CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2, 3, 4.2, 4.3, 4.5, 4.6, 4.7, 4.8, 4.9, 4.10, 4.11, 4.12, 4.14, 4.15, 5, 7, 8, 9 **CRD04**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-sixth Session

FAO Headquarters, Rome, Italy

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(Comments from Panama)

ITEM 2: REPORT BY THE CHAIRPERSON ON THE 84TH AND 85TH SESSIONS OF THE EXECUTIVE COMMITTEE (INCLUDING MATTERS REFERRED)

Panama appreciates the great efforts by the CAC and recognizes the objectivity of its decisions and recommendations, as well as the agreements presented in the CCEXEC Executive Committee.

ITEM 3: AMENDMENTS TO THE PROCEDURAL MANUAL

Panama appreciates the effort and the titanic work that the Codex Committee on General Principles has developed and we agree with the recommendations that were taken into consideration in reference to Section 6, which deals with the members of the Codex Commission, where the 33rd Session of the Codex Committee on General Principles (CCGP33) agreed to recommend that CAC46 approve the transfer of Section 6 (Membership), Membership of the Codex Alimentarius Commission from the Procedural Manual (PM) of the Codex to the Codex website with a link to the list provided in the Procedures Manual, thus ensuring that the list can be updated without publishing new editions of the manual itself.

Furthermore, in compliance with the recommended changes in editorial format in Section 2 Development of Codex Standards and Related Texts, Section 3, Guidelines for Subsidiary Bodies and Section 7 Relationship with Other Organizations, we agree, Panama agrees with support for the modifications that are intended to be included. They are amendments and inclusions favorable for a better understanding and timeliness of the Codex Manual of Procedures.

ITEM 4.2: FAO/WHO COORDINATING COMMITTEE FOR LATIN AMERICA AND THE CARIBBEAN

Panama thanks Ecuador for its excellent management as a leader in the Latin American and Caribbean region, in addition to recognizing the hard work carried out in the CCLAC meetings, laying the foundations for said work even in the midst of the Covid-19 pandemic, achieving power recommend amendment to the provisions on labeling of non-retail containers of the Regional Standard for Coyote Coriander (CXS 304R-2011), the Regional Standard for Lucuma (CXS 305R-2011) and the Regional Standard for yacón (CXS 324R-2017), and that after analyzing it we agree with the definitive adoption of these regulations.

Also in relation to the provisions on food additives of the Regional Standard for coyote cilantro (CXS 304R-2011) and the Regional Standard for lucuma (CXS 305R-2011), Panama agrees to their inclusion and that they be presented before CAC 46 for approval, given that the CCAF at its 53rd meeting also approved the provisions on food additives in nine standards, including the regional ones mentioned as a result of the work with CCLAC.

ITEM 4.3: CODEX COMMITTEE ON FOOD HYGIENE

Panama wishes to extend our most pleasant recognition and appreciation for the work carried out within the Codex Committee on Food Hygiene.

We agree with its approval in step 5/8 of the Guidelines for the control of Shiga toxin-producing Escherichia coli (ECTS) in raw beef, fresh green leafy vegetables, milk

raw beef and cheeses based on raw milk and sprouted seeds (general section, Annex I on raw bovine meat and Annex III on raw milk and cheeses based on raw milk), given that at the 53rd meeting of the Committee of the Codex on Food Hygiene was raised and validated that there were no outstanding issues to be addressed in the general section or the annexes on raw beef and raw milk and raw milk cheeses, agreed to refer to 46. 10th CAC session the proposed draft guidelines and these two annexes for adoption at Step 5/8 (APPENDIX III).

We emphasize that, in the Codex Committee on Food Hygiene, it was detailed in REP23/FH that the only work that returned to process 2/3 to collect information was the annexes on fresh green leafy vegetables and seeds germinated with to be redrafted and circulated for comments, and an EWG was established for this purpose, chaired by Chile and co-chaired by the US, Kenya and New Zealand.

Guidelines for the safe use and reuse of water in food production and processing (general section and Annex I), in its approval stage 5/8, Panama agrees with its content and final approval.

