CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/LAC 14/19/7**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

FAO/WHO REGIONAL COORDINATING COMMITTEE FOR LATIN AMERICA AND THE CARIBBEAN

19th Session

San José, Costa Rica, 10 – 14 November 2014

CODEX WORK RELEVANT TO THE REGION

Introduction

1. In response to the request from the 27th session of the Codex Alimentarius Commission (July 2004)[1] on the role of Coordinating Committees, the FAO/WHO Regional Coordinating Committee for Latin America and the Caribbean, at its 14th session (December 2004) "*agreed that its role should be to exercise strategic coordination and to establish the Region's position on issues under discussion in Codex in order to achieve a balance between the interests and concerns of different regions in relation to Codex standards and related texts, and that the planning of regional work should contribute to the strengthening of the Coordinating Committee*".[2] In this context, the Committee also "*agreed that questions of interest to the Region would be a permanent agenda item in the future*".[3]

2. At the 25th session of the Codex Committee on General Principles (April 2009), the discussion on the Terms of Reference of Coordination Committees included a specific request from the FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC) to clarify whether the current Terms of Reference for the Coordinating Committees could be interpreted to give them full freedom to issue regional opinions on all themes under discussion in Codex of strategic importance to the region concerned.

3. The Committee on General Principles (CCGP) took note of the opinions of other Coordinating Committees that generally agreed that the current Terms of Reference should remain unchanged, because the current Terms of Reference were sufficiently broad to allow Coordinating Committees to formulate regional positions among members, where necessary, and that the possibility to carry out this activity was adequately covered by bullet point (g) "exercises a general coordinating role for the Region and such other functions as may be entrusted to it by the Commission".[4]

4. The CCGP concluded the discussion by confirming that full freedom was given under the current Terms of Reference of FAO/WHO Coordinating Committees to issue regional opinions on all themes under discussion in Codex of strategic importance to the region concerned and to promote the adoption of regional positions on strategic subjects, and that there was therefore no need to modify the Terms of Reference.

5. In this regard, Circular CL 2012/38-LAC asked governments to present items on issues of regional interest for consideration at the next Committee meeting (including a summary of the matter of interest, background, issue or concern for the region, as well as any recommendations or conclusions put forward for the Committee's consideration).

6. The proposals received were compiled by the CCLAC Coordinator. Six countries (Brazil, Colombia, Cuba, Costa Rica, Dominican Republic and Uruguay) expressed their concerns and/or interests relating to Codex work.

7. Below is a summary of proposals, along with any conclusions and/or recommendations.

8. The proposals presented by the Region's member countries in response to CL 2012/38-LAC are detailed in the Annex.

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[1] ALINORM 03/41, para. 154; ALINORM 04/27/41 para. 135-136.
[2] ALINORM 05/28/36, para. 49
[3] ALINORM 05/28/36, para. 70
[4] ALINORM 09/32/33, para.100-103

Risk Analysis Principles applied by the Pesticide Residues Committee

Brazil, Colombia, Costa Rica, Cuba and Paraguay have voiced particular concerns relating to the inconsistent risk analysis principles of the various Codex committees, as there are no other Codex committees that establish lifespans for their standards (with a special emphasis on the provisions of the Procedural Manual, par. 1 and 34, "General Principles of the Codex Alimentarius*", "*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" and its session on "Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius"). The matter will be analysed by the Committee on General Principles in 2015, as per the Codex Alimentarius Commission.

Recommendation

To ask the Codex Committee on General Principles to analyse the inconsistency in the risk analysis of the various committees, and to recommend a way of solving these inconsistencies, such that the Codex Pesticide Residues Committee may make its decisions in accordance with other Committees, as Codex decision-making should be based on scientific principles, and pesticide MRLs should therefore not be revoked based on the passage of time.

Implementation of the Codex Strategic Plan 2014-2019

Brazil referred to the need to implement the Codex Strategic Plan 2014-2019 in accordance with the Codex Procedural Manual. This would ensure that the Codex continues to base its decisions on scientific principle and to take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade (rather than factors outside its mandate).

Recommendations

Implementation of the Codex Strategic Plan 2014-2019 should be strictly in accordance with the current Codex Procedural Manual. This ensures that that the Codex continues to base its decisions on scientific principle and to take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade (rather than factors outside its mandate).

Codex needs to base its decisions on scientific principles and risk assessment, in view of the status of Codex as a reference body under the WTO SPS Agreement, and should not base its decisions on factors outside its mandate. The Codex Secretariat should maintain a firm line and ensure proper governance so that Codex remains focused on its mandate and continues to contribute to public health and maintaining fair trade practices in the years to come.

Procedures for the Elaboration of Codex Standards and Related Texts

Brazil expressed its concern on changes to the Procedural Manual, and particularly on the Procedures for the Elaboration of Codex Standards and Related Texts, as the current provisions on the Rules are sufficient in terms of transparency and coordination of work among the general subject committees and commodity committees.

Recommendation

Not to support either proposed amendment submitted to the 37th session of the Commission for adoption (Appendix IV), for the following reasons:

Proposal 1: *Information on the relation between the proposal and other existing Codex documents,* ***as well as any ongoing Codex work;***

It is not necessary to add "***as well as any ongoing Codex work***", as this is already included in the following wording of the text: "*other existing Codex documents"***.** Were the reference to existing Codex standards or adopted Codex documents, then there might be a need to add the proposed wording.

Proposal 2: "*Advice on the need for coordination of work among the relevant Codex subsidiary bodies"*

Throughout the process of monitoring the Strategic Plan and the process to develop standards, the Executive Committee carries out coordination work that we deem sufficient to promote coordination among Codex subsidiary bodies.

