JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Forty-fourth Session

Prepared by Panama and supported by the Dominican Republic, Brazil, Colombia, Mexico, Costa Rica

Agenda Item 2 - Report by the Chairperson on the 80th and 81st Sessions of the Executive Committee (including matters referred) – Document: REP21/EXEC1 and REP21/EXEC2

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION
Eighty-first Session Virtual
28, 29 October, 1, 2, 3 and 5 November 2021

Prepared by Panama and supported by the Dominican Republic, Brazil, Colombia, Mexico, Costa Rica

OBSERVATIONS TO Agenda Item 6 - Sub-committee on the application of the Statements of Principle concerning the role of Science – Document: CX/EXEC 21/81/6.

GENERAL COMMENT

Panama and Dominican Republic value the previous work carried out by the Codex Secretariat (document: CX/EXEC 19/77/10) which, at the time, was exhaustively reviewed as well as the "Manual Codex Procedure" and its appendix on 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", with the purpose of trying to identify aspects that could be relevant or critical in understanding the causes of “differences of opinion” and of “difficulties” in reaching consensus in the application of these Codex principles, in the “search” for a “possible solution to the identified problem”. Subsequently, the review, analysis and evaluation of the document continued: CX/EXEC20/78/7, the "Interim Report of the Subcommittee of the Executive Committee: Application of the Declarations of Principles regarding the role it performs Science" (document: CX/EXEC-CRD3) and the Report of the 78th meeting of the Executive Committee (document: REP20/EXEC1, paragraph 101), where it was requested from the Codex Secretariat, in collaboration with FAO and WHO, to develop a “first draft of the operational guidelines” in accordance with the mandate of the subcommittee,... “with a view to obtaining comments on their understanding and application of the Declarations”.
Panama and Dominican Republic thank, are interested in and supports the beginning of this important new work on the development of a "Draft Guidelines" that will facilitate the implementation of the "Declarations of Principles", clarifying the extent to which "other legits factors can be taken into consideration" relevant to "Health protection and the assurance of fair practices in the food trade" in the Codex decision-making process, as noted at the 75th and 78th meetings of the Executive committee. (References: REP19 / EXEC2, paragraph 81, REP19/EXEC2 Appendix IV, CX / EXEC-CRD3 and REP20 / EXEC1, paragraph 101).

SPECIFIC COMMENTS

Article 1 of the Statutes of the Codex Alimentarius Commission, contained in the "Procedural Manual", refers to the object (fundamental purpose) of the Joint FAO / WHO Food Standards Program, which is: (a) to protect the health of consumers and ensure fair practices in the food trade.

Specific comment: We must bear in mind that "Health is a state of complete physical, mental and social well-being, and not only the absence of affections 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 "Determinants of Health"). Therefore, we consider extremely important to understand that food safety, although it can be considered as the most important or critical attribute or factor of food quality from the perspective of Public Health related to foodborne diseases (FBD), it is not the only factor related to Health. On the contrary, there are definitely "other factors or other legitimate aspects" related to food that must be considered for the (integral) protection of Health, related to the physical, mental and social well-being of the consumer; such as: dietary and nutritional aspects and their relationship with non-communicable diseases (NCDs); its appropriate name and promotion; its integrity, authenticity and / or composition, its form of production, preparation, presentation and / or conservation; your fitness, suitability, sanity; among other attributes that must be met. For that reason, it is not acceptable, from the perspective of Public Health (Comprehensive Health), neither the lack of integrity nor hygiene, neither the deception nor the fraud nor the induction to error or confusion to the consumer.

The "Manual of Procedures" of the Codex Alimentarius, in the final part, contains an APPENDIX on the "GENERAL DECISIONS OF THE COMMISSION", which establishes the following:

STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT82.

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

Specific comment: It is not a question of ensuring the "commercial quality of the food" (such as, for example, the characteristics of size, shape, color, taste, appearance, texture, aroma, etc.); but to ensure the attributes and / or requirements of the "Sanitary Quality of food", which are related to "Public Health" and "equitable or fair practices". These attributes are: Safety, Health (sanitation, aptitude and hygiene) and Integrity (nutritional and economic) of the food.

