

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda item 9

CX/CF 24/17/9-Add.1

March 2024

ORIGINAL LANGUAGE ONLY

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEx COMMITTEE ON CONTAMINANTS IN FOODS**

**17<sup>th</sup> Session**

**15-19 April 2024**

**Panama City, Panama**

**CODE OF PRACTICE/GUIDELINES FOR THE PREVENTION AND REDUCTION OF CIGUATERA POISONING**

**Comments at Step 3 in reply to CL 2024/6-CF**

submitted by

Australia, Canada, Chile, Cuba, Ecuador, Egypt, European Union,  
Iraq, Japan, New Zealand, Panama, Philippines, USA and Venezuela

## **Background**

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2024/6-CF<sup>1</sup> issued in January 2024. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

## **Explanatory notes on the appendix**

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format.

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<sup>1</sup> <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>  
<https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF>

**ANNEX****GENERAL COMMENTS**

<b>COMMENT</b>	<b>MEMBER / OSERVER</b>
<p>Australia maintains its support for this work and would like to thank the United States of America, France, Panama and Spain for leading the EWG and preparing the draft Code of Practice for the Prevention or Reduction of Ciguatera Poisoning.</p> <p>The CoP includes a list of marine organisms known or suspected to be associated with CP, as well as a mention of general types of methods that are applicable to CTX testing, rather than a list of specific analytical methods.</p> <p>Australia supports the advancement of the CoP in the step procedure to Step 5 pending consideration of the following proposed amendments prepared in consultation with an industry working group (Safefish).</p>	<b>Australia</b>
Canada supports the CoP for the prevention or reduction of ciguatera poisoning prepared by the EWG.	<b>Canada</b>
<p>Chile revisó las recomendaciones de esta carta circular y el documento CX/CF 24/17/9. Al respecto,</p> <p>Chile quisiera emitir los siguientes comentarios:</p> <ul style="list-style-type: none"> <li>- Chile está de acuerdo con mantener la mención del género Fukuyoa en el CdP.</li> <li>- Chile está de acuerdo con incluir una declaración general en el CdP respecto de la recomendación de uso de patrones migratorios en el desarrollo de mapas de algas/peces tóxicos, entendiendo que esto es una sugerencia y queda sujeto a su factibilidad en la práctica.</li> <li>- Chile está de acuerdo en que el CdP no mencione métodos específicos, sino que se remita a los métodos presentados en el informe publicado por la FAO/OMS del 2020 "Report of the Expert Meeting on Ciguatera Poisoning".</li> <li>- Chile está de acuerdo en que debe incluirse en el CdP una lista de organismos marinos de los que se sabe o se sospecha están asociados con la intoxicación ciguatera a modo de ejemplo, y por lo tanto solicita que se conserve en el CdP.</li> </ul>	<b>Chile</b>
En cuanto a CL 2024/6-CF Código de prácticas/lineamientos para la prevención o reducción del envenenamiento por ciguatera, Cuba considera que es útil disponer de este documento por cuanto la ciguatera es un peligro asociado a algunas especies de pescados, por lo que apoya la elaboración de este código de prácticas.	<b>Cuba</b>
<p>El problema de Intoxicación por Ciguatera (IC) es un tema que Ecuador, lo toma en cuenta, y, si bien el consumo de peces que tengan ciguatoxinas (CTX), puede dar como resultado problemas gastrointestinales (por ejemplo, vómitos, diarrea), problemas neurológicos (por ejemplo, mareos, jaquecas), problemas cardiovasculares (por ejemplo, hipotensión, bradicardia), y algunos síntomas especialmente característicos de la IC, como alodinia térmica y parestesia. Por lo general, la IC no es mortal, sin embargo, la exposición a las CTX puede agravar los efectos de cualquier problema de salud subyacente del sistema cardiovascular o nervioso, y causar la muerte.</p> <p>En este sentido, si bien Ecuador según el listado del Apéndice I del CdP, no se encuentra dentro de listados de organismos marinos de los que se sabe o se sospecha que están asociados a la IC, en el, si estamos en la zona del Pacífico, donde se menciona que es una de las regiones en donde se ha dado este tipo de problemas. Por lo cual es necesario que se tome las precauciones del caso para evitar problemas por IC.</p>	<b>Ecuador</b>
Egypt thanks the work done by chair and co-chair of the Electronic Working Group.	<b>Egypt</b>

Egypt agrees to advance this draft Code of Practice for the next step.	
Agree	<b>Iraq</b>
New Zealand would like to thank the Chair and Co-Chairs of the Electronic Working Group on the work undertaken to draft the Code of Practice/Guidelines for the prevention or reduction of ciguatera poisoning.  In the CoP, there are a few comments that relate the size of fish to the risk of ciguatera poisoning. This has been disproven, i.e., there appears to not be a correlation between the size of the fish and ciguatoxicity. It is suggested the text is modified.	<b>New Zealand</b>
Panama appreciates the work carried out and agrees with the document presented and its content. We consider it important to advance this Code of Practices to its next stage. Considering that enough important elements have been collected during the existing GTE.  Panamá agradece el trabajo realizado y está de acuerdo con el documento presentado y del contenido del mismo, consideramos importante el avance de este Código de Prácticas a su siguiente etapa. Considerando que se han recabado suficientes elementos importantes durante el GTE existente.	<b>Panama</b>
The Philippines supports the proposal to identify and discuss key issues that need further consideration, including decisions described in paragraph 9 of the document, before the progression of the document in the step procedure.	<b>Philippines</b>
The United States chaired the EWG that prepared the draft CoP for the prevention or reduction of ciguatera poisoning and appreciates the input of all member countries that contributed to work in the EWG. The United States supports advancing the CoP in the step procedure.	<b>USA</b>

