



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION
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HISTORY AND IMPLICATIONS
OF THE FOURTH PARAGRAPH OF THE STATEMENTS OF PRINCIPLE

(Prepared by the Codex Secretariat)

1. BACKGROUND

1.1 CCEXEC75 (2018) when discussing the critical review¹ noted concerns regarding the decision of CCRVDF24 (2018)² not to advance the proposed draft MRLs for zilpaterol hydrochloride to Step 5 despite consensus in that Committee on the validity of the relevant JECFA risk assessment. The relevance of considerations beyond the Codex mandate was also questioned.³

1.2 A representative of the FAO Legal Office provided a joint FAO/WHO legal opinion on whether relevant Codex procedures had been followed at CCRVDF24 concluding that there was “no reason to suggest that the decisions taken at the CCRVDF breached any rule of Codex”⁴ (see also Appendix 1, para 35.1).

1.3 In discussing additional suggestions offered by the Legal Office on clarifying procedural considerations, CCEXEC75 requested the Codex Secretariat (in cooperation with the Legal Office and the Codex Chair and Vice Chairs) to prepare a paper on the history and implications of the Fourth Paragraph of the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account* (in the following referred to as Statement 4):

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

1.4 CAC41 endorsed⁵ the conclusions of CCEXEC75 and the present document has been prepared to respond to the request. It contains the history of voting in Codex, the history of the development of the Statements of Principle on the Role of Science (section 2 and appendix 1); a history of the Codex acceptance procedure (section 3 and appendix 2); a possible interpretation of Statement 4 (section 4); reflections on aspects of decision taking in Codex (section 5) and Conclusions (section 6).

1.5 The issue in question is closely related to how Codex takes decisions and how it can reconcile or acknowledge different opinions, considerations and positions of members on complex topics which may go beyond the mandate of Codex, while also being mindful of the need to set standards based on science in a timely manner to protect the health of consumers and ensure fair practices in the food trade. *The Statements of Principle on the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account* were developed to address these issues and in particular Statement 4 was designed to allow those members holding other considerations not to accept a standard without preventing action by Codex, which is why its impact is of particular interest.

¹ CX/EXEC 18/75/2 Add.1, Appendix 4

² REP18/RVDF

³ REP18/EXEC2-Rev.1, para 30

⁴ REP18/EXEC2-Rev.1, paras 31–32

⁵ REP18/CAC, para 12

1.6 Since the adoption of the Statements, Codex has succeeded in adopting hundreds of texts, despite the fact that not all members have accepted the adopted texts (see Section 5.3.2), which could point to either successful implementation of the Statements or be related to the possibility to have reservations mentioned in Codex reports. On the other hand, in particular the topic of MRLs for growth promoting substances, which was at the start of the discussion of the Statements, has troubled the Commission periodically, and for those cases it could be concluded that Statement 4 has not achieved its goal. The present document examines this situation further and looks in particular in section 5 at different ways that Codex members are using to deal with difficult situations. The conclusions summarize the status and make some suggestions for further exploration.

2. VOTES IN CAC (1963-2018)

2.1 Table of votes on standards (see also Appendix 1 for the individual report excerpts)

Year	Topic
1969	Honey
	Margarine (description)
	Margarine (max. water content)
1970	Flour treatment agents
1991	4 MRLs for growth promoting substances
1995 January: WTO established	
1995 July: CAC adopted statements of principle	
1995	5 MRLs growth promoting substances
	MRLs for bST
1997	CCFICS guideline
	MRLs for bST
	Natural Mineral waters
2001 Criteria on "other factors" are included in the statements of principle	
2005 CAC removes acceptance procedure	
2007	Emmental footnote
2011	MRLs for Ractopamine
2012	MRLs for Ractopamine
	MRLs for Ractopamine

2.2 Analysis

2.2.1 In the 56 years of history of the Codex Alimentarius Commission, members voted 14 times on issues related to standards adoption. Five times before the establishment of WTO and 9 times after that. 7 of the votes were related to growth promoting substances. Most votes ended with a narrow margin for or against, showing how divisive the relevant topics were.

2.2.2 Votes on Commodity standards in 1969/70 were decided quickly when the room seemed divided in order to resolve certain issues.

2.2.3 More “serious” voting, touching fundamental principles of Codex, such as basing itself on science and striving to find consensus, started with the vote on four MRLs in 1991, prior to the establishment of the WTO, followed by subsequent votes from 1995 onwards on certain veterinary drugs used for production enhancement (e.g. growth promoting substances), the CCFICS guidelines, Natural Mineral waters and Emmental cheese.

3. THE CODEX ACCEPTANCE PROCEDURE

3.1 Codex texts give Codex members guidance in building up their food safety regulatory regimes without exerting legally binding force. However, Codex texts were meant to be implemented to promote harmonization of rules in international trade and their application and related notification was strongly encouraged by the Commission.

3.2 The Commission established the “acceptance procedure” which was a substantial formal text within the Codex Procedural Manual. Even during its development, the Codex Acceptance procedure was seen as complex and difficult to apply by members. The complexity is admitted in the procedure itself (see appendix 2). It is doubtful if it was ever fully implemented as the Secretariat would have at any time lacked the capacity to follow up on its complex provisions.

3.3 Initially only sufficiently “accepted” Codex texts became Codex standards: The acceptance procedure was part of a 11 step elaboration procedure (step 8: adoption of a “recommended standard”; step 9: recommended standard is sent to all members; step 10: secretariat publishes acceptance notifications received; step 11: text is published as a world-wide Codex standard when the Commission determines that it is appropriate in light of the acceptances received) (See Codex Procedural Manual 4th edition 1975). This was changed in the next edition of the PM (5th edition, 1981), when the current 8 step procedure was implemented.

3.4 The acceptance procedure also contains the notion of Codex standards as “presumptive” standards i.e. the standard should be followed in the absence of another (see also Appendix 2).

3.5 With the adoption of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) in 1995, WTO recognized Codex standards, guidelines and recommendations explicitly as reference points for food safety, independent of formal acceptance of the standards or any other notification in accordance with the Codex acceptance procedure. Codex standards have also served as a reference under the WTO Agreement on Technical Barriers to Trade (TBT Agreement), although that agreement does not mention Codex explicitly.

3.6 Revision of the acceptance procedure to accommodate the situation was discussed at several sessions of the CCGP and CAC. In this context it was also noted that members had not consistently provided the relevant information to the Codex secretariat through the (voluntary) Codex acceptance procedure, whereas under WTO there was a notification requirement.

3.7 CAC28 (2005) agreed to remove the acceptance procedure from the Procedural Manual and the task of monitoring use of Codex standards was entrusted to the FAO/WHO Coordinating Committees (RCC), with limited success. This task is currently being reviewed in the context of the revitalization of the RCC.

4. HISTORY AND POSSIBLE INTERPRETATION OF STATEMENT 4

The origins of the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which other Factors are Taken into Account* date back to CAC19 (1991) when a first vote on MRLs for growth promoting substances was taken. The Statements were adopted at CAC21 (1995) and already at the same session there were further votes on the same topic. In this context it should be noted that the main dissenting parties on MRLs for growth promoting substances also opposed Statement 4 (see Appendix 1 for more information on the history). This section examines Statement 4 in more detail.

4.1 Condition 1: “Agree on the necessary level of protection of public health”

4.1.1 The condition means firstly that the subject under discussion is related to health and safety aspects of a Codex text (“protection of public health”). The *Statements of Principle relating to the Role of Food Safety Risk Assessment* require that “*Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.*” All Codex food safety texts will thus be based on an appropriate risk assessment.

4.1.2 The term “necessary level of protection of public health” is not further defined in Codex but bears some resemblance to “Appropriate level of sanitary or phytosanitary protection” as contained in the WTO-SPS Agreement which is defined as: “The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.”

4.1.3 In the case of an MRL for veterinary drugs for example, the agreement of the level of protection of public health could mean that there is agreement on the value of the MRLs suggested in the relevant JECFA risk assessment for managing the risk.