Recombinant Bovine Somatotropin (rBST) – Standard held at Step 8

Brazil and Costa Rica remarked that recombinant bovine somatotropin (rBST) is a veterinary drug that has been held at step 8 since 1999, despite having the scientific basis needed for approval by the Codex Alimentarius Commission. As it will be analysed once more at the 2015 meetings of the Committee on Residues of Veterinary Drugs in Foods (CCRVDF) (at its 22nd session) and the Codex Alimentarius Commission, the CCLAC should adopt a position on the matter based on the use of the scientific principle in Codex decision-making.

Recommendation

Given that this discussion will be included on the agenda of the 22nd session of CCRVDF and the 38th session of CAC (both of which are to be held in 2015), the recommendation for CCLAC countries – based on the repeated assessments of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluding that the drug is harmless – is to support the approval of MRLs for bovine somatropins, on the basis that the region has maintained the position of supporting the scientific principle in Codex decision-making.

Proposed amendments to the Terms of Reference of the Committee on General Principles

Brazil and Costa Rica proposed a harmonization of the Terms of Reference to be discussed at the next CCGP meeting.

Recommendation

For CCLAC to consider the aspects discussed in the relevant document in order to propose a harmonization to the Terms of Reference to be discussed at the next CCGP meeting in 2015.

Meetings of coordinating countries during CCEXEC

Costa Rica considered it important to propose that the Codex Executive Committee (CCEXEC) establishes an informal meeting for countries that are Codex Regional Coordinators to exchange experiences with a view to increasing interregional coordination (on the Thursday of the CCEXEC meeting prior to the Codex Alimentarius Commission).

Recommendations

For Codex to encourage meetings between regional coordinators that are not additional meetings, but rather informal coordinator meetings involving open and sincere discussions of the issues being discussed in Codex or that regions wish to table.

For informal meetings to be held in the framework of the Codex Commission and the meetings of the Committee on General Principles.

Shiga-like toxin producing E. coli (STEC) in meat and other food

Uruguay presented its concern to CCLAC and the Committee on Food Hygiene (CCFH) on the prioritization of the issue of “Shiga-like toxin producing E. coli (STEC) in meat and other food”.

Recommendations

To propose the formulation of a guideline or standard to establish procedures for checking the possible presence of STEC O157 or non-0157 STEC in food.

To request scientific advice from WHO/FAO for the purposes of carrying out a microbiological risk assessment of intensive and extensive meat-production systems (as well as other foods considered high risk or that may constitute public health issues).

Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork

Brazil felt that the proposed Guidelines should be general, without any mention of specific products or raw materials, as the purpose of this type of document could be misinterpreted and the information used for unnecessary health regulations that would not serve to protect consumer health or ensure fair practices in the food trade.

Recommendations

The examples used in the proposed Guidelines should be general, without any mention of specific products or raw materials, as the purpose of this type of document could be misinterpreted and the information used for unnecessary health regulations that would not serve to protect consumer health or ensure fair practices in the food trade.

Statements such as “subject to the national legislation of the importing country” or “subject to approval by the relevant authority” should not be used in the Codex.

Other species, such as *Bos indicus,* should be included when referring to beef in these Guidelines.

Note 161

Costa Rica put forward a new proposal for the wording of the replacement for Note 161 in the use of some sweeteners in food categories from the *General Standard for Food Additives (*GSFA).

Recommendation

Costa Rica proposed that consideration be given to the following wording for note 161: *"**To replace sugar wholly or partly, or in products where no sugar is added during manufacture**."*

Justification: The use of sweeteners would not be subject to a reduction in energy as in the current proposal. The technological function of these additives is to sweeten, rather than reduce calories. Costa Rica considered that the requirement to limit the use of sweeteners to products with a "25% reduction in energy" limits innovation. The industry has already been working to reduce the calories of many products in several countries. However, technological considerations such as impact on taste must also be considered. In some cases, energy has been reduced by more than 25% using sweeteners in order to meet consumers' taste expectations as much as possible.

Use of Note 161 in the Codex Committee on Food Additives (CCFA)

Brazil recommended that considerable collaborative efforts be made to replace Note 161 with one that does not refer to national legislation and that does consider concerns relating to the compliance with the GSFA preamble. It also recommended that other Codex committees ensure that new provisions referring to Note 161 or national legislations are no longer used in Codex standards.

Recommendation

Although the use of Note 161 has been significantly reduced in provisions on GSFA provisions on food additives in recent years, the use of this Note has caused a major issue for CCFA, which has made considerable yet unsuccessful efforts to resolve the situation.

Owing to the status of the Codex standards in the framework of the WTO SPS Agreement, the Codex Alimentarius (as a reference organization) has to base its decisions on solid scientific principles or knowledge, bearing in mind its purpose to protect consumer health and ensure fair food trade practices.

Although the Codex Alimentarius recognizes that standards and related texts are not a substitute or alternative to national legislation, while also recognizing that each country's laws and administrative procedures contain provisions with which it is essential to comply, the use of notes that refer to national legislation in the Codex standards (such as Note 161) undermine Codex Alimentarius efforts to provide harmonized international standards on food additives.

Considerable collaborative efforts should therefore be made to replace Note 161 with one that does not refer to national legislation and that does consider concerns relating to the compliance with the GSFA preamble. It also recommended that other Codex committees ensure that new provisions referring to Note 161 or national legislations are no longer used in Codex standards.

Processed Cheese

Uruguay analysed the discussion document on processed cheese, with a view to strengthening a regional consensus on the most relevant aspects, in the run up to a physical meeting scheduled for early 2015 on the proposed draft of the Standard.

Recommendations

To present a solid regional position in the various stages of the drafting of the standard, seeking alternatives for those points on which broad consensus was not reached in previous discussions.

