

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda item 8

CX/CAC 23/46/21 Add. 1

Original language only

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEx ALIMENTARIUS COMMISSION

Forty-sixth Session

FAO Headquarters, Rome, Italy

27 November – 2 December 2023

### COMMENTS ON THE DRAFT GUIDANCE ON THE APPLICATION OF THE STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEx DECISION MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT (SOP)

(Comments in reply to CL 2023/32/OCS-CAC)

*Comments of Argentina, Australia, Canada, Costa Rica, Ecuador, Egypt, European Union, Indonesia, Iraq, Japan, Kazakhstan, Kenya, Malawi, Malaysia, Norway, Panama, Paraguay, Peru, Thailand, United Kingdom, Uruguay, USA and CropLife International, ICBA, IDF/FIL, IFT*

#### BACKGROUND

1. This document compiles the comments on the draft guidance on the Application of the statements of principle concerning the role of science in the codex decision making process and the extent to which other factors are taken into account (SoP). The comments are those received through the Codex Online Commenting Systems (OCS), or via email by the time this document was issued. The comments are as shown in Appendix I.
2. OCS is an online tool that enables Codex Contact Points to submit comments on draft texts in a standardized way, thus providing more transparency and better management of comments on different Codex texts as requested through Circular Letters. Since its launching at CAC39 (2016), the OCS has been used for different Codex Committees.

#### EXPLANATORY NOTES ON APPENDIX I

3. The comments received are presented in a table format, with two columns as follows:
  - First column – Presents the comments with the rationale.
  - Second column – Presents the provider of the comments (name of country or observer)

**GENERAL COMMENTS**

COMMENT	MEMBER / OBSERVER
<p>El objetivo principal del trabajo que se llevó adelante nunca estuvo orientado a reabrir el texto de la Declaración de Principios ni tampoco a reinterpretar su alcance, que por otra parte es absolutamente claro. sino brindar orientación práctica para “operacionalizarlas” y propiciar una aplicación coherente en todos los Comités de Codex. No consideramos necesario mas trabajos sobre esta cuestión por el momento. Se debe comenzar a examinar como se aplican en la práctica.</p>	<b>Argentina</b>
<p>Australia strongly supports the final product conveyed by CCEXEC83 to CAC45. The document provides succinct, practical guidance for Codex subsidiary bodies and their chairpersons and members. It is very helpful in developing a shared understanding of how to apply the statements of principle in the risk management process. The flow diagram is clear and useful. In our view, with the removal of the square bracketed text, the draft guidance would be an excellent final document. We do not support Codex doing further work on the bracketed text, and certainly not on the rest of the document. Let’s get the guidance published so that it an be used to assist committees to give consideration to other factors.</p>	<b>Australia</b>
<p>Canada believes that the current guidance is serviceable and fairly reflects the comments made and thoroughly considered by the CCEXEC subcommittee. We note that at CAC45, the Codex Chairperson indicated that the current guidance was a serviceable document and was used to guide certain discussions at CAC45. We recall some discussions on this guidance at CCEXEC were challenging and have concerns that opening up the text to include other new concepts or issues discussed by CCEXEC that we know to be contentious risks unravelling the good progress achieved towards consensus. Canada has specific comments below on the questions asked.</p>	<b>Canada</b>
<p>The EUMS are of the opinion that the flowchart should be removed from the guidance. It is noted that the draft text of the guidance already provides information on options and different scenarios. The possible further work on the guidance should focus on these aspects. The EUMS disagree that the current flowchart would provide a satisfactory visual decision-guide facilitating the operationalisation of SoP as indicated in paragraph 1 of Appendix II of REP22/EXEC2. A flowchart should only be maintained if it fully reflects the different options and scenarios provided in the draft text and if it is ensured that the detailed information and clarifications provided in the draft text are duly considered by the Chairpersons and the membership.</p> <p>The EUMS welcome the suggestion that the draft guidance is for chairpersons and Members. It is however noted that the guidance is largely devoted to Chairpersons. The aspects related to Codex Members would need to be further developed. These aspects should notably include guidance on the presentation of other factors that are accepted on worldwide basis (see reply to point c). The guidance should also include information for Members on the difference between issuing reservations and abstaining for acceptance (see reply to point d).</p> <p>The draft guidance invites chairpersons to make a number of determinations. The EU and its Member States are of the opinion that the guidance should provide further information on the elements that a chairperson should consider to make these considerations (see in particular paragraphs 13, 14, 16, and 21). See also the reply to question c above.</p> <p>The EUMS would like to note that paragraph 1 of Appendix II, REP22/EXEC2 “(...) when Members agree on the science and necessary level of public health protection but hold differing views about other considerations (...)” could be read in a way that other considerations are not based on science. On the contrary, the elaboration of a process to consider other factors (see also reply to question c) should include considerations on scientific information related to these factors (e.g. scientific information on negative environmental effects) that should be available or should be obtained in the process of the standard development.</p>	<b>European Union</b>
<p>We consider that it is necessary to continue discussions on the draft guidelines. There is still no common understanding of the practical implications "abstaining from acceptance".</p>	<b>Kazakhstan</b>

<p>New Zealand appreciates the opportunity to comment on CL 2023/32/OCS-CAC the 'Request for comments on the draft guidance on the application of the Statements of Principle concerning the role of Science in the Codex decision making process and the extent to which other factors are taken into account (SoP)'.</p> <p>We would like to thank the Codex Senior Leadership specifically for the valuable work in developing both serviceable and robust draft guidance. We consider this guidance provides the necessary clarification of the decision-making process to operationalise Statement 4 of the SoP or the extent to which other factors (or 'other considerations') are taken into account. It is our view that this guidance will greatly enhance science-based decision making in Codex. Indeed, we have already seen the draft guidelines inform the decision making process for zilpaterol at CAC45.</p> <p>New Zealand has the following comments in response to CL 2023/32/OCS-CAC.</p> <p>We acknowledge a key principle in the development of Codex standards is to ensure that the Codex decision-making process is based on sound science.</p> <p>The Statements of Principle (SoP) concerning the role of science in the Codex decision-making process (adopted by CAC21 in 1995) established a pathway for science-based decision making in Codex. As new challenges have arisen over time, members have sought further elaboration and clarification of this pathway where deemed necessary. For example, in 2001, CAC24 agreed to Criteria for the Consideration of the 'Other Factors' Referred to in the Second Statement of Principle.</p> <p>In recent times, some members have expressed that there was a lack of clarity with respect of how 'other factors' not relevant to Codex may be considered in the decision-making process.</p> <p>We consider this draft guidance provides the necessary clarification of the decision-making process to operationalise Statement 4 of the SoP or the extent to which other factors (or 'other considerations' as they are referred to in the principles themselves) are taken into account. In doing so, the draft guidance provides a way for members to formally opt-out of using the standard without further debating their views on other considerations.</p> <p>New Zealand therefore supports the finalisation at CAC46 of the Guidance for Codex Chairpersons and members on the application of the statements of principles concerning the role of science in the Codex decision making process and the extent to which other factors are taken into account.</p>	<p><b>New Zealand</b></p>
<p>The United Kingdom has followed this work closely and welcomes the opportunity to comment on the specific questions posed to members in CL-2023/32. We are grateful to the sub-group of the Executive Committee and its Chair for the progress they have made towards finalising this guidance.</p> <p>The United Kingdom was amongst a handful of members that chose to abstain from acceptance, in accordance with SoP4, at CAC45 during the discussions which ultimately led to a vote on the MRL for Zilpaterol Hydrochloride. We are hopeful that the SoP guidance will provide the necessary clarity and assurances to those members who like the UK wish to maintain their opposition to this standard. The United Kingdom's decision to abstain from acceptance was not taken lightly, and for transparency we signalled clearly that we were maintaining our opposition and expressing that opposition procedurally through abstention from acceptance so as not to prevent a decision. It was evident during the discussions, and (if confirmation was needed) by the outcome of vote that the standard does not command a global consensus as a significant number of members (40% of votes cast) signalled through their vote against/abstention that they were opposed and would not use the standard. However, we are hopeful that the SoP guidance, when finalised can at least help members reach a consensus on how to move forward without the need for a divisive vote. For this to happen Section C (ii) of the guidance needs to provide the necessary assurance to</p>	<p><b>United Kingdom</b></p>

