CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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CODEX ALIMENTARIUS COMMISSION

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WORK FROM THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

REPORT ON FURTHER INFORMAL CONSULTATIONS ON ZILPATEROL HYDROCHLORIDE BY THE CHAIRPERSON AND VICE-CHAIRPERSONS OF THE CODEX ALIMENTARIUS COMMISSION

(Prepared by the Chairperson and Vice-Chairpersons of the Codex Alimentarius Commission)

Introduction

The 44th Session of the Codex Alimentarius Commission (CAC44) tasked the Chairperson and Vice-Chairpersons of CAC (CVCs) "to undertake informal consultations with all relevant parties to encourage and enable sustained effort to build consensus in advance of CAC45" and "to submit a report two months in advance of CCEXEC83 to inform its further monitoring and critical review, and then to inform further discussion at CAC45".

The mandate given by CAC44 to us recognised the important role of CCEXEC and we updated CCEXEC82 following an initial round of consultation with eight Codex Member countries, one Codex Member Organization, one observer organization and one Committee Chairperson which took place between 3 March 2022 and 4 May 2022. The update was provided in a written report, published as a working document for CCEXEC82 to aid transparency.[1]

CCEXEC82 noted our report and supported further informal dialogue led by CVCs including, but not limited to, informal discussions on a regional basis, noting that these did not replace bilateral discussions between Members.

In light of the conclusions of CCEXEC82, we (CVCs) liaised with Regional Coordinators to convene an informal consultation meeting for each region, each of which was open to all Members of that region. These meetings were held between 11 and 18 August 2022. They followed a common core agenda (Annex 1), with Regional Coordinators and Members able to propose additional items for discussion.

We also wrote to all Members and Observers offering further informal discussions with them. It was open to all Members and observers to request an informal consultation discussion with us, either individually or as groups of Members with common views. We held three informal discussions outside of regional informal consultation meetings, on 23 and 24 August 2022.

Through this round of regional and other informal consultation meetings, we engaged with over 300 people in total, representing 98 Members countries, one Member organisation and four Observers (Annex 2).

CCEXEC82 proposed that our report to CCEXEC83 and CAC45 should indicate the broad rationale for positions taken by Members in discussions as a means to promoting mutual understanding and should also identify opportunities to reach consensus where they may exist.

[1] CX/EXEC 22/82/2 Add.1

The summary contained in Annex 3 records and analyses the key themes and issues that have arisen in this round of informal consultation discussions, guided by the suggestions made by CCEXEC82. As was the case in our previous report, this does not attribute specific views or comments to individual participants.

Recommendation

We recommend that CCEXEC83 and CAC45 **note** the content of this report, and that the CVCs will continue to engage with Members and Observers following their submission of this report and as we approach CAC45 in fulfilment of the mandate from CAC44 to encourage and enable sustained effort to build consensus.

We recommend that CCEXEC83 **considers** any recommendations it may provide to CAC45 in relation to the proposed draft MRLs for zilpaterol, in the context of its continuing critical review.

Annex 1

AREAS FOR DISCUSSION IN REGIONAL INFORMAL CONSULTATIONS ON ZILPATEROL (as proposed by CVCs)

- CVCs will invite the Regional Co-ordinator to open discussion by restating the key positions taken by Members of the region in the discussions to date. CVCs will be particularly interested to hear the rationale for positions that have been adopted, and to hear any changes in position.
- CVCs will invite any reflections from Members of the region on CVCs' report to CCEXEC82 (CX/EXEC 22/82/2 Add. 1).
- CVCs will probe whether the draft flowchart regarding the Statements of Principle that was discussed at CCEXEC82 is helpful (REP22/EXEC1 Appendix II). Does it make clearer the process we might follow in the discussion at CAC45? Are any parts not clear? Does it provide routes that may be used to avoid a vote?
- CVCs will ask Members:
    - whether they have taken part in any bilateral or plurilateral discussions since the CVCs' first round of informal consultations?
    - whether there are any areas of concern where they believe compromise has been reached, or will be reached in advance of CAC45?
    - whether they are anticipating any further such discussions?
- CVCs will ask the Regional Co-ordinator and members what they now see as the most likely outcome of discussions at CAC45, and in particular whether they foresee any opportunities for Codex Members to reach consensus?
- With reference to the measures to facilitate consensus that are set out in the procedural manual, the view of CVCs is that we have a well-established scientific basis for the proposed MRLs, that these have been the subject of thorough discussion at CCRVDF, CCEXEC and CAC, and that we have organised informal meetings open to all Members to identify opportunities for consensus. CVCs will ask Members whether they would support a proposal to redefine the objective of the work on zilpaterol such that we might agree a risk management recommendation, rather than adopt Codex MRLs?
- CVCs will ask Members what impact adopting a standard, or not, would have on consumer health protection and trade for your country. CVCs will ask whether any such potential impacts could be evidenced.
- CVCs will ask Members what impact adopting a standard, or not, would have on the functioning and reputation of Codex as an international standard-setting body. CVCs will ask whether any such potential impacts could be evidenced.

