity, specificity, positive

predictive value and relevant error rates. Testing should address ambiguous ingredient names, multifunctional additives, compound ingredients, regional terminology, translated declarations, carry-over or incidental additives and cases in which technological function cannot be inferred reliably from the ingredient name alone. The classifier code, version history, quality-assurance procedures and human review protocol should be sufficiently transparent for independent reproduction.

The analytical scope should also be aligned with the draft model's stated exclusions. Annex 1 excludes formula targeting infants up to 12 months, which is narrower and differently framed than the stated exclusions for FSDU and BMS. WHO should identify precisely which Codex product categories were included and excluded and align the analytical exclusions with a clear Codex-based definition of FSDU.

Finally, replace “missed” with the neutral formulation “products in the UPF reference set not identified by the integrated model”. Improving concordance with Nova should not itself be a basis for adding further ingredient markers or for evaluating the success of the draft model.

9. Technical or practical concerns

ISDI identifies the following principal technical and implementation concerns. The scientific rationale for these recommendations is set out in the preceding sections.

A. Consistency of scope definitions

Apply the Codex CXS 146-1985 FSDU exclusion consistently in the draft model, decision tree and analytical methodology.

B. Interpretation of products not identified by the model

Assess validity against the draft model's stated public health purpose, not principally by maximising reproduction of the Nova classification. Avoid terminology implying that every “UPF”-classified product not identified by the draft integrated model is a false negative.

C. Broader “UPF” markers

Do not interpret the presence of any of the ingredients categorised in the analysis, such as whey, casein, lactose, dextrose, maltodextrin, emulsifiers, thickeners, gelling agents, added fibre or modified starch, as evidence of an adverse nutritional profile, sensory enhancement or a need to moderate consumption.

D. Multifunctional ingredients

Require reliable determination of ingredient function where classification depends on purpose. The sensitivity analysis showing substantial changes when declared function is taken into account demonstrates that function is not a minor technical detail.

E. Scientific basis for sensory-ingredient criteria

Publish the scientific evidence review and decision framework supporting flavours, colours and sweeteners as standalone criteria, including evidence of incremental predictive value beyond nutrient composition and product context.

F. Sensory ingredients in FSDU

Recognise that sensory characteristics in FSDU, including foods for special medical purposes, may support safe and appropriate use, nutritional adequacy and patient acceptability. Apply the FSDU exclusion before any criterion is assessed.

G. Nutrient criteria

The proposed nutrient criteria should be reconsidered at product level. WHO's recommendations for saturated fatty acids, sugars and sodium apply to overall dietary intake, in which different foods and food categories make different contributions to energy, nutrients of public health concern and nutritional adequacy. Translating diet-level recommendations directly into thresholds for individual foods does not establish that a food exceeding such a threshold should itself be classified as a food to be consumed in moderation.

This concern is particularly relevant to criteria expressed relative to energy content. Ratio-based criteria may produce counterintuitive results for foods with different energy densities and may penalise relatively low-energy foods because of naturally occurring nutrients. WHO should demonstrate that the proposed product-level criteria validly distinguish foods relevant to the model's stated public-health purpose, including through testing against foods and food categories forming part of healthy dietary patterns and relevant food-based dietary guidance.

More generally, product-level criteria should be validated using a basis appropriate to the particular nutrient, food category and intended regulatory purpose, rather than assuming that population-level dietary intake recommendations can be transferred directly to individual foods. WHO should assess potential unintended consequences for nutrient delivery, reformulation and the coherence of the resulting classifications with dietary guidance.

H. Reformulation incentives and separate reporting

ISDI AISBL. Registry No. 0798.133.816
Sq. de Meeûs 35, 1000 Brussels, Belgium
secretariat@isdi.org | **www.isdi.org**

Report nutrient and ingredient triggers separately so that nutritionally meaningful reformulation remains visible. Assess whether an ingredient trigger could obscure improvements from sodium or sugar reduction or discourage their replacement where appropriate.