<p>members considering abstention from acceptance. In this regard the UK does not consider the two options set down in paragraphs 19 &amp; 20 as an “either or” choice as they are not mutually exclusive (see our comments below on the use of footnotes), as recording key parts of a discussion/opposition in the report and the use/inclusion of footnotes are established practice. The UK believes more members would choose abstention from acceptance if there was clarity and certainty about this course of action. The UK therefore suggests the following additions to the definition contained in paragraph 6: Abstention from acceptance refers to a member’s choice to express their continued opposition and signal that they do not intend to use the Codex standard/text at the national level or for trade purposes. A Member may choose to express the intention not to accept a text by recording a reservation in the report of the meeting at which the text is adopted and/or request consideration, as appropriate, by the committee of the inclusion of a footnote in the standard to ensure transparency. The term is not related to the abolished Codex acceptance procedure.</p>	
<p>General Comments: The United States agrees with the points made at CAC45 and CCEXEC that the guidance document, and in particular the flowchart, is a useful tool that can guide discussion of issues and assist chairpersons in those infrequent circumstances when there is broad consensus on the risk assessment/level of health protection afforded by a proposed Codex text, but Codex members hold differing views about other considerations. The United States also continues to support the decision by the CAC Chairperson and Chairperson of the Executive Committee Sub-Committee that developed the guidance to close debate on the issue, and CAC45’s conclusion to commend the progress made and share the guidance with members and committee chairpersons for their use in situations where the Statements of Principle (SoP) come into play. This enables Codex to gain experience with application of the guidance and inform potential future refinements. The original goal of the work was not to re-open or re-interpret the Statements, but to provide practical guidance to “operationalize” them and promote consistent application across committees. At this time, the United States does not believe further debate would be productive, until more experience with the current guidance is gained.</p>	<b>USA</b>
<p>International Council of Beverages Associations (ICBA) thanks the Secretariat for the opportunity to submit these comments. For more than 20 years, ICBA has served as an Observer at Codex and actively participated in different Committees and Working Groups, recognizing the important role that Codex plays in the development of science- and risk-based food safety standards. We appreciate your consideration of our comments.</p>	<b>ICBA</b>
<p>The Institute of Food Technologists, a scientific member organization of over 12,000 scientists, appreciates the opportunity to provide comments to the CAC 45 request regarding the draft guidance on the application of the Statements of Principle (SoP) concerning the role of Science in the Codex decision making process and the extent to which other factors are taken into account within SoP.</p> <p>IFT believes that the proper review and use of sound, repeatable scientific research and analysis for decision making within the development of Codex food standards, guidelines and codes of practice is a critical pillar of the Codex process, and that the SoP’s are a crucial guidance tool for all the Codex Committee work. For example, the strong support evidenced during CAC 45 by both Codex members and observers for the work of JECFA during the discussions is indicative of the importance of the SoP’s and the related guidance document on the application of them to Codex decisions.</p> <p>IFT also believes that statement 2 of the SoP regarding the use of other legitimate factors (OLF) should always strictly adhere to the Scope and Mandate of Codex. Hence, IFT supports the draft guidance document position that "CAC will take into account, where appropriate, OLF's relevant to (HUMAN) health protection and promotion of fair practices in food trade...". Likewise, IFT supports the draft guidance position that "OLF's that are not relevant to the purpose (AND MANDATE) of Codex, as determined by the Criteria for the consideration of the OLF's in the 2nd Statement of Principle should not be taken into account in risk management (NOR RISK ASSESSMENT) discussions in Codex." IFT believes that it is important for all Codex members and observers to have a common understanding of OLF's in this regard and would encourage Codex to develop training for Committee chairs and members to help strengthen such common understanding. In the preceding paragraph, IFT has added (in CAPS) additional words of clarification to the current draft guidance document under SOP #2 that we would</p>	<b>IFT</b>

suggest might be useful with the implementation of the guidance document and that are aligned with the Codex Scope and Mandate. IFT supports the implementation of the draft guidance for all Codex work as soon as possible.	
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## SPECIFIC COMMENTS

<b>Is the option to use a footnote in a standard appropriate? (Paragraph 20 of Appendix II, REP22/EXEC2)</b>	
<p>No estamos de acuerdo con incluir una nota a pie de página en una norma donde se indique el nombre de los países que se oponen a su adopción. Las notas al pie se determinan caso por caso y están destinadas a brindar información adicional o aclaratoria sobre cuestiones propias de la misma.</p> <p>Creemos que se debe utilizar la opción 1. No creemos que se apropiado y nos oponemos firmemente a que la posición individual de un miembro quede reflejada en el pie de página de una norma del Codex.</p> <p>Cualquier referencia a la posición de los Miembros puede quedar en el report de la reunión como se ha hecho tradicionalmente. Es importante considerar que las normas del Codex constituyen la norma de referencia internacional para la Organización Mundial de Comercio y que las consecuencia de notas al pie con los nombres de país que se oponen o no la aceptan podría desvirtuar la naturaleza de la norma misma.</p>	<b>Argentina</b>
<p>No - Australia is strongly opposed to the guidance including an option for recording the use of Statement 4 in a footnote to a standard. The purpose of the draft guidance is to provide guidance on the application of the statements of principle. The active part of the application of the statements is centred around the use of 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.</p> <p>The key gap filled by this guidance is a gap in the membership's collective understanding about how to use Statement 4 in the context of discussions on other factors in the risk management process. The draft guidance provides excellent practical guidance about the situation in which members could consider using Statement 4 and how Chairpersons could facilitate this consideration within committees. Recording the use of Statement 4 is not obligatory but can help with transparency. Discussions related to other factors should be captured in the report of meetings. If other factors are accepted as OLFs and take into account in the risk management decisions, how and when this has occurred should be clear in the report. It would make logical sense to also capture in the report where other factors were considered and concluded that they were not OLFs and could not be included in the risk management decisions. If members chose to use Statement 4 as a result to of this decision then it would be captured here alongside the discussion.</p> <p>It does not make logical sense to include a footnote in a standard when that footnote would specifically relate to matters that are not relevant in Codex risk management and therefore not relevant to the standard in which the note would be. Recording the use of Statement 4 can help with transparent reporting of the deliberations of committees and there are existing procedures that allow for the use of Statement 4 to be recorded in the report.</p> <p>As such Australia supports finalizing the draft guidance by deleting the square bracketed text.</p>	<b>Australia</b>
<p>Canada is of the view that it is not appropriate to use a footnote within a standard to acknowledge the use of Statement 4 of the Statements of Principle (SoP). This would go against CCEXEC advice that footnotes should be kept to a minimum and creates what appears to be a new mechanism reminiscent of the acceptance procedure, noting that in this case the term "acceptance" does not refer to the abolished acceptance procedure (CX/EXEC 19/77/10). While it is true that footnotes of a general or technical nature have been used in some Codex standards after careful consideration and on a case-by-case basis, this proposed footnote represents a type of footnote not previously used in Codex standards. Including a specific Member's opposition to a standard within the standard could create the perception of a hierarchy of lesser standards and could lead to unintended consequences such as lessened desire for consensus building by Members (e.g. if they know that an option indicating non-acceptance in the standard is available), thus diluting the value of the standard. It could also create a situation where</p>	<b>Canada</b>

<p>Members are required to determine the use of the Codex standard in their national context at the time of adoption. Adopting a standard with references to the national intent of a Member country would require regular reviews and updates. We do not believe this to be in line with best practices, particularly as the benefits of this option have not been demonstrated in the face of the potentially significant negative outcomes. We note that members can record their dissenting views consistent with current practice in the report, including through reservations.</p>	
<p>Costa Rica se opone rotundamente a la inclusión de la nota al pie de página en una norma por los siguientes factores:</p> <ul style="list-style-type: none"> <li>• Se desconoce las implicaciones jurídicas que una nota al pie como la que se propone conlleva, por ejemplo, en un panel de solución de controversia ante la OMC;</li> <li>• La inclusión de una nota como la que se propone puede generar confusión con las notas a pie de página de carácter técnico.</li> <li>• Las notas al pie de página en la práctica se usan con el objeto de brindar claridad sobre el contenido técnico de la norma y no corresponde a las buenas prácticas de normalización.</li> <li>• Las declaraciones de principios referentes a la función que desempeña la ciencia en el proceso</li> <li>• decisorio del Codex y la medida en que se tienen en cuenta otros factores. Establecen en el párrafo 4: “Si se plantea la situación de que los miembros del Codex están de acuerdo sobre el grado de protección de la salud pública que se necesita, pero tienen opiniones diferentes sobre otros aspectos, los miembros podrán abstenerse de aceptar la norma en cuestión, sin que ello impida necesariamente al Codex adoptar su decisión”; pero no indican que en la norma se debe enumerar la aceptación o no aceptación de una norma del Codex por parte de los miembros.</li> <li>• Los informes deben ser claro y sucintos, reflejar las preocupaciones manifestadas por sus países miembro y como se logró el consenso por la cual se derivan las conclusiones; de manera que no sea necesaria la inclusión de notas al pie.</li> </ul> <p>Adicionalmente, CR no considera práctico incluir una nota al pie en una norma, para justificar aspectos que claramente deben reflejarse en el informe.</p> <p>Finalmente, Costa Rica quisiera resaltar que, si bien es cierto las notas al pie son una herramienta comúnmente utilizada en la redacción de documentos normativos para proporcionar aclaraciones, definiciones, referencias cruzadas u otros tipos de información adicional, incluso como bien se menciona, el Codex las ha utilizado para incluir ejemplos concretos o casos prácticos para ilustrar cómo se aplica una disposición específica, es importante tomar en consideración que debe ser utilizadas con moderación y de manera coherente para evitar sobrecargar el documento con información innecesaria que incluso puede confundir al usuario de dicha norma.</p>	<p><b>Costa Rica</b></p>
<p>Ecuador está de acuerdo con la utilización de la nota al pie de página en una norma, según las consideraciones del párrafo 20 del Apéndice II del documento (REP22/EXEC2); es importante que se ponga atención al criterio de que cuando se proponga y acuerde esta opción, el contenido y la ubicación de la nota a pie de página debería ajustarse a las convenciones y prácticas del Codex relativas al uso de notas a pie de página en los textos del Codex, según indica el párrafo 20 del apéndice II.</p>	<p><b>Ecuador</b></p>
<p>YES , food note is important because it clarify what want to say and consider reference</p>	<p><b>Egypt</b></p>
<p>The EUMS would like to recall that (foot)notes of technical nature are already included in some Codex standards after careful consideration and on a case-by-case basis and have helped to overcome deadlocks in negotiations (See Section 5.4 of CC/EXEC 19/77/10 that identifies a number of examples of such (foot)notes). Footnotes recording the abstention from acceptance of a standard would serve the same purpose and additionally ensure transparency in the Codex risk management decision process in link with the Working principles for risk analysis for application in the framework of the Codex Alimentarius and in particular paragraph 31 that states that the risk management process should be transparent, consistent, and fully documented.</p> <p>The EUMS are of the opinion that the option to use a footnote is a critical option that should remain in the guidance. The inclusion of such footnote may be essential for the Codex members who are considering to abstain from acceptance. The EUMS are thus in favour of retaining Paragraph 20 in the context of further discussions aiming at the finalisation of the guidance. In this context, the EUMS are also of the opinion</p>	<p><b>European Union</b></p>

