CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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SAMPLING PLANS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN (AT STEP 4)

Comments at Step 3 in reply to CL 2023/20-CF

submitted by

Argentina, Canada, Chile, Egypt, Iraq, Japan, Kazakhstan, Kenya, Peru, United Arab Emirates, USA, ICUMSA and World Food Programme (WFP)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/20-CF[1] 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
El EWG recomienda que el CCCF considere: (i) la adopción de 5 kg como tamaño de muestra de laboratorio y 25 g como tamaño de porción de prueba para maíz en grano, destinados a mayor procesamiento. (ii) la alineación de los planes de muestreo para sorgo, arroz descascarillado y arroz pulido con el muestreo propuesto plan para las aflatoxinas en el grano de maíz. (iii) la armonización de los planes de muestreo de harinas, sémolas y copos derivados del maíz y a base de cereales con los planes de muestreo de alimentos para lactantes y niños pequeños para DON y fumonisinas. (iv) planes de muestreo propuestos para las categorías de alimentos seleccionadas como se muestra en el Apéndice I en base a las conclusiones proporcionados en los párrafos 15-18 y los datos/información proporcionados en el Apéndice II, incluida su preparación para adopción final por la Comisión del Codex Alimentarius (CAC46, 2023). No hay comentarios acerca de los planes de muestreo. Se deben corregir las Reglas de decisión (decision rules) de los cuadros del anexo I ya que no coinciden con los niveles máximos.	**Argentina**
Canada supports the proposed sampling plans for aflatoxins in certain cereals and cereal-based products outlined in CL 2023/20-CF and the rationale provided for these proposals in CX/CF 23/16/7, which has adequately taken into account Canada's comments provided in previous CLs and those made at CCCF15 (2022). Canada supports a 1 kg laboratory sample weight (and a 25 g portion weight) for maize flour, meal, semolina and infant cereal-based foods for all types of consumers, which aligns the sampling plans for these commodities with the DON and fumonisins sampling plans in the same commodities. Canada also supports the higher laboratory sample weight of 5 kg (and a 25 g test portion weight) proposed for whole grains, i.e. maize grain destined for further processing, husked rice, polished rice and sorghum. A 5 kg laboratory sample weight is still operationally practical and reduces the sampling variance for aflatoxins in whole grains, as well as the probability of misclassifying a lot of grain. Canada agrees that a 50:50 ratio of AFB1: AFB2+AFG1+AFG2 is reasonable. Based on available Canadian data, a 50:50 ratio may underestimate the proportion of AFB1 in a grain sample. However, assuming a 50:50 ratio is practical as it allows for reasonable analytical limits of detection and quantification to be defined in the performance criteria that accompany the sampling plan. In summary, Canada can support the sampling plans for total aflatoxins in certain cereals and cereal-based products outlined in CL 2023/20-CF and CX/CF 23/16/7, Appendix I, for adoption by CCCF16.	**Canada**
Chile agradece la oportunidad de presentar observaciones sobre los planes de muestreo para el total de aflatoxinas en cereales y productos a base de cereales, incluidos alimentos para lactantes y niños pequeños. Al respecto, y considerando los argumentos entregados en el documento CX/CF 23/16/7, Chile quisiera comentar lo siguiente:	**Chile**

