CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED TO THE COMMISSION FOR ADOPTION

(Comments submitted by 25 June 2015)

Part 1 – Standards and related texts submitted for adoption

Committee on Nutrition and Foods for Special Dietary Uses
Comité sur la nutrition et les aliments diététiques ou de régime
Comité sobre Nutrición y Alimentos para Regímenes Especiales

List of Food Additives in CODEX STAN 72-1981 (Proposed draft revision) (para. 152, Appendix VI, Part 1).

Comments of European Union

The European Union (EU) maintains its reservation as to the inclusion of substance INS 1450 (starch sodium octenyl succinate) in section A of the Standard because there is no technological need for this additive in infant formulae.

CCNFSDU agreed to include substance INS 1450 in part 4 of section A of the Standard for hydrolysed protein and/or amino acid based infant formula in the amount of 2g/100ml of the product ready for consumption (this amount is higher than the previous of 1.2g/100ml).

While the EU could accept the use of INS 1450 at 2g/100ml in formulae for special medical purposes, in the EU's view there is no technological need for this additive in infant formula (i.e. section A of the Standard).

Committee on Pesticide Residues
Comité sur les résidus de pesticides
Comité sobre Residuos de Plaguicidas

MRLs for pesticides (Proposed Draft) (para.118, Appendix III).

Comments of European Union

The EU supports the adoption of all the proposed draft MRLs in Appendix III of REP 15/PR with the exception of the draft MRLs for the substances/commodities below for which the EU requests that its reservations are included in the report of CAC 38.

The EU has a policy in place whereby EU MRLs will be aligned with Codex MRLs if three conditions are fulfilled: (1) that the EU sets MRLs for the commodity under consideration, (2) that the current EU MRL is lower than the CXL, and (3) that the CXL is acceptable to the EU with respect to areas such as consumer protection, supporting data, and extrapolations. Reservations address the cases where the EU considers the third criterion not to be met, with the aim of increasing transparency and predictability regarding the impact of the work of the Codex Alimentarius Commission on EU legislation.

DITHIOCARBAMATES (105): The EU does not support the adoption of proposed draft MRL for cumin seed because the dietary risk assessment was not based on the worst case.

TRIFORINE (116): The EU does not support the adoption of all the proposed draft MRLs because of concerns on the residue definitions.

PROPAMOCARB (148): The EU does not support the adoption of proposed draft MRLs for eggs; poultry fats; poultry meat; poultry, edible offal of; and leek; because of the different residue definitions (poultry commodities), and an acute intake risk (leeks) because of the lower ARfD established in the EU.

BUPROFEZIN (173): The EU does not support the adoption of the proposed draft MRL for coffee beans because of the potential formation of toxicologically relevant degradation products during coffee processing.

MYCLOBUTANIL (181): The EU does not support the adoption of proposed draft MRLs for peaches (including nectarine and apricots) due to different policies on extrapolation used by JMPR and in the EU, and for peppers due to different policies on data requirements applied by JMPR and the EU.

FENPROPATHRIN (185): The EU does not support the adoption of proposed draft MRLs for citrus fruits; coffee beans; edible offal (mammalians); eggs; mammalian fats (except milk fats); meat (from mammals other than marine mammals); milks; plums; peppers; poultry fats; poultry meat; poultry, edible offal of; soya bean (dry);strawberry; tea, green, black, (black fermented and dried); tomato; tree nuts due to the lack of data on the technical specifications of the active substance used to derive the reference values and the residue definition; and for peppers and tomatoes due to acute intake concerns.

PYRACLOSTROBIN (210): The EU does not support the adoption of the proposed draft MRL for apricots due to the different extrapolation policies followed by the EU and the JMPR.

DIMETHOMORPH (225): The EU does not support the adoption of proposed draft MRL for fruiting vegetables other than cucurbits because of different extrapolation policies used by the JMPR and in the EU.

PROTHIOCONAZOLE (232): The EU does not support the adoption of proposed draft MRLs for bush berries and fruiting vegetables, cucurbits (except watermelon) because of the differing residue definitions and ARfDs used by the JMPR and established in the EU.

EMAMECTIN BENZOATE (247): The EU does not support the end-points used to derive the new ARfD of of 0.02 mg/kg body weight.

SULFOXAFLOR (252): The EU does not support the adoption of all the proposed draft MRLs because the evaluation of Sulfoxaflor is still ongoing in the EU.

BENZOVINDIFLUPYR (261): The EU does not support the adoption of all the proposed draft MRLs because the evaluation of Benzovindiflupyr is still ongoing in the EU.

FENAMIDONE (264): The EU does not support the adoption of proposed draft MRLs for flowerhead brassicas and fruiting vegetables other than cucurbits (except chili pepper, fungi, sweet corn) due to differing extrapolation rules applied in the EU and by the JMPR.

FLUENSULFONE (265): The EU does not support the adoption of proposed draft MRLs for fruiting vegetables, cucurbits; and fruiting vegetables, other than cucurbits (except sweet corn and mushrooms) because of concerns on the available data for assessment of certain metabolites, and the use of the TTC approach, a methodology still under review in the EU.