4.2 Condition 2: “Hold differing views about other considerations”

4.2.1 There is no definition of “other considerations” related to statement 4, thus this could mean any factor whether legitimate or not, applicable on a worldwide basis or not, within or outside the mandate of Codex.

4.2.2 CAC24 (2001) addressed the issue of “other factors” in relation to the second statement of principle by adopting the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle* which (among other) “Recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide” and further clarified that “Only those other factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex.” .

4.3 Result 1: “May abstain from acceptance of the relevant standard”

4.3.1 The question of whether the reference to “acceptance” in Statement 4 of the *Statements of Principle* is related to the Codex acceptance procedure has been discussed at different times. When the acceptance procedure was removed from the Codex Procedural Manual in 2005 some other consequential changes were made and in CCGP22 (2005) it was proposed also to review the term “acceptance” in Statement 4. It was agreed that the reference to “acceptance” in the *Statements of Principle* should not be understood as a reference to the acceptance procedure and therefore could be retained. The report does not contain any advice on how to interpret “acceptance”. The Committee agreed to retain the four *Statements of Principle* without any change and CAC29 (2005) agreed to remove the acceptance procedure leaving Statement 4 untouched.

4.3.2 In CCGP25 (2009) the same issue was raised again by Japan to review the use of the term “acceptance” in statement 4 and while the CCGP did not agree to review the statement, it agreed to recommend to the Commission to insert a footnote to Paragraph 4 of the *Statements of Principle* indicating that the Acceptance Procedure had been abolished in 2005. CAC32 (2009) followed the same position as in 2005 and agreed not to insert the footnote.

4.3.3 This issue is also mentioned in the Legal Office statement presented at CCEXEC75 (2018) which contemplates a link between the term “acceptance” used in Statement 4 and the abolished acceptance procedure but does not reflect the previous CCGP/CAC conclusions on that point.

4.3.4 While the acceptance procedure existed, non-acceptance of a veterinary drug residue MRL for example, would have meant that the member: “*should indicate in what ways its present or proposed requirements differ from the Codex maximum limit and, if possible, the reasons for these differences.*” (see Appendix 2). This can be seen quite in line with the logical understanding of the word “acceptance”. A relevant reservation based on Statement 4 in the Commission report could include similar elements.

4.3.5 Statement 4 was developed while the Codex acceptance procedure existed and both co-existed from 1995-2005. During this time then, Statement 4 allowed the abstention from this formal procedure. Until 2005 many Codex members were not WTO members and acceptance made sense to them. After abolishing the acceptance procedure, the notification of non-acceptance takes the form of a reservation. It is outside the context of this document to evaluate which situation would have given more weight to the opinion of the dissenting party.

4.4 Result 2: “Without necessarily preventing the decision by Codex”

4.4.1 This could be interpreted in the following way: If the members that hold different considerations are content with the possibility given by 4.3 i.e. agree to have their reservation/ non-acceptance noted in the Commission and/or a committee report, then they would not “need” to “prevent” a decision by Codex.

4.4.2 As the Codex procedures contain the possibility to vote, no Codex member can ultimately “prevent” a decision taken by Codex, but decisions can be delayed by prolonged discussions to find a consensus.

5. DECISIONS IN CODEX

5.1 Consensus

5.1.1 Codex does not have a definition of consensus in its Procedural Manual. Consensus in Codex is not unanimity. Consensus in Codex is what the Chairperson rules in his/her conclusion. The pros and cons of having a definition were discussed extensively at CCGP25 (2009) and CAC32 (2009) decided not to proceed with work on defining consensus.

5.1.2 Over the years, consensus was increasingly embedded in the way Codex works. Rule XII, 2 of the Rules of Procedure specifies: "The Commission shall make every effort to reach agreement on the adoption or amendment of standards by consensus. Decisions to adopt or amend standards may be taken by voting only if such efforts to reach consensus have failed."

5.1.3 Consensus building is also mentioned as one of the core values in the Codex strategic plan and measures to facilitate consensus are contained in two places of the Procedural Manual (Section III: *Guidelines to Chairpersons of Codex Committees and TF* (2004, 2009, 2010) and Appendix: *Measures to facilitate consensus* (2003)).

5.1.4 The Guidelines to chairpersons build on the Measures and later added the possibility to use a facilitator which has been used in Codex on two occasions: by CCFL with regards to labeling foods produced using modern biotechnology, where the Chairperson served as facilitator in a physical meeting; and by CAC with regards to MRLs for ractopamine, where an external facilitator led meetings of the friends of the Chair.

5.1.5 In line with the FAO rules on the conduct of plenary sessions, Members may disagree with the ruling of the Chairperson and present an alternative proposal which is put to a vote. This has happened only once in the Codex Alimentarius Commission (CAC30 (2007) – Emmental cheese).

5.1.6 The way consensus is implemented in Codex puts a high responsibility on the Chairperson but also allows the application of tools such as Statement 4 or reservations to disagree with the decisions while allowing Codex to move forward.

5.2 Application of Statement 4

5.2.1 There does not seem to be evidence that statement 4 has been explicitly invoked in Codex until now. This may be due to the fact that dissenting opinions have been noted in the reports of meetings as reservations or objections consistent with Statement 4 without explicitly referring to it.

5.2.2 In CCRVDF24⁶, the Codex Secretary noted that the situation in the committee was in conformity with the conditions of Statement 4. The Chairperson proposed to those members agreeing with the JECFA risk assessment but opposing moving the MRLs forward because of "other considerations" to abstain from acceptance in line with Statement 4 as no country had submitted a concern form under the CCRVDF procedure raising a scientific concern and the majority of members had stated that they agreed with the JECFA evaluation, however this was not agreed.

5.3 Reservations/ Objections

5.3.1 The Rules of Procedure (Rule X.1) contain the right of members to request that minority opinions be included in the reports of the Commission (which *mutatis mutandis* also applies to Codex committees). The *Guidelines on the Conduct of Meetings of Codex Committees and Ad Hoc Intergovernmental Task Forces* (Section III of the Codex Procedural Manual) contain the following paragraph (which has existed in the Codex Procedural Manual since its first edition (1968)):

"Delegations ... who wish their opposition to a decision of the Committee to be recorded may do so, whether the decision has been taken by a vote or not, by asking for a statement of their position to be contained in the report of the Committee. This statement should not merely use a phrase such as: "The delegation of X reserved its position" but should make clear the extent of the delegation's opposition to a particular decision of the Committee and state whether they were simply opposed to the decision or wished for a further opportunity to consider the question".

⁶ REP18/RVDF, para 48

5.3.2 Codex members often express reservations to decisions of the Codex Alimentarius Commission and/or of Codex committees, as a means of informing other Members about their position with regards to elements of a text; the whole text or the timing of adoption of a text without preventing its adoption.

5.3.3 Codex members have on occasion proposed that reservations to the adoption of standards in Codex reports could be taken into account in international bi-lateral trade agreements⁷. Some member countries and one-member organization (the European Union) have decided that certain Codex texts will automatically be integrated into their legislation unless a reservation has been expressed.

5.4 Building differences of application into the standard

5.4.1 Codex Committees have on occasion used footnotes to resolve differences by leaving certain provisions up to national authorities. The following paragraphs contain examples.

5.4.2 CAC/GL 23-1997, footnote 3: “Conditions for nutrient content claims for dietary fiber in liquid foods to be determined at national level.

5.4.3 CAC/GL 9-1987, footnote 4: “Internationally, there are different regulatory approaches to how voluntary addition of essential nutrients is legally framed and/or managed by competent national and/or regional authorities. In all these approaches, some form of regulatory oversight is required. There are approaches whereby addition of essential nutrients is generally permitted within a regulatory framework that can restrict foods or categories of foods to which nutrients may be added and set specific limits for those nutrients. There are other approaches that may be described as conditional voluntary. In one example, the framework in place describes all the foods or categories of foods to which manufacturers may choose to add nutrients, along with the nutrients and levels of nutrients. In another of these examples, if a manufacturer chooses to make a statement on the label indicating that a nutrient has been added, then certain nutrients are required to be added at specified levels. Also, in another example, if a manufacturer chooses to add an essential nutrient to certain foods, they must do so in accordance with policies on addition of nutrients and/or meet requirements in place in relation to the nutrients and amounts for addition.”