### SPECIFIC COMMENTS

Para 1.	<p>Ciguatoxins (CTXs) are a class of toxins produced by marine dinoflagellates. These toxins enter the <u>marine food chain</u> through <del>consumption by herbivorous fish or shellfish and shellfish, including some echinoderms, that consume CTX-containing microalgae.</del> CTXs can bioaccumulate in <u>these and higher trophic level predatory fish, marine organisms.</u> Ciguatera poisoning (CP) is an illness resulting from <del>human consumption of these marine organisms, primarily fish and shellfish, that have accumulated</del> <u>containing toxic levels of CTXs.</u> CP has become a global health <del>issue concern</del> and is increasing in <del>prevalence</del> <u>incidence</u> due to factors that likely include climate change. Coastal communities that rely on local fishing as a food supply and as a source of income are particularly at risk from increasing occurrences of CP. In 2018, FAO and WHO convened a joint expert meeting to perform an evaluation of CTX and provide guidance for development of risk management options (published in 2020 as <i>the Report of the Expert Meeting on Ciguatera Poisoning: Rome, 19-23 November 2018</i>).</p> <p>Rationale : Improves text to be more specific on exposure routes and clarifies that the beginning of the paragraph is focused on marine food webs, not human food chain. There is evidence that CTXs bioaccumulate in certain benthic invertebrates (bivalves, echinoderms, echinoids), crustaceans and cephalopods; in addition to higher trophic level predatory fish. Some of these invertebrates are known or suspected to be associated with CP (Annex I). Incidences of CP is different to prevalence.</p>	<b>Australia</b>
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Para 2.	<p>The benthic dinoflagellate genus <i>Gambierdiscus</i> is the main producer of CTXs, and some species of <i>Fukuyoa</i> may also produce CTX-like toxins. These dinoflagellates tend to grow in tropical and subtropical marine environments, in calm waters and near shallow reefs. Benthic refers to their growth near the bottom of an aquatic environment; <i>Gambierdiscus</i> and <i>Fukuyoa</i> are also known to attach to various substrates (e.g., turf algae, macroalgae, and coral). Recent reports have identified these organisms in more temperate regions as well, including Korea, Japan, northern territories of New Zealand, southern Australia, the northern Gulf of Mexico, and the Mediterranean Sea, as sea temperatures rise as a result of climate change. CTXs were initially categorized as belonging to one of three major classes that corresponded with their global location; however, experts now recommend that toxins be categorized into four classes, derivatives of <del>CTX-4</del>ACTX4A, <del>CTX-3</del>CCTX3C, C-CTX, and I-CTX, according to their chemical structure (I-CTX structures have not been fully determined). CTXs are lipophilic, do not degrade under heat or mild pH changes, and are known to be resistant to degradation by cooking, freezing, or canning processes. They may undergo structural transformations as they are metabolized by marine organisms, often increasing in toxicity as they do so. More than 30 unique analogues of CTXs have been reported and many more have yet to be fully characterized.</p> <p>Should be written according to the description in the FAO/WHO expert meeting report. No hyphen required.</p>	<b>Japan</b>
Para 2.	<p>The benthic dinoflagellate genus <i>Gambierdiscus</i> is the main producer of CTXs, and some species of <i>Fukuyoa</i> may also produce CTX-like toxins. These dinoflagellates tend to grow in tropical and subtropical marine environments, <del>in calm waters and near shallow</del> typically associated with coral reefs. Benthic refers to their growth near the bottom of an aquatic environment; <i>Gambierdiscus</i> and <i>Fukuyoa</i> are also known to attach to various substrates (e.g., turf algae, macroalgae, and coral). Recent reports have identified these organisms in more temperate regions as well, including Korea, Japan, northern territories of New Zealand, southern Australia, the northern Gulf of Mexico, and the Mediterranean Sea, <del>as sea temperatures rise as a result of climate change</del>. CTXs were initially categorized as belonging to one of three major classes that corresponded with their global location; however, experts now recommend that toxins be categorized into four classes, derivatives of CTX-4A, CTX-3C, C-CTX, and I-CTX, according to their chemical structure (I-CTX structures have not been fully determined). CTXs are lipophilic, do not degrade under heat or mild pH changes, and are known to be resistant to degradation by cooking, freezing, or canning processes. They may undergo structural transformations as they are metabolized by marine organisms, often increasing in toxicity as they do so. More than 30 unique analogues of CTXs have been reported and many more have yet to be fully characterized.</p> <p>Rationale: Correlation with climate change suggested to be moved into paragraph 1.</p>	<b>Australia</b>
Para 2.	<p>The benthic dinoflagellate genus <i>Gambierdiscus</i> is the main <u>known</u> producer of CTXs, and some species of <i>Fukuyoa</i> may also produce CTX-like toxins. These dinoflagellates tend to grow in tropical and subtropical marine environments, in calm waters and near shallow reefs. Benthic refers to their growth near the bottom of an aquatic environment; <i>Gambierdiscus</i> and <i>Fukuyoa</i> are also known to attach to various substrates (e.g., turf algae, macroalgae, and coral), <u>though they can also be detected in the water column</u>. Recent reports have identified these organisms in more temperate regions as well, including <u>for example</u> Korea, Japan, northern territories of New Zealand, southern Australia, the northern Gulf of Mexico, and the Mediterranean Sea, <del>as</del>. <u>Their populations in temperate regions would benefit from the warming trends in sea temperatures rise</u> as a result of climate change. CTXs were initially categorized as belonging to one of three major classes that corresponded with their global <del>location</del> <u>location</u> (Pacific P-CTXs, Caribbean C-CTXs and Indian Ocean I-CTXs); however, experts now recommend that toxins be categorized into four classes, derivatives of CTX-4A, CTX-3C, C-CTX, and I-CTX, according</p>	<b>European Union</b>

	<p>to their chemical structure (I-CTX structures have not been fully determined). CTXs are lipophilic, do not degrade under heat or mild pH changes, and are known to be resistant to degradation by cooking, freezing, or canning processes. They may undergo structural transformations as they are metabolized by marine organisms, often increasing in toxicity as they do so. More than 30 unique analogues of CTXs have been reported and many more have yet to be fully characterized.</p> <p>Recent reports do not imply that these organisms are new in the area.</p>	
Para 2.	<p>Se considera que la frase "Inicialmente, las CTX se categorizaron como pertenecientes a una de las tres clases principales, que se corresponden con su localización global; no obstante, actualmente los expertos recomiendan que las toxinas se categoricen en cuatro clases, conforme a su estructura química" es ambigua. Se sugiere emplear una redacción distinta.</p>	<b>Venezuela (Bolivarian Republic of)</b>
Para 3.	<p><del>CTXs can accumulate in herbivorous marine fish and other marine organisms, such as gastropods and bivalves, that feed in marine reef environments and consume CTX-containing benthic dinoflagellates<sup>3</sup>. The impact of CTXs to humans is primarily through the consumption of wild-caught herbivorous fish, whereby humans consume wild-caught, herbivorous fish or predatory fish or shellfish that have accumulated toxins from consumption of CTXs. (The risk of herbivorous fish (risk of intoxication from aquacultured fish is considered to be low). Size-The diet of the individual marine organism is the primary contributing factor for CTX accumulation; however the size and age of marine organisms are believed to also influence CTX accumulation; however, the diet of the individual fish is the primary contributor. CTXs are lipophilic and may be present in tissues such as meat (flesh), head, liver, viscera, and roe (eggs). The 2020 FAO/WHO Report of the Expert Meeting on Ciguatera Poisoning referenced more than 425 species of fish that have been identified as having been contaminated with CTXs, including examples such as barracuda, amberjack, grouper, snapper, and parrotfish. Many of these fish are territorial, which can help identify vulnerable fishing areas, though territories can overlap and change with time. CTXs do not appear to be fatal to fish and there are no outward signs that a fish has CTX contamination caught in the wild is contaminated, such as change in fighting ability, behaviour, taste, odour, or texture; meaning that toxin analysis is required.</del></p> <p>Rationale: Sentence on accumulation moved to first para. As the diet is the primary contributing factor for CTX accumulation, this should come before any association with size and age. Whilst toxin analysis is required to confirm CTX contamination the inclusion of the phrase 'toxin analysis is required' risks inferring that maximum limits or presence/absence detection is required as part of a risk management strategy.</p>	<b>Australia</b>
Para 3.	<p>CTXs can accumulate in herbivorous marine fish and other marine organisms, such as gastropods and bivalves, that feed in marine reef environments <u>microalgae</u> and consume CTX-containing benthic dinoflagellates. The impact to humans is primarily through fish, whereby humans consume wild-caught, herbivorous fish or predatory fish that have accumulated toxins from consumption of herbivorous fish (risk of intoxication from aquacultured fish is considered to be low). Size and age are believed to influence CTX accumulation; however, the diet of the individual fish is the primary contributor. CTXs are lipophilic and may be present in tissues such as meat (flesh), head, liver, viscera, and roe (eggs). The 2020 FAO/WHO Report of the Expert Meeting on Ciguatera Poisoning referenced more than 425 species of fish that have been identified as having been contaminated with CTXs, including examples such as barracuda, amberjack, grouper, snapper, and parrotfish. Many of these fish are territorial, which can help identify vulnerable fishing areas, though territories can overlap and change with time. CTXs do not appear to be fatal to fish and there are no outward signs that a fish has CTX contamination, such as change in behaviour, taste, odour, or texture; meaning that toxin analysis is required.</p>	<b>European Union</b>