AMINOCYCLOPYRACHLOR (272): The EU does not support the adoption of proposed draft MRLs for edible offal (mammalian); mammalian fats (except milk fats); meat (from mammals other than marine mammals); and milks due to questions over potential genotoxicity and metabolism for the metabolite CPCA.

DICHLOBENIL (274): The EU does not support the adoption of proposed draft MRLs for brassica (cole or cabbage) vegetables, head cabbage, flowerhead brassicas; cane berries; celery; cereal grains; fruiting vegetables, cucurbits; fruiting vegetables, other than cucurbits (except sweet corn and mushrooms); grapes; leafy vegetables; mammalian fats (except milk fats); meat (from mammals other than marine mammals); milks; onion, bulb; onion, welsh; pulses; edible offal (mammalian); eggs; poultry, edible offal of; poultry fats and poultry meat; because of the approaches used when considering the significance of the 2,6-dichlorobenzamide in soil (rotational crops) and in livestock, and the use of the poultry metabolism study to derive MRLs for poultry commodities.

FLUFENOXURON (275): The EU does not support the adoption of all the proposed draft MRLs because of concerns on the residue definitions in plant and animal commodities, the lack of a dietary burden calculation and the possible presence of the degradate Reg. No 4064702 in tea infusions.

MESOTRIONE (277): The EU does not support the adoption of proposed draft MRLs for asparagus; bush berries; cane berries; cranberry; edible offal (mammalian); eggs; meats (from mammals other marine mammals); milks; okra; poultry, edible offal of; poultry meat; rhubarb and sugar cane due to different residue definitions established by JMPR and the EU.

Committee on Residues of Veterinary Drugs in Foods
Comité sur les résidus de médicaments vétérinaires dans les aliments
Comité sobre residuos de medicamentos veterinarios en los alimentos

MRLs for derquantel (sheep tissues), emamectin benzoates (salmon and trout tissues) and monepantel (sheep tissues) (Proposed Draft) (paras 70, 75 and 90, Appendix IV).

Comments of Costa Rica, European Union and Peru

COSTA RICA

Costa Rica agradece la oportunidad de expresar sus comentarios sobre cuestiones que se someten para adopción de la CAC y en ese sentido apoya los límites máximos de residuos propuestos para los siguientes medicamentos veterinarios: DERQUANTEL (agente antihelmíntico), BENZOATO DE EMAMECTINA (agente antiparasitario), MONEPANTEL (antihelmíntico), aunque en Costa Rica no se encuentran registrados

EUROPEAN UNION

The European Union (EU) can support the adoption of the proposed draft MRLs with the exception of the MRLs for monepantel for which the EU reiterates its reservation expressed at CCRVDF because of intake concerns: the Codex MRLs for monepantel are equivalent to 118% of the EU ADI (admissible daily intake) when using the TMDI (theoretical maximum daily intake) approach for the exposure assessment.

PERU

En cuanto a la propuesta de que el Comité solicite al JECFA una evaluación de si es conveniente utilizar LMR para peces de aleta, moluscos y crustáceos o bien establecer subgrupos para determinadas especies dentro de cada uno de estos grupos, el Perú está de acuerdo con lo planteado en el numeral 75, siempre y cuando se proporcione el fundamento científico para cada uno de ellos.

Tener en cuenta que para el caso de Benzoato de emamectina, la Unión Europea según el Reglamento (UE) N° 37/2010 considera para peces un LMR de 100ug/Kg (músculo y piel en proporciones normales). Sin embargo, no se contemplan especies específicas de peces.

RMRs for dimetridazole, ipronidazole, metronidazole and ronidazole (Proposed Draft) (paras 92, Appendix VII).

Comments of Costa Rica

Costa Rica apoya las recomendaciones sobre la gestión de riesgos para residuos de medicamentos veterinarios (REP15/RVDF párr. 92 y Apéndice VII) ya que alerta a los países sobre preocupaciones importantes para la salud y a su vez, otorga la facultad a los países de desarrollar su legislación de la manera que lo estimen conveniente.

Committee on Sugars
Comité sur les sucres
Comité sobre Azúcares

Standard for Non-centrifugated Dehydrated Sugar Cane Juice (Draft) (CL 2015/16-CS).

Comments of Brazil, Philippines and United State of America

BRAZIL

Brazil would like to send further clarification such as to reflect our most exported non centrifugated sugar – açúcar mascavo on the proposed Codex Standard.

At our responses to CL 2013-9CS and CL 2014-35CS, we suggested to the WG to differentiate the various non-centrifugated sugars and/or to expand/flexible the proposed values to encompass all products under the provisions of the Standard.

Although most non-centrifugated dehydrated sugars listed on the proposed draft Standard (CL 15/16-CS) may fall under the proposed specifications of the physical and chemical characteristics table, Brazil would like to highlight that açúcar mascavo does not fit the proposed values for reducing sugars and protein content.

Açúcar mascavo fits product definition as set at Section 2 and is the most important non-centrifugated dehydrated sugar produced and exported in Brazil.