In our opinion, the most relevant points concern composition:

- The content of cheese is one of the points creating the most divergence of opinions among countries. The aim should be a flexible position stating that cheese is the main ingredient, with a minimum value to be set. Furthermore, a minimum cheese variety to be processed should be established for processed cheeses with a variety name (this minimum cheese content could also be expressed in a maximum lactose content, minimum starch or other options).
- The addition of other ingredients such as starch and gelatine may be related to the minimum cheese content, and their use or otherwise could be regulated by each country's relevant authorities, thereby helping to achieve consensus for the drafting of the standard.
- The product labelling is the information used by the consumer, and should be clear and complete. Detailing cheese content on the label helps to prevent deception and makes it possible to use variable percentages of cheese in the product.

Annex

RISK ANALYSIS PRINCIPLES APPLIED BY THE CCPR

Brazil, Colombia, Costa Rica, Cuba and Paraguay have raised particular concerns on this matter (for further details, see: ALINORM 07/30/33, (par. 27- 34), ALINORM 08/31/24, (par. 129 to 134), CX/PR 08/40/7, ALINORM 09/32/24 (par. 178), REP14/CAC (par. 46)).

Brief summary of the issue

The Procedural Manual, under "*General Principles of the Codex Alimentarius",* state:

"The Codex Alimentarius Commission and its subsidiary bodies are committed to revision as necessary of Codex standards and related texts to ensure that they are consistent with and reflect current scientific knowledge and other relevant information. When required, a standard or related text shall be revised or removed in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts. Each member of the Codex Alimentarius Commission is responsible for identifying, and presenting to the appropriate committee, any new scientific and other relevant information which may warrant revision of any existing Codex standards or related texts". However, there is no period established for the validity of its documents.

Furthermore, the Procedural Manual (under 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, par. 1) state:

"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". It is therefore vital for Codex decision-making to be based on scientific principles, rather than other factors. This principle is not consistent with decisions taken within CCPR, as they continue to revoke maximum residue limits on the basis of the passage of time. The revision of food safety standards should be based on scientific risk assessment and that MRLs should therefore be re-evaluated by JMPR when new scientific data were available and should not be revoked only on the basis of commercial considerations or lapse of time, especially in view of the status of Codex standards in the framework of the SPS Agreement (this comment was made by Chile, see ALINORM 09/32/36, par. 155).

With regard to the above, the Procedural Manual (under Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*"* par. 34) states:

"In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade among its Member countries and select measures that are no more trade-restrictive than necessary". In this sense, revoking MRLs without a scientific basis to determine harm to health would dilute such legitimate Codex objectives.

There are no other Codex committees that set a time period for their standards.

Recommendation

To ask the Codex Committee on General Principles to analyse the inconsistency in the risk analysis of the various committees, and to recommend a way of solving these inconsistencies, such that the Codex Pesticide Residues Committee may make its decisions in accordance with other Committees, as Codex decision-making should be based on scientific principles, and pesticide MRLs should therefore not be revoked based on the passage of time.

Implementation of the Codex Strategic Plan 2014-2019

Brazil: need to implement the Codex Strategic Plan 2014-2019 in accordance with the Codex Procedural Manual. This would ensure that the Codex continues to base its decisions on scientific principle and to take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade (rather than factors outside its mandate). For further details, see the Procedural Manual (under 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, par. 1 and 2, document G/SPS/GEN/1253, 14 June 2013).

Brief summary of the issue

"The integration of other legitimate factors in risk management should not create unjustified barriers to trade; particular attention should be given to the impact on developing countries of the inclusion of such other factors."

The Codex Strategic Plan 2014-2019 was approved at the 36th Session of the Codex Alimentarius Commission (2013) (see REP13/CAC, par. 173), and Brazil and Costa Rica consider that activity *2.1.3 – Ensure that all relevant factors are fully considered in exploring risk management options in the context of Codex standard development* – contains provisions of concern to some countries of the Latin America and Caribbean Region.

In 2014, the Executive Committee and the Commission agreed to set up a framework for following up implementation of the Strategic Plan, including mechanisms for the systematic compilation of data.

Real or potential impact of the matter on Codex and the Region's countries

According to document G/SPS/GEN/1253 of 14 June 2013, scientific principles are the essential basis for establishing and, where relevant, updating Codex standards, guidelines and recommendations. In order to function properly, the multilateral trade system must have knowledge, data and resources that can be used to improve international procedures and quickly establish health and phytosanitary standards based on scientific principles. Negotiators of the SPS Agreement clearly stipulated in the Agreement text that Codex was the relevant international standard-setting organization in food safety because they recognized that its standards were based on scientific principles and risk assessment.

Science should form the basis for food standards and the national and international control systems, in order to ensure the production of safe food and consumer protection. Furthermore, measures related to food safety improve the sustainability of food supply chains, facilitate trade and help guarantee food security.

Many Members have often stated, in SPS and other settings, their concern for the increase in sanitary and phytosanitary measures not based on international standards, guidelines or recommendations (or those with insufficient scientific basis). These measures can unduly restrict trade and appear motivated by aims that are not the legitimate aims expressed in international trade standards.

In the light of these recent concerns, and with a view to achieving the objectives of the SPS Agreement, it is important to reaffirm:

- The need for international standards, guidelines and recommendations based on scientific principles;
- The need to support and strengthen confidence in international SPS standard-setting organizations, and particularly Codex;
- The need for scientific basis whenever a Member decides to impose sanitary or phytosanitary measures that represent a higher level of protection than that afforded by measures based on the relevant international standards, guidelines or recommendations.

The Members of the SPS Committee can make a positive contribution to minimizing the negative effects on trade through their actions within the SPS Committee itself and in other relevant international SPS standard-setting organizations, to ensure that standards, guidelines and recommendations are faithful to the spirit and objective of the SPS Agreement.