We are convinced that the new work proposed brings with it added value to Codex regulations, we support Proposal for new work on the development of Guidelines for food hygiene control measures in traditional food markets, as well as the proposed revision of the Guidelines on the application of general principles of food hygiene for the control of pathogenic Vibrio species in foods of seafood origin (CXG 73-2010).

ITEM 4.5: CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Panama appreciates the great work carried out by the Codex Executive Committee, the Presidents, and the members of the CAC, in relation to the work of Zilpaterol Hydrochloride.

The majority of members voted at the 45th Session of the Codex Commission (CAC45) in favor of adopting the MRLs for Zilpaterol Hydrochloride (bovine fat, kidney, liver and muscle) at Step 5 and, based on Codex procedures, the MRLs would be circulated for comments at Step 6, for consideration by CAC46 at Step 7 and for consideration for adoption at Step 8 by CAC46 (REP22/CAC paragraphs 139, 140) .

We highlight the risk assessments that JECFA has carried out over the years (REP15/RVDF, para. 40, REP17/RVDF, para. 74), based on the solid scientific data available, in which no identified safety problems associated with the use of Zilpaterol Hydrochloride; as well as the fact that no Codex member has submitted to CCRVDF or JECFA additional scientific data or evidence demonstrating adverse effects on food safety at the recommended doses (MRL 3.5 µg/kg for liver, 3.3 µg/kg for kidney and 0.5 µg/kg of muscle in cattle).

At CAC45, the JECFA Secretariat explained that the health-based guideline values for Zilpaterol were based on the most sensitive toxicological parameter, which, in this particular case, is acute effects. Furthermore, the acute reference dose was based on results obtained in human volunteers, which is very strong evidence of maximum confidence. (REP22_CAC paragraph 108).

Limiting the progress of a draft standard for the establishment of an MRL without providing any scientific data undermines the work of the committee and Codex as a whole, since it ignores and does not respect the procedure for the approval of standards, which are based, as in this case, in the evaluations carried out by JECFA, which is the Group of Independent Experts that carry out risk assessments of additives, contaminants and veterinary drugs, which provide the risk assessments that ensure that Codex standards meet their objectives and are based on all available scientific information. Likewise, we are concerned about the negative impact on the international harmonization process that these repeated delays without scientific evidence and the introduction of factors without due scientific justification in accordance with the Codex mandate are having in the adoption of Codex standards, which could affect the credibility of Codex as a reference body for quality and food safety.

Factors without proper scientific justification consistent with the Codex mandate should not influence risk management to achieve consensus. Decisions should be based on risk assessment and/or health benefit analysis, taking into account, where appropriate, other legitimate factors that are within the mandate of Codex and that are relevant to the protection of the health of animals. consumers and the promotion of fair practices in the food trade, as indicated in the Procedure Manual.

Based on the recommendations that JECFA has made and the broad and extensive discussions that have been had in CCRVDF and CAC, we recommend that the MRL for Zilpaterol Hydrochloride be adopted at Step 8, and the countries that have expressed disagreement can express their reservations.

We note that paragraph 4 of the Declarations of Principles states that "If the situation arises that Codex Members agree on the degree of public health protection necessary, but have different views on other aspects, Members may abstain to accept the standard in question, without necessarily preventing Codex from adopting its decision". With this in mind, and taking into account that the proposed standard for the establishment of MRLs for Zilpaterol Hydrochloride has a scientific basis that supports its use as a reference standard in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization (WTO), we confirm that there is broad support to advance this draft standard to Step 8.