Annex 2

MEMBERS, OBSERVERS AND OTHERS PARTICIPATING IN INFORMAL CONSULTATION DISCUSSIONS WITH CVCs, AUGUST 2022

Members and observers participating in regional informal consultations

CCAFRICA

Benin; Botswana; Burundi; Côte d'Ivoire; Democratic Republic of Congo; Guinea-Bissau; Kenya; Liberia; Morocco; Rwanda; Senegal; South Africa; The Gambia; Togo; Uganda; Zambia

African Union; ECOWAS

CCASIA

Afghanistan; Bangladesh; Cambodia; China; Indonesia; Japan; Malaysia; Republic of Korea; Singapore; Thailand

CCEURO

Austria; Belarus; Bosnia and Herzegovina; Czech Republic; Cyprus; Denmark; European Union; Estonia; Finland; France; Greece; Hungary; Ireland; Kazakhstan; Kyrgyz Republic; Latvia; Netherlands; North Macedonia; Norway; Poland; Portugal; Russian Federation; Spain; Sweden; Switzerland; Türkiye; Turkmenistan; United Kingdom

CCLAC

Antigua and Barbuda; Argentina; Bahamas; Barbados; Belize; Bolivia; Brazil; Chile; Colombia; Costa Rica; Dominican Republic; El Salvador; Ecuador; Guatemala; Guyana; Haiti; Honduras; Jamaica; Mexico; Nicaragua; Panama; Paraguay; Peru; St Vincent and the Grenadines; Trinidad and Tobago; Uruguay; Venezuela

CAHFSA; IICA

CCNASWP

Australia; Canada; Fiji; New Zealand; Tonga; United States of America; Vanuatu

CCNE

Egypt; Iran; Iraq; Jordan; Kuwait; Lebanon; Libya; Saudi Arabia; Syria; Yemen

Palestine

Members participating in bilateral informal consultations

Brazil

European Union

United States of America

Annex 3

REPORT ON FURTHER INFORMAL CONSULTATIONS ON ZILPATEROL HYDROCHLORIDE BY THE CHAIRPERSON AND VICE-CHAIRPERSONS OF THE CODEX ALIMENTARIUS COMMISSION

Summary of discussions

General

We heard appreciation from Members for the substantial efforts made to date in open engagement and discussions with the aim of facilitating resolution of outstanding issues in relation to the proposed draft MRLs for zilpaterol.

There was also a recognition of the use of the informal consultation meetings as a means of building awareness and understanding of the issues among the Codex membership, supporting the active engagement of Members in the resolution of the zilpaterol issue.

We heard an appetite to pursue a continuing and open dialogue in the search for progressive solutions, recognising that decisions lie with the membership of Codex. Independently of this programme of informal consultations, Members continue to hold bilateral and plurilateral discussions relating to the progress of draft proposed MRLs for zilpaterol in Codex.

Science and risk assessment considerations

We heard from Members across different regions about the importance of Codex decisions being science-based. Members expressed a need to respect and support expert scientific advisory bodies and ensure they are strong. We heard from Members across different regions who acknowledged the robustness of the JECFA risk assessment, several of whom were of the view that any outcome other than the adoption of MRLs would demean and undermine the work of JECFA.

We heard continuing concerns from Members in two regional informal consultation meetings relating to the lack of MRLs proposed for edible offal other than liver and kidney that were widely consumed locally.