Para 4.	<p>Humans <u>can</u> experience CP when they consume fish or other marine organisms contaminated with CTXs. Generally, the symptoms of CP are acute and can appear within several hours of consuming contaminated food or up to 48 hours after consumption. CP symptoms include gastrointestinal issues (e.g., vomiting, diarrhoea), neurological issues (e.g., dizziness, headaches), cardiovascular issues (e.g., hypotension, bradycardia), and some symptoms that are especially characteristic of CP, such as cold allodynia and dysesthesia. In general, CP is not fatal, but exposure to CTXs can exacerbate existing cardiovascular or nervous system health issues and result in death. There is no specific treatment for CP, but symptoms can be managed with palliative care if the illness has been correctly identified.</p> <p>Consumption of fish does not always lead to poisoning, so it is an expression of possibility.</p>	<b>Japan</b>
Para 4.	<p>Humans experience CP when they consume fish or other marine organisms contaminated with CTXs. Generally, the symptoms of CP are acute and can appear within several hours of consuming contaminated food or up to 48 hours after consumption. CP symptoms include gastrointestinal issues (e.g., vomiting, diarrhoea), neurological issues (e.g., <del>dizziness</del><u>paresthesia</u>, <del>headaches</del><u>cold allodynia</u>), cardiovascular issues (e.g., hypotension, bradycardia), and some <u>of these</u> symptoms that are especially characteristic of CP, such as cold allodynia and dysesthesia. In general, CP is not fatal, but exposure to CTXs can exacerbate existing cardiovascular or nervous system health issues and result in death. There is no specific treatment for CP, but symptoms can be managed with palliative care if the illness has been correctly identified.</p> <p>These are more common and characteristic of acute neurological disorders of CP. See Figure 10 of the FAO/WHO expert meeting report.</p>	<b>Japan</b>
Para 4.	<p>Humans experience CP when they consume fish or other marine organisms contaminated with CTXs. Generally, the <u>signs and</u> symptoms of CP are acute and can appear within several hours of consuming contaminated food or up to 48 hours after consumption. CP symptoms include gastrointestinal issues (e.g., vomiting, diarrhoea), neurological issues (e.g., dizziness, headaches), cardiovascular issues (e.g., hypotension, bradycardia), and some symptoms that are especially characteristic of CP, such as cold allodynia and dysesthesia. <del>In general, CP is not</del> <u>rarely</u> fatal, but exposure to CTXs <u>may prove extremely debilitating and can exacerbate existing the impact of pre-existing cardiovascular or nervous system health issues and result in death</u> neurological conditions. There is no specific treatment for CP, but <u>some</u> symptoms can be managed with palliative care if the illness has been correctly <del>identified</del> <u>diagnosed</u>.</p> <p>Rationale: We are aware of some anecdotes from severely impacted people indicating that the chronic symptoms seem difficult to manage.</p>	<b>Australia</b>
Para 4.	<p>Se sugiere cambiar el término "paliativo". De acuerdo con la Organización Panamericana de la Salud (OPS), los cuidados paliativos se destinan a pacientes con enfermedades potencialmente mortales, e incluyen la prevención y alivio del sufrimiento, así como otros aspectos físicos, psicosociales y espirituales. De acuerdo al contexto del documento y del párrafo, se considera que un término como "sintomático" pudiera ser más adecuado.</p>	<b>Venezuela (Bolivarian Republic of)</b>
Para 6.	<p>Consuming CTX-contaminated fish was once geographically limited to local residents and visitors to tropical and subtropical <del>regions</del> <u>regions with suitable coral reef habitats</u>, but global trade of fish and <u>the impacts of climate change, including an increase in ocean temperatures due to climate change temperature, prevalence of cyclones and changes in currents</u>, have caused CP illnesses to be observed among a wider range of <u>individuals and reported in non-CTX endemic countries</u>. Isoforms of CTXs that were formerly found to be endemic to specific regions can now be found in other areas of the world. Some regions have been monitoring CP cases for many years, developing expertise in analysis and area management, and some are experiencing an increase in CP as an emerging issue and must learn how to develop monitoring programs and regulations to protect the public.</p>	<b>Australia</b>

	Rationale: Incidences of CP have been linked to more than increasing ocean temperatures.	
Para 6.	Consuming CTX-contaminated fish was once geographically limited to local residents and visitors to tropical and subtropical regions, but global trade of fish and an increase in ocean temperatures due to climate change have caused CP illnesses to be observed among a wider range of non-CTX endemic countries/countries in temperate regions. Isoforms of CTXs that were formerly found to be endemic to specific regions can now be found in other areas of the world. Some regions have been monitoring CP cases for many years, developing expertise in analysis and area management, and some are experiencing an increase in CP as an emerging issue and must learn how to develop monitoring programs and regulations to protect the public.	European Union
Para 7.	Successful surveillance and monitoring of CTXs depends on the availability of accurate analytical methods validated according to international standards/standards/guidelines. Presently, such formal validation is limited due to the lack of certified standards and certified or uncertified matrix reference materials. The analytical methods currently available for detection of CTXs are diverse and take advantage of different properties of the toxins (e.g., structure, cytotoxicity) and encompass both screening and quantitative measurements. Most CTX detection methods are suitable for analysing a variety of matrices (i.e., algae or seafood tissues) and some have sufficient sensitivity to detect CTXs at the levels that may be associated with adverse health effects in humans (e.g., the U.S. Food and Drug Administration has established guidance levels of 0.1 µg/kg C-CTX-1 equivalents and 0.01 µg/kg CTX-1B in fish; the EFSA CONTAM Panel (2010) indicated that 0.01 µg P-CTX-1 equivalents/kg fish is expected not to exert effects in sensitive individuals). CTX analogues are believed to vary depending on the strain of toxin producing algae, as well as the metabolism of marine organisms. CTXs are collected from CTX-producing algae or extracted from contaminated marine organisms; a limited number of analogues can be synthesized (e.g., P-CTX-3C, P-CTX-1B, and 51-hydroxy-CTX-3C). The algae grow slowly and can be difficult to culture, and a large quantity of ciguatoxic fish material is required for the isolation of toxins, which means production of standards is limited.  Various international guidelines for method validation exist and should not be limited to standards.	Japan
Para 7.	Successful surveillance and monitoring of CTXs depends on the availability of accurate analytical methods validated according to international standards. Presently, such formal validation is limited due to the lack of certified standards and certified or uncertified matrix reference materials. The analytical methods currently available for detection of CTXs are diverse and take advantage of different properties of the toxins (e.g., structure, cytotoxicity) and encompass both screening and quantitative measurements. Most CTX detection methods are suitable for analysing a variety of matrices (i.e., algae or seafood tissues) and some have sufficient sensitivity to detect CTXs at the levels that may be associated with adverse health effects in humans (e.g., the U.S. Food and Drug Administration has established guidance levels of 0.1 µg/kg C-CTX-1 equivalents and 0.01 µg/kg CTX-1B in fish; the EFSA CONTAM Panel (2010) indicated that 0.01 µg P-CTX-1 equivalents/kg fish is expected not to exert effects in sensitive individuals). CTX analogues are believed to vary depending on the strain of toxin producing algae, as well as the metabolism of marine organisms. CTXs are collected from CTX-producing algae or extracted from contaminated marine organisms; a limited number of analogues can be synthesized (e.g., <del>P-CTX-3C</del> CTX1B, <del>P-CTX-1B</del> CTX3C, and <del>51-hydroxy-CTX-3C</del> 51-hydroxyCTX3C). The algae grow slowly and can be difficult to culture, and a large quantity of ciguatoxic fish material is required for the isolation of toxins, which means production of standards is limited.  Also should be changed the order of description taking the relevance into account.	Japan

