

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 9

CX/CF 23/16/9-Add.1

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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**MAXIMUM LEVELS FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN NUTMEG, DRIED CHILI AND PAPRIKA,
GINGER, PEPPER AND TURMERIC AND ASSOCIATED SAMPLING PLANS
(AT STEP 4)**

Comments at Step 3 in reply to CL 2023/24-CF

submitted by

Argentina, Canada, Chile, Egypt, Iraq, Japan, Peru, Republic of Korea, United States of America (USA),

American Herbal Products Association (AHPA) and

International Commission for Uniform Methods of Sugar Analysis (ICUMSA)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/24-CF¹ issued in February 2023. 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 Annex

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

¹ <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**

COMMENT	MEMBER/ OBSERVER
<p>Chile agradece la oportunidad de presentar observaciones sobre los niveles máximos para el total de aflatoxinas y la ocratoxina A en la nuez moscada, el chile y el pimentón desecados, el jengibre, la pimienta y la cúrcuma y planes de muestreo asociados.</p> <p>Al respecto, y considerando los argumentos entregados en el documento CX/CF 23/16/9, Chile quisiera comentar lo siguiente:</p> <p>- Chile considera que, tomando en cuenta la heterogeneidad de niveles máximos a nivel mundial, sería conveniente establecer niveles máximos para todas las especies revisadas en el documento, y no sólo para Chile desecado y nuez moscada, como se expresa en el apéndice I Parte I del documento.</p>	Chile
<p>Agree with regards.</p>	Iraq
<p>El Perú desea agradecer a la Secretaría de la Comisión del Codex Alimentarius, Programa Conjunto FAO/OMS sobre Normas Alimentarias, respecto a la solicitud de observaciones sobre los niveles máximos para el total de aflatoxinas y la ocratoxina A en la nuez moscada, el chile y el pimentón desecados, el jengibre, la pimienta y la cúrcuma y planes de muestreo asociados.</p> <p>En esta ocasión, el Perú considera que se ha realizado un excelente trabajo, no presentando comentarios u observaciones sobre la propuesta presentada.</p>	Peru
<p>Note to encourage broad clarification of the operational definition of total aflatoxin.</p>	AHPA
<p>English and Spanish versions use both No and Number/Numero in tables and descriptions. It would be better to use Number/Numero for all cases. The French version is consistent with the use of Nombre.</p>	ICUMSA

SPECIFIC COMMENTS**PART I: MAXIMUM LEVELS**

COMMENT	MEMBER/ OBSERVER
<p>Jengibre, pimienta blanca y negra y cúrcuma</p> <p>Argentina acuerda con las propuestas de límite del Apéndice I:</p> <p><u>Aflatoxinas totales NM propuestos para:</u></p> <p>1. Chile desecado y nuez moscada: 20 µg/kg</p> <p>2. Jengibre, pimienta blanca y negra, y cúrcuma: Dado que la mayor parte de las muestras han dado como resultado ND (no detectable) y que el porcentaje de rechazos tampoco es una preocupación importante, es redundante fijar NM para estas especias.</p> <p><u>Ocratoxina A NM propuestos para:</u></p> <p>3. Chile desecado y nuez moscada: 20 µg/kg</p> <p>4. Jengibre, pimienta blanca y negra y cúrcuma: Dado que la mayor parte de las muestras han dado como resultado ND y que el porcentaje de rechazos tampoco es una preocupación importante, es redundante fijar NM para estas especias.</p>	<p>Argentina</p>
<p>Dried Chili Pepper and Nutmeg: 20 µg/kg</p> <p>Canada suggests that the wording of this proposed ML for Total Aflatoxins indicate both "dried chili pepper and dried paprika" if indeed that is the intent, as well as "dried nutmeg" to remove potential ambiguity about the scope of the proposed ML.</p> <p>Canada would like to point out that according to Table 4b of CX/CF 23/16/9, the rejection rate associated with this proposed ML of 20 µg/kg for OTA in dried chili pepper and dried paprika ranges from 13~36% and would therefore not appear to meet the definition of achievability.</p> <p>As described above under Total Aflatoxins, Canada suggests that the wording of the proposed ML for Ochratoxin A indicate both "dried chili pepper and dried paprika" if indeed that is the intent, as well as "dried nutmeg" to remove potential ambiguity about the scope of the proposed ML.</p>	<p>Canada</p>
<p>Dried Chili Pepper and Nutmeg: 20 µg/kg</p> <p>Egypt suggests MLs 10 µg/kg for total aflatoxins in Dried Chili Pepper and Nutmeg</p> <p>Egypt suggests MLs 20 µg/kg for Ochratoxin A in dried Chili pepper and 15 µg/kg in Nutmeg</p> <p>Ginger, Black & White pepper and Turmeric</p> <p>Egypt suggests MLs 10 µg/kg for total aflatoxins in Ginger, Black & White pepper and Turmeric</p>	<p>Egypt</p>