5.4.4 CXS 72-1981, footnote 17: Levels may need to be determined by national authorities. This standard also refers directly to national legislation, see in 3.2.3.

5.4.5 CXS 192-1995, note 161: A food additive provision with this footnote is “*subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.*” (Section 3.2 of Preamble deals with the justification for the use of food additives and calls for consideration of the potential for misleading consumers, in addition to the need for a finding of no appreciable health risk.)

5.4.5.1 In recent years, disagreement between members favoring and opposing use of Note 161 has prevented progression of a number of new food additive provisions found to be safe by JECFA.

5.4.5.2 CCFA has attempted to find alternatives to the text of the note which would rather than making reference to national legislation, explain how the consensus was reached while respecting the science of Codex i.e. the JECFA safety assessment is not questioned but reference is made to the different use made of the compound by different members.

5.4.5.3 The revised draft for the note recently proposed at CCFA51 (2019) reads: “*Some Codex Members allow use of additives with sweetener function in all foods within this Food Category while others limit additives with sweetener function to those foods with significant energy reduction or no added sugars.*”

5.5 Holding a standard at Step 8

5.5.1 The Codex 8-step elaboration procedure includes the possibility that the Commission holds a draft standard at Step 8 after it has been referred to the CAC at that step. There are no further conditions on this or restrictions on how long standards can be held at Step 8. The Draft MRLs for rBST have been held at that step since the 1990s with discussions on the matter on various occasions.

⁷ See, for example, the draft text for TTIP: ...*Parties shall ensure that tolerances and maximum residue levels adopted by the Codex Alimentarius Commission after the entry into force of this Agreement will be applied by each Party without undue delay unless the importing Party had signaled a reservation in the Codex Alimentarius Commission.*
http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153026.pdf

5.5.2 Other standards have been held at Step 8 for short periods to allow for finalization of certain parts of the standard or endorsement by general subject committees. In addition to rBST MRLs, the Ractopamine MRLs were also held at Step 8 until they were ultimately adopted by the CAC by vote.

5.5.3 CCGP discussed the issue between 2010 and 2014 without making any recommendations to the CAC for procedural changes.

5.5.4 The last activity in this context was a facilitated session that took place at the margins of CAC36 (2013) and discussed at CCGP where the representative of WTO: *“expressed concern that the SPS agreement might contribute to the blockage of adoption of Codex standards. The intent of the SPS Agreement was to encourage the development of harmonized worldwide standards and promote more use of these standards. Although there was a clear preference that WTO members base their food safety requirements on Codex standards, it was equally clear that there was no obligation to use the Codex standard if it would not achieve a government’s desired level of health protection. Countries could instead base their measure on an appropriate risk assessment, which might differ from the risk assessment used by Codex, as long as they complied with the SPS rules, which also call for the risk management decision to be consistent with previous decisions. The underlying concern of the WTO rules was to ensure that SPS measures were not used for protecting industries from foreign competition, but only for protecting consumer health. The WTO representative stressed that the obligations of governments were the same whether a Codex standard existed or not.”*⁸

5.6 Not developing a Codex text: Amenability to standardization

5.6.1 CCEXEC has the responsibility for carrying out the Critical Review one part of which for new projects or revisions is an assessment against the *Criteria for the Establishment of Work Priorities*. These are described in the Procedural Manual under the “Criteria applicable to general subjects”, item (d), Amenability of the subject of the proposal to standardization. The same item exists in the “Criteria applicable to commodities”.

5.6.2 Amenability of the subject of the proposal to standardization is not further defined for general subjects while for commodities in this context “information should be provided on: which quality factors are essential for the identity of the product e.g. definition, composition, etc.; and characteristics of the commodity (e.g. differences in definition, composition, and other quality factors that may vary across countries and regions) that would have to be accommodated in the standard.”

5.6.3 Up until now CCEXEC has not yet declared topics as “not amenable to standardization” when new work was discussed. Such discussions have however been held in the context of the Critical review of the monitoring of standards development as questions of amenability to standardization may not arise until after work begins (see also 5.7).

5.6.4 If a subject is not considered as amenable to standardization (criterion (d)) by Codex because, with reference to paragraph 4 of Statements, Members may “hold different views about other considerations”, it could recommend to the CAC not to approve the work in question. In deciding this, the Commission will also consider the remaining Criteria (a), (b), (c) and (e). For residues of veterinary drugs, the legal opinion given to CAC35, reproduced in Appendix 1, 31.3 should also be considered.

5.6.5 It is part of the critical review to assess whether it is possible that a project can be completed successfully within a reasonable timeframe.

5.6.6 CAC declaring a topic as not amenable to standardization, would not prevent that members use relevant risk assessments by FAO/WHO Expert bodies or request such assessments. However, such requests would likely not have the same priority as requests from Codex Committees.

5.7 Not developing a Codex text: Discontinuing work

5.7.1 If consensus is difficult to reach Codex has on occasion decided to abandon a standardization project such as the CCFL discussion on defining the term “natural” or the revision of the *Standard for Processed Cheese*.

5.7.2 There are no strict criteria for the Commission when to discontinue work and the decisions are taken on a case by case basis. CCEXEC58 (2006) agreed on the following criteria to facilitate the conduct of monitoring of standards development:

⁸ CX/GP 14/28/4, para 10

- When progress on a standard is delayed due to the need for scientific advice, the Executive Committee could encourage FAO and WHO to schedule an expert consultation to provide such advice in a timely manner, and recommend suspension of work until such time as scientific advice became available;
- When scientific advice has been provided and a standard has been under consideration for more than five years, the Executive Committee should urge the Committee concerned to take action within a specified timeframe;
- When an item has been considered for several sessions without any progress and there is no prospect of reaching consensus, the Executive Committee could propose suspension of work at a particular Step in the Elaboration Procedure for a specified period of time or discontinuation of work, or corrective action to be taken to achieve progress, fully taking into consideration the information provided by the subsidiary body concerned.⁹

5.7.3 If a project is discontinued, similar to 5.6.6 a risk assessment developed by FAO/WHO Expert bodies would still be available to members, but there would be no recognized international standard.

6. CONCLUSIONS

Before and since the entry into force of the WTO SPS and TBT Agreements in 1995, Codex has developed and adopted hundreds of standards, guidelines and codes of practice and thousands of MRLs and MLs by consensus and, where applicable, based them on the scientific advice provided by FAO and WHO. Codex standards have protected the health of consumers and ensured fair practices in trade worldwide. Codex meetings have created and maintained an international network of risk managers who know how to work collaboratively together. When consensus was difficult to reach, Codex members have proceeded in different ways in accordance with the procedural possibilities. In the following we conclude on these individually and include suggestions.

6.1 Adoption by vote

In very few cases votes have been taken to adopt a standard, and in most of these cases the margin for or against was narrow. As consensus building is a core value of the Commission, adopting a standard by vote with narrow results, though procedurally correct, is seen as divisive and experience suggests that voting is likely to remain exceptional in Codex.

6.2 Holding a standard at step 8

“Parking” a draft standard at Step 8 is a rarely used possibility. Presently one draft standard has been held over many years. This has the potential to lead to periodical prolonged discussions. It is also a constant reminder of unachieved work of unclear status where even the original need for having a standard may no longer be fulfilled or relevant risk assessments outdated. The Commission could reconsider work on criteria for standards held at step 8 however it should be noted that previous such work in the CCGP concluded without any recommendations.

6.3 Building differences of application into the text

This approach has allowed Codex to set standards needed by members based on the available science while acknowledging different situations in different countries/regions. This approach can be useful but also has the danger of weakening international standards if use is made of leaving provisions to “national legislation”.

6.4 Not approving new work or discontinuation of work because of non-amenable to standardization

6.4.1 The options of not starting a new project or to discontinue an existing project are options not or not frequently used by the Commission. There is no clear guidance as to when to declare a general subject matter as not amenable to standardization and not to approve new work or when to abandon an approved project.