<p>that the second sentence of paragraph 20 is not necessary in the context of this guidance.</p> <p>It is thus proposed that paragraph 20 would read as follows:</p> <p>Option 2- Use of footnotes in standard 20. The Commission or subsidiary bodies may determine, if appropriate and in the interests of greater transparency with regard to the application of Statement 4, that a footnote might be included in the relevant standard. Where this option is proposed and agreed, the content and placement of the footnote should be in line with Codex conventions and practices related to the use of footnotes in Codex texts.</p> <p>In line with this comment, the EUMS are of the opinion that the brackets should be removed from paragraph 18: 18. Where one or more Member(s) use Statement 4 of the SoP and abstain from acceptance of the relevant standard while not preventing its advancement, existing procedures allow for the use of Statement 4 to be recorded [in more than one way].</p>	
Yes	<b>Iraq</b>
<p>Option 2, using a footnote in a standard for recording an abstention of acceptance, is not appropriate. Japan believes that the use of a footnote should not be included as an option in the guidance.</p> <p>Japan recognizes that some Codex standards contain a footnote or note which doesn't have a technical nature, to address the different views on an issue. Such use of footnotes in these standards was extensively discussed and was agreed as a result of compromise by the relevant Committee. Careful considerations on the use of footnotes are needed on a case-by-case basis at the committee level. Japan is concerned that Option 2 could normalize the use of footnotes to record a particular Member's position, including not only an abstention of acceptance but reservation. Given that there is the possibility that Members expressing an abstention of acceptance might change their position in the later stage, Option 2 is also impractical in terms of maintaining and updating.</p> <p>The Codex standards are "the final products" that build on the efforts of Members in Codex core values. Japan believes that the guidance should not provide any options which might undermine the value of Codex standards.</p>	<b>Japan</b>
<p>Comment Kenya does not support the use of a footnote in the standard but rather proposes the reservations to be retained as part of the main meeting report.</p> <p>Rationale Footnotes are more useful in giving information that assists in the interpretation of a standard.</p>	<b>Kenya</b>
<p>Malaysia is of the view that recording Members abstention from acceptance of relevant Codex standard in the report of the meeting is sufficient. The inclusion of footnote to record reservation in the standard to be adopted is not necessary as the country policy and decision may change over time and that having an abstention in a Codex standard could imply other members as accepting the standard while Codex no longer has acceptance procedure.</p>	<b>Malaysia</b>
<p>New Zealand does not support the option of using a footnote in a Codex standard to acknowledge a member's use of Statement 4 of the SOP.</p> <p>New Zealand considers that the use of such a footnote in a standard would likely undermine the very essence of science-based Codex standards – to protect the health of consumers and ensure fair practices in the food trade.</p> <p>The use of footnotes in Codex standards, (seen on occasion) is not best practice.</p> <p>A key concern of the use of such a footnote is that the consequences of doing so are not fully understood.</p> <p>As such there is a risk such a footnote would cause a contradiction with members' WTO obligations.</p>	<b>New Zealand</b>

<p>Additionally, while the challenges of including such footnotes in a standard have been discussed extensively to date, the real value or benefit of including such a footnote has not been articulated.</p> <p>Finally, the option of including acknowledgement of a member's use of Statement 4 or the SOP in the committee report will achieve the purpose of a transparent decision making process and a permanent reference for any member country to refer to (and do so without the risk of devaluing Codex standards).</p>	
<p>Yes, the option to use a footnote is appropriate, it is a critical option that should remain in the guidance. Footnotes are already included in Codex standards to clarify and have in some instances helped to overcome deadlocks in negotiations. Footnotes recording the abstention from acceptance of a standard would serve the same purpose and additionally ensure transparency in the Codex risk management decision process and would be in line with the Working principles for Risk Analysis for application in the framework of the Codex Alimentarius para. 31: "31. The risk management process should be transparent, consistent, and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties."</p> <p>The inclusion of such footnote may be essential for Codex members who are considering abstaining from acceptance. We are thus in favour of retaining Paragraph 20. However, the paragraph would need some amendments as the second sentence of paragraph 20 is not necessary in this guidance as it is not usual procedure for Codex to specifically agree on text in footnotes (ref discussion/decision of footnote 5 in CXC 61-2005 (2021)).</p> <p>It is thus proposed that paragraph 20 would read as follows:  20. The Commission or subsidiary bodies may determine, if appropriate and in the interests of greater transparency with regard to the application of Statement 4, that a footnote might be included in the relevant standard.</p> <p>In line with this comment, we are of the view that the brackets should be removed from paragraph 18:  18. Where one or more Member(s) use Statement 4 of the SoP and abstain from acceptance of the relevant standard while not preventing its advancement, existing procedures allow for the use of Statement 4 to be recorded in more than one way.</p>	<b>Norway</b>
<p>No lo recomendaríamos.  We would not recommend it.</p>	<b>Panama</b>
<p>Paraguay cree conveniente que la nota al pie de página es adecuada siempre que sirva para indicar la fuente de una cita o la referencia de lo mencionado en el texto, no así para otra finalidad.</p>	<b>Paraguay</b>
<p>Consideramos que no sería adecuado utilizar una nota a pie de página en una norma cuando uno o más miembros utilicen la Declaración 4 y se abstengan de aceptar la norma en cuestión sin impedir su adelanto, consideramos adecuado la opción 1 (párrafo 18 del Apéndice II del documento REP22/EXEC2), es decir consignar en el informe de la reunión la abstención de aceptar la norma Codex.</p>	<b>Peru</b>
<p>Singapore is of the view that the option to use a footnote in a standard is not appropriate.</p> <p>The reasons why these factors are not considered as "other legitimate factors" when the Codex Standard was under deliberation is because these factors are neither relevant to the health protection of consumers nor to the promotion of fair practices in the food trade, and/or that they cannot be accepted on a worldwide basis. Therefore, there is little value to include these factors in the footnote of the standard.</p> <p>Allowing the inclusion of these footnotes could cause Codex standards to be used to promote national concerns which are neither within Codex's mandate nor be accepted on a worldwide basis.</p>	<b>Singapore</b>