Recommendations

Implementation of the Codex Strategic Plan 2014-2019 should be strictly in accordance with the current Codex Procedural Manual. This ensures that that the Codex continues to base its decisions on scientific principle and to take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade (rather than factors outside its mandate).

Codex needs to base its decisions on sound science, in view of the status of Codex as a reference body under the WTO SPS Agreement, and should not base its decisions on factors outside its mandate. The Codex Secretariat should maintain a firm line and ensure proper governance so that Codex remains focused on its mandate and continues to contribute to public health and maintaining fair trade practices in the years to come.

Procedures for the Elaboration of Codex Standards and Related Texts

Brazil expressed its concern on changes to the Procedural Manual, and particularly on the Procedures for the Elaboration of Codex Standards and Related Texts. For further information, see REP14/GP (par. 88-98), CX/GP 14/28/9.

Brief summary of the issue

The changes to the Procedural Manual, and particularly on the Procedures for the Elaboration of Codex Standards and Related Texts are not necessary, as the current provisions on the Rules are sufficient in terms of transparency and coordination of work among the general subject committees and commodity committees.

Recommendation

Not to support either proposed amendment submitted to the 37th session of the Commission for adoption (Appendix IV), for the following reasons:

Proposal 1: *Information on the relation between the proposal and other existing Codex documents,* ***as well as any ongoing Codex work;***

It is not necessary to add "***as well as any ongoing Codex work***", as this is already included in the following wording of the text: "*other existing Codex documents"***.** Were the reference to existing Codex standards or adopted Codex documents, then there might be a need to add the proposed wording.

Proposal 2: "*Advice on the need for coordination of work among the relevant Codex subsidiary bodies"*

Throughout the process of monitoring the Strategic Plan and the process to develop standards, the Executive Committee carries out coordination work that we deem sufficient to promote coordination among Codex subsidiary bodies.

Recombinant Bovine Somatotropin (rBST) – Standard held at Step 8

Brazil and Costa Rica remarked that recombinant bovine somatotropin (rBST) is a veterinary drug that has been held at step 8 since 1999, despite having the scientific basis needed for approval by the Codex Alimentarius Commission. As it will be analysed once more at the 2015 meetings of the Committee on Residues of Veterinary Drugs in Foods (CCRVDF) (at its 22nd session) and the Codex Alimentarius Commission, the CCLAC should adopt a position on the matter based on the use of the scientific principle in Codex decision-making. For further information, see: CX/GP 12/27/3 (par.20-30), REP12/CAC, (par. 80-86), REP13/CAC, (par. 84), Report No. 78 of JECFA submitted by CAC is available at: http://www.fao.org/3/a-i3745e.pdf (November, 2013).

Brief summary of the issue

MRLs for BSTs have a scientific basis for being approved by the Codex Alimentarius Commissions (JECFA assessments No. 40, No. 50 and No. 78), and failure to approve them would weaken Codex work and hamper the harmonization of national legislations (as bovine somatropins are registered in the following 21 countries: Bolivia (Plurinational State of), Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Honduras, Jamaica, Lebanon, Mexico, Pakistan, Panama, Peru, Republic of Korea, South Africa, Uruguay, Venezuela (Bolivarian Republic of), United States of America and Puerto Rico).

Recommendation

Given that this discussion will be included on the agenda of the 22nd session of CCRVDF and the 38th session of CAC (both of which are to be held in 2015), the recommendation for CCLAC countries – based on the repeated assessments of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluding that the drug is harmless – is to support the approval of MRLs for bovine somatropins, on the basis that the region has maintained the position of supporting the scientific principle in Codex decision-making.

Proposed amendments to the Terms of Reference of the Committee on General Principles

Brazil and Costa Rica: see background in the following documents: REP14/GP (par. 36-43); REP14/CAC (par. 37-41). Recommendation

For CCLAC to consider the aspects discussed in the relevant document in order to propose a harmonization to the Terms of Reference to be discussed at the next CCGP meeting in 2015.

Meetings of coordinating countries during CCEXEC

Costa Rica considered it important to propose that the Codex Executive Committee (CCEXEC) establishes an informal meeting for countries that are Codex Regional Coordinators to exchange experiences with a view to increasing interregional coordination (on the Thursday of the CCEXEC meeting prior to the Codex Alimentarius Commission).

Brief summary of the issue

Lack of interregional coordination.

Recommendations

For Codex to encourage meetings between regional coordinators that are not additional meetings, but rather informal coordinator meetings involving open and sincere discussions of the issues being discussed in Codex or that regions wish to table.

For informal meetings to be held in the framework of the Codex Commission and the meetings of the Committee on General Principles.

Shiga-like toxin producing E. coli (STEC) in meat and other food

Uruguay presented its concern to CCLAC and the Committee on Food Hygiene (CCFH) on the prioritization of the issue of "Shiga-like toxin producing E. coli (STEC) in meat and other food".

Background: The group of Shiga-like toxins producing E. coli (STEC) that are verotoxin producing or verotoxigenic (**VTEC**) are also called enterohaemorrhagic (**ECEH)**, and include the strains *E.coli* O157:H7 and other non-O157:H7 strains.

The **STEC** is a group of *E. coli* strains able to produce toxins that are very similar to that produced by *Shigella dysenteriae* type 1.

Shiga toxins can be detected using the Vero cell toxicity test, which is why this group is also known as verotoxin producing or verotoxigenic (**VTEC**) *E. coli*.

E.coli Shiga toxins (verotoxins) have different clinical presentations in humans, ranging from simple diarrhoea to haemorrhagic colitis, which can turn into haemolytic uraemic syndrome (**HUS**). That is why the group is also known as enterohaemorrhagic *E. coli* (**ECEH**).