6.4.2 With respect to new work, it is worth to note that proposals and project documents are usually discussed and in the relevant Committees and if agreed, forwarded to the CCEXEC for critical review. The procedure is however different for residues of pesticides or veterinary drugs and for food additives and contaminants and some related texts, which follow procedures established by the Committees concerned and endorsed by the Commission.

⁹ ALINORM 06/29/3A, para. 47. The criteria were endorsed by the CAC 29 (2006) (Ref. ALINORM 06/29/41, para. 13).

6.4.3 Further criteria might be needed as to what amount of time and work investment is reasonable and weigh this against failure to set a standard for which originally there was a need. This topic could be looked at in the context of the current regular review of Codex work management and the review of the critical review.

6.5 Reservations/ statements of principle

6.5.1 The choice to use reservations or to oppose to a Codex decision is the prerogative of Codex members. Reservations are used often in Codex meetings and facilitate the adoption of Codex texts. Many of these reservations may have been related to situations as described in the Statements.

6.5.2 The reasons why on many occasions Codex members are content using reservations when they disagree with Codex decisions and why on other occasions this does not seem possible may vary.

6.5.3 The rules of procedure (X.1) mention “minority opinions”, and it is certainly true that in most cases when reservations are made in Codex meetings, the number of reservations is significantly less than half of the delegations present.

6.5.4 The preference not to use reservations but to prefer to prevent adoption may also be related to the insecurity as to how Codex standards could be used as references in other contexts e.g. WTO SPS dispute settlement panels. Neither the Codex Secretariat, nor FAO and WHO can speculate on this last point. Codex members who are also members of WTO may wish to explore this topic in the framework of WTO.

6.5.5 The initial motivation to develop “Statements of Principle on the Role of Science...” arose from situations related to addressing the complex issues in relation to MRLs for growth promoting substances. However, while the Statements may have facilitated some discussions, they did not resolve the issue (see also para 5.2.2).

6.5.6 Codex members may wish to explore how consistent application of the *Statements of Principle Concerning the Role of Science* could help to allow Codex to set standards that are needed by members and are based on science, while acknowledging different situations in different areas of the world.

6.5.7 Codex members may also consider following up on the suggestions made in the legal opinion transmitted to CCEXEC75 which mentions “a review of the Statements of Principle to better clarify the extent to which “other legitimate factors relevant for health protection and fair trade practices” may be taken into account in the adoption of Codex standards” (see appendix 1, 35.1).

APPENDIX 1: CODEX HISTORY WITH REGARDS TO VOTING (RELATED TO STANDARDS) AND GENESIS OF THE STATEMENTS OF PRINCIPLE

1. CAC6 (1969) – Votes on three commodity standards

1.1 Honey: Proposal of Canada to designate the Standard for Honey as a world-wide Codex standard and not as a Regional standard.

VOTE: Proposal defeated by 15 votes to 9 with 11 abstentions.

1.2 Margarine: Proposal by the delegation of the Netherlands to delete the word "usually" from the description of product. "*As opinion appeared to be more or less divided on this issue, it was decided to proceed to a vote*".

VOTE: The Commission decided by 16 to 14 with 7 abstentions to delete the word "usually" from this sub-section.

1.3 Margarine: Proposal of the U.K. delegation to insert the following additional provision in Section III (essential composition and quality factors) of the standard: "Maximum water content: 16% of the product, by weight". "*In view of divergency of opinion on this issue, it was decided to proceed to a vote.*"

VOTE: The Commission decided by 18 to 16 with 3 abstentions to adopt the U.K. amendment.

2. CAC7 (1970) – Vote on flour treatment agents

The delegation of Switzerland proposed that the Commission should instruct the Codex Committee on Food Additives not to proceed with its work on flour treatment agents.

VOTE: The Commission decided by 18 votes to 5 with 6 abstentions not to accept the proposal of the delegation of Switzerland.

3. CAC19 (1991) – Consensus on science but disagreement because of other factors - First vote on growth promoters

3.1 CAC19 considered the adoption of Maximum Residue Limits (MRLs) for Estradiol-17 β , Progesterone, Testosterone and Zeranol. EEC members, while not objecting to the evaluation of JECFA, opposed adoption of the proposed MRLs on the grounds that use of these substances for growth-promoting purposes was banned in EEC countries. Reasons for this position were: concerns about different aspects of the use and control of hormones; the need to take into account the clear concerns of European consumers on the safety of meat produced with growth hormones and the opposition expressed by the European Parliament and consumer organizations.

3.2 Other delegations also agreed with the JECFA evaluation, did not oppose adoption of the MRLs but noted that the use of hormones for growth-promotion was not allowed in their countries because this use did not comply with principles of Good Agricultural Practices. They pointed out that these compounds were also used for therapeutic purposes.

3.3 Other delegations noted that the work of Codex was consistently based on sound scientific principles and that the JECFA evaluation confirmed that health issues in relation to residues of these substances in food were not a cause for concern. They stated that: the use of the compounds in accordance with Good Agricultural Practice did not pose health risks; that consumer concerns could be addressed through other means; individual countries could prohibit hormone applications as growth promoters regardless of the Commission's decision concerning international trade; the worldwide use of these compounds for therapeutic purposes strongly supported the need for an MRL to facilitate international trade, as it was difficult to determine the purposes for which the compounds were introduced. It was also noted that the technical need for hormones had been amply demonstrated. These comments were felt to be especially relevant to the current negotiations concerning sanitary and other technical barriers to trade in the GATT Uruguay Round, as this body has already recognized Codex as the primary international technical organization which works strictly within scientific principles and procedures. Deviating from these basic and founding principles of the Commission was felt to have serious implications for Codex.

VOTE: CAC decided by roll-call vote (12 in favor; 27 against; 9 abstentions) not to adopt the MRLs¹⁰.

¹⁰ ALINORM 91/40, paras. 54 - 62

4. CCRVDF6 (1991) – Legal opinion on science

4.1 The United States presented a paper¹¹ following the decision by CAC19 not to adopt the above MRLs and stated that the procedural process allowed for scientific discussion, but that procedural reform was needed to ensure that the final recommendations of the Commission should be basically science-oriented. The Delegation noted that although no Delegation at CAC or in the CCRVDF during the elaboration process had questioned the safety of draft MRLs, the Delegation expressed concern that the vote on the Draft MRLs for hormones was perceived as a judgement on the safety of the substances.

“The Secretariat informed the Committee that the FAO Legal Counsel had noted that the Statutes, Rules and Procedures of the Commission did not bind the Commission to science as the basis of the decision-making process. Other factors, in particular economic considerations, were explicitly mentioned in the Procedural Manual. Nevertheless, the experience of the Commission was that decisions in the past had followed recommendations of expert committees. In this case, the decision of the CAC not to adopt the Draft MRLs at Step 8 should be seen as a decision based other considerations and that the scientific integrity of the safety evaluations had not been questioned. The principle problem was not with the safety of the substances and their residues, but in the public perception of their safety. The Secretariat stated that it was clear that the governments represented at CAC had acted in the light of their own national situations, and that the decision clearly reflected this. The Secretariat further stated that it would be preferable to consider the Commission decision as an isolated incident and not as a precedent for future considerations.”

4.2 CCRVDF6 referred the matter to CCEXEC with a request that they determine whether this issue should be discussed by CCGP or by CAC.¹²

5. CCEXEC39 (1992) – Proposal that Codex should adopt a standard in no issues with science

5.1 The Executive Committee referred to the paper presented to CCRVDF6 (CX/RVDF 91/2-Add. 1) containing a proposal that:

“The Commission should examine the process by which draft standards recommended by a Codex Committee that are based on thorough scientific assessments by JECFA are evaluated. Unless new scientific information is presented by a delegation which calls into question the validity of the draft standard, thus requiring referral back to a committee, the Commission should adopt the standard.”