<p>Furthermore, the footnotes could potentially encourage technical discussions to be restarted or factors to be added when they were otherwise resolved, or not raised, during previous discussions within Codex subsidiary bodies and/or Joint FAO/WHO Expert Committees (e.g., JECFA, JMPR, JEMRA, JEMNU). The allowance of footnotes could therefore open the possibility for it to be perceived as an additional interpretation of the conclusions drawn from previous discussions and deliberations, and lead to an undermining of consensus building and the Codex goal of promoting harmonization.</p>	
<p>Thailand supports the use of a footnote to explicitly express the intention of a member country to abstain from acceptance of the Codex standard/text for use at the national level. This option can complement the option of recording the use of Statement 4 in the report for greater transparency and openness.</p> <p>For the use of the footnote, it could be used on a case-by-case basis, determined by the CAC or subsidiary bodies. The content of the footnote may contain only a statement that this standard/text has been adopted with the use of Statement 4 of the SoP. The names of the countries using Statement 4 and their rationale can be elaborated in the report of the meeting at which the standard/text is adopted.</p> <p>Therefore, Thailand supports maintaining the text of para. 20 and removing the square brackets.</p>	<b>Thailand</b>
<p>The United Kingdom has consistently argued that a footnote should accompany the MRL for Zilpaterol Hydrochloride, not least to provide the necessary transparency that records how a decision was reached in the absence of a global consensus. We have noted that many members who support adoption have commented that a footnote would weaken the standard, whilst also noting the status of Codex texts as being voluntary. These two statements are at odds with one another. Some have also expressed concerns about the use of footnotes and the danger of setting an unhelpful precedent.</p> <p>In reality, footnotes are ubiquitous in Codex and are used for a variety of reasons, their purpose may be explanatory or modifying in nature. In veterinary drugs there is a note pertaining to Clenbuterol, in the General Standard for Food Additives there are over 500 notes and in the recently adopted AMR Code of Practice, footnote 5 was not universally supported but provided the necessary assurances for some members to enable advancement and final adoption of the text. The UK considers footnotes to be a valuable tool that can help broker compromise. In the context of the SoP the use of footnotes should be considered on a case-by-case basis. On zilpaterol the UK has argued that a footnote would provide the necessary transparency, including for those members that intend to use the standard as they should not need to read the report to appreciate that a significant number of members maintained their opposition to the standard, and that the outcome - a decision to adopt - was only possible when those members opposed stood aside and expressed their continued opposition through abstention from acceptance.</p>	<b>United Kingdom</b>
<p>No. No es una práctica adecuada para un organismo de normalización. Transmite señales extremadamente confusas respecto de la naturaleza de la norma, en especial, es contradictoria con su fundamento científico.</p>	<b>Uruguay</b>
<p>The United States strongly opposes inclusion of the bracketed text in Paragraph 20 in the final guidance. Some types of footnotes may be useful, in the context of the guidance previously provided by CCEXEC on the use of footnotes in Codex texts and should be considered on a case-by-case basis. The type of note apparently contemplated in the bracketed language, however, would cite the positions of individual Codex members. This type of note has never been used in Codex and would not be appropriate in an adopted text. Such notes would undermine the value of Codex standards. They would also be impractical, since at the time of adoption members are generally not able to determine how a text will be applied within their national or regional contexts. It is also unclear if members would have the ability to amend or delete a footnote once they had practical experience of implementing the standard, at which point they may discover that their objection was unnecessary. Further, it was never within the Terms of Reference for this work to develop new procedural mechanisms.</p> <p>The United States is also concerned that such a practice would be counter to World Trade Organization (WTO) member obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to ensure that any sanitary measure is based on scientific evidence. The WTO SPS Agreement establishes a foundation for transparency based on notifications. The Agreement requires members to notify proposed SPS measures (such as laws, decrees or ordinances which are applicable generally), or changes to measures,</p>	<b>USA</b>

<p>which are not substantially the same as an international standard, guideline, or recommendation and may have a significant effect on trade. The SPS Committee has also encouraged members to notify draft proposed measures that are based on the relevant international standard, for even greater transparency. WTO notifications take place when members have determined their proposed course of action after careful evaluation of the relevant international standard in their national or regional context.</p> <p>The introduction of a footnote in Codex standards listing the acceptance or non-acceptance of the standard by particular countries appears to undermine this foundation of transparency by establishing a dual process. A footnote listing acceptance or non-acceptance of a Codex standard cannot fulfil WTO members' legal obligations or provide some form of protection in the WTO. In fact, Codex abolished its acceptance procedure with the advent of the WTO and the obligatory notification process established in the SPS Agreement. Having two separate processes for indicating acceptance or non-acceptance of Codex standards, is bound to create confusion and potentially contradictory statements, which Codex sought to avoid by abolishing its own acceptance procedure.</p> <p>When the former acceptance procedure was replaced by the WTO notification process, Codex clearly noted that the use of the word "acceptance" in Statement 4 was not related to the former formal acceptance procedure. The draft SoP guidance clarifies this by offering the following explanation:</p> <p>Abstain from acceptance' refers to a Member's choice to not use the Codex standard/text at the national level. A Member may choose to express the intention not to accept a text by recording a reservation in the report of the meeting at which the text is adopted. The term is not related to the abolished Codex acceptance procedures. (REP22/EXEC2, Appendix II, Paragraph 6.)</p> <p>This is consistent with long-standing and widely accepted Codex practice. The United States believes that introduction of a footnote listing individual members' acceptance or non-acceptance of a Codex standard goes far beyond the intent of Statement 4, which is to accommodate and record members' differing views on considerations for the standard that extend beyond food safety / public health. A footnote indicating individual member positions could have far-reaching implications for Codex and would jeopardize Codex's standing as the international food safety reference body.</p> <p>For these reasons the United States does not support the use of a footnote listing acceptance or non-acceptance of a Codex standard by members. Such an approach would also be in conflict with guidance given previously by the CCEXEC to limit the use of footnotes. Any formal record of members' dissent/reservations properly belongs in reports of Codex sessions, not within the adopted standards.</p>	
<p>CropLife International's view is that the use of a footnote in a standard is not appropriate. As the information on standards often is provided and published in databases, information given in footnotes might get lost. Secondly, CropLife International would like to seek clarification whether footnotes need to be updated through the step procedure, as footnotes might be set based on concerns by members which might be revised or become obsolete, but might not warrant the full review of the standard.</p>	<b>CropLife International</b>
<p>ICBA believes there are rational reasons to adopt footnotes to record positions in some situations. However, in the context of the Statement of Principle 4, the footnote approach may unintentionally invite a negative perception of Codex standards and their relevance. This is particularly concerning at this moment as Codex is reinforcing the role of science in risk assessments and development of texts.</p> <p>ICBA agrees with the Members at CCEXEC83 who supported the deletion of Option 2 on the basis that using footnotes could take away the value and standing of Codex texts. Specifically, we support the comment made in paragraph 69 of REP22/EXEC2 with respect to the use of footnotes "... promoting its widespread and unjustified use to reflect national concerns ... could undermine consensus building and the Codex</p>	<b>ICBA</b>

<p>goal of promoting harmonization.” We further note that comments related to national practices or concerns related to a text may be captured in the meeting report.</p>	
<p>IDF’s historic commitment to Codex is rooted in Codex’s own commitment to publishing science and risk-based standards that protect public health and facilitate fair practices in food trade. Over the last 60 years, Codex standards have benefited and protected dairy consumers and dairy producers around the world by increasing the amount of safe, high-quality milk and dairy products available in international trade.</p> <p>Although the use of footnotes for technical matters is generally accepted in Codex texts, we do not support the use of footnotes as described in Paragraph 20 of Appendix II, REP22/EXEC2. The inclusion of footnotes related to the invocation of Statement 4 of the SoP, as opposed to recording such an invocation in the main body of the report for the meeting, could lead to significant misunderstandings regarding the significance of such a footnote and its intended applicability in relation to the adopted Codex text. Codex develops voluntary international standards, codes of practice, and guidelines for international harmonization that governments can be assured reflect current science, risk-based food safety assessments, protect public health and ensure fair practices in food trade. Such notes have the potential to undermine any effort to formally adopt Codex standards, codes of practice and guidelines by Codex members, potentially raising questions about the scientific basis of the text, the quality and value of the risk assessment utilized, whether a country should adopt the Codex text and how such text with footnotes should be interpreted and enforced.</p> <p>In this context, it is important to note the substance of Statement 4 of the SoP. That Statement envisions invocation in instances where “members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations...” In other words, this Statement is intended to be used when the public health implications are clear and there is consensus that public health will not be harmed through the adoption of the standard in question. And, it may be invoked at the discretion of a member that wishes to abstain from accepting the standard based on factors outside the scope and mandate of Codex. Thus, the inclusion of a footnote related to Statement 4 in an adopted Codex standard will not contribute to protecting public health. However, it has the potential to disrupt fair practices in food trade by raising confusion about the status of a Codex standard based exclusively on considerations outside the scope and mandate of Codex, that are highly specific to a member or members, and which are not accepted on a worldwide basis.</p> <p>It is worth noting that the inclusion of such footnotes could have major implications for Codex resources, potentially diverting Codex’s finite resources away from more pressing completion and updating of Codex documents with a positive public health impact. It is reasonable to assume that the conditions necessitating a member or members to invoke Statement 4 may change overtime. If such footnotes are allowed, it is reasonable to assume that they will proliferate, resulting in a “Note 161” situation that held up work in the Codex Committee on Food Additives (CCFA) for many years and took efforts by the Codex Alimentarius Commission, Codex Secretariat and member countries to solve and allow the work of CCFA to proceed. The footnotes as described in Paragraph 20 of Appendix II, REP22/EXEC2 are likely to recreate the same difficulties as created by “Note 161”, drain limited Codex resources and impede the work of Codex. The lessons learned from “Note 161” need to be applied to the proposed footnote approach.</p> <p>It is understood that Codex member countries can exercise their own judgement related to the applicability of Codex text to their national food safety objectives (FSO) as long as the Codex text is science- and risk-based, clear and not subject to misunderstanding and misinterpretation. Utilizing the footnotes could become resource intensive exercise, necessitating discussion in Codex subsidiary bodies and the Commission without clear benefit or certainty of resolution.</p> <p>Because the adoption of Codex standards remains totally voluntary for members and because of the potential significant consequences of including confusing footnotes that potentially undermine the legitimacy of a Codex standard, we support only Option 1 as noted in para 18 of REP22/EXEC2. Recording the invocation of Statement 4 of the SoP and indicating a desire to abstain from acceptance can be done</p>	<p><b>IDF/FIL</b></p>