Considering this, as well as Activity 1.2.2 of the Codex Alimentarius Strategic Plan 2014-2019, we would like to ask for the inclusiveness of the proposed draft Standard such as to reflect that it is "…in response to needs identified by Members and in response to factors that affect … fair practices in the food trade".

Specific Comments:

Although paragraph 6 of CL 15/16-CS informed that the list of common names in the footnote is not exhaustive, we would like to share the vision that the insertion of açúcar mascavo to the Footnote nr 1 is needed not to impact international trade of Açúcar Mascavo.

Another approach should be to remove all examples listed, not to generate dubious interpretation of the Standard.

DRAFT CODEX STANDARD FOR NON-CENTRIFUGATED DEHYDRATED SUGAR CANE JUICE [1]
{ Names used in certain countries and regions for non-centrifugated dehydrated sugar cane juice: Açúcar Mascavo (Brazil); Chancaca (Chile, Ecuador and Peru); Gur or Jaggery (India); Jaggery and Khandsari (South Asia); Kokutou and kurozatou (Japan); Mascabado (Philippines); Panela (Bolivia, Colombia, Honduras, Nicaragua, Panamá and others); Papelón (Venezuela and some Central-American countries); Piloncillo (Mexico); Rapadura (Brasil and Cuba); Tapa de Dulce, Dulce Granulado (Costa Rica). }

Rationale:

To specify that our most produced and exported non centrifugated sugar – açúcar mascavo, is under the scope of the Standard.

Inserting a footnote for the exemption of Açúcar Mascavo from the proposed values for Reducing Sugars and Proteins as set below:

3.2.4 Physical and chemical characteristics

"Non-centrifugated dehydrated sugar cane juice" shall fulfill the conditions shown in the following table as appropriate.

Requirement	COMPOSITION ON A DRY BASIS	
	Value	
	Minimum	Maximum
Ash (% m/m)	0.9	--
Saccharose (% m/m)	80.7	91
Reducing sugars (% m/m)	4.5 *	8.1
Proteins in % (N X 6.25)	0.2 **	--

* 1.5% for Açúcar Mascavo (Brazil) and/or Kokutou and kurozatou (Japan)

** 0.1% for Açúcar Mascavo and Rapadura (Brazil)

Rationale:

Proposed values are needed to encompass Brazilian Rapadura and Açúcar Mascavo.

According to values obtained from research as well as from production of "Non-centrifugated dehydrated sugar from cane juice" in Brazil:

Reducing sugars (%).

The minimum value for reducing sugars should be 1.5%, to allow correction of the cane juice to impede sugar invertion to values above the maximum limit.

Correction of cane juice in Brazil is performed by the adoption of CaO as a processing aid. CaO holds pH of sugar cane juice to 7.0, avoiding reducing sugars formation and, consequentially, moistening of final product.

Additionally, there are Brazilian sugar cane varieties breaded for higher sucrose content. Such varieties during the processing steps presents very low reducing sugars content.

Proteins

The minimum value for proteins should be 0.1% to allow the use of Brazilian sugar cane varieties with very low protein content. Such varieties lead to products with reduced protein content due to further removal of proteins along the processing steps of Açúcar mascavo and rapadura (e.g., scum removal).

PHILIPPINES

General Comments:

Again, the Philippines would like to bring to the attention of the Committee the following proposals we had previously submitted, but were not acknowledged or might have been overlooked:

1. To replace ~~Mascabado (Philippines)~~ with Muscovado (Philippines) in the Footnote, page 3 of CL 2015/16-CS May 2015, wherein non-centrifugated dehydrated sugar cane juice is known in certain regions.

Rationale: Mascabado is a trade name of one of our local producers/exporters and not the common name of this commodity. The common name of this commodity is Muscovado.

2. To amend the title of the standard from "Non-Centrifugated Dehydrated Sugar Cane Juice" to "Non-Centrifugal Cane Sugar".

Rationale: The Philippines agrees on the comment made by USA that "Non-Centrifugal" is the appropriate term to be used in the Standard. Non-Centrifugated is not a standard term use in the sugar industry, at least in English speaking countries. Moreover, it is important to note that we are developing standard for sugar, not for sugar cane juice, hence, the word "juice" be deleted in the title of the standard. "Non-centrifugal" clearly describes the distinguishing characteristic of this type of sugar compared to other sugars. "Cane sugar" will specifically identify the commodity in development and its primary source. Ergo, "Non-centrifugal cane sugar" be adopted for defining the product in this Standard, instead.

3. The Draft Standard be retained at Step 6

Rationale: This is to allow member countries to further comment and sought for adoption at a higher step only after the various comments by member countries particularly on provisions on Physical and Chemical Characteristics and the Methods of Analysis and the name of the product are fully taken into account. The Philippines believes that no substantial consensus has been reached specifically on these provisions.