COMMENT	MEMBER/ OBSERVER
<p>Japan appreciates the opportunity to provide comments as follows:</p> <p>Japan is of the view that on one hand, the levels of aflatoxins and OTA in foods shall be as low as possible as they are highly toxic with carcinogenicity but on the other hand, as consumption of spices are generally small. Taking these concepts in mind, Japan offers the following comments on individual issues:</p> <p>(i) Maximum levels for dried chili and nutmeg</p> <p>Japan expresses some concern about excluding the data when the LOQ values were not reported while the LOD values were available and can be utilized instead. However, as the spices are not generally consumed in a large amount, we do not insist on this issue.</p> <p>(i-a) Aflatoxins</p> <p>Japan can support the proposed ML for dried chili pepper and nutmeg to be advanced to Step 5 taking into consideration the acceptable rejection rates and submitted data.</p> <p>Among spices imported in Japan in the past 3 years, there are 20 lots of dried chili pepper and 18 lots of nutmeg that violated the ML for aflatoxins in Japan (10 µg/kg). Among these lots, 11 lots of dried chili pepper and 17 lots of nutmeg were found to contain higher concentrations of aflatoxins than 20 µg/kg, up to about 400 and 700 µg/kg respectively. This fact strongly shows the need for establishing an ML for aflatoxins in these commodities to protect the health of consumers. The proposed level is higher than the ML for aflatoxins in Japan for all foods but Japan can support the ML of 20 µg/kg.</p> <p>(i-b) OTA</p> <p>Japan supports to advance the proposed ML for dried chili pepper and nutmeg to be advanced to Step 5 taking into consideration the acceptable rejection rates and submitted data.</p> <p>In the limited surveillance of OTA in certain imported spices including dried chili powder in Japan, the highest levels were found in dried chili powder, up to 18 µg/kg (LOQ=0.1 µg/kg). Therefore, Japan agrees with the proposed level of 20 µg/kg for dried chili pepper to protect the health of consumers.</p> <p>In the same surveillance, the highest concentration of OTA found was 0.2 µg/kg. However, taking into consideration the submitted data and the acceptable rejection rates, an ML of 20 µg/kg for nutmeg is acceptable for Japan.</p> <p>(ii) Other spices</p> <p>(ii-a,b) <u>Aflatoxins and OTA</u></p> <p>Japan agrees not to establish an ML for aflatoxins or OTA for other spices.</p> <p>We think it important to regulate aflatoxins and OTA which are highly toxic. However, applying the ALARA principle (2–5% of rejection rates) to the submitted data would lead to very low ML proposals, which may not be possible to quantify with routine analytical methods. Therefore, Japan agrees not to establish an ML of aflatoxins or OTA for these other spices for the time being.</p> <p>In Japan, in the limited surveillance of imported spices, only one lot of turmeric showed high level of aflatoxins of 20 µg/kg. In the same surveillance, ginger (3 lots) was found to contain OTA less than 0.1 µg/kg; black and white pepper (5 lots) up to 1 µg/kg; and turmeric (4 lots) up to 0.4 µg/kg.</p>	<p>Japan</p>