We also heard some concerns regarding establishment of a withdrawal period and the potential for higher chronic intakes of zilpaterol by individuals with high levels of consumption of meat and edible offal from treated animals. Members with these concerns suggested that, in preparation for CAC45, the JECFA secretariat might prepare a simple summary document that explained the basis of the JECFA evaluation of zilpaterol and addressed the concerns raised in this informal consultation process.

Risk management and other considerations

We heard that, in addition to being science-based, Codex and its Members should abide by its rules of procedure, which provided sufficient tools for us to resolve the discussion of proposed draft MRLs for zilpaterol. We heard the need to respect the rule of law, in that having agreed a set of rules and procedures we should hold ourselves and each other to account for following them. In this context, there was concern at what some perceived as exceptionalism in our approach to exploring avenues for resolution of current disagreements, and a particular concern that the exploration of new tools and approaches could set unhelpful precedents.

We heard from Members across different regions whose current national regulations did not permit the use of zilpaterol. We noted the range of positions held by these Members regarding the draft proposed Codex MRLs for zilpaterol, which included:

- those who, in the event of MRLs for zilpaterol being adopted by Codex, would align their national regulations with the new MRLs;
- those who would not commit to changing their national regulations but who would support the adoption of Codex MRLs for reasons that included: the facilitation of trade between other Codex Members at a time of particular food security and food sovereignty challenges; recognition that their national situation should not impede the establishment of an international standard; and their belief this would be the procedurally correct course of action;
- those who would enter reservations to the adoption of Codex MRLs, on the basis of non-alignment with their current national regulations; and
- those who remained fundamentally opposed to the adoption of Codex MRLs for zilpaterol or other growth promoters, which they see as being incompatible with the current bans on zilpaterol within their own jurisdictions; the clear preference of many of those Members would be the discontinuation of this work.

We also heard frustration regarding the sustained position of this latter group of Members from others whose national regulations did not permit the use of zilpaterol but whose position was other than fundamental opposition to the adoption of Codex MRLs, and the perceived paucity of rationale for the sustained position of fundamental opposition which was preventing the ability to debate and resolve whether there were any Other Legitimate Factors (OLFs) that should be considered in this case. We heard an expectation that Members opposed to the adoption of Codex MRLs should either provide a rationale and scientific evidence to support consideration of one or more OLFs, or should enter a reservation and make or sustain national provisions preventing the use of zilpaterol or import of meat containing residues of zilpaterol to the extent that this would be consistent with their international obligations. The rationales offered for this expectation included:

- the need to act in the interest of Members who engaged in trade in meat from animals treated with zilpaterol;
- a belief that advancement and adoption of MRLs should be the default approach when, as in this case, there was general agreement on the risk assessment and necessary level of consumer health protection and the absence of other factors within the remit of Codex and accepted on a worldwide basis;
- an acknowledgement of the inherently divisive nature of voting as a means of resolving this issue, at a time when there was a sense that Codex should come together and unite in the service of our mission.

We sought feedback on our report to CCEXEC82 on the earlier, more limited round of informal consultation meetings. Regarding the first point above, we heard the view that if the one instance we identified in that report of disruption to trade due to the lack of Codex MRLs for zilpaterol were an isolated occurrence, we should look to a bilateral trade agreement to resolve it rather than an international Codex standard. In the current round of informal consultation meetings, given their broader reach, we heard reports of a more extensive network of trading relationships that exist between exporting countries with significant livestock economies in which zilpaterol is licensed and used, and importing countries in the same or different regions many of which do not have national MRLs for zilpaterol in edible tissues and lack the national capacity in quantitative risk assessment to develop them. We heard this characterised as an overall global interest in adoption of Codex MRLs for use by those Members who need them for the purpose of consumer health protection and trade facilitation, and to support the further development of their livestock economies. We heard from a Regional Economic Integration Organisation in one region which included both exporters and importers that, while there was a need for technical assistance to Members to enhance capacity for implementation of Codex MRLs for zilpaterol, for example around sampling and analysis, the first and vital step for consumer health protection and trade facilitation would be adoption of Codex MRLs.

We also heard a contrary view, that the adoption of Codex MRLs for zilpaterol despite knowing the strong positions of some Members against the use of growth promoters would work against the objective of Strategic Goal 3 to deliver impact through recognition and use of Codex standards as we would be adopting standards in the full knowledge they would not be used globally.