5.2 The Executive Committee noted the opinion expressed by several of its members that science should be the basis for all Codex recommendations while recognizing that other factors may affect the decision-making process. The draft GATT/Uruguay Round Sanitary and Phytosanitary decision, which invoked the concepts of risk assessment, equivalency and transparency, was considered to be very relevant in terms of making scientific determinations.

5.3 The Executive Committee, recommended that the proposal should be examined by the Codex Committee on General Principles at its next session, but took no position on the proposal.¹³¹⁴

6. CCGP10 (1992) – Further discussion of the proposal

6.1 The United States presented its views¹⁵ on the vote of CAC19 on growth-promoting hormones and supported a review of the Commission's procedures for the elaboration of standards so as to strengthen public perception of the impartiality and competence of Codex. It stated that Codex should demonstrate that it was a genuinely neutral intergovernmental body and that it must show that its standards, guidelines and other recommendations rested on a sound scientific basis. Although it recognized that other factors might be involved in arriving at Codex decisions, the Delegation believed that these matters should be dealt with separately from the scientific considerations.

6.2 The Delegation suggested that a working group be established to propose recommendations along these lines. The Delegations of Canada and New Zealand associated themselves with the statement of the Delegation of the United States. Several other delegations expressed their support for the principle that Codex recommendations should be based on the best scientific opinion available, but that there were other non-scientific criteria, such as economic factors or consumers' concerns, which needed be taken into account in

¹¹ CX/RVDF 91/2-Add. 1

¹² ALINORM 93/31, paras 13-16

¹³ ALINORM 93/3, paragraphs 56 to 58

¹⁴ At the time CAC was meeting every two years and CCEXEC had the power to take certain decisions on behalf of the CAC

¹⁵ ALINORM 93/33, para. 69

arriving at Codex recommendations. They expressed support for any proposal which would lead to greater transparency of the 'Codex process.

6.3 Other delegations noted that in situations where there were no Codex standards developed from the recommendations emanating from FAO/WHO Expert Panels, disciplines on the application of national standards in these areas to internationally traded products could still be applied through other legal instruments.

6.4 CCGP agreed to discuss the new United States proposal in full at its next session. It requested the Secretariat, with the assistance of consultants as necessary, to prepare a discussion paper to be distributed for government comments well in advance of the Committee's next session.

7. CAC20 (1993) – MRLs continue to be held – CCGP is requested to develop guidance

Agreed to hold the maximum residue limits for the growth-promoting hormones, confirming the CCEXEC39¹⁶ recommendation to refer the matter on science and other factors to CCGP. CAC also requested CCGP to consider developing guidance on how science and other factors should be considered for possible integration into its elaboration procedures and decision-making process.

8. CCGP11 (1994) – No conclusion in CCGP on statements of principle

Discussed the issues related to the role of science and other factors but did not come to any conclusion¹⁷.

9. CCEXEC41 (1994) – Develops statements of principle on the role of science

9.1 The Executive Committee was grateful for the work of the CCGP in considering and attempting to resolve some complex issues, however it considered that it should resolve this issue at this time, as the executive organ of the CAC, to facilitate the further work on aspects of the issue in the work programmes.

9.2 The CCEXEC developed the statements as later adopted.

9.3 The Executive Committee decided that the above statements of principle would provide clear guidance to the Commission and that consequently the Procedural Manual should not be considered for amendment in relation to these matters.

10. CAC21 (1995) – Statements adopted by CAC – work on revision of the acceptance procedure initiated – Votes on several growth promoters

10.1 The Commission discussed the draft statements of principle exhaustively. The CAC rejected the proposal of the members of the European Union to amend the statements as follows (strike-out for proposed deletion and underline for proposed addition).

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

Statement 2: When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the ~~[health protection of]~~ consumers and for the promotion of fair practices in food trade, assessed in a transparent manner.

Statement 3: In this regard it is noted that food labelling *can* play an important role in furthering ~~[both of]~~ these objectives.

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

10.2 The statements were finally adopted as originally drafted and the members of the European Community expressed their opposition to the decision.

10.3 The Commission decided as a priority for CCGP to amend the acceptance procedure in light of the creation of the WTO.

10.4 Draft maximum limits for 5 growth hormones at step 8. The motion of the member countries of the EU to adjourn the debate on the adoption was defeated in a vote.

¹⁶ ALINORM 93/40, paras 151 ff.

¹⁷ ALINORM 95/33, paras 17 - 27

VOTE: 28 votes in favor; 31 votes against; 5 abstentions.

The Commission decided to vote by secret ballot on the adoption of the 5 draft MRLs.

VOTE: 33 votes in favor of adoption; 29 votes against adoption; 7 abstentions.

10.5 Discussion after the vote

Para 46: *"The Observer of the European Community commented that it was regrettable that this important and far-reaching decision was made by a secret ballot which was contradictory to the Commission's decision to increase transparency. He further noted that it cast doubts on the validity and value of Codex work and standards and that consequences would be grave including the European Community's rethinking of participation in Codex work. The Delegations of the Netherlands, Sweden, and Finland stressed that the latter statement by the Observer was made on behalf of the European Commission but not on behalf of the European Union or its member countries and dissociated themselves from the latter statement. The Delegation of Spain, on behalf of the European Union, recalled the right of the Commission of the European Community to make as many comments as it felt necessary as an observer, but also dissociated itself from the latter statement. The Delegation of the United Kingdom dissociated itself from the entire statement."*

10.6 Draft Maximum Residue Limits for Bovine Somatropine at Step 8: The motion of the member countries of the EU to adjourn the debate on the adoption was accepted in a roll-call vote.

VOTE: 33 votes in favor; 31 votes against; 6 abstentions.

11. CCGP12 (1996)¹⁸ – Discussion on where to include the principles

CCGP discussed the inclusion of the Statements of Principle on the role of science and recommended to include them in an appendix to the Procedural Manual together with the four statements relating to the role of food safety risk assessment. The Committee also stated that this appendix would be further developed to incorporate other policy decisions which provide essential guidance from the Commission to the subsidiary bodies.

12. CAC22 (1997) – Decision to include the statements of principle in an Appendix to the PM – Votes on a CCFICS guideline – Vote on rBST – Vote on Natural Mineral Waters

12.1 The Commission agreed to include them in the Procedural Manual a new Appendix¹⁹ incorporating all general policy decisions of the Commission, which provide essential guidance from the Commission. The Commission also adopted the Statements of principle on food safety risk assessment.

12.2 The Commission adopted the Draft Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems by a show-of-hands vote

VOTE: 46 votes in favor of adoption; 16 votes against adoption and 7 abstentions.

12.3 The Delegation of the Netherlands expressing the views within the European Union, presented a proposal to suspend the consideration of the adoption of the MRLs for BST pending the re-evaluation of scientific data by JECFA and the CCRVDF and the examination of the application of the "other legitimate factors" in relation to BST by the Committee on General Principles.

VOTE: 38 votes in favor; 21 votes against; 13 abstentions.

12.4 A roll-call vote was called for the adoption of the Draft Revised Standard for Natural Mineral Waters by one Delegation and Japan proposed the use of a secret ballot. The Commission decided, by show of hands, (in favor of the secret ballot - 22, roll-call - 39 countries), to resolve the matter by roll-call vote. The Delegation of Egypt emphasized that on matters such as the one under discussion, issues should be resolved by consensus rather than by a voting procedure.

VOTE: 33 votes for adoption; 31 votes against; 10 abstentions.

13. CCGP13 (1998) – Other legitimate factors in risk analysis and BST

The Committee recognized that no consensus existed at this stage on the application of other factors in the case of BST and that further discussion was needed. It agreed that although the general and specific issues

¹⁸ ALINORM 97/33, paras 5 - 7

¹⁹ ALINORM 97/37, para 25

under consideration were related, they should be clearly identified in order to avoid confusion and to facilitate discussion. To this effect, the Committee agreed that two papers should be prepared by the Secretariat on these issues: 1) consideration of other legitimate factors in the framework of risk analysis as recommended by the Commission, and 2) application of other legitimate factors to the case of BST. The Committee agreed to return to these matters at its next Session. It was noted that the Committee should endeavor to decide the latter issue at its 14th Session so that the matter could be considered by the Commission at its 23rd Session. It was further noted that the general consideration of other legitimate factors should be viewed as a longer-term process. The Committee reasserted the primary role of science in health-related issues, as reflected in the current work on risk analysis in relation to food safety²⁰.