transparently, has been used effectively in the past in many Codex Committee meetings as well as at the Commission, without creating confusion, taking away limited Codex resources or undermining the status of the forthcoming Codex standard.	
IFT believes that the use of a footnote in a standard is not an appropriate approach due to the potential unintended consequences of the use of such footnotes. Despite a few prior examples of this occurring with Codex committees, IFT believes it not to be a helpful practice, and that noting member country reservations or concerns within a particular Codex report document is the appropriate process to follow. We would also add that specific observer organizations and their names should not be allowed to request reservations or concerns to be part of either a Codex written report document nor any footnotes, if such were ever allowed. At most, IFT believes that a Codex report may note that there were in general, observer concerns to a particular Codex text decision, but that such concern details nor the organizations bringing them forth should be recorded in them. If observer organizations wish to go on record regarding a Codex discussion topic, they can do so by using the standard process of submitting a CRD to the Committee or Commission that becomes part of the overall record.	<b>IFT</b>
<b>Should the guidance also cover new work proposals?</b>	
No, el proyecto de orientaciones está enfocado en promover la aplicación práctica y consistente de las Declaraciones, en particular de la Declaración 4. Creemos que no es necesario abarcar propuestas de nuevos trabajos.	<b>Argentina</b>
<p>No – Australia strongly opposes covering new work proposals in this guidance.</p> <p>The statements of principle relate to consideration of other factors specifically within the risk management part of the standard development process. Accordingly, and correctly, the draft guidance document has been drafted to assist members and chairpersons to apply the statements of principle in the context of work that has already been approved, and after a risk assessment has been completed and agreed upon, if necessary for that work. It would make no sense to devise guidance on how to use the statements of principles in a context for which they were not designed to be used.</p> <p>There are already guidelines on the application of the criteria for the establishment of work priorities, and there is a critical review process of new work proposals. This framework is being strengthened through further work by the Codex Secretariat, in line with a recommendation from CCEXEC83, to prepare guidance on how to apply existing procedures to ensure that Members do not perceive procedural obstacles to submitting new proposals for work in this and other areas of Codex.</p>	<b>Australia</b>
<p>Canada is of the view that the guidance should not cover new work proposals. The proposal to include new work proposals into the guidance has been previously discussed at CCEXEC83 and has not been included. (see REP22/EXEC2 paras 77 and 78). CAC42 agreed on the development of practical guidance on the operationalization of the Statements of Principle Concerning the Role of Science to promote their consistent application, but not to reopen or change the SoP. As such, the objective of the guidance is to assist with resolving situations when Members agree on the science and necessary level of public health protection but hold differing views about other considerations (REP22/EXEC2 Appendix II para 1). Opening up the guidance to include other new concepts risks unravelling the good progress achieved towards consensus. It is clear that the SoP apply to decision-making for risk management in order to select the appropriate prevention and control option to address a risk. As SoP 1 states, risk management decisions are to be informed by a science-based risk assessment which would help CAC to understand, measure and describe those risks that are known and what is not known.</p> <p>The potential use of this guidance to halt consideration of new work proposals risks the assurance of a safe domestic food supply for those countries that rely on Codex standards, impedes industry innovation, and creates barriers to international food trade.</p> <p>Canada strongly holds the view that the guidance is intended to be applied once all information, including science-based risk assessment, is gathered in order to make risk management decisions.</p>	<b>Canada</b>

<p>El Manual de Procedimiento establece claramente el procedimiento para la elaboración de normas del Codex y textos afines y es en esta etapa donde deben identificarse si la nueva propuesta de trabajo cumple con los objetivos del Codex para que en el futuro de dicho trabajo y su respectivo avance de trámites no se tengan que “resolver esas situaciones que surgen con escasa frecuencia” tal como se menciona en la introducción y consideraciones generales de estas orientaciones, especialmente “cuando los miembros están de acuerdo sobre los aspectos científicos y el grado de protección de la salud pública que se necesita, pero tienen opiniones diferentes sobre otros aspectos”</p> <p>En ese sentido, Costa Rica considera que el objetivo de las orientaciones es específico y que solo deben ponerse en práctica con la respectiva asesoría de los comités de expertos cuando proceda.</p> <p>Las orientaciones no fueron creadas para esta etapa del proceso, además al inicio de las nuevas propuestas de trabajo, los comités de expertos aun no han realizado ninguna evaluación de riesgos y, por lo tanto, tampoco existen recomendaciones para la gestión de riesgos y por ende, el Codex no podría cumplir su objetivo de protección de la salud de los consumidores.</p>	<b>Costa Rica</b>
<p>Ecuador considera que es oportuno que las orientaciones abarquen también las propuestas de nuevos trabajos, con la finalidad de reforzar las determinaciones existentes hacia este tema y la viabilidad de los mismos.</p>	<b>Ecuador</b>
<p>It depends : if the guidance does not refer to NEW proposal of work , we can add</p>	<b>Egypt</b>
<p>The EUMS note that paragraph 4 of Appendix II, REP22/EXEC2 (Scope) states that other considerations may be raised by Members at any stage of standard development. The EUMS agree with this interpretation and are thus of the opinion that the guidance should cover new work proposals. Guidance should notably be provided on how proposals should, where relevant, address other factors that are accepted on a worldwide basis. This aspect is currently absent from the draft guidance which only includes “Considerations of Codex texts for possible adoption at Step 5, Step 8 or Step 5/8” and no considerations of the preceding steps or project proposal stage. The guidance should also include considerations on how to reach conclusions on the amenability of a work proposal for global standardisation and the worldwide need of the proposed standard.</p>	<b>European Union</b>
<p>No</p>	<b>Iraq</b>
<p>Japan is of the view that the guidance does not need to cover new work proposals. It was developed to support Codex Chairpersons and its Members in resolving the situations that arise infrequently during the process of advancing or adopting standards when Members agree on the science and necessary level of public health protection but hold differing views about other considerations. Such infrequent situations generally arise in discussions on whether to advance or adopt a standard at Step 5, Step 8 or Step 5/8. Therefore, Japan believes that the scope of the guidance does not need to be expanded.</p>	<b>Japan</b>
<p>Comment Yes Rationale This will ensure that all concerns are considered at the initial stages of the step procedure for elaboration of Codex Standards.</p>	<b>Kenya</b>
<p>The guidance is explicitly linked to the use of Statement 4 of the SOP which requires as a first step there to be a lack of consensus because of other factors/other considerations. Our view is that the guidance therefore should not cover new work proposals, which would be beyond the scope of work agreed by CCEXEC81.</p>	<b>New Zealand</b>

<p>We note that paragraph 2 in the SoP refers to other legitimate factors and the whole process from the start of work until the decision: “When elaborating and deciding upon food standards etc” and that paragraph 4 of Appendix II, REP22/EXEC2 (Scope) states that other considerations may be raised by Members at any stage of standard development. Consequently, we agree that the guidance should cover new work proposals. We therefore support development of guidance on how proposals should, where relevant, address other factors that are accepted on a worldwide basis.</p>	<b>Norway</b>
<p>Consideramos que efectivamente, así es y por eso lo recomendaríamos absolutamente al CCEXEC. We believe that indeed it is, and for this reason we would absolutely recommend it to the CCEXEC.</p>	<b>Panama</b>
<p>Paraguay no considera importante que en las orientaciones se aborden las propuestas de nuevos trabajos ya que se tienen bien especificado en otras Secciones del Manual de Procedimientos.</p>	<b>Paraguay</b>
<p>Las orientaciones deberían aplicarse para toda decisión necesaria fuesen nuevos trabajos o no, considerar que el objetivo inicial era prestar apoyo a los presidentes del Codex (la Comisión y sus órganos auxiliares) y a sus miembros con miras a resolver las situaciones que surgen con escasa frecuencia durante el proceso de adelanto o adopción de normas cuando los miembros están de acuerdo sobre los aspectos científicos y el grado de protección de la salud pública que se necesita, pero tienen opiniones diferentes sobre otros aspectos.</p>	<b>Peru</b>
<p>Referring to the Measures to Facilitate Consensus in the Procedural Manual, a new work proposal should not be submitted if the scientific basis is not well-established. New work proposals which do not have strong scientific basis should not be presented for advancement in the step procedures. Therefore, there is no need for the guidance to be made applicable to new work proposals.</p>	<b>Singapore</b>
<p>This guidance can be considered during the critical review of new work proposals, particularly the case where other legitimate factors and/or other considerations are anticipated. In addition, the member country developing a new work proposal can consider this guidance during the development of the proposal. This could, subsequently, prevent the Codex Committees and the Commission from a prolonged discussion and eventually conclude without consensus.</p>	<b>Thailand</b>
<p>The United Kingdom considers that the guidance could apply to new work proposals, including the critical review as this could act as an early warning sign that “OLFs” or “other considerations” may complicate the work.</p>	<b>United Kingdom</b>
<p>No identificamos la necesidad de nuevas orientaciones, sino la aplicación de las ya vigentes</p>	<b>Uruguay</b>
<p>No, the guidance is designed to promote practical and consistent application of the Statements, and in particular Statement 4, which only applies in the phase of risk management, after an appropriate risk assessment has been completed and questions about the risk assessment have been resolved. It was never contemplated to include guidance on other aspects of Codex procedure as part of this effort.</p> <p>The United States notes further that the Secretariat is currently charged with preparing guidance on how to apply existing procedures to ensure that members do not perceive procedural obstacles to submitting proposals for new work (REP CEXEC22/2, Paragraph 100). The CAC did not approve or request additional work in this area as part of guidance on the SoP.</p> <p>Finally, the United States believes that any guidance for new work proposals should instruct members not to block new work proposals especially as no risk assessment has yet been performed by the independent Codex risk assessment bodies (JECFA, JEMRA, JMPR and JEMNU) and no risk management decision has been taken by Codex committees. Such actions would prevent risk assessment and risk management recommendations, such as those developed by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) that sometimes recommend that competent authorities prevent residues in food. If new work could be blocked simply because an individual member or group of members does not use a substance, Codex would be prevented from providing all other members with valuable public health protection guidance by either establishing a safe level or providing a Risk Management Recommendation to limit the use of the substance. Such actions blocking new work would undermine a core value and function of Codex which is the protection of consumer health.</p>	<b>USA</b>