2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

Specific comment: These are specifically legitimate "other factors" or "other aspects" that are strictly related to Health and fair practices in the food trade, which are different from the attributes or requirements related to food safety, such as, for example: the suitability, fitness, nutritional quality and / or economic integrity of foods.

3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.

Specific comment: Precisely, food labeling, complemented by good education, must provide consumers with truthful information (not false, misleading or misleading, nor liable to create in any way an erroneous impression of its nature in any way), that allows them a correct and / or adequate decision of acquisition, management and consumption. This information can become of critical importance for the Health and well-being of the consumer through the assurance of the "Sanitary Quality of food".

4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

Specific comment: In this case, we consider it necessary to clarify that the reference to the "protection of Public Health" is directly related to the assurance of food safety and the corresponding [scientific] evaluation
of risks regarding the safety of food [physical, biological and / or physiological implications in humans]. This principle allows valid scientific decisions to be made despite the persistence of different opinions about "other legitimate aspects" or "other legitimate factors" that must be strictly related to "Health" and "fair trade" (according to the mandate and the Codex principles, see paragraph 2. In this case, if agreements or consensus are not reached in the risk management stage, despite “arguments for or against a certain option” (always accompanied by due scientific support on other aspects of a biopsychosocial or economic nature), it allows that one member or more members may refrain from accepting the rule in question.

Criteria to take into account the other factors mentioned in the 2nd Declaration of Principles.

When health and safety matters are concerned, the Statements of Principle Concerning the Role of Science and the Statements of Principle Relating to the Role of Food Safety Risk Assessment should be followed; When health and safety matters are concerned, the Statements of Principle Concerning the Role of Science and the Statements of Principle Relating to the Role of Food Safety Risk Assessment should be followed;

Specific comment: In this case, the specific reference to "Health" is directly related to the assurance of food safety and the application of science in the corresponding risk assessment with respect to food safety (focused in the implications of a physical or physiological nature, without including other considerations related to aspects of a biopsychosocial nature that are also part of the integral health approach of individuals and the population)

Other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;

Specific comment: In this case, without a doubt, we consider that if it is possible to determine what would be the "other legitimate aspects" or "other legitimate factors" referred to in the 2nd paragraph of the “Declaration of Principles”; However, we consider that it is necessary to be able to demonstrate its strict relationship with the "protection of Health" and / or with the “assurance of fair trade” (in accordance with the mandate and Codex principles).

Consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;

Specific comment: It is understood that these are "other legitimate factors" strictly related to "Health" and / or "fair trade" (according to the mandate and Codex principles, see paragraph 2).

Recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide;

Specific comment: totally agree. Only those other factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;

Specific comment: totally agree. In the framework of Codex, only other factors that can be accepted at the global level can be taken into account, or at the regional level when it comes to regional standards and related texts;

The consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;

Specific comment: For the formulation of certain recommendations in risk management focused on possible implications of "other specific legitimate factors" related to "Health protection" and / or "fair trade assurance" (according to the mandate and the Codex principles), their consideration should be documented and justified on a case-by-case basis. This “examination" should be supported by specialized scientific studies and / or accompanied by the results of a specific risk assessment process for each case.
The feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;

**Specific comment:** totally agree.

The integration of other legitimate factors in risk management should not create unjustified barriers to trade\(^5\): particular attention should be given to the impact on developing countries of the inclusion of such other factors.