14. CCGP14 (1999) – Criteria for other legitimate factors/ application to bST

14.1 Other legitimate factors in the framework of risk analysis

14.1.1 The Committee agreed that other factors should be defined according to the principles of transparency, objectivity, and proportionality and that their application should be clearly documented in the decision process. The Committee recognized that there was no consensus on the integration of a number of other factors including animal health, animal welfare and the environment, and agreed that the document should be revised in the light of the above discussion for further consideration at the next session.

14.1.2 The Representative of WTO indicated that under the TBT Agreement member countries could take measures addressing environment, animal welfare or other legitimate objectives; under the SPS Agreement they could take measures to protect animal and plant life and health on their territory, and noted that measures concerning animal health relevant for international trade were the competence of OIE.

14.1.3 The Committee agreed to ask the relevant committees to identify and clarify the relevant factors taken into account in their work, in the framework of risk analysis, as this would facilitate the general debate in the CCGP on other legitimate factors.

14.2 Other legitimate factors and BST

The Committee noted that Delegations remained divided on the consideration of other factors as requested by the Commission in the mandate given to the Committee and that as a result it had not been possible to arrive at a consensus decision. It agreed to inform the Commission accordingly.²¹

15. CAC23 (1999) – MRLs for rBST continue to be held

15.1 The Delegation of the United States stated that in its opinion, the scientific evaluation should be the only determining factor for the adoption of the MRLs, and that on the basis of these evaluations the MRLs should be adopted. Nevertheless, the Delegation noted the lack of consensus on this issue and proposed that the MRLs be held at Step 8 with a view to resuming their consideration in the future at such a time as it appeared that it might be possible to arrive at a consensus.

15.2 The Delegation of Germany, speaking on behalf of the Members of the European Union present at the Session, referred to the written comments submitted to the Commission (ALINORM 99/21, Part I, Addendum 3 and re-stated that the adoption of the MRLs would not be appropriate. The Delegation supported the proposal to retain the MRLs at Step 8.

15.3 No other views being presented by Members, the Commission therefore **decided** to hold the MRLs at Step 8 in accordance with the provisions contained in the introductory paragraphs of the Uniform Procedure for the Elaboration of Codex Standards and Related Texts.

16. CCGP15 (2000)/ CCGP16 (2001) – Discussions on other legitimate factors

Developed criteria for other legitimate factors.

17. CAC24 (2001) – adopts criteria on other legitimate factors

17.1 Recognizing that there was no consensus on the inclusion of a reference to the recommendations of other organizations, the Commission agreed to delete paragraph 7 of the criteria. CAC also discussed the need for a reference to the World Trade Organization and the WTO SPS and TBT Agreements in paragraph 9 concerning barriers to trade and agreed that the relevant text should be retained as a footnote. The 17.2

²⁰ ALINORM 98/33, paras 59 - 70

²¹ ALINORM 99/33A, paras 64 ff.

Commission adopted the other paragraphs without change and noted that the amended Criteria would be included in the Appendix to the Procedural Manual after the Statements of Principle²².

18. CCRVDF15 (2004)²³ – MRLs for Ractopamine held at step 4

Due to lack of consensus retained the MRLs for Ractopamine at step 4.

19. CCGP22 (2005) – Proposal to abolish the acceptance procedure

19.1 Recommended to the Codex Alimentarius Commission the abolition of the acceptance procedure and reviewed in detail the required proposed amendments to the Procedural Manual of the Codex Alimentarius Commission, including the Statutes of the Commission.

19.2 Several delegations pointed out that the reference to “acceptance” in the Statements of Principle should not be understood as a formal reference to the acceptance procedure and therefore could be retained. The Committee therefore agreed to retain the four Statements of Principle without any change²⁴.

20. CAC28 (2005) – Remove acceptance procedure

Agreed to remove reference to the acceptance procedure in the PM²⁵.

21. CAC30 (2007) – Vote on Emmental

On the basis of the debate, the Chairperson closed the discussion and concluded that the revised Standard for Emmental had been adopted, with the amendments made in the endorsement process by the Committee on Food Additives and Contaminants, and the strong opposition of the Delegation of Switzerland recorded in the report.” (ALINORM 07/30/REP, para 77). Switzerland challenged this conclusion and the matter was voted on.

VOTE: 23 in favor of the motion of Switzerland; 70 against; 11 abstentions.

22. CCGP25 (2009) – Discussion on acceptance; definition of consensus

22.1 Statements of Principle

Following a proposal from Japan to review the use of the term “acceptance” in statement 4, the Committee agreed that no revision of the Statement of Principle should be considered but recommended to the Commission to insert a footnote to Paragraph 4 of the Statements of Principle indicating that the Acceptance Procedure had been abolished in 2005²⁶.

22.2 Consensus

CCGP25 extensively discussed the concept of consensus in Codex. The Committee agreed a number of actions related to the facilitation of consensus but remained divided on the need for a definition of consensus (para 87). The Commission was invited to advise the CCGP how to move forward on this issue.

23. CAC32 (2009) – Discusses acceptance – Holds ractopamine MRLs – Starts work on standards held at step 8

23.1 Expressed the view that the use of the term “acceptance” in the Statements of Principle was not intended as referring to the Acceptance Procedure abolished in 2005. The Commission therefore agreed to retain the text of the Statements of Principles unchanged²⁷.

23.2 CAC32 decided to hold the MRLs for Ractopamine at Step 8.²⁸ The Commission established an EWG to prepare a discussion paper for consideration of the CCGP on situations leading to standards held at step 8.²⁹

23.3 With regards to consensus CAC32³⁰ endorsed a number of proposals from CCGP:

²² ALINORM 01/41, paras 93 - 98 and page 89

²³ ALINORM 05/28/31, para 88-92

²⁴ ALINORM 05/28/33A, paras 88 - 89, Appendix II.

²⁵ ALINORM 05/28/41, paras 30 - 36

²⁶ ALINORM 09/32/33, para 111

²⁷ ALINORM 09/32/REP, para 21, Appendix II.

²⁸ ALINORM 09/32/REP, paras 66-79

²⁹ ALINORM 09/32/REP, para 80

³⁰ ALINORM 09/32/REP, paras 199-218

- Brochure for Chairs to instruct them how to apply the concept of consensus uniformly across committees
- Use of a facilitator
- Use of a participant satisfaction survey form to be completed by delegates containing questions on the performance of the chairperson
- Problematic issues to be brought to the CCEXEC and the informal meeting of chairs for appropriate action
- Convening an informal meeting of chairs
- Explore possibilities for developing a reference document for delegates on consensus building

CAC32 decided not to continue discussions on a definition of consensus but to continue that CCGP continue working on an additional phrase to be added to the Guidelines for Chairpersons.

24. CCGP26 (2010) – EWG on standards held at step 8

24.1 CCGP26 agreed on an additional sentence to be included in the Guidelines to Chairpersons: “Where there is opposition to an issue under discussion, the chairperson should ensure that the views of concerned members be taken into consideration by striving to reconcile conflicting arguments before deciding whether consensus has been reached.”

24.2 CCGP26 established an EWG on standards held at step 8 with the explicit statement not to reopen the statements of principle or hold up current work.³¹

25. CAC33 (2010) – Hold Ractopamine MRLs – Start “Friends of the Chair” process

25.1 CAC33 agreed the additional sentence proposed by CCGP.

25.2 CAC33 continued to hold the MRLs for Ractopamine at Step 8 and started the facilitated process of “friends of the chair.”³²

26. CAC34 (2011) – First vote on whether or not to vote on Ractopamine MRLs – Historical paper on rBST requested

26.1 Friends of the Chair could not find consensus on how to proceed with ractopamine (adopt or discontinue or continue holding at step 8). The Chairperson proposed a vote on the question if Codex should proceed with a vote to adopt the MRLs (vote1).

