



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-sixth Session

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APPLICATION OF THE STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT (SoP)

(Comments of Panama)

Panama appreciates the work prepared by the President and vice presidents of the Forty-sixth Session of the Codex Commission (CAC46) for providing the opportunity to address an issue of high importance for the future of Codex. We deeply value the exceptional work of the Executive Committee, the Codex Secretariat and its subsidiary advisory bodies of FAO and WHO, especially the Subcommittee in charge of developing the guide for the implementation of the “Declarations of Principles”.

After an exhaustive analysis of documents and the previous work of the Codex Secretariat, Panama considers that the development of the “Draft Guidelines” on the implementation of the “Declarations of Principles” is the best way to address difficult situations that have generated historical controversy among some member countries in the last 30 years of Codex.

The “Panama Proposal” seeks to promote consensus formulas and agreements among Codex member countries, based on science. We seek to contribute to the development of this guide or orientation, which clarifies how to address “other legitimate factors” in the evaluation, management and communication of Health risks and benefits. This approach is not limited only to physical or physiological factors, but also highlights the need to analyze biopsychosocial risks and benefits aligned with the “dual mandate of Codex”.

Throughout its 60 years, the Joint FAO/WHO Codex Program has managed food standards to protect consumer health and ensure equitable practices in the food trade. The essence of the proposal seeks to consider “Other Legitimate Factors” through scientific methods supported by research and risk-benefit analysis. Panama wishes to serve as a mediator and conciliator between blocks of countries, urging them to base positions on valid scientific studies and the “draft Guidelines on the implementation of the Declaration of Principles.”

At CAC44, Panama presented a room document ([CAC/44 CRD/6](#)), accessible through the hyperlink: where it presents an overview of the importance of addressing this issue. Later, at CAC45, Panama presented another room document ([CAC/45 CRD05](#)), with a specific working proposal, accessible via the hyperlink: as a follow-up contribution to this important issue: “Decision guide/flow chart for chairs in discussions related to the advancement or adoption of standards in all steps” – Revised (PROPOSAL PREPARED BY PANAMA)”. We invite member countries, observers, the Codex Secretariat and the international sponsoring advisory organizations of FAO and WHO to seriously consider its revision.

SPECIFIC COMMENTS

The 45th Session of the Commission considered the draft Guidelines that had been developed for Codex Chairmen and Members and commended the progress made; and noted that, “although the text as annexed to the report of the 83rd session of the Executive Committee was not final, it urged members to take it into account,

as appropriate, during the development process and advancement of standards; and consider next steps to be taken at its 46th session." A circular letter was sent to members and responses were received from only 22 members (Including Panama).

There was widespread satisfaction with the draft guidance and its usefulness in handling situations where members agree on PART of the scientific aspects. Panama considers that ALL Codex decisions must be based on scientific aspects; and therefore, as established in the Declarations of Principles, the "other legitimate factors" considered for the protection of the health of consumers and the assurance of fair or equitable practices in the food trade, must also be considered. It is important not to confuse these "other legitimate factors" with different opinions on aspects contrary to the dual mandate of Codex.

We consider that, in addition to some general and specific observations already raised by Panama in(CAC/45 CRD05),if it is necessary to conclude this important work,including an operational definition of "other legitimate factors", andwithout deleting the diagramthat could serve as a guide in evaluating all possible situations or cases in the Codex standards management process, from the first stages in which proposals for new work are considered.

On the other hand, we must not confuse the scope of the "double mandate" and the objectives of the FAO / WHO Codex Alimentarius, which clearly refers to the "Protection of the Health of consumers" and the "assurance of equitable and/or fair practices in food trade" with a more specific focus on the type of practical "sanitary measures" related to general agri-food health, which are considered in the Agreement on Sanitary and Phytosanitary Measures of the World Trade Organization (WTO) or with the legitimate aspects considered in the WTO Agreement on Technical Barriers to Trade. Public (human) Health is much broader, and in effect, encompasses "other legitimate factors" that are integrative and that are determinants of Health of a biopsychosocial nature that are not traditionally considered in the context of agricultural, livestock or agri-food health.

Proposed Justification Codex Panama CAC46

Considerations on analysis, evaluation and communication of risks and benefits to Health.

Fundamental reason:

The object (fundamental purpose) of the Joint FAO/WHO Food Standards Programme, which is: (a) to protect the health of consumers and ensure equitable practices in the food trade.

Specific comment: We must keep in mind that "Health is a state of complete physical, mental and social well-being, and not merely the absence of infirmities or diseases" (WHO Constitution, 1948). This definition shows us that Health has a dimension beyond the simple physical manifestation of a visible pathology or disease (objectively measurable signs and symptoms), but that it has a broader scope and a much more complex dimension of a Biopsychosocial nature (which includes consider "Determining Factors of Health").