Escherichia coli was first identified as a human pathogen in 1982, when the United States detected two outbreaks of haemorrhagic colitis caused by *E.coli* O157:H7 (which is rare to this day).

Since then, there have been and continue to be recorded outbreaks caused by *E.coli* O157:H7, as well as other serotypes such as O26, O103, O104, O111, O113, O121 and O145.

CCFH ACTIVITIES

In 1999, the Codex Committee on Food Hygiene (CCFH) defined and agreed on pathogen-product combinations that would have to be considered by FAO/WHO experts using a microbiological risk assessment of food, including enterohaemorrhagic *E. coli* in sprouted seeds and minced beef.

Various CCFH sessions have confirmed that the work on enterohaemorrhagic *Escherichia coli* remains a priority, although there has been no significant progress in recent years.

At the most recent CCFH meeting (the 45th session in 2013), the CCFH Working Group for Establishment of Priorities agreed that the future CCFH work programme could include a new proposal on controlling verotoxigenic *E. coli* (VTEC) in beef.

The Committee agreed to send members a Circular to ask them about the work priorities for the Committee's future programme.

Uruguay's response to the Circular prioritized the new proposal on controlling verotoxigenic *E. coli* (VTEC) in beef.

Although the matter has been discussed by the CCFH, the main focus has been on *E.coli* O157:H7. A review is therefore requested in order to establish standards or guidelines that include the non-O157 STEC, as the number of cases worldwide has risen (as well as underreporting owing to insufficient epidemiological and laboratory monitoring). It should also be pointed out that analytical methods are more advanced for detecting *E.coli* O157 than non-O157 *E.coli*.

Brief summary of the issue

For the past several years, the United States and some European Union countries have drafted and applied standards on *E. coli* O157:H7 and other non-O157:H7 STEC.

For instance:

In 2008, the United States established requirements for *E. coli* O157:H7. In 2012, the United States established requirements for non-O157:H7 STEC to determine the presence of serogroups O26, O45, O103, O111, O121 and O145. (Docket nº FSIS-2010-0023).

The European Union is working on a draft document for the control of STECS (O104, O157, O103, O111, O145). Although there are no general guidelines on the issue, several Member States apply various unharmonized procedures, such as rejecting meat shipments in some cases that have been classed as potentially pathogenic. The rejection of beef and lamb/mutton containers from various export countries has risen from 0 in 2011 to 11 in 2012, 47 in 2013 and 37 in the first eight months of 2014.

As a result, countries that supply meat to European countries (as well European importers) are concerned about the high economic impact of such rejections.

In the light of the lack of international harmonization, it is vital to study and formulate a Codex guideline or standard that tackles this issue, such that food can be assessed based on its risk level of significance for public health, as well as establishing (on a case-by-case basis) the priority strains and the appropriate diagnostic methods based on scientific criteria.

This should also consider the various types of production and consumption of a food, as well as study of the associated food chain.

Humans can be infected through direct contact with an infected person or animal carrier, or indirectly through the atmosphere, food, drinking water or surface water containing STEC-contaminated faecal matter of human or animal origin.

Recommendation

To propose the drafting of a guideline or standard that defines procedures to check for the possible presence of STEC O157 and non-O157 in food.

To request scientific advice from WHO/FAO for the purposes of carrying out a microbiological risk assessment of intensive and extensive meat-production systems (as well as other foods considered high risk or that may constitute public health issues).

OTHER BUSINESS: GUIDELINES FOR THE CONTROL OF NONTYPHOIDAL SALMONELLA SPP. IN BEEF AND PORK MEAT

BRAZIL: the proposed guidelines for the control of nontyphoidal *Salmonella* spp. in beef and pork meat was approved as a new work at the last Codex Alimentarius Commission – CAC (2014). This document will be part of the discussion at 46th session of Codex Committee on Food Hygiene (Lima, Peru, 17 – 21 November 2014). The document was prepared by the electronic working group led by the United States of America and co-chaired by Denmark.

The U.S. and Denmark prepared initial drafts of the Guidelines, one for beef and one for pork.

The proposed draft Guidelines are organized to be similar in approach with the Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat (CAC/GL 78-2011).

The preharvest section will reference the appropriate OIE chapter, which is currently under development or to be developed.

The CCFH46 is invited to consider the Proposed Draft Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (Parts1, 2 and 3). Part 1 contains the language common to the control of Salmonella in beef and pork; Part 2 contains the sections specific to beef controls; and Part 3 contains the sections specific to pork controls.

The EWG recommends that the Committee also considers the following list of issues:

The structure and format of the document. The Guidelines are currently in three parts to facilitate drafting. The Committee is asked if they should be incorporated into one document, or left as three, with the common language sections being the main document with the beef and pork specific sections attached as appendices (or annexes). Consider a thorough review of the control measures in the guidelines to assure that there is justification or validation of GHP-based measures and documentation for reduction of *Salmonella* for the hazard-based measures. Also, measures overlapping the general measures in the Code of Hygienic Practice for Meat (CAC/RCP 58-2005) should be identified to eliminate unnecessary duplication.

Consider whether to seek scientific advice. The Committee at the 45th Session noted that at this stage no scientific advice would be required from FAO and WHO, but that it was important for FAO and WHO to participate in the EWG in order to provide necessary information. The Representative of FAO, speaking on behalf of FAO and WHO at the 45th Session, emphasized that, should the Committee require scientific advice, it was important to consider that it takes an average of 18 to 24 months for FAO and WHO to deliver robust scientific advice and therefore this needed to be factored into the timelines for development of the Guidelines. The Committee should consider if, and when, a consultation from FAO and WHO will be necessary. A consultation by FAO and WHO was convened to review the Salmonella in chicken meat guideline and was found to be very useful for finalizing that document. A similar consultation for the beef and pork guidelines could be similarly useful. It is recommended that the Committee requests that FAO/WHO:

- Conduct a literature search to ensure that any relevant measures for control of Salmonella in beef and pork are identified for the Committee's effort.
- Convene an expert consultation meeting to review the draft document for beef and pork, and use the literature review to assist them in their review.
- Consider the need for a risk profile or a web-based tool.