26.2 CAC34 decided by roll-call vote (63 in favor; 54 against; 6 abstentions) to proceed with Vote1 by secret ballot.

26.3 CAC34 decided by secret-ballot (59 for; 68 against; 9 abstentions) NOT to proceed with a vote on the MRLs.

26.4 CAC34 held the MRLs at step 8.

26.5 CAC34 requested the Codex Secretariat to prepare a paper on the history of discussions of the MRLs for bovine somatotropin (bST) which had been held since CAC23 (1999).

27. CCGP27 (2012) – No consensus on recommendations for standards held at step 8

CCGP27 discussed the results of the EWG on standards held at step 8³³. None of the recommendations was agreed. CCGP27 agreed to hold a facilitated discussion group on root causes for standards held at step 8.

³¹ ALINORM 10/33/33, paras 106-116

³² ALINORM 10/33/REP, paras 49-60

³³ REP12/GP, paras 10-32

28. CCRVDF20 (2012)³⁴ – Seeking advice from CAC on zilpaterol

With regards to the question whether or not to include zilpaterol on the Priority list the Committee could not reach consensus and, therefore, decided to request advice and direction from the Commission regarding the appropriate steps to take regarding making a decision whether or not to include a veterinary drug in the Priority List.

29. CCEXEC66 (2012)³⁵ – Discussing if there are any other options to solve the issue of ractopamine

29.1 CCEXEC66 in the context of the critical review (monitoring of standards development) recalled that the draft MRL for BST was held at Step 8 since 1999 and that the draft MRL for ractopamine had been held at Step 8 by the last session of the Commission and also recalled that the next session of the Committee on General Principles would consider a document on the status of standards and related texts held at Step 8.

29.2 CCEXEC then discussed the merit of holding additional formal or informal meetings to find a consensus and after some discussion, the Committee agreed that the decision to convene an in-session meeting to discuss the issue of ractopamine should be left to the Committee on General Principles, which could decide either to convene a separate working group or if practically possible, an in-session working group which could build on the conclusions which would have been made in the discussions on standards held at Step 8. One member noted that this possibility was conditional on the progress which would be achieved in the CCGP on this question. It was also noted that informal discussions between members could always take place during or between Codex sessions.

30. CCEXEC67 (2012)³⁶ – Some discussion on zilpaterol hydrochloride

30.1 The Chairperson recalled that in the Committee there had been no consensus on the inclusion of zilpaterol in the Priority List and that this matter had been referred to the Commission by the CCRVDF.

30.2 One Member expressed the view that, as there had been no consensus in the CCRVDF to change current criteria for inclusion of substances in the priority list, the Committee should have included zilpaterol in the Priority List in conformity with the established process, and therefore the question put forward to the Commission was not appropriate.

30.3 The Chairperson noted that the question would be discussed in the CAC as requested by CCRVDF.

31. CAC 35 (2012)³⁷ – Second vote on whether to vote on Ractopamine MRLs; Vote on MRLs; Legal opinion on Zilpaterol

31.1 BST: CAC35 discussed the history of rBST and decided to continue holding the MRLs pending JECFA re-evaluation³⁸.

31.2 Ractopamine³⁹

31.2.1 The Commission discussed the MRLs for Ractopamine at length to establish mainly if all efforts had been made to reach consensus. The Chairperson proposed a vote on the question if Codex should proceed with a vote to adopt the MRLs (vote1).

31.2.2 CAC35 decided by show of hands (92 in favor; 41 against; 3 abstentions) to proceed with Vote1 by secret ballot.

VOTE: CAC35 decided by secret-ballot (68 for; 64 against; 4 abstentions) to proceed with a vote on the MRLs.

31.2.3 There was consensus to proceed with the next vote by secret ballot.

VOTE: CAC35 decided by secret-ballot (69 for; 67 against; 7 abstentions) to adopt the MRLs.

³⁴ REP12/RVDF paras 110-114

³⁵ REP12/EXEC1, paras 8-13

³⁶ REP12/EXEC2

³⁷ REP12/CAC

³⁸ REP12/CAC, paras 67-86

³⁹ REP12/CAC, paras 87-120

31.2.4 After the vote many delegations expressed their position with regards to the decision.

31.3 Zilpaterol⁴⁰

With regards to the referral of the question of the inclusion of zilpaterol in the priority list for JECFA evaluation, the Commission held the following discussion:

“The Representative of the Legal Counsel of FAO, speaking on behalf of the legal offices of both FAO and WHO, noted that compliance with the criteria could not, normally, trigger an automatic decision for inclusion in the Priority List and that members of Codex would normally retain a degree of discretion on inclusion of a veterinary drug in the Priority List.

The Representative indicated that there was a clear need for predictable procedures in Codex and noted that a consistent practice in the CCRVDF had been established over the years. It was, therefore, reasonable for Codex members to expect that when a compound met the criteria for inclusion in the list, inclusion would follow. On that basis, the legal offices considered that a veterinary drug should be included in the Priority List for JECFA evaluation if it meets the criteria of paragraph 13 of the Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs. He further recalled that acceptance of new work required approval by the Commission irrespective of inclusion of drugs in the priority list by CCRVDF. If changes to the criteria or procedures were needed, the appropriate channels of Codex could be followed, for example through the Committee on General Principles.

The Chairperson concluded that, based on the above legal opinion, zilpaterol should be included in the Priority List for JECFA evaluation, that no further guidance was required for the CCRVDF, that risk management decisions should follow the risk assessment and that the Commission approved the Priority List with the addition of zilpaterol hydrochloride. On this basis, the CCRVDF would initiate work based on the recommendations of the JECFA evaluation.

The Delegations of China, Croatia, Egypt, European Union, Norway and Switzerland expressed their reservation to this decision.”

32. CAC36 (2013)

In the margins of the session, a CCGP facilitated discussion on the root causes of standards held at step 8 was held.

33. CCGP28 (2014)

The Committee welcomed the report of the facilitated session on standards held at step 8 which did not present any recommendations and the chairperson concluded the discussion on this item and invited the committee to take note of the document presented.^{41 42}

34. CCRVDF24 (2018)⁴³

34.1 CCRVDF discussed MRLs for Zilpaterol Hydrochloride at step 4. CCRVDF expressed strong support for the robust scientific evaluation carried out by JECFA. CCRVDF further emphasized that there were no public health or scientific concerns regarding the proposed draft MRLs.

34.2 CCRVDF did not find consensus on moving the MRLs for adoption to step 5 for reasons outside the mandate of CCRVDF and CAC.

34.3 The Secretariat mentioned the possibility for the dissenting parties to invoke para 4 of the statements of principle.

34.4 The Chairperson ruled that there was no consensus and to hold the MLRs at step 4. 29 members expressed their opposition to this decision.

⁴⁰ REP12/CAC, paras 169-178

⁴¹ CX/GP 14/28/4

⁴² REP14/GP, paras. 20 - 25

⁴³ REP18/RVDF, paras 40-55

35. CCEXEC75 (2018)⁴⁴

35.1 In response to a query whether relevant Codex procedures had been followed by the CCRVDF Chairperson in holding the MRLs for Zilpaterol hydrochloride, a representative of the FAO Legal Office presented the following joint FAO/WHO legal opinion (reproduced entirely here):

“A question has arisen whether or not it was procedurally correct to hold a proposed standard at step 4 of the Procedures for the Elaboration of Codex Standards and Related Texts in the absence of consensus to move the standard to step 5. Such a decision was taken by the Codex Committee on Residues of Veterinary Drugs (CCRVDF) at its last, 24th Session held in April of 2018.

The matter attracted some controversy, as evidenced by a number of reservations that were included in the report of the Session. Such reservations questioned the holding of the draft standard at step 4 under the circumstance that the members opposing the standard did not, in fact, challenge the scientific analysis, which confirmed that a certain Maximum Residue Limit (MRL) for Zilpaterol would not present a risk to human health. Instead, the absence of consensus in the Committee up to that point was based on factors other than scientific factors, within the Codex Alimentarius mandate.