Ref.: STATEMENTS OF PRINCIPLES REGARDING THE ROLE PLAYED BY SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT.

1. The food standards, guidelines and other recommendations of the Codex Alimentarius shall be based on the principle of sound scientific analysis and data, involving the exhaustive examination of all relevant information, so that the standards ensure the quality and safety of the products. food supplies.

Specific comment: See: Quality Attributes and their value for the Consumer!

QualityIt is the degree to which a set of characteristics inherent to an object (product, service, process, person, organization, system or resource) meets requirements. (ISO 9000:2015).

The "quality of food" refers to the set of properties or attributes that give it value and/or that satisfy certain requirements or expectations of customers or consumers. Therefore, we consider it extremely important to point out that, although food safety can be considered the most important or critical attribute or factor of food quality from the perspective of Public Health related to foodborne diseases (FBD).), is not the only factor related to Health. On the contrary, there are definitely "other factors or other legitimate aspects" related to the (comprehensive) protection of Health, related to the physical, mental and social well-being of the consumer, which must also be scientifically evaluated; such as: dietary and/or nutritional aspects and their relationship with non-communicable diseases (NCDs); its appropriate naming and promotion; its integrity, authenticity and/or composition, its form of production, preparation, presentation and/or conservation; his fitness, suitability, health; among other attributes or requirements that must be met. For this reason, it is not acceptable, from the perspective of Public Health (Comprehensive Health), neither a lack of integrity nor hygiene, nor deception or fraud, nor induction of error or

confusion to the consumer.

Comprehensive Public Health Approach:

Foods are not only related to the risks of possible adverse effects on health, due to the possibility of contamination or the presence of biological, chemical or physical hazards, or with the possibility of considering other harmful factors related to their condition, composition or presentation. ; but, in addition, they represent important contributions and benefits to Health, whether due to their composition characteristics, nutritional qualities, or other protective factors for Health. Therefore, not only must the risks related to possible harmful factors be analyzed, evaluated, managed and communicated; but also, the possible benefits related to other protective Health factors must be analyzed, evaluated, managed and communicated.

Is there consensus on risk assessment, and benefit assessment, to ensure an adequate level of public health protection, including ensuring equitable or fair practices in food trade?

Fundamental reason:

Reference: Adequate level of sanitary or phytosanitary protection — DEFINITIONS - Agreement on the Application of Sanitary and Phytosanitary Measures (AMSF/WTO). Note: Only focuses on “risks resulting from the presence of additives, contaminants, toxins or pathogenic organisms.” But it does not include the other Public Health measures, and measures to ensure equitable or fair practices in food trade, which cover the other biopsychosocial aspects of Health and trade, explained above.

Could further advice be helpful? scientist of the relevant risk assessment body and benefit assessment body, including the evaluation of other legitimate factors considered determinants of Health, including ensuring equitable or fair food trade practices?

Fundamental reason:

As we have already explained before, we consider not only necessary, useful and convenient the scientific risk assessment by the FAO / WHO expert advisory bodies, currently in operation, such as: JECFA, JMPR, JEMRA and/or JEMNU, but we consider that scientific evaluation of the possible health benefits is also required, including the assurance of equitable or fair food trade practices. This is why we consider it necessary, useful and convenient to create and implement a new FAO/WHO expert advisory committee to evaluate, with scientific rigor, not only other risk factors, but also protective and/or protective factors. or the possible benefits related to the biopsychosocial aspects considered determinants for Health.

Consult the relevant risk assessment and benefit assessment body for scientific advice.

Fundamental reason:

Not only the possible risks but also the possible health benefits must be evaluated on a scientific basis. To do this, it is necessary to have the advice of specialists and experts in other scientific areas more related to the determinants of Health and social determinants of Health (which include psychological, sociological and economic studies).

After verifying that there is consensus on the risk assessment related to ensuring food safety; determine whether: Is the persistent lack of consensus due to differences in the approach of interpretations over other legitimate factors such as the stability of Codex statements of principles?

Fundamental reason:

Risk assessment related to food safety assurance is only one part of a broader scientific process, which includes the evaluation of risk and protective factors and possible health benefits and the assurance of equitable or fair practices. in the food trade.

Consideration of Other Legitimate Factors

Fundamental reason:

Ref: STATEMENTS OF PRINCIPLES REGARDING THE ROLE PLAYED BY SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT.

Are the Other Legitimate Factors in accordance with what is established in the Codex Declarations of Principles?