Possible routes to resolution

There was general acceptance of the views advanced by CVCs that progress in discussions of the proposed draft MRLs for zilpaterol was not dependent on completion of the work of the CCEXEC subcommittee on operationalisation of the Statements of Principle. There was widespread interest in better understanding the work of the subcommittee and the practical guidance it was developing. As part of each regional informal consultation meeting, we took the opportunity to update the wider Membership on progress in the work of the CCEXEC subcommittee on operationalisation of the Statements of Principle. These updates, and the continuing work they are based on, were generally appreciated and sparked discussions on the application of elements of the draft flowchart to the anticipated discussion of zilpaterol at CAC45, as a result of which Members said they better understood how operationalisation of the Statements of Principle might be used.

We heard from Members in one region their concern that the scope of the work on operationalisation of the Statements of Principle had been constrained to the application of Statement 4 and, to a lesser extent, Statement 2 in discussions on whether standards should be advanced or adopted at Step 5, Step 8 or Step 5/8. Their view was that the Statements of Principle could apply at all stages of the standards development process and that guidance was needed that covered all stages.

We heard from Members in another region that the current draft flowchart should be more definitive in identifying the point(s) in the process where a vote would be considered. It was felt that this clarity would help both chairpersons and Members to navigate the process.

We heard views for and against the potential use of footnotes to standards to indicate where standards had been adopted through a process that included one or more Members abstaining from acceptance. These differences of views reflected those we have heard in discussions in the CCEXEC subcommittee.

There were requests and support from Members in several regions for further webinars or virtual workshops with Members to build awareness and promote understanding of how the Statements of Principle could be used, in advance of CAC45.

In line with the conclusion of CCEXEC82 that we should identify opportunities to reach consensus where they may exist, we explored whether Members would support a proposal to redefine the objective of the work on zilpaterol such that rather than adopt a formal standard in the form of Codex MRLs we might agree a related text such as:

- a risk management recommendation;
- a reference to the JECFA risk assessment which noted the proposal of MRLs that would deliver an appropriate level of human health protection but did not adopt them as Codex MRLs;
- a note that provided for differential application of Codex MRLs for zilpaterol in trade with Members where growth promoters were not permitted for use in food-producing animals.

Views were divided. We heard from some Members who cautiously welcomed the suggestion that we might explore approaches other than adoption of Codex MRLs, acknowledging the possibility that this might provide a basis for compromise and consensus. Those Members acknowledged this would require significant further work and would need to be tested against other considerations. We heard from other Members, across several regions, who had grave concerns and would be strongly opposed to any suggestion that we might develop risk management recommendations or other approaches to zilpaterol short of Codex MRLs. The rationale provided for these views included:

- an approach which elaborated a related text, and not a formal standard, would be legitimate where scientific data are insufficient and/or incomplete, but that is not the case for zilpaterol, where the JECFA risk assessment is generally supported – and therefore, an approach other than the adoption of MRLs would demean the JECFA opinion and would show a lack of resolve on the part of Codex to support science-based decision-making;
- concern at the precedent that would be set by a risk management recommendation in the absence of any human health concern;
- a concern that, given that some national legislative frameworks enable or require the implementation of Codex standards into national regulations but are silent on the implementation of different instruments, an output which was not a Codex standard may face problems in implementation and may not achieve the anticipated outcome of consumer health protection and trade facilitation.

We heard that, whichever routes were used in resolving the discussion and debate at CAC45, it would be important for the language used by the chairperson in summarising and concluding the discussion, and the language used in the report of the meeting, to appropriately acknowledge the provisions in current Codex procedures that were used as the basis for the resolution.

We heard some interest in thinking about the elements, including the current and possible further work on the Statements of Principle. that may form part of a package that would provide a meaningful and systemic solution for zilpaterol and similar issues that may be considered by Codex. There was an acceptance that this would require more time and the appetite and openness of other Members to conduct this work, which was not guaranteed.

While we consistently heard a continuing preference to proceed without recourse to voting, we also sensed a reluctant but growing expectation more generally among Members that it may take a vote to break the current deadlock and even, from some, overt support for a vote as they felt we have exhausted, or are close to exhausting, all reasonable efforts to find consensus. We heard that we should ensure that such a vote were, as far as possible, amicable and mutually respectful.