Para 7.	<p><u>7. Successful surveillance and monitoring of CTXs depends on the availability of accurate epidemiological data and/or analytical methods validated according to international standards. Presently, such formal validation of analytical methods for CTXs is limited due to the lack of certified standards and certified or uncertified matrix reference materials. The analytical methods currently available for detection of CTXs are diverse and take advantage of target different properties of the toxins (e.g., structure, cytotoxicity) and encompass both screening and quantitative measurements. Some analytical methods can simultaneously quantify individual CTX analogues, while others are more selective in the congeners that can be detected. Most CTX detection methods are suitable for analysing a variety of matrices (i.e., algae or seafood tissues) and some have sufficient sensitivity to detect CTXs at the levels that may be associated with adverse health effects in humans (e.g., the U.S. Food and Drug Administration has established guidance levels of 0.1 µg/kg C-CTX-1 equivalents and 0.01 µg/kg CTX-1B in fish; the EFSA CONTAM Panel (2010) indicated that 0.01 µg P-CTX-1 equivalents/kg fish is expected not to exert effects in sensitive individuals). CTX analogues are believed to vary depending on the strain of toxin producing algae, as well as the metabolism of marine organisms. CTXs are collected—can be extracted from CTX-producing algae or extracted from contaminated marine organisms; a limited number of CTX analogues can be synthesized (e.g., P-CTX-3C, P-CTX-1B, and 51-hydroxy-CTX-3C). The algae <i>Gambierdiscus</i> and <i>Fukuyoa</i> dinoflagellates grow slowly and can be difficult to culture, and a large quantity—quantities of ciguatoxic fish material is—are required for the isolation of toxins, which means production of CTX standards is limited.</u></p> <p>Rationale: Epidemiological data is currently the best source of data for management. There may not be a need to include the US FDA guidance levels and the EFSA CONTAM Panel level as written in the CoP. It is understood that the guidance level of 0.01 µg/kg for CTX-1B is at borderline of limits of detection, limits of quantification are often higher. The 2018 FAO/WHO Report of the Expert Meeting on Ciguatera Poisoning, points out that “No methods have been validated, and, in the majority of studies, certified reference materials were not available; hence, reports and comparisons of EC50, LOD, LOQ, and/or LD50 cannot be compared or verified”.</p>	<b>Australia</b>
Para 7.	<p>Successful surveillance and monitoring of CTXs depends on the availability of accurate analytical methods validated according to international standards. Presently, such formal validation is limited due to the lack of certified standards and certified or uncertified matrix reference materials. The analytical methods currently available for detection of CTXs are diverse and take advantage of different properties of the toxins (e.g., structure, cytotoxicity) and encompass both screening and quantitative measurements. Most CTX detection methods are suitable for analysing a variety of matrices (i.e., algae or seafood tissues) and some have sufficient sensitivity to detect CTXs at the levels that may be associated with adverse health effects in humans (e.g., the U.S. Food and Drug Administration has established guidance levels of 0.1 µg/kg <del>C-CTX-1</del><u>C-CTX1</u> equivalents and 0.01 µg/kg <del>CTX-1B</del><u>CTX1B</u> in fish; the EFSA CONTAM Panel (2010) indicated that 0.01 µg <del>P-CTX-1</del><u>CTX1B</u> equivalents/kg fish is expected not to exert effects in sensitive individuals). CTX analogues are believed to vary depending on the strain of toxin producing algae, as well as the metabolism of marine organisms. CTXs are collected from CTX-producing algae or extracted from contaminated marine organisms; a limited number of analogues <del>can be</del><u>have been</u> synthesized (e.g., P-CTX-3C, P-CTX-1B, and 51-hydroxy-CTX-3C). The algae grow slowly and can be difficult to culture, and a large quantity of ciguatoxic fish material is required for the isolation of toxins, which means production of standards is limited.</p>	<b>Japan</b>
Para 7.	<p>Successful surveillance and monitoring of CTXs depends on the availability of accurate analytical methods validated according to international standards. Presently, such formal validation is limited due to the lack of certified standards and certified or uncertified matrix reference materials. The analytical methods currently available for detection of CTXs are diverse and take advantage of different properties of the toxins (e.g., structure, cytotoxicity) and encompass both screening and quantitative measurements. Most CTX detection methods are suitable for analysing a variety of matrices (i.e., algae or seafood tissues) and some have sufficient sensitivity to detect CTXs</p>	<b>Canada</b>



	<p>at the levels that may be associated with adverse health effects in humans (e.g., the U.S. Food and Drug Administration has established guidance levels of 0.1 µg/kg C-CTX-1 equivalents and 0.01 µg/kg CTX-1B in fish; the EFSA CONTAM Panel (2010) indicated that 0.01 µg P-CTX-1 equivalents/kg fish is expected not to exert effects in sensitive individuals). CTX analogues are believed to vary depending on the strain of toxin <b>and species</b> producing algae, as well as the metabolism of marine organisms. CTXs are collected from CTX-producing algae or extracted from contaminated marine organisms; a limited number of analogues can be synthesized (e.g., P-CTX-3C, P-CTX-1B, and 51-hydroxy-CTX-3C). The algae grow slowly and can be difficult to culture, and a large quantity of ciguatoxic fish material is required for the isolation of toxins, which means production of standards is limited.</p>	
Para 7.	<p>Successful surveillance and monitoring of CTXs depends on the availability of accurate analytical methods validated according to international standards. Presently, such formal validation is limited due to the lack of certified standards and certified or uncertified matrix reference materials <b>although advancements in this area are progressing</b>. The analytical methods currently available for detection of CTXs are diverse and take advantage of different properties of the toxins (e.g., structure, cytotoxicity) and encompass both screening and quantitative measurements. Most CTX detection methods are suitable for analysing a variety of matrices (i.e., algae or seafood tissues) and some have sufficient sensitivity to detect CTXs at the levels that may be associated with adverse health effects in humans (e.g., the U.S. Food and Drug Administration has established guidance levels of 0.1 µg/kg C-CTX-1 equivalents and 0.01 µg/kg CTX-1B in fish; the EFSA CONTAM Panel (2010) indicated that 0.01 µg P-CTX-1 equivalents/kg fish is expected not to exert effects in sensitive individuals). CTX analogues are believed to vary depending on the strain of toxin producing algae, as well as the metabolism of marine organisms. CTXs are collected from CTX-producing algae or extracted from contaminated marine organisms; a limited number of analogues can be synthesized (e.g., P-CTX-3C, P-CTX-1B, and 51-hydroxy-CTX-3C). The algae grow slowly and can be difficult to culture, and a large quantity of ciguatoxic fish material is required for the isolation of toxins, which means production of standards is limited.</p>	<b>Canada</b>
Para 7.	<p>Successful surveillance and monitoring of CTXs depends on the availability of accurate analytical methods validated according to international standards. Presently, such formal validation is limited due to the lack of certified standards and certified or uncertified matrix reference materials. The analytical methods currently available for detection of CTXs are diverse and take advantage of different properties of the toxins (e.g., structure, cytotoxicity) and encompass both screening and quantitative measurements. <u>However, there are no internationally agreed harmonized protocols to determine CTXs yet.</u> Most CTX detection methods are suitable for analysing a variety of matrices (i.e., algae or seafood tissues) and some have sufficient sensitivity to detect CTXs at the levels that may be associated with adverse health effects in humans (e.g., the U.S. Food and Drug Administration has established guidance levels of 0.1 µg/kg C-CTX-1 equivalents and 0.01 µg/kg CTX-1B in fish; the EFSA CONTAM Panel (2010) indicated that 0.01 µg P-CTX-1 equivalents/kg fish is expected not to exert effects in sensitive individuals). CTX analogues are believed to vary depending on the strain of toxin producing algae, as well as the metabolism of marine organisms. CTXs are collected from CTX-producing algae or extracted from contaminated marine organisms; a limited number of analogues can be synthesized (e.g., P-CTX-3C, P-CTX-1B, and 51-hydroxy-CTX-3C). <u>The algae responsible dinoflagellates grow slowly in laboratory conditions and can be difficult to culture, maintain and to scale up their biomass;</u> a large quantity of ciguatoxic fish material is required for the isolation of toxins, which means production of standards is limited.</p>	<b>European Union</b>
Para 9.	<p>This document provides guidance on recommended practices to prevent or <del>avoid</del> <u>reduce</u> CP for different types of stakeholders including government authorities, fish sector operators (fishers, seafood processors, and seafood retail workers), health care professionals, and consumers. Because of differences in CTXs, analytical methods and standards, and regional incidence levels of CP, not all recommended practices will be applicable in all situations or to all stakeholders.</p>	<b>Australia</b>
Para 10.	<p>As knowledge improves and reliable methods become available, national authorities <del>could establish</del> <u>should consider establishing or strengthen-strengthening</u> programs to monitor <u>outbreaks and</u> CTXs in algae, sentinel fish species, and fish for consumption. Overall, the function of monitoring programs is to provide information that may be used to develop warnings of the potential for CP problems and</p>	<b>Australia</b>