Fundamental reason:

It is important to emphasize that subjective considerations on “any type of factors” outside the mandate of Codex are not acceptable; rather, only “Other Legitimate Factors” should be considered that have been demonstrated on a scientific basis to be in accordance with what is established in the “Codex Declarations of Principles”. Other Legitimate Factors are taken into account when deciding on risk management options (including labeling) with the process fully documented, including the rationale for incorporating them, on a case-by-case basis;

Fundamental reason:

It is important to emphasize that these are not “any type of factors” outside the mandate of Codex; but of "Other Legitimate Factors" that have been demonstrated on a scientific basis to be in accordance with what is established in the "Codex Declarations of Principles", including the justification for incorporating them, case by case.

At CAC45, Panama presented the room document accessible through the hyperlink: ([CAC/45 CRD05](#)), with a specific working proposal as a contribution and follow-up to this important issue: “Decision guide/flow chart for chairs in discussions related to advancing or adopting standards at all steps” – Revised (PROPOSAL PREPARED BY PANAMA)”.

Example of a Model for the Critical Examination by CCEXEC

New Project - First Stages

Table that summarizes a first comparative analysis of different “legitimate factors” (in accordance with the “double Codex mandate”) based on specific recommendations from experts and/or specialists in different areas or competencies in Food Public Health.

Draft standard: xxxxxx		
Technical position	Agree Technical justification	Disagreement Technical justification
a) Factors related to safety and Communicable Diseases (ETA)	Answer:	Answer:
b) Factors related to food, nutrition and/or a healthier diet and chronic Non-Communicable Diseases (NCDs)	Answer:	Answer:
c) Other Legitimate Factors of a Biopsychosocial nature related to Health and fair practices in the food trade.	Answer:	Answer:
Conclusion: (comments, observations, suggestions and/or recommendations)		
Answer:		

Simplified analysis of the situation (“historical controversy”) and the usefulness of the “Codex Guide for the practical application of the Declarations of Principles” and the determination of “Other Legitimate Factors”.

Specific example: “Beta adrenergic agonist medications for veterinary use as “growth promoters” in food animals.

Problem (differences in opinion, vision and/or approach)	Possible Causes (evaluate arguments used by both parties)	Possible solutions
Position A: “Supports the advancement and respective use and MRLs.”	A: Consider the “JECFA Risk Assessment” sufficient (from the exclusive point of view of “safety security”: “Food Safety”). However, ..., have not presented arguments or supports either for or against a possible scientific evaluation of “other risks” and/or benefits related to “Other Legitimate Factors”, considering a priori that “they are outside the mandate of Codex”.	Clarify the definition and scope of the concept of Health and Public Health (Biopsychosocial perspective); the “dual mandate of Codex” and the “Declarations of Principles”; the “safety of safety”: “Food Safety”; and Risk/Benefit Analysis. a) “Codex Guide for the Practical Application” of the “Declarations of Principles” and the determination of “Other legitimate Factors”. b) New FAO/WHO Committee or Group of Experts to evaluate risks and benefits related to “Other Legitimate Factors”.
Position B: “It opposes the use and advancement and respective MRLs.”	B: Considers “not legitimate or justified” (from the point of view of a use that is not therapeutically justified to treat animal diseases). However, ..., they have also not presented clear and forceful	References to results on other types of scientific studies (epidemiological, psychological, sociological, and/or economic) that clearly demonstrate the justification for considering them relevant and fulfilling the “dual mandate of Codex”. Consider the

	scientifically based arguments or supports regarding its possible relationship with “Other Legitimate Factors” in accordance with the “double mandate of the Codex”.	validity (and usefulness) or otherwise of risk/benefit management through a Labeling measure with specific information for the consumer.
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Example Case #1 (“Growth Promoters”)

Comparative table with example of possible differences in approach between countries and/or regions (hypothetical situation)