COMMENT	MEMBER/ OBSERVER
<p>Dried Chili Pepper and Nutmeg: 20 µg/kg</p> <p><u>Comment:</u> Kenya objects to the use of 20 µg/kg in Dried Nutmeg and Chilli and proposes the use of a single ML of 10 µg/kg for all the mentioned spices as was discussed in CCCF15</p> <p><u>Justification:</u> The national legislation sets the ML at 10 µg/kg. The single ML facilitate trade across spices as discussed in para 187(i) of the CCCF15 report.</p>	Kenya
<ul style="list-style-type: none"> • The United States does not object to the proposed MLs of 20 µg/kg for AFT and OTA in dried chili pepper and nutmeg. <ul style="list-style-type: none"> o The United States requests clarification on whether the ML would apply to paprika or just chili pepper. • The United States agrees that MLs may not be needed for AFT and OTA in black and white pepper and turmeric, given the lower rejection rates for these spices. However, ginger appears to have higher rejection rates and more review may be appropriate. • CCEXEC83 recommended to extend completion of work to 2024. If further work occurs: <ul style="list-style-type: none"> o GEMS data from 2022 and 2023 should be included in the evaluation. o Quantified data submitted without a limit of quantification (LOQ) do not have to be excluded from the data analysis. o The EWG could assign a value for non-detects based on the LOD/LOQ rather than assigning all NDs a value of 0. o As noted in paragraph 3 of CX/CF 23/16/9, the EWG should include an analysis of which data were included or excluded and year to year variation by region. Information on how spices were classified as ground versus whole, if information was incomplete, would also be helpful. o We note that the first two rows of Tables 4a and 4b present the number of samples in data ranges [0 (ND) and 0.01 – 4.99 µg/kg], while the other rows show the percentage of spice samples that are less than proposed MLs. Therefore, it would be appropriate to present the first two rows in a separate table(s). An additional simple table that summarizes the proposed MLs and rejection rates also would be helpful. 	USA
<p><u>Total Aflatoxins</u></p> <p>AHPA encourages the addition of a statement here or elsewhere in the document to clarify that total aflatoxin is operationalized as the sum of AFB1, AFB2, AFG1 and AFG2.</p>	AHPA

PART II: SAMPLING PLANS

COMMENT	MEMBER/ OBSERVER
<p>-Especificar dimensiones para las especias con tamaño grande y pequeño de partícula. -Evaluar la posibilidad de disminuir los tamaños de muestra de especias con tamaño grande y pequeño de partícula, debido a la dificultad de homogeneización en el laboratorio y el elevado costo relativo de las muestras.</p>	Argentina
<p>A Canadian stakeholder indicates that although these quantities make sense for grains, they may be excessive for spices. They may be cumbersome to sample, time and labour-intensive to homogenize for lab analysis, and cost prohibitive to importers and exporters.</p> <p>Canada would like to reiterate its comment on this topic from circular letter CL 2022/45-CF:</p> <p>Canada questions whether the proposed sample weights of 20 kg for large-particle spices and 10 kg for small-particle spices could pose a problem for sampling and sample preparation (e.g. homogenization), as 10 kg or 20 kg of spices, whether fresh or ground, would occupy orders of magnitude greater volume than other commodities (e.g. grain or nut products). Furthermore, Canada questions whether the comparatively higher cost of spices per kg relative to that of grain would result in large costs to the importer/manufacture and whether there is potential that this could become a trade impediment.</p> <p>The Committee may wish to discuss whether a smaller sample weight might be more appropriate or practical. Canada is not a significant producer of the spices under consideration for ML elaboration, but should other member countries have data on sampling variability and heterogeneity of mycotoxin contamination specific to spices that would inform an appropriate sampling weight, this information may be useful to discuss.</p>	Canada
<p>Respecto de los planes de muestreo asociados expuestos en el apéndice I Parte II del documento, Chile cree necesario clarificar el criterio para clasificar de acuerdo al tamaño de partícula (por ejemplo rango de tamaño). Además, Chile quisiera consultar si, por el tipo de matriz (especias), y el tamaño de muestra propuesto, se ha considerado si se podría producir un problema para la homogeneización de la muestra, por el volumen que significaría.</p>	Chile
<p>Japan appreciates the opportunity to provide comments as follows:</p> <p>Japan is of the view that on one hand, the levels of aflatoxins and OTA in foods shall be as low as possible as they are highly toxic with carcinogenicity but on the other hand, as consumption of spices are generally small. Taking these concepts in mind, Japan offers the following comments on individual issues:</p> <p>(iii) Sampling plan</p> <p>In general, Japan agrees with the proposed sampling plan as they are similar to the quarantine practice in Japan.</p> <p>We are of the view that like any other food items, appropriate sample size depends on the unit weight (grain, seed, etc.) of the food of concern. In the case of spices, this should also apply, e.g., whole nutmeg and powdered nutmeg. However, we do not insist on this issue as the consumption of spices is generally small.</p> <p>As for decision rule for aflatoxins, our comments on the way to sum up the four components of aflatoxins in cereals and cereal-based RTE meals for infants and young children also apply to aflatoxins in spices.</p>	Japan

COMMENT	MEMBER/ OBSERVER
Kenya supports the associated sampling plans for all products mentioned in Part II of appendix I.	Kenya
In the sampling plan, it is necessary to classify the particle size into specific numbers(figures), not large and small.	Republic of Korea
<ul style="list-style-type: none">The proposed sampling plan does not specify what is considered large/small particle size for spices. For clarity and consistency, large and small particle sizes should be defined.	USA