	<p>provide feedback notices to the fishing industry or consumers to warn against fishing in certain areas. It <del>may be</del> <u>is currently</u> impractical (i.e., costly, and labour-intensive) to test fish to a sufficient degree for the complete prevention of CP, but recommendations outlined below should help to reduce the prevalence of CP <del>by identifying areas and fish to avoid.</del></p> <p>Rationale: Testing individual fish prior to market is likely to be cost prohibitive and to remain so for the near future. This is due to both a low prevalence of contamination and a lack of affordable and validated analytical techniques. For example, there is limited data on the prevalence of ciguatoxins (CTX) in fish harvested in Australian waters in which ciguatera has previously been detected.</p>	
Para 11.	<p><del>Environmental monitoring</del> <u>Monitoring</u> may be undertaken with a two-tiered approach: initial test of <i>Gambierdiscus</i> or <i>Fukuyoa</i> algae or fish using a functional biological screening method, then confirmation of any positive results using a chemical analytical method to identify well-known toxins and determine CTX content. Local officials <del>should</del> <u>may</u> determine if there are sentinel species of fish that consume toxic algae and whether monitoring those fish as well as predatory fish that feed <u>on these</u> in the area is appropriate. A <u>non-exhaustive</u> list of fish known or suspected to be associated with CP is included as Annex I. This list is <del>non-exhaustive and is</del> provided as an example to users of the CoP.</p> <p>Rationale: To distinguish between monitoring of epidemiological cases and outbreaks and samples.</p>	<b>Australia</b>
Para 11.	<p>Monitoring may be undertaken with a two-tiered approach: initial test of algae or fish using a functional biological screening method, then confirmation of any positive results using a chemical analytical method to identify well-known toxins and determine CTX content. Local officials should determine if there are sentinel species of fish that consume toxic algae and whether monitoring those fish as well as predatory fish that feed in the area is appropriate. A list of fish known or suspected to be associated with CP is included as Annex I. This list is non-exhaustive and is provided as an example to users of the <del>CoP</del> <u>Code of Practice (CoP)</u>.</p>	<b>Japan</b>
Para 13.	<p>Monitoring of both algae and fish is recommended, as the concentration and/or CTX profile of benthic dinoflagellates does not always correlate to contamination in fish; i.e., a high concentration of CTX in an algal bloom may not correlate to a high concentration of CTX in local fish, and certain species of fish may contain high concentrations of CTXs even though the density of dinoflagellates in the sea water is low. This relationship has been used by some national authorities <u>or individual entities</u> to set limits on size or species of fish permitted for consumption from a particular region.</p> <p>Rationale: Individual entities is recommended to be included as in Australia the Sydney Fish Market is not a national authority.</p>	<b>Australia</b>
Para 14.	<p>Because toxin profiles may differ when collected from algae versus when collected from fish <u>and humans</u> (due to metabolism), it is important to experimentally determine the correlation between environmentally sampled toxins and toxins isolated from fish and humans to enable traceback and targeted surveillance activities. It may be possible to identify the preferred substrate for dinoflagellates (e.g., seagrass and macroalgae) and if there is a selectivity or preference by herbivores for consumption of those substrates in a region.</p> <p>Since it has been reported that low-toxic analogues may be converted into highly toxic ones in human metabolism, “and humans” should be added.</p>	<b>Japan</b>
Para 14.	<p>Because toxin profiles <del>may typically differ when collected from in</del> algae versus <del>when collected from contaminated fish (due (and</del></p>	<b>Australia</b>

	<p><u>potentially humans due</u> to metabolism), it is important to experimentally determine the correlation between environmentally sampled toxins and toxins isolated from fish and humans to enable traceback and targeted surveillance activities. It may be possible to identify the preferred substrate for dinoflagellates (e.g., seagrass and macroalgae) and if there is a selectivity or preference by herbivores for consumption of those substrates in a region.</p> <p>Rationale: It has been well established that toxin profiles differ and transform as they move through the food web/chain. Whilst the science is still unclear, potential metabolism/oxidisation of CTXs in humans may be a factor when less toxic analogues dominate the toxic meal.</p>	
Para 14.	<p>Because toxin profiles may differ when collected from algae versus when collected from fish (due to <del>metabolism</del>) <u>metabolism and behavior, for instance large migratory species that can feed in other areas</u>, it is important to experimentally determine the correlation between environmentally sampled toxins and toxins isolated from fish and humans to enable traceback and targeted surveillance activities. It may be possible to identify the preferred substrate for dinoflagellates (e.g., seagrass and macroalgae) and if there is a selectivity or preference by herbivores for consumption of those substrates in a region.</p>	<b>European Union</b>
Para 15.	<p>National or regional authorities could consider developing maps of areas toxic algae grow and identifying the species of fish that feed in those areas. These maps may be useful to competent authorities when trying to determine if an area needs to be closed to fishing by commercial firms or recreational fishermen (some species of fish are known to exhibit high site fidelity). Maps indicating toxic fish or algae should be updated at reasonable intervals as blooms or migratory patterns may change season-to-season or with climate change, and results can be more precise as testing methods improve. Creating high-risk maps may not be appropriate for all regions, e.g., it may be difficult for countries or regions with many islands and coral <del>reefs</del> <u>reefs because high-risk areas are variable</u>.</p> <p>In order to be more specific about why this practice is not appropriate in all regions, Japan suggest to add “because high-risk areas are variable” to the end of this sentence.</p>	<b>Japan</b>
Para 15.	<p>National or regional authorities could consider developing maps <del>of areas toxic algae grow</del> <u>based on epidemiological data and identifying identified the species-prevalence of fish that feed <i>Gambierdiscus</i> and <i>Fukuyoa</i> species in a region, and the associated food chains for toxin transfer in</u> those areas. These maps may be useful to competent authorities when trying to determine if an area needs to be closed to <del>fishing by commercial firms or and recreational fishermen (some species of fish are known to exhibit high site fidelity)</del> fishing. Maps indicating toxic fish or algae should be updated at reasonable intervals as blooms or migratory patterns may change season-to-season or with climate change, and results can be more precise as testing methods improve. Creating high-risk maps may not be appropriate for all regions, e.g., it may be difficult for countries or regions with many islands and coral reefs.</p> <p>Rationale: Epidemiological data is currently the best source of data for management. Paragraph 3 already stated that many of these fish are territorial – “high site fidelity” here is repetitive.</p>	<b>Australia</b>
Para 16.	<p>Proposed Change: The Philippines supports the proposal to include practical measures in the development of maps of toxic algae/fish if they are scientifically supported. Otherwise, the current general statement should suffice.</p>	<b>Philippines</b>

	<p>Rationale: Currently, the Philippines does not have a comprehensive map of areas where toxic algae are grown and identification of the species of fish that feed in those areas. It would be beneficial if practical measures for developing complex maps, if scientifically supported, are indicated in the proposed COP to provide further guidance.</p>	
Para 17.	<p>National or regional authorities <del>could develop a</del> <u>should consider developing and routinely updating an epidemiological</u> database to collect information on human illnesses, which includes the species of the fish suspected of causing the illness and its original catch area if known (for countries reporting CP). Ideally, the data collected by these programs should include the origin <u>and date of capture of</u> contaminated fish, the fish species involved, the CTX analogue <del>profile</del> <u>profile from meal remnants (if available) and the patient (if achievable)</u>, the concentration of toxins, <u>severity of short and long term</u> symptoms experienced by the patient, the amount of fish consumed, <del>testing results from meal remnants,</del> and other relevant information. Examples of monitoring programs that report information on CP <del>are</del> <u>are given below</u>.</p> <p>Rationale Routinely updating the database is an important as developing the database. Date of capture is important to help elucidate temporal factors/allow for modelling of factors likely to drive incidence of CP. Connecting epidemiological data with toxicological data will be key to building a database that can inform future risk management options.</p>	<b>Australia</b>
Para 17.	<p>The EU and its Member States (EUMS) propose to include the following information after the bullet point of EU/Rapid Alerts System for Food and Feed:</p> <ul style="list-style-type: none"> <li>• Government of Canary Islands: <a href="https://www.gobiernodecanarias.org/pesca/temas/Control_calidad_productos/ciguatera.html">https://www.gobiernodecanarias.org/pesca/temas/Control_calidad_productos/ciguatera.html</a></li> </ul>	<b>European Union</b>
Para 17.	<p>Debido a que se asocia intoxicación por ciguatera solo con especies de peces, sino también otros tipos de animales marinos consumidos por el humano, se sugiere ampliar la redacción en consecuencia, tanto en este párrafo como en aquellos donde corresponda. En este párrafo en particular se sugiere establecer bases de datos para recopilación de información de enfermedades humanas que incluya las especies de peces sospechosas de causar la enfermedad. Sin embargo, tanto en el escrito del documento como en el Anexo I "Lista de organismos marinos de los que se sabe o se sospecha que están asociados a la IC" se mencionan otros organismos no ícticos, como moluscos bivalvos, caracoles e incluso medusas, estrellas de mar, erizos y pepino de mar.</p>	<b>Venezuela (Bolivarian Republic of)</b>
Para 18.	<p>National or regional authorities could utilize social science approaches such as surveys and interviews to solicit information from local fishers about which areas yield toxic fish. Local fishers often possess knowledge about areas of CP risk, and this information represents a cost-effective way to supplement more costly surveillance <u>of toxins in algae or fish by analytical methods</u>.</p> <p>Japan proposes to be more specific as many different types of surveillance appear in the document.</p>	<b>Japan</b>
Para 19.	<p>When authorities are notified of CP cases occurring in an area not known to be endemic for CP, it is important to first identify the species of fish involved, locate the area of capture, determine the amount (weight) of fish the patient consumed, and recover any meal remnants for confirmation of CTXs. Investigation of the concentration <u>and profile of</u> CTXs in the <del>algae, fish, and other animals</del> <u>algae in</u></p>	<b>Japan</b>