Impact

We invited views on the impact that adopting a standard, or not, would have on consumer health protection and trade for Members, or on the functioning and reputation of Codex as an international standard-setting body.

We heard that, for those Members in whose jurisdictions zilpaterol would continue not to be approved for use, there would be little anticipated impact in terms of consumer health protection following the potential adoption of Codex MRLs for zilpaterol. This position was shared by Members who supported adoption of Codex MRLs for zilpaterol and those who opposed. Some of these Members acknowledged there may be some trade friction in relation to product they imported that contained detectable residues of zilpaterol.

We heard concern that a failure to adopt Codex MRLs for zilpaterol would have a significant but unquantified impact on the network of trading relationships that exist between exporting countries in which zilpaterol is licensed and used, and importing countries in the same or different regions many of which do not have national MRLs for zilpaterol in edible tissues and lack the national capacity in quantitative risk assessment to develop them. This would be characterised as a failure by Codex to address the needs of its Members, as set out in Strategic Goal 1, and would have particularly negative impacts on developing countries, which Codex risk analysis procedures direct us to give particular attention to.

We heard more interest, and concern, regarding the impact that adopting MRLs for zilpaterol or not might have on the functioning and reputation of Codex and the integrity of its decision-making processes. Some felt that the vote on adoption of MRLs for ractopamine had been inherently divisive and had negatively impacted collaboration between Members on a wider range of issues within Codex, fearing that this might also be one of the consequences were MRLs for zilpaterol to be adopted only after one or more votes. Some felt that not adopting Codex MRLs for zilpaterol would have significant negative effects on the reputation of Codex for science- and rules-based decision-making, particularly given the widespread acceptance of the JECFA scientific evaluation in this case, and on the willingness of individuals or countries to continue to invest in FAO/WHO joint expert committees and ad hoc consultations. Some pointed to the reputational damage and opportunity cost that Codex might suffer if zilpaterol remained under discussion in Codex for several more years without resolution. Others still were keen that we should avoid all these possible negative impacts which, in their view, made the case for the use of reservations or abstention from acceptance by those Members opposed to adoption.

Some Members were keen to highlight the prolific standards development work undertaken by Codex and took the view that the outcome of discussions on this one standard would have a limited impact that we should not exaggerate.

Other Members thought that the adoption of Codex MRLs for zilpaterol would demonstrate the willingness of Codex to embrace the potential of new, safe compounds that could improve food security and food sovereignty.

Other issues

We heard concerns about the impact that the decision to convene CAC45 as a physical meeting with virtual participation may have on the level of attendance and hence the inclusivity of the discussion on the proposed draft MRLs for zilpaterol, noting in particular that a vote with a low turnout would be potentially damaging for Codex. Members also raised questions on procedural aspects of the anticipated discussion of proposed draft MRLs for zilpaterol at CAC45.

We also received a request to support use of the Codex Trust Fund to once again support travel and participation in CAC45 and other meetings for delegates for eligible countries, as we explore physical and hybrid meeting modalities.

Following on from our discussions on progress in the work of the current CCEXEC subcommittee, we were asked whether work on operationalisation of the Statements of Principle might continue beyond CAC45, should there be the appetite among Members. This goes beyond the scope of our informal consultations on zilpaterol and would be a question to be considered by CCEXEC83 in the first instance.

We were invited to speculate on the implications of various potential outcomes of the anticipated CAC45 discussion of zilpaterol in relation to international trade obligations and considerations related to the work of the World Trade Organization. While acknowledging that these considerations may be relevant for Members, who may as a result seek advice from specialised trade lawyers, they are not considerations relevant to how as CVCs we should facilitate discussions in Codex.

<u>Analysis and commentary by CVCs</u>

We thank all Members and Observers who participated in this round of informal consultation meetings for their open and honest engagement. These meetings were characterised by two way discussion in which CVCs posed questions, listened and responded to feedback, and explained related work in CCEXEC and how it might help move us towards consensus. In line with the conclusions of CCEXEC82, we probed for the rationale of Members who spoke both in support of and against advancement of the proposed draft MRLs for zilpaterol and the responses we received are included in our report above.