Country or Region A	Country or Region B
<p>Allowed the use of “growth promoting substances”.</p> <p>Based on scientific safety risk assessment (e.g., JECFA) that “supports and/or has conclusively demonstrated” that, if appropriate GPV and MRLs were applied, there would be no significant cause for concern regarding the “safety of the food safety”.</p>	<p>Not allowed the use of “growth promoting substances”.</p> <p>Although they also agree with the results of the scientific safety risk assessment (e.g., JECFA) that “supports and/or has conclusively demonstrated” that, if appropriate GVP and MRLs were applied, there would be no significant reason for concern regarding “food safety security.”</p>
<p>In this case, the economic costs associated with animal production and productivity are probably lower than the costs that would occur without the use of these substances.</p> <p>Hypothetical example for illustrative purposes only: 25% less expensive. Therefore, the price of the final product (meat) on the international market could be 25% lower.</p>	<p>In this case, the economic costs associated with animal production and productivity are probably greater than the costs that would occur with the use of these substances.</p> <p>Hypothetical example for illustrative purposes only: 25% more expensive. Therefore, the price of the final product (meat) on the international market could be 25% higher.</p>
<p>In this case, the final consumer could benefit economically from a lower price to be able to purchase the product (that is, they would have greater access), taking advantage of this competitive production advantage (which also economically benefits the respective producing sector).</p>	<p>In this case, the final consumer would surely have to pay a higher price to be able to acquire the product (that is, they would have less access), due to this competitive production disadvantage (which probably negatively affects the respective producing sector from an economic point of view).</p>
<p>In this case, the regulatory decision (see: risk/benefit management and communication), both of the health authorities and of the “social and economic pressure groups of the country or region A, was based solely on the aspects related to the “safety of final food safety” (Food Safety), which is considered, without a doubt, the most important and critical factor related to Public Health, but not the only factor.</p> <p>However, they did not consider the views of Comprehensive Health (understood as a complete state of physical, mental and social well-being, and not just the absence of disease), which, for many other consumers, in other countries of the world where that does not allow the use of substances as growth stimulators in slaughter animals, the right to decide whether or not to consume this type of food for their “peace of mind” is important (decision: exposure tolerance level with a tendency to 0), although they have to pay a higher price to be able to acquire a food “free of these substances” (psycho-social aspect, cultural and/or economic reason).</p>	<p>In this case, the regulatory decision (see: risk/benefit management and communication), both of the health authorities and of the “social and economic pressure groups of the country or region B”, is not based solely on the aspects related to the “safety of final food safety” (Food Safety), which is considered, without a doubt, the most important and critical factor related to Public Health, but not the only factor.</p> <p>However, they have considered “other factors” related to Comprehensive Health (understood as a complete state of physical, mental and social well-being, and not just the absence of disease), which, for many other consumers, in other countries around the world in which the use of substances as growth stimulators in slaughter animals is not permitted, the right to decide whether or not to consume this type of food for their “peace of mind” is important (decision: level of tolerance to exposure with a tendency to 0), although they have to pay a higher price to be able to acquire a food “free of these substances” (psycho-social aspect, cultural and/or economic reason).</p>

Country or Region A	Country or Region B
<p>These considerations regarding “other legitimate factors” relevant to Health and fair commercial practices that have previously been justified with due scientific support, could be addressed through other risk/benefit management and communication measures; such as, for example, the application of specific labeling standards, including the use of “warnings” when warranted and scientifically justified, through appropriate studies and evaluations, not only of the “security of safety”, but also, from the biopsychosocial perspective, including economic considerations.</p>	
<p>In this case, the regulatory decision (see: risk/benefit management and communication), both of the health authorities and of the “social and economic pressure groups of the country or region A”, considered that it is not necessary “ this type of labeling measures and/or warnings”; Consequently, any product that meets only the MRLs (thereby guaranteeing food safety), regardless of whether or not “growth-promoting substances” were used in its production, is allowed “market access.”</p>	<p>In this other case, the regulatory decision (see: management and communication of risks / benefits), both of the health authorities and of the "social and economic pressure groups of the country or region B", considered that if it is necessary “this type of labeling and/or warning measures”; Consequently, all products must comply not only with the MRLs (thereby guaranteeing the safety of the food), but also with the proper labeling, regardless of whether or not they have used “growth-promoting substances” in their production, an additional condition for that they are also allowed “access to the market.”</p>
<p>In this case, consumers can purchase the product at the best possible price.</p>	<p>However, in this case, it would be the consumers themselves who would finally decide what type of product to purchase, based on their culture, preferences, level of education, the information contained in the labeling of the product offered in the market (property declarations and /or some type of warning about it) and the price assessment.</p>
<p>It is possible that, with the passage of time, the level of international scientific knowledge in this regard will improve and the experience acquired by consumers in different countries and/or regions of the world will allow unifying regulatory decision criteria and selection of management and communication options. harmonized risk/benefit ratios that allow better rules of competitiveness in the markets and greater benefits for the health of consumers, including the economy of all sectors.</p>	