Regarding the MRL for nicarbacin (chicken), extrapolated MRLs to ruminants and finfish, namely: All other ruminants:

- Amoxicillin (muscle, fat, liver, kidney, milk)
- Benzylpenicillin (muscle, liver, kidney, milk)
- Tetracyclines (muscle, liver, kidney, milk)
- Cyalothrin (muscle, fat, liver, kidney, milk)
- Cypermethrin (muscle, fat, liver, kidney)
- Deltamethrin (muscle, fat, liver, kidney)
- Moxidectin (muscle, fat, liver, kidney)
- Spectinomycin (muscle, fat, liver, kidney, milk)
- Levamisole (muscle, fat, liver, kidney)
- Tilmicosin (muscle, fat, liver, kidney)
- All other finfish
- Deltamethrin (muscle)
- Flumequina (muscle)

For adoption at step 5/8, given the recommendations of JECFA, who completed the re-evaluation and addressed all the issues raised during the 25th session of the CCRVDF and approaches proposed for this work, recommended after the extensive study final adoption, to which Panama agrees with this recommendation.

And in relation to the MRL for ivermectin (fat, kidney, liver and muscle of sheep, pig and goat), we would agree with the suspension, given that within the CCRVDF it was also agreed to suspend work on previous MRLs for ivermectin (sheep, pigs and goats (fat, kidneys, liver and muscle) at step 7 and report to the 46th session of the COMMISSION accordingly.

We also agree with the work that will be developed in the GTE, regarding the Priority List of veterinary drugs that require evaluation or re-evaluation by JECFA.

ITEM 4.6: CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Panama extends its support and backing to the management carried out by the Codex Committee on Nutrition and Special Diets, highlighting the timely progress regarding the regulations discussed.

In relation to the Revision of the Standard for follow-up formula (CXS 156-1987), we agree with its advancement to approval procedures 5/8 and 8, since within the CCNFSDU an agreement had been reached on the title, structure and preamble and recalling at CCNFSDU42 the text currently at Steps 4 and 7, CCNFSDU43.

- Proposed draft revised standard with title appearing in Appendix II; the structure and Preamble together with the remaining sections of Parts A and B, agreed at CCNFSDU42, to CAC46 for adoption at Step 5/8; Parts of the text at Step 7 of the draft Revised Standard for follow-up formula.
- For follow-up formula for older infants and products for young children) for adoption at Step 8.

So our initial position within the CCNFSDU was that a preamble was not required, however, if maintained, a simple and factual statement should be sufficient since all the requirements are already covered in the Standard itself, so We express our agreement with paragraphs 1 and 3, expressing a reservation for paragraph 2.

Paragraph 1. This Standard is divided into two parts: Part A covers follow-up formula for older infants and Part B covers nutrient-added drink for young children or nutrient-added product for young children or drink for young children or the product

for small children.

Paragraph 2. The application of this Standard should be consistent with national health and nutrition policies and relevant national/regional regulations, in addition to taking into account the recommendations made in the International Code of Marketing of Breastmilk Substitutes, according to the national context. (We express a national reservation, given that contrary to the consensus reached by the Committee, it conflicts with international trade obligations and the guidelines provided by the Executive Committee).

Paragraph 3. Relevant guidelines and policies of the World Health Organization (WHO) and resolutions of the World Health Assembly (WHA) were taken into account in the development of this Standard and may provide additional guidance to countries.

Panama agreed with the approval in procedure 5/8 definitively, and it was also pointed out within CCNFSDU that it is advisable to have a standard that is divided into two sections, clearly defined, such is the case of section A. , which refers to follow-up formula for older infants and section B deals with the toddler drink with added nutrients or the toddler product with added nutrients or the toddler drink or toddler product. Accepting the proposal: Standard for follow-up formula for older infants and product for young children, with a footnote stating: Other equivalent names for this product are Added Nutrient Drink for Young Children or Product with added nutrients for young children or Drink for young children.

Regarding the Amendments to the Standard for Packaged Foods for Infants and Children (CXS 73-1981) and the Reference Lists of Nutrient Compounds for Use in Foods for Special Dietary Purposes Intended for Infants and Young Children (CXG 10- 1979), Panama agrees with its definitive adoption.