	<p>the area would be the next step to determine if an area needs to be restricted to fishing.</p> <p>Should be listed in the order in which they are more likely to detect CTXs. It is difficult to find the CTXs producing algae in the first place.</p>	
Para 19.	<p>When authorities are notified of CP cases occurring <del>in an area not known to be endemic for CP</del>, it is important to first identify the species of fish involved, locate the area of capture, determine the amount (weight) of fish the patient consumed, and recover any meal remnants for confirmation of CTXs. Investigation of the concentration of CTXs in the algae, fish, and other animals in the area would be the next step to determine if an area needs to be restricted to fishing.</p> <p>As Japan consider that this sentence is a matter recommended to the authorities regardless of whether CP is endemic or not, we propose that this text be deleted.</p>	Japan
Para 19.	<p>When authorities are notified of CP cases occurring in an area not known to be endemic for CP, it is important to first identify the species of <del>fish</del> <u>seafood</u> involved, locate the area <u>and date</u> of capture, determine the amount (weight) of fish the patient consumed, <u>record the type and severity of symptoms, and recover any meal remnants (if available)</u> for confirmation of CTXs. <del>Investigation</del> <u>An initial risk assessment should include identification of whether the seafood was sourced locally or imported from another area. Identification of whether the implicated seafood species was a migratory or sedentary species will inform whether investigations of the concentration of CTXs in the algae, fish, and other animals in the local area would be the next step are required to determine appropriate risk management options (that may include if an area needs to be restricted to fishingfishing).</u></p> <p>Rationale It is recommended that the date of capture and type and severity of symptoms should also be identified and recorded, where known. Prior to any environmental investigations being triggered to better understand the CP risk in an area not previously known to harbour ciguatoxic fish. An initial risk assessment could be undertaken, including identification of whether the fish was sourced locally caught and imported, as well as determination of whether the implicated seafood was a migratory species. Restricting an 'area' to fishing is one risk management option.</p>	Australia
Para 20.	<p>When possible, national, regional, and local authorities could develop maximum levels (MLs) for the concentration of CTXs permitted in susceptible fish (e.g., the U.S. Food and Drug Administration has established guidance levels of 0.1 µg/kg <del>C-CTX-1-C-CTX1</del> equivalents and 0.01 µg/kg <del>CTX-1B-CTX1B</del> in fish; the EFSA CONTAM Panel (2010) indicated that 0.01 µg <del>P-CTX-1-CTX1B</del> equivalents/kg fish is expected not to exert effects in sensitive individuals). Because of current limitations in analytical methods and toxic equivalency factors of different CTXs, MLs may not be appropriate for all toxins or regions.</p>	Japan
Para 20.	<p>When <del>possible, national, regional,</del> <u>sufficient data linking epidemiology and local toxicology is available,</u> national authorities could <del>develop</del> <u>consider developing</u> maximum levels (MLs) for the concentration of CTXs permitted in susceptible fish (e.g., the U.S. Food and Drug Administration has established guidance levels of 0.1 µg/kg <del>C-CTX-1</del> equivalents and 0.01 µg/kg <del>CTX-1B</del> in fish; the EFSA CONTAM Panel (2010) indicated that 0.01 µg <del>P-CTX-1</del> equivalents/kg fish is expected not to exert effects in sensitive individuals). Because of current limitations in analytical methods and toxic equivalency factors of different CTXs, MLs may not be appropriate for all toxins or regions.</p> <p>Rationale: The establishment of MLs should be at a national level. Current knowledge gap is the linking of sufficient epidemiological and toxicological data to inform setting of MLs and this should be included in the CoP.</p>	Australia

	As above there may be no need to include the US FDA guidance levels and the EFSA CONTAM Panel level as written in the CoP. There is a risk this these guidance levels could become a de facto maximum level. It is understood that guidance level of 0.01 ug/kg for CTX-1B is at borderline of limits of detection, limits of quantification are often higher. The 2018 FAO/WHO Report of the Expert Meeting on Ciguatera Poisoning, points out that “No methods have been validated, and, in the majority of studies, certified reference materials were not available; hence, reports and comparisons of EC50, LOD, LOQ, and/or LD50 cannot be compared or verified”.	
Para 20.	<p>Proposed change: The Philippines recommends exploring alternative approaches to specifying the Maximum Levels (ML) for CTX concentration in susceptible fish within the COP, instead of proposing specific numerical values.</p> <p>Rationale: The Philippines recognizes the current limitations in analytical methods for CTX testing, which may not yet be fully established in all regions or countries. Therefore, proposing a specific Maximum Level (ML) for CTX concentration in susceptible fish within the COP might not be the most suitable approach at this time. The Philippines encourages continued collaboration and capacity building efforts to improve analytical capabilities for CTX testing globally. This will allow for a more informed and data-driven approach to establishing MLs in the future, ensuring the safety of consumers while considering the specific circumstances of different regions.</p>	<b>Philippines</b>
Para 21.	<p><del>Some countries have established</del> National, region and local authorities could establish limits on size and/or species of fish that can be caught and sold because they are prone to causing CP. Some examples are given below <u>to Annex X</u>:</p> <p>As this part is not a recommendation but a specific example, Japan proposes to amend it to a code of practice and move it to the Annex instead of the main text. Japan also proposes the Japan's practice as follows:</p> <ul style="list-style-type: none"> <li>• Japan maintains a negative list of domestic and import fish species that are forbidden. Fish species in the list can be imported only if the same species caught in the specific sea area of the exporting country are usually eaten, no CP has occurred, and it is tested and confirmed to be free of CTX. In addition, some local governments have established a list of fish species that are recommend not to be sold or consumed, and a size limit (length and/or weight) of some fish species known to be linked to CP.</li> </ul>	<b>Japan</b>
Para 21.	<p>The EUMS propose to replace the following bullet point: “• Canary Islands (Spain) has a protocol to be carried out in authorized points of first sale, by which certain species must be checked above a certain weight.” by “• Canary Islands (Spain) has a protocol to be carried out in authorized points of first sale, by which specimens belonging to a list of species, equal or above a certain maximum weight, must be checked to discard CTX activity in flesh tissue prior to their commercialization.”</p>	<b>European Union</b>
Para 22.	If appropriate, national, regional, and local authorities should develop regulations and voluntary guidelines to minimize the possibility that CTX-contaminated fish are caught or sold. Depending on the point of application, these may include requirements for food hygiene	<b>Japan</b>

	systems that include Hazard Analysis and Critical Control Point (HACCP) plans. <del>Authorities may</del> <u>In that case, authorities should</u> conduct inspections to ensure that the HACCP plan contains the appropriate critical limits, monitoring procedures, and record-keeping elements, and is properly and consistently implemented.	
Para 25.	Standardized protocols for testing of <del>algae or fish matrices</del> <u>or algae</u> should be used so that results are comparable across laboratories or between regions and countries. This includes monitoring <i>Gambierdiscus</i> and <i>Fukuyoa</i> diversity (e.g., molecular approach vs. morphotaxonomy, how to approach inclusion of new species) or when collating epidemiological data. CTX testing should be done using single or multi-laboratory validated methods to ensure comparability of results.  Should be listed in the order of testing priority.	Japan
Para 25.	Standardized protocols for testing of <u>passive water samples</u> , algae or fish matrices should be used so that results are comparable across laboratories or between regions and countries. This includes monitoring <i>Gambierdiscus</i> and <i>Fukuyoa</i> diversity (e.g., molecular approach vs. morphotaxonomy, how to approach inclusion of new species) or when collating epidemiological data. CTX <u>sample collection and testing</u> should be done using single or multi-laboratory validated methods to ensure comparability of results.  Rationale: Inclusion of passive water samples to align with text in paragraph 12. It is recommended that any technique used for monitoring purposes be standardised.	Australia
Para 27.	Analytical methods with the capability to quantify toxins should be used, either methods that measure individual CTX analogues or methods that report the sum of all toxins present (i.e., cannot distinguish individual analogues). Because CTX profiles are known to vary by location or marine species, different reference <del>standards</del> <u>materials</u> may be needed based on the toxin profile observed and method used.	Japan
Para 28.	When possible, laboratories should store aliquots of CTX-contaminated fish or algae. These naturally contaminated samples can be used for development of <del>standard</del> <u>reference</u> materials or to share with other researchers performing method validations.	Japan
Para 28.	When possible, laboratories should <del>store</del> <u>consider storing</u> aliquots of CTX-contaminated fish or algae. These naturally contaminated samples can be used for development of standard materials or to share with other researchers performing method validations.  Rationale: Provides greater flexibility for the laboratory and future method development.	Australia
Para 28.	When possible, laboratories should store aliquots of CTX-contaminated fish or algae. These naturally contaminated samples can be used for development of standard materials or to share with other researchers performing method validations. <b><u>Progress in method development is limited by the availability of reference materials. However, recent advancements in culturing, materials handling and chemical characterization have significantly improved the capabilities to make reference materials. Algal producers of toxins in culture and fish with varying metabolite profiles are available.</u></b>	Canada
Para 29.	Entities with expertise in analytical methods <b><u>and in developing reference materials</u></b> are strongly encouraged to share knowledge and expertise and initiate collaboration with regions that are developing or improving their surveillance and monitoring activities.	Canada