Specific Comments:

Section 1. SCOPE

This Standard applies to ~~non-centrifugated dehydrated sugar cane juice~~ non-centrifugal cane sugar as defined in section 2, intended for human consumption, including for catering purposes or pre-packaging as appropriate, as well as to the product intended for subsequent processing, where indicated. This Standard does not cover the product obtained from the reconstitution of its components.

Section 2. PRODUCT DEFINITION

For clarity, the Philippines reiterates its previous proposal on the following edits to the definition:

" Non-~~centrifugated~~ centrifugal cane sugar ~~dehydrated sugar cane juice~~" is the product obtained from the evaporation of sugar cane ~~juice~~ *Saccharum officinarum L.* juice, which contains amorphous microcrystals, invisible to the naked eye, which maintains its constituent elements, such as ~~saccharose~~, sucrose, glucose, fructose, and minerals.

Rationale:

a. Saccharum officinarum L. is the scientific name of sugar cane, therefore, "juice" should be written after its scientific name.

b. "Saccharose" be changed to "sucrose" throughout the document. Sucrose is the standard term used in the sugar industry and this was also suggested by the USA.

Section 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.1 Basic Ingredients

The Philippines reiterates its previous proposal to read as "Sugar cane ~~juice~~ *(Saccharum officinarum L)* juice"

3.2 QUALITY FACTORS

The Philippines proposes the following edits and to rephrase the sentence to read as follows:

3.2.2 Flavour and aroma

The flavour and aroma shall be characteristic of the product. The product shall be free of any ~~unpleasant~~ other objectionable sensory characteristics

3.2.3 Defects

The product shall be free from defects such as foreign ~~materials~~ matters, ~~or softening~~. ~~It may not be fermented or show~~ signs of fermentation, fungal attacks, presence of insects and /or its fragments, or softening.

Physical and Chemical Characteristics:

The Philippines reiterates its previous position to change "Saccharose" to Polarization, delete proteins in the Requirement, and to consider lump and powder/amorphous to be similar or equivalent to solid and granulated instead .

Likewise, the Philippines would like to point out that using "Composition on a Dry Basis" is confusing that the product has high moisture content. 91% sucrose content on a dry basis is not a reflective of its true percent sucrose content by mass. It is also more convenient to include its moisture content as one of its quality factors rather than putting it on a separate table. Further the Philippines would like to clarify on the rationale of having minimum values for ash. Like moisture, a low value for ash suggest better quality. Ash should have maximum values. Values to be specified in square brackets should be from validated test methods.

"Non-~~centrifugated~~ centrifugal ~~dehydrated sugar~~ cane ~~juice~~ sugar" shall fulfill the conditions shown ~~below in tables 1 and 2~~, in the following table as appropriate.

~~**Requirement**~~ **Composition and Quality Factors**	~~**COMPOSITION ON A DRY BASIS**~~ **Value**	
	Minimum	**Maximum**
Moisture (%m/m) Lump Powder/Amorphous		9.0 5.0
Ash (% m/m)	0.9	
Saccharose (% m/m) Polarization,°Z		91
Reducing sugars, (% m/m)	4.5	
~~Proteins in % (N x 6.25)~~	~~0.2~~	

Section 8. LABELLING

The Philippines reiterates its previous proposal to change the name from "Non-Centrifugated Dehydrated Sugar Cane Juice" to "Non-Centrifugal Cane Sugar" and "Lump" and "Powder or amorphous Panela".

8.1 Name of the Product

8..1.1 The product name "~~non-centrifugated dehydrated sugar cane juice~~" "non-centrifugal cane sugar" may be followed by the ordinary name currently accepted in the country of origin or retail sale.

8.1.2 The style shall be included as part of the name, as follows:

a) ~~Non-centrifugated dehydrated sugar cane juice~~ non-centrifugal cane sugar (common name of the product, e.g. "~~Solid~~ Lump Panela").

b) ~~Non-centrifugated dehydrated sugar cane juice~~ "Non-centrifugal cane sugar" (common name of the product e.g. "~~Granulated~~ Powder (or Amorphous Panela")

Section 9. METHODS OF ANALYSIS AND SAMPLING

The Philippines reiterates its previous proposal to use ICUMSA methods whenever possible. We support the United States position that AOAC methods for sugar tend to be outdated, and should be supplanted by ICUMSA, which are specific for sugar products and maintained up to date. We, also note that besides the Philippines and the United States, several member countries have also supported the use of ICUMSA methods.

Likewise, most of the methods specified in the Codex Recommended Method of Analysis and Sampling (Codex Stan 234-199) for sugars are ICUMSA methods. The General Subject 3 in the ICUMSA Methods Book is for the analysis of Specialty Sugar in which Non-Centrifugal-Cane Sugar is categorized. As agreed in the 36th CAC Session, this matter should be referred to the CCMAS.

In consonance with our proposal to remove Protein from the Composition and Quality Factors, we also propose the deletion of Protein in the Methods of Analysis.

Further, Polarization, as it replaces "Saccharose" should have a different method from Reducing Sugars as both parameters should and can be analyzed separately.