Flavours and sweeteners may support reductions in sugars or other nutrients of public health concern while preserving product acceptability. Treating the presence of these ingredients as an independent reason to classify a product as one to be consumed in moderation could therefore discourage reformulation efforts that improve the nutritional profile of foods and beverages. WHO should assess this potential effect before applying a single integrated classification across regulatory instruments.

I. Definition of free/added sugars

There is no internationally harmonised Codex definition of free or added sugars. The definitions selected for the draft model therefore require explicit justification, particularly where they differ from definitions used in national regulatory frameworks. The proposed approach includes sugars derived from fruit and vegetable juices, including 100% juices, whereas under some national frameworks, including the U.S. FDA approach, sugars naturally present in 100% juice are not generally declared as added sugars. WHO should assess the implications for international harmonisation, implementation, consumer understanding and cross-jurisdictional comparability.

J. Sports foods and sports drinks

Sports foods and drinks, are specifically formulated to support physiological functions, such as hydration and endurance performance. Carbohydrates and electrolytes contained in these products serve recognised functional roles during prolonged physical activity. Application of the proposed profiling criteria may inadvertently classify products designed for exercise performance as less healthy despite their intended nutritional purpose.

Sports foods and drinks meet the Codex definition of FSDU, irrespective of whether a product-specific Codex standard has been established, so they should be excluded from the scope of the model.

K. Evidence appropriate to regulatory purpose

Specify the evidentiary standard, decision rule, proportionality assessment and impact analysis expected for each intended regulatory application. Evidence supporting initial classification should not automatically be treated as sufficient for measures with legal, commercial or financial consequences.

10. Section-specific comments

Executive Summary

- State that classification is an initial input into policy design and does not itself determine a specific regulatory consequence.
- Distinguish the draft integrated model from the Annex 1 “UPF” classifier and describe reported overlap as concordance rather than independent validation.
- Retain prominently and consistently that the draft model does not determine whether an individual food is healthy or unhealthy and that inclusion of specified ingredients does not imply that they are unsafe so that the classification results are not understood or communicated as determining the healthiness of foods or the safety of ingredients.

Glossary

- Add a definition of FSDU based on the Codex CXS 146-1985 definition, with illustrative examples providing operational clarity.
- Clarify that the FSDU exclusion applies both to products covered by specific Codex commodity standards or guidelines and to products meeting the Codex CXS 146-1985 definition where no product-specific standard has been established.
- Distinguish classification results expressly from conclusions about healthiness, ingredient safety or suitability for a particular regulatory measure.

Section 1

- Recognise that translation of population dietary recommendations into product-level criteria should consider the intended population and dietary role of the product.
- Explain and validate the translation of population-level dietary recommendations into product-level thresholds, recognising that an individual food may exceed a diet-level threshold while forming part of a healthy dietary pattern in an appropriate quantity and context.
- Assess whether the same thresholds, if applied outside the model’s packaged-food scope, would also identify fresh, minimally processed or whole foods in ways that call the specificity of the criteria into question.

Section 2.2

- Consider implementation experience from existing national and regional nutrient profiling systems and healthy-food classification approaches, including evidence of best practices, implementation challenges and unintended consequences.

Section 2.3

- Provide the evidence review and decision framework used to select flavours, colours and sweeteners as standalone criteria.
- Evaluate and report the incremental validity of nutrient criteria alone, sensory ingredients alone and the combined model, including the product categories comprising the additional set identified only through flavours, colours or sweeteners and whether their inclusion improves performance against independent dietary, behavioural or health-related outcomes.
- Assess whether the two independent classification routes may obscure nutritionally beneficial reformulation or discourage the use of ingredients that enable reductions in nutrients of public health concern.
- Avoid wording suggesting that the presence of a specified ingredient necessarily demonstrates increased consumption unless supported by ingredient-specific evidence.