Application of Guidance and steps to assess implications related to “other legitimate factors” in a given “Proposed Codex Standard”			
Purpose (general objective of Codex standards): to protect Health of consumers and ensure fair practices in the food trade.			
ID of the possible implications related to protective factors and/or risks related to Health and “equitable practices”	<p><i>Application of the “Statements of Principles concerning the role of Science in the Codex decision-making process and the extent to which Other Factors are taken into account.”</i></p> <p>Conditions:</p> <p>“...shall be based on the principle of sound scientific data and analysis, involving exhaustive examination of all relevant information...”</p> <p>“...take into account, where appropriate, other legitimate factors relevant to the protection of consumer health and the promotion of equitable practices in the food trade...”</p> <p>“...Other legitimate factors relevant to health and fair business practices may be identified in the risk management process, and risk managers should indicate how this influences the selection of risk management options...”</p> <p>“...the consideration of other specific factors in the development of risk management recommendations made by the Codex Alimentarius Commission and its subsidiary bodies, including the justification for incorporating them, on a case-by-case basis, should be clearly documented; ...”</p>		
a) Safety	Risk assessment (JECFA/JMPR/JEMRA)	Risk management (Ex.: Maximum additive doses; LMRP; LMRMV; NM pollutants or toxins; Microbiological limit / microbiological criterion).	Codex Decisions: Acceptance *Observation: “...Situations have arisen where Codex members agree on the degree of public health protection that is needed (from a “safety” point of view), but have different opinions. about other aspects... ”
b) Aspects Nutritional	Risk assessment (JEMNU)	Risk management (“...food labeling plays an important role in promoting these objectives...”)	Codex Decisions: Acceptance
c) Other factors	Risk/Benefit Assessment: Panama has proposed consider the convenience or relevance of the possibility of creating a special committee or group of FAO/WHO experts to evaluate and validate scientific studies on other biopsychosocial aspects related to Health and equitable practices).	Risk/Benefit Management and Communication: (“...food labeling would play an important role in promoting these objectives...”).	Codex Decisions: Acceptance or Reservations? Best Option: Application of Paragraph 4 of the “Declarations of Principles”.

Case Example #2 (GMO)

*References:

EU.Regulation (EC) 1829/2003 is stricter than previous regulations regarding labeling. It applies to food and feed that contain, are composed of or have been produced from GMOs, and also to those containing ingredients produced from GMOs.

USES.Congress passed the National Disclosure Standard for Bioengineered Foods in 2016 (**GENETICALLY MODIFIED FOODS (GMO) LABELING LAW**). This required the United States Department of Agriculture (USDA) to establish a labeling standard for genetically modified foods. These requirements were originally scheduled to go into effect in July 2018, but the USDA extended implementation two years after a public comment period. On December 20, the USDA published the official law, which they will implement in early 2020 and will require food companies to comply by January 1, 2022. In the United States, the labeling of genetically modified (GM) foods is regulated by federal laws and regulations. These labels often use terms such as "genetically modified" or "bioengineered" to inform consumers about the presence of genetically modified ingredients. Law enforcement is typically done through complaints and regulatory oversight [1].

Draft standard: xxxxxx		
Technical position	Agree Technical justification	Disagreement Technical justification
a) Factors related to safety and Communicable Diseases (ETA)	Answer:	Answer:
b) Factors related to food, nutrition and/or a healthier diet and chronic Non-Communicable Diseases (NCDs)	Answer:	Answer:
c) Other related Legitimate Factors of a Biopsychosocial nature related to Health and fair practices in the food trade.	Answer:	Answer:
Conclusion: (comments, observations, suggestions and/or recommendations)		
Answer:		

*1Definition Review Proposal:

Other Legitimate Factors(OFL): Biopsychosocial factors that are within the scope and mandate of Codex and are globally acceptable. They refer to all those relevant, additional considerations, other than food safety, and that are directly related to the protection of consumer health and ensuring fair and loyal commercial practices in the global food trade.

These OFL may include, but are not limited to, biological and psychosocial aspects, including ethical, cultural, economic and technological aspects that impact both the safety and quality of food, and consequently, equity and transparency. of international food trade.

The identification and evaluation of these OFLs aim to strengthen the protection of consumer health and guarantee an equitable and responsible trade environment in the food field, in line with the principles and objectives established by the FAO/WHO Codex Alimentarius. .

The consideration of OFL forms and must be part of the process not only of [risk management] but also of the process of risk analysis and analysis of benefits for Health and must not affect the scientific basis [of the risk analysis, that is that is, a] of the risk assessment carried out in parallel by the previously formed scientific advisory bodies of the FAO/WHO that are experts in toxicological, microbiological or nutritional assessments (JECFA, JMPR, JEMRA and/or JEMNU), which are They focus mainly on "food safety security" but not on other types of health-related risks or benefits that are of a biopsychosocial nature, including cultural and economic factors.

Panama Proposal (Revised and updated for CAC46): Decision guide/flow chart for chairs and members in discussions regarding the promotion or adoption of standards at all steps 1