Provision	Method	Principle
Moisture	~~AOAC 925.45~~ ICUMSA GS2/1/3/9-15 (2007)	Gravimetry, drying at atmospheric pressure
Ash	~~AOAC 900.02 Method 1~~ ICUMSA GSI/3/4/7/8-13 (1994)	~~Gravimetry~~ Conductimetry
(~~Saccharose~~) Polarization	~~AOAC 923.09~~ ICUMSA GSI/2/3/9-1 (2007)	~~Volumetry, Lane and Eynon (modified)~~ Polarimetry
~~Protein~~ Reducing sugars	~~AOAC 981.10~~ ICUMSA GS1/3/7-3(2005)	~~Raw protein (N x 6.25)~~ Lane and Eynon Constant Volume

UNITED STATES OF AMERICA

General Comments

At this time, the United States does not support the adoption of this document at Step 8. We believe that it is still premature to advance the document for final adoption as there are still outstanding issues that need to be addressed. The comments from Brazil and Mexico provided in Annex II of the Circular Letter indicate that additional work is needed. In addition, the United States suggests that the analytical methods issues should be referred to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for endorsement before further advancement of this document. Therefore, we propose retaining the document at Step 6 for further consideration and comment.

Specific Comments

The United States had submitted comments in response to 2012/35/CS on various aspects of this standard that are not addressed in this document. These items are still of concern. Specifically:

- The term, “Non-Centrifugated Dehydrated Sugar Cane Juice” is excessively long and is not a common name for this sugar. It would be preferable to use the term “non-centrifugal sugar” as a name for this food. In any case, the term “centrifugated” is not an English term. This term should be replaced with the word “centrifuged” or “centrifugal” wherever it appears in the document.
- This product is not juice, but a form of sugar (produced traditionally without centrifugation). FAO has a previously established definition for “non-centrifugal cane sugar”: http://data.fao.org/dimension-member?entryId=3e29a4b1-a142-470c-9077-10d7f9a5c8ea.
- The term “raspadura” needs to be included. It is the name of the product in Panama and Cuba. The term “rapadura” is included but this is the Portuguese term used by Brazil.
- The International Commission for Uniform Methods of Sugar Analysis (ICUMSA) analytical methods should be used, rather than only the Association of Official Analytical Chemists’ (AOAC) methods. This proposed standard does not take into account the ICUMSA methods and lists only AOAC methods.
- We are concerned about the method selected for protein--AOAC 981.10 method, since it appears to be a “protein in meat” method.
- We recognize that the ICUMSA methods for iron and sulfite are for white sugars, so they may not work as well for this commodity. However, the ICUMSA conductivity ash method would work and is much quicker, easier, less cumbersome, less equipment intensive, and safer than the AOAC ash method. In fact, ICUMSA did studies to show the equivalence of results between conductivity methods and ash methods. As far as we are aware, no studies were presented to show why the AOAC methods should be preferred over the ICUMSA methods. Additionally, all of the AOAC methods require a advanced equipment which would rarely be available in a factory that makes this product.
- The United States suggests that all of the analytical methods should be referred to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for endorsement before further advancement of this document.

Based on the above observations, we propose retaining the document at Step 6 for further consideration and comment.

Part 2 – Standards and related texts held at Step 8 by the Commission

Draft MRLs for Bovine Somatotropin Held at Step 8 by 23rd CAC (ALINORM 03/41, para. 34).

Comments of Brazil, European Union, Kenya and Papua New Guinea

BRAZIL

ENGLISH

1. Facts

JECFA evaluated bST three times (1992, 1998 and 2014) and made the same recommendation: "*ADI and MRL not specified".*

***ADI "not specified"** means that available data on the toxicity and intake of the veterinary drug indicate a large margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs.*

***MRL "not specified"** means that available data on the identity and concentration of residues of the veterinary drug in animal tissues indicate a wide margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs.*

This means that JECFA concluded that the use of the bST does not represent a hazard to human and that there is no need to specify a numerical ADI and the presence bST residues in the named animal product does not present a health concern and that there is no need to specify a numerical MRL.

2. Background

The 40th JECFA (**1992**), in view of the lack of impact on human food safety, recommended an ADI and MRL "not specified" for bST which applied to somagrebove, sometribove, somavubove and somidobove.

At its 8th Session (**1994**), the CCRVDF recommended the adoption of the Draft Maximum Residue Limits for bST at Step 8 of the Procedure for consideration at the 21st Session (**1995**) of the Commission. In this session, the Commission, after a vote process, decided to adjourn the debate on this issue to its next meeting.

At the 22nd Session (**1997**), the Commission, after a vote process, decided again to adjourn the debate on this issue, requested the JECFA for the re-evaluation of bST and the Codex Committee on General Principles (CCGP) to examine the application of the "other legitimate factors" in relation to bST.

The 50th JECFA (**1998**) again concluded that bST can be used without appreciable health risk to consumer and reaffirmed its previous ADI and MRLs "not specified" for somagrebove, sometribove, somavubove and somidobove.

The draft Maximum Residue Limits for bST were again considered for adoption at Step 8 by the Codex Alimentarius Commission at its 23rd Session (**1999**), which decided "to hold" the draft MRLS for bST at Step 8.