  The references to a risk profile and to a web-based tool, which were originally part of the previous chicken Codex document, were not included in these documents for beef and pork. The main reason is that neither exists for control of Salmonella in beef and pork. In terms of a risk profile, the Committee should consider the need for one given that the discussion paper presented at CCFH45 detailed the global issue with Salmonella in beef and pork and its contribution to foodborne disease and in light of FAO and WHO limited resources. As for a web-based tool, the experience with the chicken-based web tool is very limited at this time. CCFH should discuss whether another web tool for beef and pork will be useful to develop at this time.

2. Objectives and Scope

The primary objective of these Guidelines is to provide information to governments and industry on the control of nontyphoidal Salmonella in beef and pork meat that aim to reduce foodborne disease whilst ensuring fair practices in the international food trade. The Guidelines provide a scientifically sound international tool for robust application of GHP- and hazard-based approaches for control of Salmonella in beef and pork meat according to national risk management decisions. The control measures that are selected can vary between countries and production systems.

These Guidelines are applicable to all nontyphoidal Salmonella that may contaminate beef and pork meat (Bos Taurus and Sus scrofa domesticus) and cause foodborne disease. The primary focus is to provide information on best practices that may be used to prevent, eliminate, or reduce levels of nontyphoidal Salmonella in beef and pork meat.

The Guidelines in conjunction with the OIE can apply to generic steps in a "controlled primary production-to-consumption" food chain for beef and pork meat produced in commercial farming systems.

Provision of flexibility in application of the Guidelines is an important attribute, when applied to the diverse beef and pork industry around the world. They are primarily intended for use by government risk managers and industry in the design and implementation of food safety control systems.

The Guidelines systematically present GHP-based control measures and examples of hazard based control measures. GHPs are pre-requisites to making choices on hazard-based control measures. Examples of hazard-based control measures are limited to those that have been scientifically evaluated as being effective under conditions of commercial use. Countries should note that these hazard-based control measures are indicative only and the references provided should be reviewed to assist application. The quantifiable outcomes reported for control measures are specific to the conditions of particular studies and would need to be validated under local commercial conditions to provide a meaningful estimate of hazard reduction. Government and industry can use choices on hazard-based control measures to inform decisions on critical control points (CCPs) when applying HACCP principles to a particular food process.

Several hazard-based control measures as presented in these Guidelines are based on the use of physical, chemical and biological decontaminants to reduce the prevalence of Salmonella positive carcasses and/or its concentration on positive carcasses. The use of these control measures is subject to approval by the competent authority, where appropriate. Also these Guidelines do not preclude the choice of any other hazard-based control measure that is not included in the examples provided herein, and that may have been scientifically validated as being effective in a commercial setting.

3. Identification of the Problem

3.1. Examples

In the section II (Elaboration of Codex texts - Guidelines on the elaboration and/or revision of codes of hygienic practice for specific commodities) of the Codex Procedural Manual states: Provisions in Codex Codes of Hygienic Practice should be drafted in a sufficiently clear and transparent manner such that extended explanatory material is not required for their interpretation.

Therefore the examples put in Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat should be general by eliminating any mention to specific products or commodities since the purpose of this type of document could be misinterpret and use the information there in as unnecessary sanitary requirements without protecting the health of the consumers and ensuring fair practices in the food trade.

3.2. Scientific Base

In view of the status of Codex standards under the WTO SPS Agreement, as a reference body, Codex needs to base its decisions on sound science basis.

Diversification of national legislation has created impediments to international trade but recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide and confusion should be avoided between justification of national measures under the SPS Agreement and their validity at the international level.

"*While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations without scientific basis should be avoided".*

Although the members of Codex have range of social, economic, political and cultural situations, these differences should not block the approval of new standards nor lead to the rejection of internationally accepted scientific research.

Codex should avoid statements such as "subject to national legislation of the importing country" or "subject to approval by the competent authority" because it could set a precedent that:

- 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;
- represents a risk for the role of Codex as an international standard-setting body; and
- weakens, and debilitates the multilateralism system of commerce around the world.

Once a *Codex* standard is adopted, every country still maintains the right to adopt any sanitary measures, as long as they are based on sound scientific justification. According to Art 3.3 of the SPS Agreement, "*Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5*".

In addition as pointed out by many countries in document G/SPS/GEN/1143 of 19 March 2012, Members should, when determining the appropriate level of protection, take into account the objective of minimizing the negative trade effects. The increase in the number of SPS measures that have inadequate scientific justification is a point of concern readily raised by many Members in the SPS Committee. These measures often unduly restrict trade and appear to be associated with objectives that are not deemed as legitimate under international trade rules.

4. Recommendations

Examples put in Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat should be general by eliminating any mention to specific products or commodities since the purpose of this type of document could be misinterpret and use the information there in as unnecessary sanitary requirements without protecting the health of the consumers and ensuring fair practices in the food trade.

Statements such as subject to national legislation of the importing country or subject to approval by the competent authority should not be used in Codex.

It is necessary include other species such as *Bos indicus* when referring to beef in these Guidelines.

NOTE 161

Costa Rica: requests ruling on new proposal for the wording of the replacement for Note 161 in the use of some sweeteners in food categories from the General Standard for Food Additives (GSFA). See background in the following documents: ALINORM 09/32/12, (par. 89), ALINORM 10/33/12, (par.70-75), REP11/FA, (par.107-114), REP12/FA, (par. 116-130), REP13/FA, (par.144-153), REP14/F, par. 91-97).