CropLife International supports that future guidance covers as well proposals for new work.	<b>CropLife International</b>
Yes. ICBA believes the guidance should cover new work proposals to ensure a consistent approach is applied to the development of any future Codex standards and guidelines.	<b>ICBA</b>
Although the Guidance appears to have far more utility for standards advancement, IDF does not oppose the guidance also covering new work proposals. While we reiterated via prior input that current Codex procedures already provide a deliberate, inclusive, and structured process to assure that draft standards and texts are progressed based on scientific evidence and risk-assessment in alignment with the Codex mandate, we appreciate the spirit of this work as reflected in the original TORs of providing “practical guidance” on “operationalizing” the SoP. If Chairpersons and member countries feel that this guidance provides relevant practical guidance to operationalize the SoP in the context of new work, we see no reason to limit its application.	<b>IDF/FIL</b>
No. IFT does not support the guidance covering new work proposals. New work proposals should be reviewed on whether they fit within the Codex Scope and Mandate when initially presented by a member country as part of the normal Codex process. Upon review and determination by either Codex Committees or CAC that a new work proposal is outside the Scope and Mandate of Codex, such new work proposals should be dropped from further consideration. IFT supports the REP22/EXEC2 conclusion in Paragraph 81 that further attempts to make significant elaborations or changes to the draft guidance text are potentially damaging to their timely implementation (e.g., as part of CAC 46).	<b>IFT</b>
<b>Considering the discussions on other legitimate factors during CAC45 (such as the specific case of MRLs for Clothianidin, Quinoxifen and Thiamethoxam REP22/CAC paragraphs 78-84), is there a need for any further guidance on this aspect?</b>	
No, no es necesaria orientación adicional. Los criterios para la consideración de otros factores establecidos en el Manual de procedimiento brindan orientación suficiente.	<b>Argentina</b>
No – Australia does not think there is any further guidance required. It is clear in the procedural manual what the criteria are for determining whether other factors qualify as OLFs – that is, relevant to Article 1a of the Statutes of the Codex Alimentarius and applicable on a worldwide basis – and when other factors may be considered – that is, in the risk management process. Further, the draft guidance and the flow diagram provides a useful tool to guide committees in applying the statements of principle, including Statement 2 and the associated criteria. It is up to the experts in the committee in question to determine whether there is sufficient evidence for other factors to be accepted as OLFs and then to consider how an OLF should be taken account of in the risk management decision.	<b>Australia</b>
Canada does not see a need for any further guidance on other legitimate factors and feels that the discussion held at CAC45 demonstrated how the SoPs could be approached during a discussion. Nor is further guidance needed for the specific case of environmental concerns as the Codex framework does not have the correct expertise available for an informed risk management decision on this other consideration.	<b>Canada</b>
No, dado que las justificaciones manifestadas para dejar la reserva están fuera del mandato del Codex.	<b>Costa Rica</b>
Se considera que según los criterios indicados en el documento REP22/CAC podría convenir no omitir los trámites 6 y 7 para ofrecer la oportunidad de seguir debatiendo al respecto, tomando en consideración el contexto global y el mandato específico del Codex para considerar los factores legítimos con el sustento científico pertinente.	<b>Ecuador</b>
No need except if any new related document	<b>Egypt</b>
The EUMS are of the opinion that it is necessary to clarify the meaning of “other factors which can be accepted on a worldwide basis” and to ensure that a process is put in place in Codex to give due consideration to this matter. The guidance should include information on this process including on how members should provide information on these factors and how they should be considered in the Codex committees.	<b>European Union</b>
The EUMS note that paragraphs 78-84 of REP 22/CAC indicate that the exchange during CAC45 did not allow to reach consensus on whether	

<p>globally accepted environmental concerns do qualify as other factors which can be accepted on a worldwide basis and thereby taken into account by Codex.</p> <p>The EUMS would in particular like to draw the attention to paragraph 84 of REP 22/CAC: “The EU suggested that countries reflect more in-depth on how Codex could take into account global concerns related to major challenges to food systems and contribute to their sustainability and the application of the One Health approach. In their view, globally accepted environmental concerns could be taken as a legitimate factor when setting MRLs for pesticides.”</p> <p>The EUMS are of the opinion that the discussion of this matter goes beyond the application of the SoPs. It comprises the contribution of Codex to the 2030 agenda for sustainable development and the transition towards more sustainable food systems as well as the application of the One Health approach to food safety. Hence, the discussion should take place in the context of the reflections on the future of Codex and the new Strategic Plan.</p> <p>In this context, the EUMS highlight that the purpose of Codex includes the promotion the coordination of all food standards work undertaken by international governmental and non-governmental organizations and that possibilities to broaden expertise of Codex to consider, for example, social and environmental impacts on the development of standards on health of consumers and trade.</p>	
<p>Considering there are still many different views on the definition of Other Legitimate Factors (OLF) as well as their application in the Codex work, Indonesia is of the view that more detailed explanations of OLF are needed to be included in this guidance, such as giving examples about the circumstances or types of factors that can be considered or classified as OLF.</p>	<b>Indonesia</b>
<p>Yes.</p>	<b>Iraq</b>
<p>Japan does not believe that any further guidance is needed on this aspect. The guidance already proposes the definition of “other legitimate factors” to support common understanding and to facilitate the operationalisation and practical application of the SoP. It is clear that Codex should not address issues which are outside the mandate of Codex to protect consumer’s health and ensure fair practices in food trade.</p>	<b>Japan</b>
<p>There is the question for clarification of an issue as legitimate. What are the signs of this?</p>	<b>Kazakhstan</b>
<p>Comment No Rationale The SoP 2 on other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade is sufficient and should be considered case by case within the mandate of Codex.</p>	<b>Kenya</b>
<p>New Zealand does not consider that there is a need for further guidance on other legitimate factors (OLFs) such as those raised in discussions at CAC45 on MRLs for Clothianidin, Quinoxifen and Thiamethoxam.</p> <p>We see no evidence that there is a lack of clarity in determining whether or not OLF/considerations should be taken into account in Codex such as in the specific case of these MRLs. In our view, if OLFs/considerations are not within the Codex mandate (or acceptable on worldwide basis), a member country has the option of applying Statement 4.</p> <p>We understand for these MRLs that the proposed reduction in MRLs is not due to food safety concerns stemming from the presence of pesticide residues in imported foods, but based on a stated interest in protecting pollinators in countries outside of the EU (and outside the mandate of Codex).</p> <p>New Zealand considers that the draft Guidance operationalising SOP 4 is robust and serviceable as it is. This fact was demonstrated by its use</p>	<b>New Zealand</b>