For the work carried out on the General Principles for the establishment of nutrient reference values - needs for people between 6 and 36 months of age, Panama agrees to advance the draft of General Principles for the establishment of Nutrient Reference Values (VRN-R)

for people from 6 to 36 months and that is adopted in Step 5; and we further agreed to re-establish the EWG, review the draft Step-by-Step Process taking into account revisions to the draft General Principles and develop an approach to propose NRV-N for the combined age group of 6 to 36 months, applying the revised draft Stepwise Process to propose NRV-N for people 6-12 months, 12-36 months and 6-36 months for the following nutrients: vitamins A, D, C, K and E, thiamine, riboflavin, niacin, vitamins B6 and B12, folate, pantothenic acid and biotin; calcium, magnesium, iron, zinc, iodine, copper, selenium, manganese, phosphorus and potassium.

ITEM 4.7: CODEX COMMITTEE ON FOOD ADDITIVES

Panama appreciates the work carried out by the Codex Committee on Food Additives, considering that it is a committee of great value and of exhaustive and complex content, we express our support for the progress of the work presented for approval in steps 5/8 and 8 below:

- Review of descriptors for food categories 12.2.1 and 12.2.2
- Inclusion of the provision for trisodium citrate (INS 331 iii)) in food category 01.1.1 of
- the General Standard for Food Additives (GSFA) (CXS 192-1995).
- Inclusion of provisions on food additives listed in food category 14.2.3 (CXS 192-1995).
- Inclusion of provisions for synthetic riboflavin (INS 101 i)), riboflavin sodium 5'-phosphate (INS 101 ii)), riboflavin from Bacillus subtilis (INS 101 iii)), riboflavin from Ashbya gossypii (INS 101 iv)) and spirulina extract (INS 134) in Table III (CXS 192-1995).
- Preliminary draft revision of Generic Names and International Additive Numbering System food (CXG 36-

1989).

- Proposed draft specifications for inclusion in the List of Codex Specifications for Food Additives (CXA 6-2021).
- Draft and proposed draft food additive provisions of the GSFA and revisions to adopted provisions (CXS 192-1995).
- Inclusion of mono- and diglycerides of fatty acids (INS 471) in food category 02.1.2 (CXS 192-1995).
- Inclusion of provisions for polyglycerol esters of fatty acids (INS 475), sorbitan esters of fatty acids (INS 491-495), and stearoyl lactylates (INS 481 i), 482 i)) from the category of food 02.1.2 (CXS 192-1995).
- Modification of notes 488 and 502 (CXS 192-1995).
- Deletion of note 301 of the provision relating to BENZOATES from food category 14.1.4 (CXS 192-1995).
- Revisions of the provisions adopted for sweeteners in different food categories (CXS 192-1995).

Panama agrees to undertake new work in relation to the Priority List of Substances proposed for evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

ITEM 4.8: CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Panama appreciates the work carried out by the Codex Committee on Food Contaminants (CCCF) and notes the following:

In relation to the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cassava and Cassava-Based Products, Panama agrees with the consensus reached in the committee where it was agreed to send the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cassava and Cassava-Based Products to the CAC and we agree to its approval at Step 8 at its 46th Session.

Other risk management practices proposed for inclusion at that time in the CoP, which were not intended to reduce mycotoxin contamination in cassava and cassava-based products, should not be included in the CoP.

Regarding the Maximum Level of lead in ready-to-eat foods for infants and young children, the CCCF agreed to an ML of 0.02 mg/kg for ready-to-eat foods for infants and young children for approval at step 8, Therefore, Panama completely agrees, in addition to recommending adoption in step 5/8 of the Maximum Level of lead in soft brown sugar, raw and not centrifuged, which was already agreed in CCCF, an ML of 0.15 mg/kg for soft brown, raw and non-centrifuged sugars for approval in procedure 5/8.

Also, Panama agrees with the recommendation that was concluded in the CCCF on the maximum level of total aflatoxins in chili and nutmeg (dried/dried) and maximum level of ochratoxin A in chili, sweet paprika and walnut dried/dried nutmeg. Panama accompanies the CCCF recommendation Agreed to the ML of 20 µg/kg for AFT in chili and nutmeg (dried/dried) and the ML of 20 µg/kg for OTA in chili, paprika and nutmeg (dried/desiccated), for adoption in procedure 5/8

Sampling plans for total aflatoxins in certain cereals and cereal-based products, including foods for infants and young children.