The 34th Session (**2011**) of the Commission, in response to concerns raised by some delegations regarding the delay in taking a decision on these MRLs, requested the Codex Secretariat to prepare a paper on the history of the discussion of the MRLs for bST in cattle tissues in Codex, including a summary of the JECFA evaluation.

At its 35th Session (2012), after discussing the issue, the Commission agreed to request JECFA to re-evaluate bST.

At 78th JECFA (November of 2013) meeting concluded that:

- There is a lack of evidence that the use of rbSTs in dairy herds contributes to antimicrobial resistance in dairy herds;

- Available new information does not change the conclusion of the 50th Committee Meeting in regards to the risk to human health due to the use of antimicrobial agents to treat mastitis;

- Available information supports the conclusions of the previous Committee that there is no significant change in the concentrations of total rbST detected in milk and tissues of rbST treated cows when compared with untreated controls;

- Considering all new information on the normal variation in IGF-I concentrations in cow milk and the effect of rbST treatment on IGF-I concentrations in milk, noted that the conclusions made at the 40th and 50th Meetings are not substantially changed;

- In concurrence with the conclusions of the previous meetings, the data demonstrated that there is no impact of rbSTs on the nutritional qualities of milk;

- Based on the data reviewed, the Committee concluded that there was no evidence to suggest that the use of rbSTs would result in a higher risk to human health due to the possible increased use of antimicrobial agents to treat mastitis or the increased potential for non-compliant antimicrobial residues in milk; and

- If any rbST residues are present in milk or tissues, they would pose a negligible risk to human health.

Therefore, based on a systematic review of the literature published since the last evaluation, the JECFA reaffirmed its previous decision on ADIs and MRLs "not specified" for somagrebove, sometribove, somavubove and somidobove, established at the fortieth meeting (WHO TRS No. 832, 1993).

3. Recommendation

- **In view of the latest evaluation, all Codex members should ask for the adoption of JECFA's recommendations for bST at the 22nd Session of the CCRVDF and at the next Commission in 2015.**

- **Codex needs to base its decisions on science.** All scientific information available for bST has been considered by JECFA. All three JECFA evaluations concluded that, if used according to Good Veterinary Practices, bST did not represent a risk to human health. So, Codex members should reinforce the imperious need to follow the sound scientific recommendations of the Codex experts groups like JECFA, JMPR and JEMRA.

The draft MRLs for bST have been held at Step 8 since 23rd Session of the Commission (1999), in other words, for more than fifteen years.

Factors outside the mandate of Codex should not influence the risk management to achieve consensus and therefore should not hold standards at step 8. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the HEALTH protection of consumers and for the promotion of fair practices in food trade, as stated in the Procedural Manual.

The delay in approving a standard that has followed each step of the Codex process and has received approval from the scientific advisory body of Codex:

- Jeopardizes the role of the FAO/WHO group of experts that supports Codex decisions;

- Discourages the participation of Codex members, particularly of developing countries, in Codex activities, as well as the development of studies and data provided by the countries and by the sponsors;

- Represents a risk for the role of Codex as an international standard-setting body; and

- Outrages against, weakens, and debilitates the multilateralism system of the world.

SPANISH

1. Los hechos

El JECFA evaluó la bST por tres veces (1992, 1998 e 2014) e hizo la misma recomendación: "*ADI y LMR no especificado*".

IDA "no especificada" *significa que los datos disponibles sobre la toxicidad y la ingesta del medicamento veterinario indican un amplio margen de seguridad para el consumo de los residuos en los alimentos cuando el medicamento se usa de acuerdo a las buenas prácticas en el uso de medicamentos veterinarios.*

LMR "no especificado" *significa que los datos disponibles sobre la identidad y la concentración de los residuos del medicamento veterinario en los tejidos animales indican un amplio margen de seguridad para el consumo de los residuos en los alimentos cuando el medicamento se usa de acuerdo a las buenas prácticas en el uso de medicamentos veterinarios.*

Esto significa que el JECFA concluyó que el uso de la bST no representa peligro para la salud humana y no hay necesidad de especificar una IDA numérica y que la presencia de residuos bST en el producto de origen animal no presenta una preocupación de salud y que no hay necesidad de especificar un LMR numérico.

2. Antecedentes

El 40º JECFA (**1992**), en vista de la falta de impacto en la seguridad alimentaria humana, recomendó una IDA y LMR "no especificado" para bST aplicada a somagrebove, sometribova, somavubove y somidobova.

En su 8ª Sesión (**1994**), el CCRVDF recomendó la adopción de los Proyectos de Límites Máximos de Residuos para la BST en el Trámite 8 del Procedimiento para su consideración en la 21ª Sesión (**1995**) de la

Comisión. En esta Sesión, la Comisión, después de un proceso de votación, decidió aplazar el debate sobre esta cuestión para su próxima reunión.

En la 22ª Sesión (**1997**), la Comisión, después de un proceso de votación, decidió volver a aplazar el debate sobre esta cuestión, pidió al JECFA la reevaluación de la bST y al Comité del Codex sobre Principios Generales (CCGP) para examinar la aplicación de los "otros factores legítimos" en relación con la bST.