Section 3.2.5, "Sugars"

- Reassess the use of percentage-of-energy criteria as product-level thresholds and demonstrate that the basis selected for sugars produces valid and proportionate classifications at product level.
- Provide a detailed justification for including sugars in 100% fruit and vegetable juices within the proposed added-sugars definition and assess implications for international harmonisation and implementation.
- Consider the demonstrated physiological properties of alternative sugars rather than automatically treating all such ingredients identically to conventional sugars.

Section 3.2.6, "Sodium"

- Validate the sodium-to-energy and absolute thresholds at product level and assess their effects on nutrient-dense products, specialised nutrition products and feasible reformulation pathways.

Section 3.3

- Replace the separate FSDU and BMS boundaries with a clear exclusion for "all foods meeting the Codex CXS 146-1985 definition of Foods for Special Dietary Uses", covering both products subject to specific Codex standards or guidelines and products meeting the general definition where no product-specific standard has been established, with reference to relevant Codex categories and supported by illustrative examples.
- Clarify the treatment of sports foods and sports drinks, including exclusion where they meet the Codex definition of FSDU and category-specific assessment where appropriate.

- Direct policy-makers towards relevant dedicated nutritional and regulatory frameworks.

Section 4

- Specify that marketing, labelling, fiscal and procurement measures have different objectives, effects and evidentiary requirements.
- Require application-specific validation, proportionality and impact assessment and, where appropriate, prospective pilot testing before implementation.
- Include consideration of the intended population, dietary context, existing category-specific regulation, relevant Codex standards and potential unintended consequences.
- Monitor whether use of a single integrated classification across different instruments discourages beneficial reformulation, and report nutrient and ingredient triggers separately.

Annex 1

- Replace “missed” with “products in the UPF reference set not identified by the integrated model”.
- Report independent validation of the automated classifier and clarify limitations of product-count analysis.

Appendix 1

- Clarify prominently that the 26-marker classifier is an analytical methodology used to construct a “UPF” comparator and is not part of the draft integrated model.

11. Other comments

ISDI encourages WHO to address the following priority questions before finalising the draft model:

1. What construct does the draft integrated model measure, and what independent evidence establishes its validity for the stated public health purpose?
2. What evidence demonstrates that flavours, colours and sweeteners add relevant predictive value beyond nutrient criteria alone, independently of ingredient safety and taking account of ingredient function and product context?
3. Why is a Nova-derived “UPF” classification an appropriate analytical comparator, and how will WHO distinguish classification concordance from independent validation, predictive validity and causation?

4. How has the automated ingredient classifier been independently validated and how representative is a product-count analysis of actual dietary exposure?
5. How will WHO ensure consistent exclusion of all Codex-defined FSDU and unambiguous treatment of foods for infants and young children across the draft model, decision tree and analytical dataset?
6. What application-specific evidence, proportionality assessment and impact analysis will be required before classification is used within marketing, labelling, fiscal or procurement measures?
7. How have the nutrient thresholds been validated at product level, and how has WHO assessed whether thresholds derived from population-level intake recommendations are proportionate when applied to individual foods?
8. How will WHO assess whether the two independent classification routes obscure beneficial reformulation or discourage the use of ingredients that enable reductions in nutrients of public health concern?
9. How will WHO distinguish between FSDU covered by specific Codex standards and FSDU for which no product-specific Codex standard exists, including sports foods formulated for defined physiological purposes?

Taken together, these concerns support the consistent exclusion of all Codex-defined FSDU, reconsideration and independent validation of the product-level nutrient criteria, removal of unsupported sensory-ingredient standalone triggers, clear separation between the integrated model and the Annex 1 “UPF” comparator, and application-specific assessment of proportionality and unintended consequences before any regulatory action is contemplated.

ISDI AISBL. Registry No. 0798.133.816
Sq. de Meeûs 35, 1000 Brussels, Belgium
secretariat@isdi.org | **www.isdi.org**