Panama agreed with the data provided regarding the isomer ratio > 50:50 AFB1: AFB2+AFG1+AFG2, that AFB1 was the most toxic isomer, and that the use of a 50:50 ratio would allow an achievable LC for the minor isomers. We recommend approval in procedure 5/8.

Panama, being Co-Chair of Ciguatera, extends the most cordial invitation to make contributions regarding this new work in progress, and the establishment of the pertinent procedures to carry out this important Code of Practices, taking as reference the scope, which provides guidance on recommended practices to prevent or avoid ciguatera poisoning.

Ciguatoxins (CTX) are a class of toxins produced by marine dinoflagellate algae. These toxins enter the food chain through the consumption of herbivorous fish and bioaccumulate in predatory fish.

Ciguatera poisoning has become a global health problem and its prevalence is increasing due to factors including climate change. Coastal communities that rely on local fisheries as a food supply and source of income are at particular risk of experiencing increasing cases of ciguatera poisoning.

Reports of CTX Contamination (CP) have been made since the 16th century. Consumption of CTX-contaminated fish was once limited to local residents and visitors in regions where toxic algae are known to accumulate, but the global fish trade has caused a wider range of countries to report CP illnesses.

Among the considerations we highlight: HACCP plans, which must include a hazard analysis; For CP, that would include local awareness of the types of fish caught for human consumption that may be susceptible to CTX accumulation and an understanding of the location of toxic areas to avoid and/or emerging areas. If applicable, a size limit on the catch or sale of fish known to accumulate CTX or a requirement that fish exceeding a size limit be tested for CTX before sale should be part of the HACCP plan.

It is important at this point to be able to know if there are countries that have an import ban on certain species or require CTX testing and how that regulation is implemented. So that in this way they can be included in the COP.

Panama agrees to discontinue work on MLs for OTA in ginger, pepper (white and black) and turmeric, as available data did not indicate a significant presence of Ochratoxin A (OTA) in these spices, and It is part of the recommendations made by CCCF16.

ITEM 4.9: CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERIFICATION SYSTEMS

Panama appreciates the work carried out by the Codex Committee on Inspection and Certification Systems for Food Imports and Exports, we agree with the approvals in process 5/8 in relation to:

Guidelines on the recognition and maintenance of equivalence of national food control systems (SNCA), as they had resolved all technical issues and proposed referring the text to the CAC at its 46th session for adoption at Step 5/8, and CCFICS, at its 26th session, endorsed all steps for the process, with the technical and formal amendments already presented.

Principles and guidelines on the use of remote audits and inspections in regulatory frameworks, where the task of preparing a discussion paper on the use of remote audits and verifications in regulatory frameworks. In an attempt to respond in a timely manner to this challenge, the CCFICS Chair had forwarded proposals for new work to the 83rd Session of the Executive Committee and to the 45th Session of CAC (2022) for consideration. critical/approval, as explained in document FICS/23/26 INF01. Approval by CAC45 allowed the EWG to develop draft guidelines for its consideration during the 26th CCFICS meeting. Furthermore, the AWG Chair and Co-Chairs reported that they had reviewed the comments sent in response to the circular letter and had prepared an updated draft, based on the CCFICS agreement. Panama agrees to the draft “Principles and Guidelines on the Use of remote audits and inspections in regulatory frameworks” for adoption in procedure 5/8.

ITEM 4.10: CODEX COMMITTEE ON FOOD LABELLING

Panama appreciates the work carried out by the Food Labeling Committee and in relation to the agreements reached at the meeting held in Canada, where the CCFL, at its 47th meeting, did not agree to include a definition of "allergen", but considered a definition of “food allergen” instead and agreed to include a definition of “food allergen” and discussed whether it was more appropriate to refer to “foods and ingredients” or “foods and substances” to cover not only foods and ingredients, but also other substances such as food additives (e.g. sulfites) and processing aids.