The draft flowchart relating to operationalisation of the Statements of Principle that had been developed in CCEXEC82 proved a useful tool to distinguish between different concerns raised by Members and to facilitate discussions of how these concerns might be resolved at the appropriate stages of any discussion of zilpaterol at CAC45. The concerns we heard regarding the lack of proposed draft MRLs for some edible offals is a case in point. As we noted in our report to CCEXEC82, the 81st meeting of JECFA (2015) concluded that there were insufficient zilpaterol residue data to adequately consider exposure to residues in lungs and other edible offals of cattle apart from liver and kidney. Reference to the draft flowchart allowed us to identify discussion of the risk assessment as an appropriate point for any remaining concerns to be raised. We have confirmed with the CCRVDF Secretariat that Members have not officially requested further MRLs through the JECFA priority list of CCRVDF, but that such requests, referencing, as appropriate, the definition of edible offal adopted by CCRVDF25, could be made and discussed at CCRDVF26, scheduled for February 2023. We discussed and agreed with concerned Members that, in the light of local patterns of consumption of meat and edible offal, if they believe health protection for their consumers from residues of zilpaterol would not be adequately assured in the meantime by adoption and use of MRLs for zilpaterol in muscle, fat, kidney and liver alone, they could enter a reservation at CAC45 accordingly.

We share the assessment we heard from one Regional Coordinator, for a region whose Members hold a range of views, that it is clear there is no consensus and that the various parties with differing views are entrenched in their respective positions. We sensed little, if any, movement in the views of Members from those we heard in the previous round of informal consultation meetings in March to May 2022. We heard of continuing dialogue between Members with different views, which we continue to strongly support, but also a sense of frustration from some at the lack of progress and a recognition that time is now growing short.

With reference to the measures to facilitate consensus that are set out in the procedural manual, the view of CVCs is that we have a well-established scientific basis for the proposed MRLs, that these have been the subject of thorough discussion at CCRVDF, CCEXEC and CAC, and that we have organised informal meetings open to all Members to identify opportunities for consensus. In order that we might thoroughly examine potentially productive routes to consensus, we took the opportunity of these informal consultation meetings to gauge the appetite of Members for any proposal to redefine the objective of the work on zilpaterol. While we heard some tentative and conditional support, we heard more and stronger opposition which, in our view, was procedurally well-founded. Our conclusion is that redefining the objective of the work on zilpaterol would be very unlikely to facilitate consensus.

Following proposals and requests we heard from Members, we will:

- suggest to the JECFA Secretariat that, in preparation for CAC45, they might prepare a simple summary document that explained the basis of the JECFA evaluation of zilpaterol and addressed the concerns raised in this informal consultation process;
- discuss with the Codex Secretariat the possibilities that may exist for webinars or virtual workshops with Members to build awareness and promote understanding of how the Statements of Principle could be used, in advance of CAC45;
- work with and support the Codex Secretariat to ensure that arrangements for CAC45, including provisions for voting if needed, are inclusive and transparent; and
- raise with the Codex Trust Fund Secretariat the requests we have heard for these funds to also be made available to support travel and participation in CAC45 and other meetings for delegates for eligible countries, as we explore physical and hybrid meeting modalities.

We will also raise with the Codex Secretariat and, as needed, the Legal Offices of FAO and WHO the questions raised by Members on procedural aspects of the anticipated discussion of proposed draft MRLs for zilpaterol at CAC45, and any other relevant issues that might arise in our preparations for CAC45. We will seek written answers to our questions and, if and when we need to use those answers, we will publish them in the wider interests of transparency.

We continue to believe that these successive rounds of informal consultations, as mandated by CAC44, have been useful in exploring the positions of Members and, to the extent that Member have been willing to share them, the rationale for their positions. However, our reluctant conclusion is that these informal consultations have been less successful in bridging the gap between the divergent positions held by Members, which seem as far apart as they were at CAC44. We will continue to make ourselves available for discussion with all Members and Observers as we approach CAC45 but time for a breakthrough in discussions is now getting short. We will therefore work closely with the Codex Secretariat and with the Legal Offices of FAO and WHO to prepare for a potential vote on zilpaterol at CAC45, noting the direction from CAC44 that we should ensure that all tools, including voting, are at the disposal of CAC45 to allow resolution of this issue.