La 50ª Sesión del JECFA (**1998**) de nuevo llegó a la conclusión de que la bST se puede utilizar sin riesgo apreciable para la salud del consumidor y reafirmó su anterior IDA y LMRs "no especificado" para somagrebove, sometribova, somavubove y somidobova.

Los proyectos de límites máximos de residuos para la bST se consideraron de nuevo para su adopción en el Trámite 8 por la Comisión del Codex Alimentarius en su 23ª Sesión (**1999**), que decidió "mantener" los proyectos de LMRs para la bST en el Trámite 8.

La 34ª Sesión (**2011**) de la Comisión, en respuesta a las inquietudes planteadas por algunas delegaciones respecto a la demora en la adopción de una decisión sobre estos LMRs, pidió a la Secretaría del Codex que preparara un documento sobre la historia de la discusión de los LMRs para la bST en tejidos de ganado en el Codex, incluyendo un resumen de la evaluación del JECFA.

La 35ª Sesión (**2012**) de la Comisión discutió el asunto y acordó solicitar al JECFA la revaluación de la bST.

La 78ª Reunión del JECFA (Noviembre de 2013) concluyó que:

- Hay una falta de evidencia de que el uso de las rbSTs contribuye a la resistencia antimicrobiana en los hatos lecheros;

- La nueva información disponible no cambia la conclusión de la 50ª Reunión del Comité sobre los riesgos para la salud humana debido al uso de agentes antimicrobianos para el tratamiento de la mastitis;

- La información disponible respalda las conclusiones anteriores de la Comisión de que no hay un cambio significativo en las concentraciones de rbST total detectadas en la leche y los tejidos de vacas tratadas con rbST en comparación con los controles no tratados;

- Teniendo en cuenta toda la nueva información sobre la variación normal de las concentraciones de IGF-I en la leche de vaca y el efecto del tratamiento con rbST sobre las concentraciones de IGF-I en la leche, señaló que las conclusiones alcanzadas en las Reuniones 40ª y 50ª no se modifican sustancialmente;

- En coincidencia con las conclusiones de las reuniones anteriores, los datos demostraron que no hay impacto de rbSTs sobre las cualidades nutricionales de la leche;

- Sobre la base de los datos examinados, el Comité concluyó que no había evidencia para sugerir que el uso de las rbSTs se traduciría en un mayor riesgo para la salud humana debido al posible uso incrementado de agentes antimicrobianos para tratar la mastitis o el aumento potencial de residuos de antimicrobianos no conformes en la leche; y

- Si cualquier de los residuos rbST están presentes en la leche o en los tejidos, plantean un riesgo insignificante para la salud humana.

Por lo tanto, con base en una revisión sistemática de la literatura publicada desde la última evaluación, el JECFA reafirmó su decisión anterior sobre las IDAs y los LMRs "no especificado" para somagrebove, sometribova, somavubove y somidobova, establecida en la 40ª Reunión (OMS TRS Nº 832, 1993).

3. Recomendación

A la vista de la última evaluación, todos los miembros del Codex deberán pedir por la adopción de las recomendaciones del JECFA para bST en la 22ª Sesión del CCRVDF y en la próxima Comisión en 2015.

El Codex debe basar sus decisiones en la ciencia. Toda la información científica disponible para la bST ha sido considerada por el JECFA. Las tres evaluaciones del JECFA concluyeron que, si se utiliza de acuerdo con las buenas prácticas veterinarias, la bST no representa un riesgo para la salud humana. Así, los miembros del Codex deberían reforzar la imperiosa necesidad de seguir las recomendaciones científicas rigurosas de los grupos de expertos del Codex como el JECFA, JMPR y JEMRA.

Los proyectos de LMRs para bST se han mantenido en el Trámite 8 desde la 23ª Sesión de la Comisión (1999), es decir, durante más de quince años.

Factores fuera del mandato del Codex no deberían influir en la gestión de riesgos para lograr el consenso y por lo tanto no debe mantener normas en el trámite 8. Las decisiones deben basarse en la evaluación de riesgos, y teniendo en cuenta, en su caso, otros factores legítimos relevantes para la protección de la salud

de los consumidores y para la promoción de prácticas equitativas en el comercio de alimentos, como se indica en el Manual de Procedimiento.

El retraso en la aprobación de una norma que ha seguido cada trámite del proceso del Codex y ha recibido la aprobación del órgano de asesoramiento científico del Codex:

- Pone en peligro el papel del grupo de expertos de la FAO/OMS que apoya las decisiones del Codex;

- Desalienta la participación de los miembros del Codex, en particular de los países en desarrollo, en las actividades del Codex, así como el desarrollo de estudios y datos proporcionados por los países y por los patrocinadores;

- Representa un riesgo para la función del Codex como organismo internacional de normalización; y

- Desafueros contra, desmejora, y se debilita el sistema de multilateralismo del mundo.