**Specific comment:** totally agree.

**Declaration of Panama with the support of the Dominican Republic**

Panama and Dominican Republic support the "*historical position of the CCLAC region*" regarding the need "*to defend the scientific basis of Codex decisions*". It is for this reason that it hopes that significant progress can be achieved with the work of preparing a "*Draft Guidelines on the implementation of the Declarations of Principles regarding thereole that Science plays in Codex decisions*, which “*further clarify the extent to which other relevant legitimate factors in the area of Health protection and assurance of fair trade practices can be taken into account in the adoption of Codex standards*”, as noted in 75th and 78th Session of the Executive Committee. (References: REP19 / EXEC2, paragraph 81; CX / EXEC-CRD3 and REP20 / EXEC1, paragraph 101).

Panama and Dominican Republic consider that with "*this important work*" can achieve the "*agreements and consensuses*" expected at the next meetings of the Executive Committee and the Codex Alimentarius Commission; and therefore, an effective application of "*these Principles*, after an adequate analysis of the "*causes*" that generate "*certain differences in approach or opinion*" and "*hinder*" the achievement of said "*consensus*", due to "*different situations in different areas of the world*".

In this sense, proposes the following:

1) It is considered it of utmost importance that all Codex member countries dialogue, agree, unify criteria and reach a consensus regarding the concept of Health defined by WHO as "*a complete state of well-being physical, mental and social*" and "*not only the absence of diseases or conditions*". In this sense, considers that Health has a broader scope and a much more complexity dimension of a Biopsychosocial nature.

2) We support the management and application of standardized sanitary measures deemed necessary to ensure food safety and the prevention of food borne diseases (FBD). However, taking into account that the fundamental purpose of Codex Alimentarius standards is "*to protect the Health of consumers*" and "*to ensure fair practices in the food trade*", we consider that the normative management of Codex is also extremely important oriented towards the control of risks related to "*Other legitimate factors*" that are properly classified as "*Determinants of Health*, for example, factors related to (chronic) non-communicable diseases (NCDs) associated with human behavior, lifestyles "*modern*", the nutrition and certain dietary patterns of some of the population in different countries of the world, as well as the consideration of "*Other legitimate factors*" related to the protection of mental Health and "*Social Determinants of Health*" that include economic considerations and their relationship with the promotion of "*fair or just practices*" in the face of the possibility of fraud, deception, misleading or confusion or mislabelling in the food trade.

3) We believe that all Codex standards should be based on sound scientific principles and that the "*Declarations of principles relating to the role of risk assessment with respect to food safety*" should be applied with all the scientific and methodological rigor that is required. From this perspective, considers that to determine the validity and applicability of "*these other specific legitimate factors*", it is necessary to indicate how this influences the selection of risk management options and clearly document their examination as well as their scientific justification to incorporate them, case by case, taking into account the possibility of applying specific labeling measures.

4) We are in the best position to support initiatives for the promotion of research work and the collection of information on scientific studies that may contribute to better support the possibility of considering "*these other specific legitimate factors*" within the framework of the Codex Alimentarius, as well as the desirability of supporting any proposal for the establishment of a Committee, Group or Meeting of Experts of FAO and WHO specialized in other scientific areas related to their analysis.

5) We believe that all Codex members should aspire to achieve the greatest possible consensus in the establishment of Codex Alimentarius standards based on Science. However, it is understandable that, in a few exceptional cases, a situation could arise in which the majority agree on the level of Health protection that is required to be achieved, from the point of view of food safety assurance, and despite this, they may
have different opinions or approaches on how to approach the management of control measures related to "these other specific legitimate factors or aspects", in these cases, we recommend that members in disagreement should seriously consider the option of refraining from accepting the rule in question by formulating a "reservation", without necessarily preventing Codex from making its decision, based on what is established in paragraph 4 of the "Declarations of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account".

6) We consider it necessary and intends to support the development of a "Draft Practical Guidelines" on the implementation of the "Declarations of Principles", which will further clarify the extent to which "other legitimate factors can be taken into consideration" relevant in "Health protection and ensuring fair practices in food trade" in the Codex decision-making process, as noted at the 75th and 78th Session of the Committee Executive. (References: REP19 / EXEC2, paragraph 81, REP19/EXEC2 Appendix IV and REP20 / EXEC1, paragraph 101).