<p>in guiding decisions on these MRLs, and zilpaterol, at CAC45.</p> <p>In line with good policy practice New Zealand would support a review of the guidance after its implementation has been embedded. This would allow the membership to determine if there are indeed any impediments to the science-based decision making process in Codex which need to be further clarified.</p>	
<p>Yes, there is a need for further guidance, however this matter goes beyond the application of the SoPs and should take place in the context of the reflections on the future of Codex since it entails to the contribution of Codex to sustainable food systems and the application of a One Health approach.</p> <p>We are of the view that it is necessary to clarify the meaning of “other factors which can be accepted on a worldwide basis” and to ensure that a process on consideration of this matter includes guidance on how members should provide information on these factors.</p>	<b>Norway</b>
<p>Consideramos que efectivamente, así es y por eso lo recomendaríamos absolutamente.</p> <p>We believe that this is indeed the case and for this reason we would absolutely recommend it.</p>	<b>Panama</b>
<p>El mandato del Codex es proteger la salud de los consumidores y garantizar prácticas comerciales justas, otros factores legítimos no se consideran dentro de las Declaraciones de Principios y sus criterios. Paraguay no considera necesario orientaciones adicionales sobre este aspecto.</p>	<b>Paraguay</b>
<p>Consideramos que sería más claro el texto si se brindara información entre la diferencia de “Otros factores legítimos” (OFL), “otros aspectos”, “abstenerse de aceptar” (brindar ejemplos).</p> <p>Se solicita aclarar el proceso para definir los OFL. Resulta pertinente aclarar quién podría presentar un OFL y el mecanismo para ser tratado. Si es por consulta en el pleno o si solo es necesario que cualquier miembro presente la propuesta.</p>	<b>Peru</b>
<p>The discussion is sufficient to provide guidance in considering other legitimate factors (such as the specific case of MRLs for Clothianidin, Quinoxifen and Thiamethoxam, REP22/CAC, paragraphs 78-84), i.e., to first determine if the factors are within Codex’s mandate, and whether the factors are relevant on a worldwide basis.</p>	<b>Singapore</b>
<p>Further explanation for Other Legitimate Factors and the differences between them and the Other Considerations could be considered. In our view, the issues related to promoting fair practices in the food trade are very broad, thus a comprehensive description could be valuable.</p>	<b>Thailand</b>
<p>The United Kingdom considers that further guidance on this aspect could help improve transparency during the advancement process and should be considered on a case-by-case basis. The chairs and members should decide if the SoP conditions have been met and explore how best to address the issues.</p>	<b>United Kingdom</b>
<p>No. Las orientaciones actuales son claras.</p>	<b>Uruguay</b>
<p>The United States believes that the Criteria for the Consideration of Other Factors as set forth in the Procedural Manual provide sufficient guidance for determination and consideration of other factors, beyond science, that may appropriately be considered in risk management decision-making in Codex (pp. 245-246, Codex Procedural Manual, 27th English edition).</p> <p>Codex Alimentarius plays a critical role in the One Health approach by being the competent international standard setting body for food safety, as recognized in the WTO SPS Agreement. Codex should be mindful to focus on its core competency to establish science-based standards for food safety and quality. It would undermine the One Health approach if Codex were to attempt to go beyond its mandate and expertise and take on issues that are within the purview of other organizations, in particular the One Health Quadripartite formed by FAO and WHO together with World Organization for Animal Health (WOAH) and the United Nations Environment Programme (UNEP). Recommendations on One Health should have as their foundation the core competencies and expertise of each individual Quadripartite member organization. The High-</p>	<b>USA</b>

Level Expert Panel on One Health may be the best body to consider the input of these organizations. Individual organizations making decisions beyond their competency and core areas of expertise may undermine this.	
CropLife International agreed with the interventions of 22 Codex members at CAC45 that the points raised by the EU do not meet the criteria for consideration of other factors referred to in the Second Statement of Principle and, with respect to environmental protection, are outside the mandate given to Codex. As interventions were made by a large number of Codex members it became clear that there is no consensus that these criteria and policies raised by the EU are not accepted on a worldwide basis; they likely even create unjustified barriers to trade. In conclusion, CropLife International is of the opinion that the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process are sufficiently comprehensive and concise and no further guidance is needed.	<b>CropLife International</b>
ICBA does not have comments on this question.	<b>ICBA</b>
Although IDF lacks specific expertise on these compounds, we did participate in CAC45. We note that the discussions on other legitimate factors during that Commission functioned effectively to resolve the concerns noted by some members consistent with relevant procedures of the Codex Procedural Manual. As a result, we believe additional guidance is not needed. We question the benefits of dedicating additional Codex resources to “other legitimate factors” (OLFs) as this term means differing things to Codex members., It will be difficult to find specific consensus, will take significant Codex resources to resolve and finalize such work, when the current Codex Procedural Manual already establishes parameters that OLFs must meet and clearly address the voluntary nature of adopted Codex text. It would appear to IDF and its members there is not a clear need for additional work on “other legitimate factors”.	<b>IDF/FIL</b>
IFT believes that the SoP and guidance document are sufficiently clear (except for minor clarification edits) and there is no need for further, written guidance on OLF's. IFT believes it is important to highlight, regarding OLF's, that they need to be within the scope and mandate of Codex as currently defined and that such OLF's would need to be acceptable on a worldwide basis for inclusion with a global standard (e.g., not be driven by only regional considerations, in which case the appropriate regional WHO/FAO Regional Coordinating Committees could address them). Additionally, IFT notes that it is always within the purview of national regulatory agencies to take into account OLF's that might be outside the Codex Scope and Mandate that they deem important to implement within their individual countries.	<b>IFT</b>
<b>Are there any other specific issues that should be addressed in the guidance and what is the rationale for doing so?</b>	
Consideramos que no existen otras cuestionone especifica a ser abordadas en las orientaciones.	<b>Argentina</b>
Australia is very happy with the guidance.	<b>Australia</b>
Canada believes that there are no other specific issues that should be addressed in the guidance. As noted above, opening up the guidance to include other new concepts or issues discussed by CCEXEC that we know to be contentious risks unravelling the good progress achieved towards consensus.	<b>Canada</b>
No	<b>Costa Rica</b>
Ecuador al momento no cuenta con cuestionones especificas a ser abordadas en el documento de orientaciones.	<b>Ecuador</b>
We can put related or referred document in a appendix to get the guidance more easy and understandable	<b>Egypt</b>
The guidance should clarify the difference between “abstention from acceptance” and “reservation”. It should also clarify the meaning of “abstention from acceptance” in the context of the WTO/SPS agreement.  Although the SoPs were adopted in 1995, there is no evidence that statement 4 has been explicitly invoked in Codex (see CX/EXEC 19/77/10, para 5.2.1). Since the possibility for Codex Members to “abstain from acceptance” is at the core of statement 4, the EU and its MS are of the opinion that a clarification of its meaning would be instrumental for a possible application of the SoPs.	<b>European Union</b>
It depends on the situation.	<b>Iraq</b>

Japan is of the view that there are not any other specific issues that should be addressed in the guidance, as the guidance covers the scope necessary for operationalisation and practical application of the SoP.	<b>Japan</b>
<p>Comment The guidance should clearly address the implications on trade where a standard advances noting the reservation of a member state.</p> <p>Rationale The reservations might be misused during trade. It should be clear what happens once a member abstains from acceptance of a standard allowing it to advance but registering reservations.</p>	<b>Kenya</b>
The draft guidance as presented has achieved the scope of work that CCEXEC81 agreed to. The practical guidance would 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 and to complement the guidance provided in the Measures to Facilitate Consensus.	<b>New Zealand</b>
<p>The guidance should clarify the difference between “abstention from acceptance” and “reservation”. It should also elucidate the meaning of “abstention of acceptance” in the context of the WTO/SPS agreement.</p> <p>Although the SoPs were adopted in 1995, there is no evidence that statement 4 has been explicitly invoked in Codex (see CX/EXEC 19/77/10, para 5.2.1). Since the possibility for Codex members to “abstain from acceptance” is at the core of statement 4, a clarification of its meaning would be instrumental for a possible application of the SoPs.</p>	<b>Norway</b>
<p>Consideramos que efectivamente, si se requiere y por eso lo hemos plasmado en el Documento adjunto denominado e identificado como: “Orientación para la Aplicación de la “Declaración de Principios” - Actualización de la Propuesta: “Proyecto Codex Panamá CAC46””</p> <p>We believe that indeed, if required and for this reason we have set it out in the attached document called and identified as: “Guidance for the Application of the "Declaration of Principles" - Update of the Proposal: "Project Codex Panama CAC46””</p>	<b>Panama</b>
Si bien en la los principios del Codex dice: “Revisión de las normas del Codex. La Comisión del Codex Alimentarius y sus órganos auxiliares se comprometen a revisar cuando proceda las normas y textos afines del Codex, con objeto de que se ajusten y respondan a los conocimientos científicos del momento y a otras informaciones pertinentes. (...)”, consideramos que las “otras informaciones pertinentes” u “otras cuestiones” pueden evaluarse en cada caso concreto y deberían considerarse en adición a los “conocimientos científicos del momento”; es decir, se debería realizar sobre la base de la información científica para una decisión de aprobación de norma Codex.	<b>Peru</b>
Nil	<b>Singapore</b>
The guidance may include the implication after a member country decides to apply either SoP2 or SoP4, especially on international trade at the WTO level or on the economic impact of the country.	<b>Thailand</b>
The United Kingdom does not wish to raise any other specific issues that should be address within this guidance.	<b>United Kingdom</b>
Como ya hemos comentado, entendemos que las orientaciones actuales son suficientes. Si analizamos la génesis de los problemas concretos que dieron origen a todas estas iniciativas, las mismas no se originaron en la ausencia de orientaciones claras, sino el deseo de quienes eran responsables de aplicarlas de evitar el desgaste elevando el tema a una instancia superior.	<b>Uruguay</b>
The United States believes that there are no other specific issues that need to be addressed at this time.	<b>USA</b>
ICBA strongly recommends greater clarification on the role and governance processes of the WHO at Codex to ensure the scientific integrity and credibility of Codex is protected. The recent duplicative aspartame reviews by the two WHO agencies, IARC and JECFA, were in contravention of existing IARC and WHO coordination procedures, and risked causing global confusion to regulators and consumers around the world. Codex should work with the WHO Secretariat to ensure that JECFA has the lead role in conducting and communicating risk	<b>ICBA</b>