Panama agrees with the proposed definition "Food allergen" means a food or ingredient [or substance or processing aid] used in foods, generally a protein or protein derivative that can cause IgE-mediated or other specific immune-mediated reactions in individuals. susceptible. It is appropriate that this consideration and new contribution to the food labeling section that is directly related to the general labeling standard, be approved in procedure 5. Given that the debate and search for information has been effective and sufficient.

Regarding the Guidelines for the provision of food information on prepackaged foods offered through electronic commerce, we also consider the WTO definition sufficiently broad and accurate, which details by “electronic commerce” means the distribution, marketing, sale or delivery of goods and services by electronic means by

methods specifically designed to receive or place orders", however, in the interest and search for consensus, Panama, reviewed the new proposal presented by the Presidency of CCFL, which details: "The production, distribution, marketing ", sale or delivery of goods and services by electronic means as appropriate to food." the points addressed in this topic, such as whether it should be a complementary text to the labeling standard or an independent text, otherwise, to reach a consensus, we also agree on its approval in procedure 5 or its advancement to a next procedure search for greater consensus at CAC 46.

Panama reviewed the point referring to Guidelines on the use of technology to provide food information and considers it appropriate to advance or follow a procedure for greater clarity of its use. In relation to our country, we have sought alternatives to promote the improvement of trade in foods in such a way that the consumer remains fully informed, despite the fact that there are policies in the case of Panama that require the consumer to keep the information at their disposal immediately, however the opening of new trade opportunities makes it possible that companies can develop strategies to guarantee that the consumer can have information within their reach, in a timely manner, and in cases or places where said information cannot be accessed, they can provide it through other conventional means already indicated by the general labeling standard. Panama recommends that a new analysis be developed through a GTE in such a way that they can collect international market behavior in relation to the use of technology as an alternative way of presenting information to the consumer without leaving aside traditional forms, which allow a range of options for Codex Alimentarius State Parties.

Panama expresses that, in relation to the point of information on small containers, I consider that it should not be an exception, since due to the medium in which the information will be offered there are no space limitations as on labels. The same thing regarding the minimum duration is decisive information for the consumer.

Panama agrees with the new work to be undertaken in relation to its review and amendment, on Amendments to the General Standard for the Labeling of Prepackaged Foods (CXS 1-1985): Labeling of Prepackaged Foods in Joint Presentation and Package Formats multiple.

ITEM 4.11: CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Panama appreciates the work carried out by the Codex Committee on Methods of Analysis and Sampling, and expresses its agreement with the approval at CAC 46 of Provisions on methods of analysis, performance criteria and sampling plans in Codex standards (CXS 234-1999, CXS 193-1995), and the pending approval 8 of the revised General Guidelines on Sampling (CXG 50-2004).

ITEM 4.12: CODEX COMMITTEE ON PESTICIDE RESIDUES

Panama appreciates the important work carried out by the Codex Committee on Pesticide Residues and expresses its agreement with the approval in process 5/8 of Maximum Residue Limits (MRL) for different combinations of pesticides and products, which have been widely studied. and backed by science (JMPR).

We agree with the proposed new work to provide a valuable tool on the Pesticide Priority List for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues, as well as work on the development of guidance for monitoring of the stability and purity of pesticide reference material and its stock solutions during long-term storage.

ITEM 4.14: CODEX COMMITTEE ON GENERAL PRINCIPLES

Panama agrees with its approval in CAC 46, in relation to Review of the procedures provided for in Section 3 (“Guidelines for auxiliary bodies”) of the Procedural Manual, as well as Issuance of a circular letter to collect proposals from the members regarding inconsistencies in the wording and obsolete content of the Procedural Manual, apart from Section 3, in such a way as to allow more information to be gathered from members and to provide clear and necessary concepts on terminologies that are considered unrelated to what it is desired to express, either by translation or by forms of expression and syntax.