EUROPEAN UNION

The European Union would like to share its views on the draft MRLs for rBST due for consideration by the 38th CAC in July 2015.

The EU recalls that, at the request of the 35th session of the CAC, JECFA 78 re-evaluated rBST. This re-evaluation looked at the safety of the substance in terms of a number of factors, including concerns linked to Antimicrobial Resistance (AMR). These AMR concerns were specifically introduced into the request to JECFA at CAC 35 due to the increasing health threat posed by growing AMR.

The EU appreciates the work done by JECFA in its re-evaluation. While it appears from JECFA's conclusions that there was sufficient data to make an informed assessment in relation to the safety of rBST residues, this does not seem to be the case for AMR. There was insufficient data to fully explore the links between the use of rBST and the incidence of AMR. The risk of mastitis in animals, arising from the increased milk yield brought about by the use of rBST, and the consequent need to use antimicrobials to treat such infection, is not a matter that can be ignored, even if the link is an indirect one.

Both the issue of residues in food and AMR fall firmly within the Codex mandate. While JECFA appears to have sufficiently addressed concerns related to rBST residues in food, this is not the case with the AMR aspects. Simply put, while the conclusions relating to residues in food can be supported, those related to AMR remain insufficiently explored and thus, concerns related to AMR remain outstanding. Codex clearly has further work to do before a decision can be taken.

AMR is a serious issue which needs to be tackled with urgency. This can been seen from recent global developments, including within the parent organisations of Codex: the FAO and WHO, where two far-reaching resolutions and a Global Action Plan have been adopted. These resolutions call for united and determined action to be taken to stem the threat of antimicrobial resistance. In particular, emphasis is placed on the One Health approach which calls for action in both the human and veterinary fields. These resolutions are addressed to, and have been supported by, the very same countries, all of whom are Members of Codex. Under the CAC's agenda this week, we are again reminded of the importance of these undertakings under Item 9(a) where clear recommendations are made by WHO and FAO to Codex to take action.[1]

The EU would like to draw attention to the fact that the use of rBST also has a negative impact on animal health and welfare. It is for these reasons that the use of rBST is banned in the EU, as well as many other countries. The EU also has a longstanding policy of not allowing the use of veterinary drugs in the absence of a therapeutic purpose i.e. for growth promotion. rBST is used solely for increasing the milk yield in dairy cows without any therapeutic indications.

In conclusion, the EU feels very strongly that it would be unwise to proceed with setting an international standard for a substance where further knowledge is required in order to rule out concerns related to AMR. Indeed Codex - as the leading, international standard-setting body for food safety - should be prudent in its approach. A standard for rBST also does not appear necessary for the purpose of ensuring safe, international trade given that rBST has been on the market and in use by 21 countries worldwide for a number of years.

For these reasons,the EU remains opposed to the adoption of an international standard for rBST at this stage.

The adoption of decisions on the basis of consensus is a core value of Codex. The EU is fully committed to this principle and trusts that a way forward to achieve consensus will be found.

[1] CX/CAC 15/38/16 Add. 1.

KENYA

Kenya supports the adoption of the standards to step 8 after taking note of the JECFA report. However the issues raised on the public health concerns needs to be addressed.

PAPUA NEW GUINEA

Papua New Guinea notes the history behind the MRLs on BST that had continued to be debated since 1992. also, PNG learns that on the 34th session in 2011 that the Commission raised the concerns of delay tactics by some delegations' disscussion on MRLs for BST in cattle tissues in codex.

At the 35th session in 2012 after the disscussion of the issue, the Commission agreed to request JECFA to re-evaluate BST.

Now PNG sees that at the 78th session of JECFA in 2014, which reviewed the literature on ADIs and MRLs for Somagrebove, Sometribove, Somavubove and Somidobove (not specific) at the 40th meeting of WHO TRS No. 832 in 1993.

In view of re-evaluation, PNG appreciates the recommendation made at 78th JECFA and 22nd CCRVDF for this CAC38 session to adopt the MRLs.

Recommendation

PNG is a developing country and its work on food standards, domestic and international trade is based on the Codex standards which it has adopted.

Therefore, PNG maintains that, decision making should be based solidly on science, so that the institutional and scientific integrety of Codex mandate remains intact.

On the issue of recombinant Bovine Somatotropin, the national Codex committee (NCC) met to debate the MRLs of recombinant Bovine Somatotropin especially on the JECFA recommended MRLs.

PNG's biggest trading partners are both Australia and New zealand. pork, beef and dairy products are the traded goods imported from Australia and New zealand, as PNG has yet to produce enough of these food items domestically. Australia and New zealand has also adopted the MRLs for dairy milk as recommended by JECFA. Therefore, it is only appropriate that PNG adopts these MRLs for diary products as C*odex* standards.

Also, PNG shares the sentiment with other countries on the issue of offals such as lung as a diet for human consumption. thus, PNG would like to see MRLs developed as it is also diet delicasy in our country.

In addition to above, PNG still like to see that previously proposed new work to be carried out on the MRLs on all parts of the dairy cows' guts by JECFA be considered.