Para 30.	Because analytical technologies will continue to evolve, it is not appropriate to recommend specific methods in a CoP. Detection of CTXs can be performed using a number of techniques, each with differing sensitivities, advantages, and limitations. Methods that have been reported in the literature are: the neuroblastoma assay (N2A), receptor-binding assay (RBA), enzyme-linked immunosorbent assay (ELISA), mouse bioassay (MBA), and liquid chromatography/mass chromatography/(tandem) mass spectrometry (LC-MS)(LC-MS or LC-MS/MS).	<b>Japan</b>
Para 30.	<p>The Philippines supports the proposal to identify practical measures related to monitoring or assessing human activity for CP reduction to be included in the COP.</p> <p>The current Philippine National Standard on the Code of Good Aquaculture Practices for Grouper only makes a general statement on the use of appropriate Codex methods of analysis for ciguatoxin. It would be beneficial that type/s of method be recommended in the COP.</p>	<b>Philippines</b>
Para 31.	<p>As mentioned in paragraph 11, monitoring may be undertaken with a two-tiered approach: initial qualitative screening of <del>algae or fish or</del> <u>algae</u> using a functional biological method (e.g., <del>RBA-N2a</del>) followed by quantitative analysis of positive samples to determine the overall concentration of CTXs. For CTXs where the structure is known and/or <del>standards reference materials</del> are available, confirmation of positive results can be performed using a method that can identify CTX analogues and determine their individual contribution to the overall CTX concentration (e.g., LC-MS). Stakeholders are encouraged to contact their national authorities for assistance or consult with international agencies such as IAEA on method development and sharing of technology. The <i>FAO/WHO Report of the Expert Meeting on Ciguatera Poisoning</i> contains a list of methods available as of 2020.</p> <p>Should be listed in the order of monitoring priority. Since RBA doesn't have good sensitivity, N2a is better for example.</p>	<b>Japan</b>
Para 31.	As mentioned in paragraph 11, <u>environmental</u> monitoring may be undertaken with a two-tiered approach: initial qualitative screening of algae or fish using a functional biological method (e.g., RBA) followed by quantitative analysis of positive samples to determine the overall concentration of CTXs. For CTXs where the structure is known and/or standards are available, confirmation of positive results can be performed using a method that can identify CTX analogues and determine their individual contribution to the overall CTX concentration (e.g., LC-MS). Stakeholders are encouraged to contact their national authorities for assistance or consult with international agencies such as <del>IAEA</del> <u>the International Atomic Energy Agency (IAEA)</u> on method development and sharing of technology. The <i>FAO/WHO Report of the Expert Meeting on Ciguatera Poisoning</i> contains a list of methods available as of 2020.	<b>Australia</b>
Para 31.	<p>The Philippines supports the proposal to identify practical measures related to monitoring or assessing human activity for CP reduction to be included in the COP.</p> <p>The current Philippine National Standard on the Code of Good Aquaculture Practices for Grouper only makes a general statement on the use of appropriate Codex methods of analysis for ciguatoxin. It would be beneficial that type/s of method be recommended in the COP.</p>	<b>Philippines</b>



Para 32.	Fish sector operators (people who work in the areas of fishing, seafood processing, and seafood retail) should <del>be aware of</del> <u>adhere to</u> any national or regional legislation for food hygiene systems that include HACCP plans pertaining to CTXs or CP in relevant commodity species. If not specifically required by authorities, firms should consider adding CP to their HACCP plans to reduce the likelihood of CTX-contaminated fish entering the marketplace. These plans could include any relevant <del>national-national, regional or local</del> limits on size or source of fish, traceability of fish products from fishing areas to retail, training on CP hazards and regulations, and criteria for rejecting shipments.  Rationale: Size limits or source of fish could be established at a regional or local level.	<b>Australia</b>
Para 34.	HACCP plans should include a hazard analysis; for CP, that would include local awareness of the species of fish caught which may be susceptible to CTX accumulation and an understanding of the location of the potentially toxic areas for avoidance. If appropriate, restrictions on the species and/or size of fish known to accumulate CTXs could be part of the HACCP plan. HACCP plans could include a requirement that fish <u>known to accumulate CTXs and above a size limit</u> are tested for CTXs before sale, but such wide-scale testing could be very costly or <del>burdensome</del> <u>burdensome and access to analytical facilities might be restrictive</u> .	<b>Australia</b>
Para 36.	Seafood processors who purchase fish directly from fishers should obtain information about fishing locations to determine the potential for ciguatoxic fish based on knowledge of the regions where CP occurs (comparing to risk maps, see paragraph 15, from <u>national or regional</u> authorities where available). Primary seafood processors should avoid purchasing fish species associated with CP from established or emerging areas linked with CP.	<b>Australia</b>
Para 37.	When MLs of CTXs in fish for consumption are established or recommended by national, regional, or local authorities (see paragraph 20), fish sector operators could set critical limits on CTX concentrations in surrogates to reduce the likelihood that commercial fish are contaminated. Surrogates could be <del>water, sentinel fish, algae, or sentinel fish-algae</del> in a particular fishing area depending on what has been determined to be appropriate for the region (see paragraphs 13-14).  Japan proposes to delete "water" as there is no clear evidence that water monitoring is effective.	<b>Japan</b>
Para 37.	<del>When</del> MLs of CTXs in fish for consumption are established or recommended by <del>national, regional, or local</del> <u>national</u> authorities (see paragraph 20), fish sector operators could set critical limits on CTX concentrations in surrogates to reduce the likelihood that <u>contaminated</u> commercial fish are <del>contaminated</del> <u>caught and sold</u> . Surrogates could be water, algae, or sentinel fish <del>in</del> <u>from</u> a particular fishing area depending on what has been determined to be appropriate for the region (see paragraphs 13-14).	<b>Australia</b>
Para 37.	Si las autoridades nacionales, regionales o locales establecen o recomiendan NM de CTX en pescado para el consumo (véase el párrafo 20), los operadores del sector del pescado pueden establecer límites críticos de concentraciones de CTX en otros <b>productos sustitutos</b> , para reducir la probabilidad de que el pescado comercial esté contaminado. Pueden ser productos sustitutos el agua, las algas o los peces centinela en una zona concreta de captura, dependiendo de lo que se haya determinado como adecuado para la región (véanse los párrafos 13-14).  Se sugiere definir qué es un "producto sustituto".	<b>Venezuela (Bolivarian Republic of)</b>
Para 38.	CTXs are known to concentrate in fish viscera, liver, heads, and roe. Therefore, it is highly recommended that these organs or body parts from fish species linked to CP are not <u>sold and/or</u> consumed. Fish production establishments should have policies and procedures for	<b>Japan</b>