ITEM 4.15: DRAFT MRLs FOR ZILPATEROL HYDROCHLORIDE IN CATTLE LIVER, KIDNEY AND MUSCLE

Panama supports the adoption of the Maximum Residue Limits (MRL) for Zilpaterol Hydrochloride (bovine fat, kidney, liver and muscle) at Step 8. We base this support on the multiple risk assessments carried out by the FAO/Joint Committee WHO Expert Committee on Food Additives (JECFA), on whose scientific findings Codex decision-making is based, as well as adherence to the Codex Procedural Manual, Codex's dual mandate of focusing on protecting consumer health and ensuring safe practices. equitable in food trade.

The majority of members voted at the 45th Session of the Codex Commission (CAC45) in favor of adopting the MRLs for Zilpaterol Hydrochloride (bovine fat, kidney, liver and muscle) at Step 5 and, based on Codex procedures, the MRLs would be circulated for comments at Step 6, for consideration by CAC46 at Step 7 and for consideration for adoption at Step 8 by CAC46 (REP22/CAC paragraphs 139, 140) .

We highlight the risk assessments that JECFA has carried out over the years (REP15/RVDF, para. 40, REP17/RVDF, para. 74), based on the solid scientific data available, in which no identified safety problems associated with the use of Zilpaterol Hydrochloride; as well as the fact that no Codex member has submitted to CCRVDF or JECFA additional scientific data or evidence demonstrating adverse effects on food safety at the recommended doses (MRL 3.5 µg/kg for liver, 3.3 µg/kg for kidney and 0.5 µg/kg of muscle in cattle).

Although additional data were provided to JECFA at its 85th meeting (2017) following the JECFA evaluation, it was concluded that the additional bioavailability data provided supports the approach used in the previous evaluation and recommended that the MRLs be left unchanged from the conclusions of the risk assessment carried out by JECFA in 2015 (81st JECFA meeting).

At CAC45, the JECFA Secretariat explained that the health-based guideline values for Zilpaterol were based on the most sensitive toxicological parameter, which, in this particular case, is acute effects. Furthermore, the acute reference dose was based on results obtained in human volunteers, which is very strong evidence of maximum confidence. (REP22_CAC paragraph 108).

As mentioned, the Codex Alimentarius is the global reference body for consumers, producers and food processors and clearly contributes with its recommendations to the national regulatory process, as well as international trade. It plays an important role in food quality and safety around the world, especially for those developing and least developed countries that do not have the necessary infrastructure, or economic resources to generate sufficient scientific support for national or regional health measures.

Limiting the progress of a draft standard for the establishment of an MRL without providing any scientific data undermines the work of the committee and Codex as a whole, since it ignores and does not respect the procedure for the approval of standards, which are based, as in this case, in the evaluations carried out by JECFA, which is the Group of Independent Experts that carry out risk assessments of additives, contaminants and veterinary drugs, which provide the risk assessments that ensure that Codex standards meet their objectives and are based on all available scientific information. Likewise, we are concerned about the negative impact on the international harmonization process that these repeated delays without scientific evidence and the introduction of factors without due scientific justification in accordance with the Codex mandate are having in the adoption of Codex standards, which could affect the credibility of Codex as a reference body for quality and food safety.

We note that paragraph 4 of the Declarations of Principles states that "If the situation arises that Codex Members agree on the degree of public health protection necessary, but have different views on other aspects, Members may abstain to accept the standard in question, without necessarily preventing Codex from adopting its decision". With this in mind, and taking into account that the proposed standard for the establishment of MRLs for Zilpaterol Hydrochloride has a scientific basis that supports its use as a reference standard in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization (WTO), we confirm that there is broad support to advance this draft standard to Step 8.

Factors without proper scientific justification consistent with the Codex mandate should not influence risk management to achieve consensus. Decisions should be based on risk assessment and/or health benefit analysis, taking into account, where appropriate, other legitimate factors that are within the mandate of Codex and that are relevant to the protection of the health of animals. consumers and the promotion of fair practices in the food trade, as indicated in the Procedure Manual.