As is often expressed, the two core values of Codex Alimentarius are science and consensus⁴⁵, both of which find expression in the Codex Procedural Manual. Standards are adopted on the basis of scientific risk assessments and voting is resorted to only once every effort have been made to reach consensus.

In such a framework, the Chairs of the Codex Commission and its subsidiary bodies must necessarily have sufficient operating margin to find ways to reach consensus. As recognized in the Guidelines to Chairpersons “Much of the responsibility for facilitating the achievement of consensus would lie in the hands of the Chairpersons.” To this end, the Chairs are encouraged, inter alia, to ensure “that matters are not progressed from step to step until all relevant concerns are taken into account and adequate compromises worked out.”⁴⁶ Such leeway should be available at all levels of the standard development process, until such time it is considered that all efforts have been made to reach consensus and voting could be resorted to as a last option.

It is further noted that the Chairs of the Codex Alimentarius Commission and its subsidiary bodies perform their duties at all times under the authority of the body that they chair. In the case at hand, the Chair’s proposed way forward was accepted by CCRVDF, even if a number of reservations were recorded.

In view of these circumstances, there is no reason to suggest that the decisions taken at the CCRVDF breached any rule of Codex.”

The above does not exclude that the Codex Alimentarius Commission further clarifies the role of science and the extent to which other factors are taken into account. In this context, it is important to note that the Statements of Principle Concerning the Codex Decision-making Process and the Extent to which Other Factors are Taken into Account make reference to the acceptance procedure as a mechanism to address the dilemmas that arise at times in connection with ‘other considerations’, while avoiding the blocking of the adoption of standards. The acceptance procedure, however, was abolished in 2005, largely due to the advent of the international trade agreements, which have altered the original nature and status of Codex standards. These developments would seem to warrant a review of the Statements of Principle to better clarify the extent to which “other legitimate factors relevant for health protection and fair trade practices”⁴⁷ may be taken into account in the adoption of Codex standards.

Such a review could consider factors, including, but not limited to, the need for an efficient standard adoption process; the science-based nature of standard setting in Codex, the role of scientific risk assessment versus risk management; the role of voting in efficient standard setting and develop ideas as to how to overcome the stalemates that sometimes arise. The Commission could be invited to refer such questions to an appropriate body for discussion and consideration, taking into account the terms of reference of the subsidiary committees of Codex.”

35.2 CCEXEC75 noted the legal opinion that in seeking consensus the CCRVDF Chairperson had acted within his authority.

⁴⁴ REP18/EXEC1, paras 30-40

⁴⁵ See for example Rule XII(2) of the Rules of Procedure of the Codex Alimentarius Commission; Guidelines to Chairpersons Of Codex Committees and Ad Hoc Intergovernmental Task Forces, Codex Procedural Manual, 26th edition, pp 110-114; Measures to Facilitate Consensus, Codex Procedural Manual, 26th edition, p. 253

⁴⁶ Guidelines to Chairpersons Of Codex Committees and Ad Hoc Intergovernmental Task Forces, *ibid.*, p. 112, and p. 113 (letter e)

⁴⁷ 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; Codex Procedural Manual, 26th edition, pp 250-251.

35.3 Conclusion: CCEXEC75 agreed to continue discussion at CCEXEC77 on the matter facilitated by a report, to be prepared by the Codex Secretariat in conjunction with the CAC Bureau and the legal counsels of FAO and WHO on the history and implications of paragraph 4 of the Statements of Principle, building on the comments made at the session.

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Reiterating the value of Codex as the preeminent international rules-based food standards-setting body, and underscoring its commitment to both science and consensus, the Commission endorsed the approach proposed by CCEXEC75.

Appendix 2: The Codex Acceptance Procedure⁴⁸

MRLs for Veterinary Drugs and Pesticide Residues⁴⁹

6.A. A Codex maximum limit for residues of pesticides or veterinary drugs in food may be accepted by a country in accordance with its established legal and administrative procedures in respect of the distribution within its territorial jurisdiction of (a) home-produced and imported food or (b) imported food only, to which the Codex maximum limit applies in the ways set forth below. In addition, where a Codex maximum limit applies to a group of foods not individually named, a country accepting such Codex maximum limit in respect of other than the group of foods, shall specify the foods in respect of which the Codex maximum limit is accepted.

(i) Full acceptance

Full acceptance of a Codex maximum limit for residues of pesticides or veterinary drugs in food means that the country concerned will ensure, within its territorial jurisdiction, that a food, whether home-produced or imported, to which the Codex maximum limit applies, will comply with that limit. It also means that the distribution of a food conforming with the Codex maximum limit will not be hindered by any legal or administrative provisions in the country concerned which relate to matters covered by the Codex maximum limit.

(ii) Free distribution

A declaration of free distribution means that the country concerned undertakes that products conforming with the Codex maximum limit for residues of pesticides or veterinary drugs in food may be distributed freely within its territorial jurisdiction insofar as matters covered by the Codex maximum limit are concerned.

B. A country which considers that it cannot accept the Codex maximum limit for residues of pesticides or veterinary drugs in foods in any of the ways mentioned above should indicate in what ways its present or proposed requirements differ from the Codex maximum limit and, if possible, the reasons for these differences.

C. A country which accepts a Codex maximum limit for residues of pesticides or veterinary drugs in food according to one of the provisions of paragraph 6.A should be prepared to offer advice and guidance to exporters and processors of food for export to promote understanding of and compliance with the requirements of importing countries which have accepted a Codex maximum limit according to one of the provisions of paragraph 6.A.

D. Where, in an importing country, a food claimed to be in compliance with a Codex maximum limit is found not to be in compliance with the Codex maximum limit, the importing country should inform the competent authorities in the exporting country of all the relevant facts and, in particular, the details of the origin of the food in question (name and address of the exporter), if it is thought that a person in the exporting country is responsible for such non-compliance.

Notion of presumptive standards in the acceptance procedure

11. A presumptive standard is one which is assumed to be the standard in the absence of any other. (A presumption in law is the assumption of the truth of anything until the contrary is proved.) Some countries have said that a Codex MRL is the presumptive limit for a pesticide residue. Countries may be able and willing to regard a Codex Standard as the presumptive standard in cases where there is no corresponding standard, code of practice or other accepted expression of the "nature, substance or quality" of the food. A country need not apply the presumption to all the provisions of the standard if the details of its additives, contaminants, hygiene or labelling rules are different from those in the standard. In such a case the provisions in the Codex Standard defining the description, essential composition and quality factors relating to the specified name and description could still be the presumptive standard for those matters.

12. The justification for regarding the Codex Standard as a presumptive standard is the fact that it is the minimum standard for a food elaborated in the CAC "so as to ensure a sound, wholesome product free from adulteration, correctly labelled and presented". (General Principles, Paragraph 3.) The word minimum does not have any pejorative connotations: it simply means the level of quality and soundness of a product judged by consensus to be appropriate for trade internationally and nationally.

⁴⁸ See Codex Procedural Manual 4th edition 1975, General Principles

⁴⁹ The complete text includes further sections on what "acceptance" means for different types of standards. For brevity only the one on veterinary drug MRLs has been included here.

13. Whether a presumptive standard would merit an acceptance would depend on whether the country concerned could say that non-conforming products could not be distributed under the same name and description laid down in the standard. However, it would enable a declaration of free circulation to be made and countries are asked to give the idea serious consideration.

Introduction to the Guidelines on the acceptance procedure

The Codex Committee on General Principles (CCGP) and the Commission (CAC) have reviewed the acceptance procedure and notifications by governments on a number of occasions. While recognizing that difficulties can arise from time to time in reconciling the obligations of the acceptance procedure with the laws and administrative procedures of a Member Country, the CCGP and the CAC have determined that the obligations are essential to the work and status of the CAC and that they should not be weakened in any way. The purpose of these guidelines therefore is to assist governments when they are considering how, in the light of the objectives of the acceptance procedure, to respond to Codex Standards.