	handling and disposal of animal by-products and animal-derived products to minimize risks to public and animal health and to protect the integrity of the food and feed chain.	
Para 38.	CTXs are known to concentrate in fish viscera, liver, heads, and roe. Therefore, it is highly recommended that these organs or body parts from fish species linked to CP are not consumed. <del>Fish production establishments</del> <u>Seafood processors</u> should have policies and procedures for handling and disposal of <del>animal-seafood by-products and animal-derived seafood-derived</del> products to minimize risks to public and animal health and to protect the integrity of the food and feed chain.	<b>Australia</b>
Para 39.	<del>National and regional authorities</del> <u>Countries and regions</u> are encouraged to share their guidance and best practices with interested parties, including training of scientists in relevant methodologies, to improve the global prevention of CP and encourage harmonization of data and reporting systems.  For consistency in the document.	<b>Japan</b>
Para 39.	Countries and regions are encouraged to share their guidance and best practices with interested parties, including <u>for the purposes of</u> training of scientists in relevant methodologies, to improve the global prevention of CP and encourage harmonization of data and reporting systems.	<b>Australia</b>
Para 41.	Agencies or other public recognized institutions that have CP or CTX databases should <u>be encouraged to share approaches on raising awareness of the risks of CP and</u> publish annual reports or other summaries on monitoring of illnesses to aid other regions in developing strategies for prevention and avoidance of CP.	<b>Australia</b>
Para 42.	Bullett ii. fishers not fishermen	<b>Australia</b>
Para 44.	Consumers <del>should</del> <u>must</u> avoid eating fish caught from a restricted area. They should also consider limiting the portion size they consume from fish species that have been linked to CP, and avoid eating the liver, roe, head, or viscera of any CP associated species.	<b>Japan</b>
Para 47.	Since CTXs may be transmitted through breastfeeding and unprotected sexual intercourse, individuals who are experiencing CP symptoms could refrain from these <del>activities</del> <u>activities for the time being as a precautionary measure</u> .  This is considered a precautionary measure rather than a preventive measure.	<b>Japan</b>
Para 48.	<del>National</del> <u>National, regional or local</u> authorities should advise healthcare professionals of the possibility of CP in patients, even in regions where CP is not endemic. If appropriate, authorities could offer training on how to identify CP in patients and how to notify a <u>national or regional</u> database of CP illnesses. Patients with symptoms of CP should be asked thoroughly about the types of fish they have consumed as well as consumption times and places.	<b>Australia</b>
Para 48.	The Philippines supports the proposal to identify practical measures related to monitoring or assessing human activity for CP reduction to be included in the COP.  Current Philippine National Standards related to grouper do not provide practical measures related to monitoring or assessing human activity for CP reduction. It would be beneficial to include practical measures on monitoring negative impacts on human activity to guide	<b>Philippines</b>

	competent authorities and food business operators.	
Para 49.	<p>The Philippines supports the proposal to identify practical measures related to monitoring or assessing human activity for CP reduction to be included in the COP.</p> <p>Current Philippine National Standards related to grouper do not provide practical measures related to monitoring or assessing human activity for CP reduction. It would be beneficial to include practical measures on monitoring negative impacts on human activity to guide competent authorities and food business operators.</p>	<b>Philippines</b>
<b>Annex I: List of marine organisms known or suspected to be associated with CP</b>		
Caranx sp.	Trevally (ulua, papio) Hawaii (U.S.A.) Australia	<b>Australia</b>
Cheilinus triolbatus	Tripletail Maori Wrasse Australia	
Cheilinus undulatus	Humphead wrasse French Polynesia, China, Hong Kong SAR, Enewetak Island, Australia	
Choerodon spp.	Tuskfish Australia	
Ctenochaetus striatus	Striped bristletooth surgeon fish Nuku Hiva (Marquesas), Tahiti, Australia	
Epinephelus coioides	Orange-spotted grouper (Goldspotted Rockcod) China, Hong Kong SAR, Australia	
Epinephelus fuscoguttatus	Large grouper (Flowery Rockcod) Enewetak Island, Kiribati, Australia	
Epinephelus lanceolatus	Giant grouper China, Hong Kong SAR, Australia	
Epinephelus tauvina	Large grouper Bikini Island, Kiribati, Australia	
Gymnothorax javanicus	Moray eel (Giant Moray) Tuamotu Archipelago and Tahiti (French Polynesia), Tarawa, Kiribati, central Pacific Ocean, Hawaii (U.S.A.), Kiribati, Australia	
Lethrinus nebulosus	Spangled Emperor Australia	
Lutjanus bohar	Two-spot red snapper (red bass) Mauritius, Minamitorishima (Marcus) Island (Japan), French Polynesia, Tubuai (Australes), Nuku Hiva (Marquesas), Hawaii (U.S.A.), French Polynesia, Enewetak Island, Bikini Island, Kiribati, India, Indonesia, Viet Nam, Australia	
Lutjanus gibbus	Humpback red snapper (paddletail) Nuku Hiva (Marquesas), French Polynesia, Enewetak Island, Bikini Island, Australia	
Lutjanus sebae	Red emperor Mauritius (Nazareth, Saya de Malha, Soudan) Australia	

<p>Scomberoides commersonianus Giant Queenfish Australia</p> <p>Scomberomorus spp. Mackerel Australia</p> <p>Seriola spp. JackKingfish Australia</p> <p>Symphorus nematophorusChinamanfish Australia</p>	
<p>The EUMS propose to include the following organism to the list. Rationale: Adding information:</p> <p>SCIENTIFIC NAME - COMMON NAME - LOCATION WHERE FOUND Acanthocybium solandri - Kingfish - Canary Islands (Spain)</p> <p>The EUMS propose to include in the box "location where found" for "Epinephelus marginatus": Canary Island (Spain).</p> <p>The EUMS propose to include the following organism to the list: SCIENTIFIC NAME - COMMON NAME - LOCATION WHERE FOUND Pomatomus saltatrix - Bluefish - Canary Islands (Spain)</p> <p>The EUMS propose to replace the information for the organism Seriola fasciata, in the box "location where found" "Selvagens Islands (Madeira Archipelago), West Africa (Canary Islands)" by "Selvagens Islands (Madeira Archipelago), Canary Islands (Spain)". Rationale; correction.</p> <p>The EUMS propose to include "Canary Islands (Spain)" in the box "location where found" for the organism Seriola spp. Rationale: Adding information.</p>	<p><b>European Union</b></p>
<p>Add "Anyperodon leucogrammicus"/"Slender grouper"/ "Okinawa (Japan)" to Annex I.</p> <p>Arothron nigropunctatus/pufferfish is thought to be a fish that causes TTX or CTX poisoning, not CTX.</p> <p>Add "Okinawa (Japan)" to Caranx ignobilis/Giant trevally (ulua).</p> <p>Add "Okinawa (Japan)" to Cephalopholis argus/Large grouper.</p> <p>Add "Okinawa (Japan)" to Epinephelus fuscoguttatus/Large grouper.</p> <p>Add "Okinawa (Japan)" to Gymnothorax javanicus/Moray eel.</p> <p>Add "Mainland and Okinawa (Japan)" to Lutjanus bohar/Two spot red snapper (red bass).</p>	<p><b>Japan</b></p>

<p>Add "Mainland and Amami (Japan)" to <i>Lutjanus monostigma</i>/One spot snapper.</p> <p>Replace "Miyazaki (Japan)" with "Mainland and Okinawa (Japan)" of <i>Oplegnathus punctatus</i>/Spotted knifejaw.</p> <p>Add "Okinawa (Japan)" to <i>Plectropomus areolatus</i>/Squaretail coral grouper.</p> <p>Add "Okinawa (Japan)" to <i>Plectropomus laevis</i>/Blacksaddled coral grouper.</p> <p>Add "Okinawa (Japan)" to <i>Variola albimarginata</i>/Lyretail.</p> <p>Add "Okinawa and Amami (Japan)" to <i>Variola louti</i>/Large grouper.</p>	
<p>The Philippines supports the proposal to retain the Annex I in the COP and proposes to add the following species of reef fish in the Philippines that is associated with Ciguatera Poisoning:</p> <ul style="list-style-type: none"> <li>- barracuda (<i>Sphyraena barracuda</i>)</li> <li>- par-rotfish (<i>Scarus quoyi</i>)</li> <li>- rabbitfish (<i>Siganus guttatus</i>)</li> <li>- grouper (<i>Ephinephelus merra</i>)</li> <li>- <i>Plectropomus leopardus</i>,</li> <li>- <i>Variola albimarginata</i></li> <li>- snapper (<i>Lutjanus campechanus</i>)</li> <li>- emperor fish (<i>Lethrinus lentjan</i>)</li> </ul> <p>Rationale: It is a useful guide for competent authorities and food business operators in identifying marine organisms that are known to be associated with CP</p>	<p><b>Philippines</b></p>