Based on the conclusions and recommendations of the various JECFA reports related to risk assessment and on the fact that the countries that oppose the advance have not presented or supported their opposition with due scientific justification in accordance with the Codex mandate, the countries mentioned request the 46th Codex Alimentarius Commission, to be held in November and December 2023, to adopt the MRL for Zilpaterol Hydrochloride at Step 8.

ITEM 5: EDITORIAL AMENDMENTS TO CODEX TEXTS PROPOSED BY THE CODEX SECRETARIAT

Panama appreciates the work carried out by the Codex Secretariat, even more so within the framework of the Celebration of the 60 years of such an important Organization. For Panama it continues to be our source of regulatory confidence, as it is endorsed by science within the different studies.

We are pleased and agree with the contributions of the Codex Secretariat, having applied a new design to the Codex texts with the objective of improving coherence and transparency, coupled with this the new image of the Codex texts, allows Readers of the standards become more friendly and expressly attractive. From Panama, we express our consent and acceptance of the new changes that were proposed at CAC45 and that today we can see with pleasure.

We have reviewed your comments to correct errors and improve the documents as a whole.

ITEM 7: REPORTS FROM THE FAO/WHO COORDINATING COMMITTEES

Panama thanks Ecuador for its excellent management as a leader in the Latin American and Caribbean region, in addition to recognizing the hard work carried out at the CCLAC meetings, laying the foundations for said work even in the midst of the Covid-19 pandemic, managing to maintain to the region united and represented.

ITEM 8: 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)

Panama appreciates the work prepared by thePresident and vice presidentsof the Forty-Sixth Session of the Codex Commission (CAC46) in addition to providing the opportunity to address an issue of high importance for the future of Codex. We value the 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”.

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”.

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.

We must keep in mind that "Health is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity" (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”).

We invite all members to review the CRD of Panama, referring to topic 8 of the CAC 46 agenda, where we explain in detail the proposal and observations on this topic.

ITEM 9: NEW FOOD SOURCES AND PRODUCTION SYSTEMS

In recent years, several new food sources and production systems have been developed and adopted with the aim of addressing the challenges of food security and sustainability. Some of the main sources and emerging production systems are:

Vertical Farming: Vertical farming involves growing plants on stacked shelves in a controlled, soilless environment. This technique allows for more efficient use of space, water and nutrients, making it a viable option for urban areas where space is limited.

Urban Agriculture: Urban agriculture refers to growing food in urban areas, such as rooftops, backyards, and public spaces. This practice encourages local production of fresh food, reduces dependence on food imports, and

promotes community resilience.

Aquaponics: Aquaponics combines aquaculture (fish farming) and hydroponics (growing plants without soil). In this system, fish waste is used as nutrients for plants, while plants filter water for growing fish. Aquaponics uses less water and energy compared to traditional growing systems.

Insects as food: Insects are an abundant source of protein, vitamins and minerals. Farming insects for human consumption, known as entomophagy, is a sustainable way to obtain protein and can help reduce pressure on conventional meat production systems.

Genetically modified crops and foods: Genetically modified crops and foods have been developed to resist diseases, insects, and adverse weather conditions, which can increase productivity and reduce the use of pesticides and herbicides. However, there are also concerns about the potential health and environmental impacts of GMOs.

Cultured meat: Cultured meat, also known as laboratory meat or in vitro meat, is produced from animal cells without the need to raise and kill whole animals. This approach reduces animal suffering, decreases the environmental impact of livestock farming, and can mitigate the risks associated with conventional meat production.

These new food sources and production systems offer innovative solutions to address current agriculture challenges, such as population growth, natural resource scarcity, and climate change. However, it is important that additional research be conducted to assess its long-term feasibility, safety and sustainability.

In recent years, Panama has implemented various initiatives to promote the diversification of food sources and production systems, however, it would be interesting to know the proposals, considering that this issue is important and Panama welcomes this step for the future.

It is notable that it will be a challenge to design a single mechanism to standardize new technologies, many of which are still in the research and development stages, and members have little or no experience or understanding of what is to come.

The Codex Alimentarius has a robust and well-resourced structure of experts who can help in the improvement of such an important topic.