Brief summary of the issue

In 2012, the CCLAC agreed to "*recommend to the CCFA to (a) evaluate on a case-by-case basis all uses of note 161 and to set a time limit for its elimination from the GSFA and (b) not use such note any longer in the development of new maximum level in the GSFA*". In 2013, CCFA decided to evaluate Note 161 on a case-by-case basis to explore the use of alternative Note(s) or other approaches that could address the concerns which have resulted in the application of Note 161, or to demonstrate that Note 161 is no longer needed for the particular provision. However, the discussion continues with a new drafting proposal to replace Note 161 in some GSFA food categories in which aspartame and acesulfame are used (with the risk of excluding many food products from the market).

The current proposal "*For use only in energy-reduced food or food with no added sugars as defined in CAC/GL 23-1997*" is a huge barrier to the industry producing nutritionally enhanced food worldwide, and CCLAC countries are therefore asked to support the wording proposed by Costa Rica.

Real or potential impact of the matter on the Codex and the Region's countries

The application of the new proposed note ***"For use only in energy-reduced food or food with no added sugars as defined in CAC/GL 23-1997"*** could create barriers to international trade and compromise the value of the Codex scientific base, as there are no current technical criteria for limiting the use of certain sweeteners in food on the basis of safety.

There is evidence that a large number of products currently on sale in the region would be seriously impacted by the approval of a note such as the one proposed in the Codex framework (see Appendix A).

Recommendation

Costa Rica proposed that consideration be given to the following wording for Note 161: ***"To replace sugar wholly or partly, or in products where no sugar is added during manufacture."***

Justification: The use of sweeteners would not be subject to a reduction in energy as in the current proposal. The technological function of these additives is to sweeten, rather than reduce calories. Costa Rica considered that the requirement to limit the use of sweeteners to products with a "25% reduction in energy" limits innovation. The industry has already been working to reduce the calories of many products in several countries. However, technological considerations such as impact on taste must also be considered. In some cases, energy has been reduced by more than 25% using sweeteners in order to meet consumers' taste expectations as much as possible.

USE OF NOTE 161 AT THE CODEX COMMITTEE ON FOOD ADDITIVES (CCFA)

Brazil: The development and use of Note 161 has been discussed a number of times over recent years at the Codex Committee on Food Additives (CCFA). Note 161 was first used at the 39th Session of the CCFA in 2007 when a lengthy discussion resulted in a compromise on a new note that could be associated with certain sweetener provisions. The agreed text was:

"Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble".[5]

The intent of the note, which could be associated with sweetener provisions, was to make clear that national authorities could require further restrictions within their jurisdictions on the use of sweeteners to ensure that the use of sweeteners would not mislead the consumer, has advantages, and is technologically justified.

[5] 3.2 JUSTIFICATION FOR THE USE OF ADDITIVES
The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable:
a) To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;
b) To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;
d) To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities. (Preamble to the Codex General Standard for Food Additives - GSFA, Codex STAN 192-1995)

During the 41st Session of the CCFA in 2009, the Committee agreed that the use of Note 161 should be limited as much as possible in order not to undermine the purpose of the General Standard for Food Additives (GSFA) to provide harmonized food additive provisions. The Committee noted the concerns of several delegations on the possible adverse impact of note 161 on the objectives of the GSFA and agreed to request comments on the application of this note, in particular, where and when it should be used.

In the 42nd and 43rd Sessions of the CCFA in 2010 and 2011, respectively, the Committee had been divided between delegations concerned over the implications of the use of Note 161 on trade which, in their view, undermined the international standard-setting efforts of Codex and the value of Codex's science based decisions and other delegations that felt that the use of Note 161 was important in particular because, in their view, the procedures established in Section 3.2 of the Preamble of the GSFA and in the Procedural Manual had not been rigorously followed. In these years, two electronic working groups (EWG) was established, led by the Netherlands and South Africa, with the aim to prepare a discussion paper containing proposals for criteria and conditions of the use of note 161 in the GSFA and to formulate recommendations to facilitate a uniform implementation of Section 3.2 of the Preamble of the GSFA to address the use of Note 161.

The discussion continued in the 44th Sessions of the CCFA in 2012. There was no objection in the Committee that the use of Note 161 should be reduced; however, there was no consensus that the Note should not be used anymore or that it should be deleted. Different proposals were made how to reduce or clarify the use of Note 161, but there was no agreement between the delegations again. As there was no consensus in the Committee on either of these proposals, the Chair of CCFA concluded that the discussion on the Agenda Item should be suspended.

In 2013, during the 45th Session of the CCFA, the Delegation of Australia prepared a discussion paper which summarized the discussion on Note 161 at the last two sessions of the Committee and highlighted the current options to move forward with this matter, namely: (i) do nothing; (ii) replace, if possible, the Note by other Note(s); (iii) revise the Preamble and remove the Note; (iv) delete the Note; and (v) establish criteria for when the Note can be used. Many delegations supported option (ii) and the consideration of Note 161 on a case by case basis.

Thereby, the Committee agreed to establish a new electronic Working Group led by the United Kingdom with the assistance of the United States of America to identify concerns regarding the provisions of sweeteners in specific food categories with Note 161 and the reasons for these concerns. The information provided to the Working Group should be used, in conjunction with the principles set out in Section 3.2 of the Preamble of the GSFA, to explore the use of alternative Note(s) or other approaches that could address the concerns which have resulted in the application of Note 161, or to demonstrate that Note 161 is no longer needed for the particular provision.