assessments related to JECFA's specific area of expertise. To prevent a similar situation in the future, we strongly recommend that the Codex Secretariat work with WHO to conduct a review of existing coordination procedures among agencies and strengthen where necessary. It is essential to protect the role of both Codex and JECFA in developing science- and risk-based food safety standards.	
Yes, fact-based, peer-reviewed science needs to serve as the foundation and basis for development of any Codex text included in Codex standards, codes of practice, and guidelines. Other than this important point, we are not aware of any other issues that should be addressed by this guidance.	<b>IDF/FIL</b>
IFT believes it would be useful for CAC or a CAC EXEC working group to elaborate on some example OLF's as an educational tool that would be within the Codex Scope and Mandate regarding risk management at Codex, as well as to reinforce that OLF's do not apply in the scientific risk assessment process. There are major differences in global approaches to risk management that are not part of the scientifically based food risk assessment process regarding human health and the safety of the food supply for consumers. IFT believes this differentiation is a source of confusion for both members and observers on the application of the SoP regarding the role of science in decision making and that it is important for Codex to address by clarifying with examples.	<b>IFT</b>
<b>Where should the guidance be published when finalized?</b>	
Opción II, manual para presidentes.	<b>Argentina</b>
Other (please indicate) Australia is of the view that this guidance should be published in the handbook for chairpersons and could be included in a handbook for delegates.	<b>Australia</b>
We believe the guidance should be included in the handbook for Chairpersons as it is a practical application. It would also be beneficial to include it in a handbook for delegates.	<b>Canada</b>
En el Manual para los presidentes.	<b>Costa Rica</b>
Se considera que el documento sobre orientaciones podría ser publicado como orientaciones del Codex independientes, por su contexto global.	<b>Ecuador</b>
Standalone codex guide lines with new issue numbers	<b>Egypt</b>
Other (please indicate)  The EUMS are of the opinion that approved final guidance on the SoP should form part of the Procedural Manual of the Codex Alimentarius Commission, which is the main source of guidance for delegations and observer organizations attending Codex meetings (option iii).	<b>European Union</b>
Since the guidance will be used by both the CVCs and all member countries, Indonesia is of the opinion that the guidance should be published as a stand-alone guidance which is easily accessible, for example through website.	<b>Indonesia</b>
Option I	<b>Iraq</b>
Japan is of the view at this time that further discussions are not needed for finalization. As noted by CAC45 (2022), Members have been sensitized to the practical application of the SoP through the process of developing the draft guidance. CAC45 also urged Members to take account of the draft guidance as appropriate during the process of standards development and advancement. Should further needs to finalize arise in the future based on Members' experiences, we might be able to resume discussions for finalization. When finalized, the guidance could be included in the Codex Chairpersons' Handbook. In that case, it would be better to update the Handbook to cover the roles of both Chairpersons and Members so that it can be more practical and useful for both Chairpersons and Members.	<b>Japan</b>

<p>It might also be useful that the guidance should be made available on the Codex website as an information document, should it be considered applicable to the scope of information document set by the Guidance on information documents agreed by CCGP28 (2014) and endorsed by CAC37 (2014).</p>	
<p>As a stand-alone Codex Guidance</p> <p>Comment Kenya proposes the guidance to be published as a stand-alone Codex Guidance</p> <p>Rationale For ease of access where members do not have to dig through the handbook for Chairpersons.</p>	<p><b>Kenya</b></p>
<p>NZ considers that the finalised guidance is best located with the SoP in the Codex Procedural Manual (PM) given the guidance is to aid the understanding of the SoP. The guidance should therefore be included in the Appendix: General decisions, and should be the fourth document under General decisions of the Commission.</p> <p>While the guidance will ultimately be used by Chairpersons, it is important that this information is placed with the SoP and in the PM to give it the appropriate status, and to ensure that it is readily accessible to the entire Codex membership.</p> <p>As a stand-alone Codex Guidance No. It is important that the guidance is located with the SOP and retained in the PM.</p> <p>In the handbook for Chairpersons For completeness, the guidance could also be referenced in the handbook for Chairpersons just as Measures to facilitate consensus building have been. It should be noted that the handbook does not currently cover the SoP themselves – this omission would need to be addressed accordingly.</p>	<p><b>New Zealand</b></p>
<p>We would like to see this as a stand-alone document (option i) since it is equally relevant for Codex chairs and the Codex membership. Codex members does not necessarily read the handbook for Chairs (therefore we do not support option ii).</p> <p>Other (please indicate) Other comments: The text of the draft guidance should provide the necessary information for the application of the SoPs. It is noted that the draft text already provides information on options and different scenarios. The possible further work on the guidance should focus on these aspects. We disagree with the fact that the current flowchart would provide a satisfactory visual decision-guide facilitating the operationalisation of SoP as indicated in paragraph 1 of Appendix II of REP22/EXEC2. A flowchart should only be maintained if it fully reflects the draft text. Therefore, we support removing the flow chart from the guidance. We are also concerned that the flow chart may be an obstacle for chairs and members in their work on finding compromises when these are needed. The draft guidance invites chairpersons to draw several determinations, therefore the guidance should provide further information on the elements that a chairperson should consider making these considerations (see paragraphs 13, 14, 16, and 21).</p>	<p><b>Norway</b></p>
<p>Como orientaciones del Codex independientes. As a stand-alone Codex Guidance Consideramos que esta sería una buena opción y por eso la recomendaríamos. We believe that this would be a good option and therefore we would recommend it.</p>	<p><b>Panama</b></p>

iii. Otros (sírvese especificar).  Si bien nos parece adecuado publicarlo en el manual para presidentes, Paraguay cree conveniente publicarlo en el Manual de Procedimientos como Apéndice de las Declaraciones de Principios sobre la función que desempeña la ciencia.	<b>Paraguay</b>
Solicitamos aclarar a qué refiere como "Orientaciones del Codex independientes". Se requiere garantizar el acceso público en general en aras de transparencia de la información, de tal forma que sea de fácil comunicación para los presidentes y miembros u observadores; asimismo, que se difunda en los talleres que se realizan a las regiones en conjunto con los Coordinadores regionales.	<b>Peru</b>
ii. In the handbook for Chairpersons iii. Other (please indicate) Procedural Manual	<b>Singapore</b>
The guidance may be made available as a part of the handbook for Chairpersons to facilitate any future amendments, where necessary.	<b>Thailand</b>
The UK could support either option, however it is important to signpost to members where they can find the guidance as both chairs and members need to understand how to interpret and apply the SoP. Regardless of the final placement of the guidance, a reference will need to be added to the section of the Procedural Manual that contains the SoP.	<b>United Kingdom</b>
Dependerá de lo que finalmente sea el contenido de dichas directivas	<b>Uruguay</b>
Other (please indicate)  The United States believes that this guidance should be captured in the handbook for Chairpersons and a handbook for delegates. History has proven that stand-alone guidance can be lost or overlooked.	<b>USA</b>
CropLife International supports option iii.) and suggests that new guidance is published in an amended version of the Procedural Manual as the envisaged guidance is provided for Chairpersons and Members but high importance for the information of observers.	<b>CropLife International</b>
As a stand-alone Codex Guidance  ICBA believes the document should be published as a stand-alone Codex Guidance.	<b>ICBA</b>
In the handbook for Chairpersons  We see the greatest utility of these guidelines in helping Codex chairpersons ensure predictable, timely advancement of Codex standards when science-based risk assessment demonstrates that a Codex standard supports and enhances public health, food safety and fair practices in the international trade of foods, yet some members have objected to standards advancement based on other factors as defined in the SoP. As a result, we believe the guidance would be best placed in the Chairperson's handbook as it has the most relevancy there.	<b>IDF/FIL</b>
IFT believes that the guidance should be published (tied to the SoP document) both as a stand-alone Codex Guidance, as well as in the handbook for chairpersons (i.e., i and ii). It is IFT's opinion that publishing it in both places is important, as publishing only in the handbook for Chairpersons would not bring the guidance clearly into the view regularly of members and observers, where much of the confusion with the use of the SoP resides. Likewise, publishing only as stand-alone guidance does not highlight the importance of the proper use of the SoP's and OLF's and the guidance text with the Codex Chairpersons, so IFT believes publishing in both places is warranted to reinforce the use and application of the SoP's and the new guidance document. As stated in the IFT answer to question d., IFT believes that it would also be important for Codex to develop and publish some example uses of the OLF's for risk management that fit within the Scope and Mandate of Codex and to also highlight that OLF's do not apply to risk assessment, which is to be done using scientific analysis conducted by a select, WHO/FAO Expert Panel (e.g., JECFA, JEMRA, etc.).	<b>IFT</b>