In pre-session Working Group, at the 46th session of the CCFA in 2014, there appeared to be a strong consensus to remove Note 161 from the GSFA and that the use of sweeteners was justified in energy reduced foods and foods with no-added sugar. However, it was evident that the Working Group could not reach consensus on the use of sweeteners in food which do not meet the definition of energy-reduced or no-added sugars.

Thus, after an extensive debate, the CCFA Chairperson noted that between the proposed Notes with the purpose to replace the Note 161 presented in the "Discussion Paper On Use Of Note 161 In Provisions For Selected Sweeteners" (CX/FA 14/46/14), option 3 (For use only in energy-reduced food or food with no added sugars as defined in CAC/GL 23-1997) was included in Recommendation 3, but that this did not imply that in the future the Committee will use the Note (based on Option 3) to solve all the problems related to Note 161.

He further noted that Recommendation[6] gave a mandate to the EWG to explore and assess the consequences and the impact of the Note and that, if the analysis will show huge consequences, the Committee would continue to explore other alternative notes. The Chairperson urged all interested Members and Observers to actively participate and provide information to allow the EWG to accomplish its mandate.

Once again, there was a general support by the Committee to: advance work on Note 161 and to establish a new EWG, led by the United Kingdom with the assistance of the United States of America, to request information on the effect of the application of the following Note: "For use only in energy-reduced food or food with no added sugars as defined in CAC/GL 23-1997" to provisions for sweeteners contained in Appendix 8 of FA/45 CRD 2.

[6] Option 1: "To replace sugar wholly or partly, or in products where no sugar is added during manufacture."
Option 2: "Limited to products in which there is a significant reduction in energy from the use of the sweetener, or where no sugar is added during manufacturing."
Option 3: "For use only in energy-reduced food or food with no added sugars as defined in CAC/GL 23-1997."
Option 4: "Products are energy reduced or with no added sugar" (i.e. to use existing Note 145).

The current EWG will utilize this information to determine if the application of this Note on a general basis for provisions for sweeteners in specific food categories is appropriate, or if alternative Notes can be developed to address concerns for the provisions for sweeteners in specific food categories when the replacement Note is not appropriate. The EWG can make recommendations on:

- The amendment of adopted provisions;
- Progression of provisions within the Step process;
- Progression of new provisions into the Step process.

2. Recommendation

Although the use of Note 161 has decreased significantly in the food additives provisions of the GSFA[7] over the years, the use of this Note has caused a significant problem to the CCFA, which has been making great efforts to resolve the situation, yet without success.

In view of the status of Codex standards under the WTO SPS Agreement, as a reference body, Codex Alimentarius needs to base its decisions on sound science basis, considering the purpose of protecting consumers' health and ensuring fair practices in the food trade.

Although the Codex Alimentarius recognizes that the standards and related texts are not a substitute for, or alternative to national legislation and recognizes also that every country's laws and administrative procedures contain provisions with which it is essential to comply, the use of Notes that make reference to national legislation in Codex standards, such as Note 161, undermines the efforts of the Codex Alimentarius to provide international harmonized food additive provisions.

Therefore, there must be a great collaborative effort for the replacement of Nota161 by another that does not make reference to national legislation and that also consider the concerns related to compliance of the preamble of the GSFA. In addition, CCFA and other Codex Committees should also ensure that new provisions that refer to Note 161 or national legislations are not more used in Codex standards.

Processed Cheese

Uruguay: the country analysed the discussion document on processed cheese, with a view to strengthening a regional consensus on the most relevant aspects, in the run-up to a physical meeting scheduled for early 2015 on the proposed draft of the Standard. See background in documents REP12/CAC, (par. 155-165), REP14/CAC, (par. 108-112).

Brief summary of the issue

This Standard has been debated for years, without any consensus achieved. This led to the revocation of standards and the completion of work by the Committee on Milk and Milk Products. However, the region's insistence on the need to have a standard has resulted in the item returning to the agenda and a reopening of the Committee on Milk and Milk Products.

Uruguay considers that this is the last opportunity to make progress in drafting a processed cheese standard, and we should focus the region's efforts on ensuring it includes the essential requirements that give the product its identity, while giving each country's relevant national authorities the possibility of specifying other parameters such as those contained in other CODEX standards (for instance, the one governing chocolate).

The lack of international standard makes it difficult to market the product, as each country can establish divergent national standards. In turn, the consumer may be deceived as there is no clear definition of what is meant by processed cheese.

Furthermore, international standards are used as a reference to formulate national standards. Therefore, although a standard leads some aspects open to the interpretation of relevant authorities, it nonetheless helps to harmonize the most pertinent requirements.

Recommendations

To present a solid regional position in the various stages of the drafting of the standard, seeking alternatives for those points on which broad consensus was not reached in previous discussions.

[7] Up to 2011, Note 161 had been assigned to 399 provisions for sweeteners and colours only in the GSFA. Since 2011, no food additive provisions with Note 161 were forwarded to, nor adopted by, the Codex Alimentarius Commission (CAC) - CX/FA 12/44/12.
Codex Alimentarius Commission, Procedural Manual, Twenty-second edition, 2014.

In our opinion, the most relevant points concern composition:

- The content of cheese is one of the points creating the most divergence of opinions among countries. The aim should be a flexible position stating that cheese is the main ingredient, with a minimum value to be set. Furthermore, a minimum cheese variety to be processed should be established for processed cheeses with a variety name (this minimum cheese content could also be expressed in a maximum lactose content, minimum starch or other options).
- The addition of other ingredients such as starch and gelatine may be related to the minimum cheese content, and their use or otherwise could be regulated by each country's relevant authorities, thereby helping to achieve consensus for the drafting of the standard.
- The product labelling is the information used by the consumer, and should be clear and complete. Detailing cheese content on the label helps to prevent deception and makes it possible to use variable percentages of cheese in the product.