COMMENT	MEMBER/ OBSERVER
– Chile está de acuerdo con la adopción de 5 kg como tamaño de la muestra de laboratorio y de 25 g como tamaño de la porción analítica para el maíz en grano, destinado a su posterior procesamiento. – Chile está de acuerdo con la armonización de los planes de muestreo para el sorgo, el arroz descascarillado y el arroz pulido con el plan de muestreo propuesto para las aflatoxinas en maíz en grano. – Chile está de acuerdo con la armonización de los planes de muestreo para la harina, la sémola, la semolina y las hojuelas de maíz, y alimentos a base de cereales para lactantes y niños pequeños con los planes de muestreo para el DON y las fumonisinas. – Chile está de acuerdo respecto de que los planes de muestreo propuestos para las categorías de alimentos seleccionadas, puedan avanzar en el procedimiento de trámites con miras a su adopción definitiva por la Comisión del Codex Alimentarius en su 46.º período de sesiones.	
Egypt appreciates the work and efforts done in the circulated document and agree on it	**Egypt**
Japan appreciates the opportunity to provide comments as follows: 1. the adoption of 5 kg as laboratory sample size and 25 g as test portion size for maize grain, destined for further processing Japan generally agrees with the above laboratory sample size and test portion size, as (1) they are the same as in the quarantine practice in Japan, and (2) usually maize grains are processed in a large batch, which would reduce the heterogeneity. 2. the alignment of the sampling plans for sorghum, husked rice and polished rice with the proposed sampling plan for aflatoxins in maize grain In general, Japan can support the proposal. However, for rice there are divergent views in Japan, to allow either lower laboratory sample size (due to the smaller weight of grains compared to maize) or higher laboratory sample size (as rice is the most important staple food and for the purpose of better protecting the health of consumers). 3. the alignment of the sampling plans for flour meal, semolina and flakes derived from maize and cereal-based foods for infant and young children with DON and fumonisins sampling plans Japan agrees with the proposal as the processing in a large scale would reduce the heterogeneity of aflatoxins in maize or other cereal grains. 4. proposed sampling plans for the selected food categories including their readiness to advance them in the Step Procedure or to submit them for final adoption by the Codex Alimentarius Commission Japan agrees with the advancement of the proposed sampling plans in the Step Procedure with some amendments and addition. In the tables, in each cell for “Decision rule”, the sum of test results of AFB1, AFB2, AFG1 and AFG2 is always shown as “15 µg”. Japan believes that the value must correspond to the respective maximum level for the food referred to, for example for husked rice, 20 µg and for polished rice 5 µg. If this is not corrected, a “lot” of polished rice with 10 µg of total aflatoxins will be accepted while it clearly violates the maximum level. For summing up the four components, it is extremely important to have a consistent and common method of summing when the test result of one component or more was below the LOQ. In reality, molecular species other than AFB1, and in some cases even AFB1, are often found at less than the LOQ. In that case, even if the concentration of AFB1 alone is lower than the ML, decision on compliance to the ML may change depending on how the results of three molecular species are handled: whether to regard the result of less than LOQ as at LOQ or at zero. This may inadvertently create a trade dispute. Therefore the CCCF should wait for a decision or agreement on this issue under the agenda item 12 on guidance on data analysis for development of maximum levels and for improved data collection.	**Japan**

COMMENT	MEMBER/ OBSERVER
5. Other comments as appropriate (v-1) Use of 50:50 ratio for AFB1:AFB2+AFG1+AFG2 Japan generally agrees to use this ratio for the following reasons: • Among the molecular species of aflatoxins, AFB1 is shown to be at higher concentrations than other three species of aflatoxins in the commodities of concern in most of the data submitted by Codex members; • AFB1 is known to be the most toxic among four components of aflatoxin and we must not overlook the presence of AFB1. Therefore, it is necessary to establish as low LOQ as possible and practicable for AFB1; • For the other three molecular species, the data submitted by Japan demonstrate mostly less than 40% of the total aflatoxins. However, if the ratio of the total of these compounds to be less than 50%, it will be more difficult and less feasible to achieve desirable performance characteristics. If, and only if, it is not possible for analytical methods to achieve a lower the LOQ for these three species than that of AFB1, Japan wishes to propose to set the LOQ for each of these three at the comparable concentrations of 50%, i.e., at the same level as that of AFB1. Since these three components are less toxic than AFB1, this is practical and feasible.	
Considering the importance of correct qualified sampling, we propose to add the following text: Personnel requirements Sampling should be carried out by specially authorized individuals who are competent to ensure that the aggregate sample is representative of the lot or sublot and that the mycotoxin content of the aggregate sample remains unchanged during its sample preparation, storage and transportation to the laboratory.	**Kazakhstan**
Kenya appreciates the work done by the EWG as chaired by Brazil and co-chaired by India and supports the proposed sampling plan for total aflatoxins in the selected food categories (certain cereals and cereal-based products including foods for infants and young children) for consideration in the advancement to the next step.	**Kenya**
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 planes de muestreo de aflatoxinas totales en determinados cereales y productos a base de cereales, incluidos los alimentos para lactantes y niños de corta edad. De acuerdo a las conclusiones que figura en el CX/CF 23/16/7, así como los datos/información presentados/evaluados en el Apéndice II, consideramos lo siguiente: La alineación de los planes de muestreo para sorgo, arroz descascarillado y arroz pulido con el plan de muestreo propuesto para aflatoxinas en grano de maíz (CX/CF 23/16/7, párrafo 19).	**Peru**

COMMENT	MEMBER/ OBSERVER
1. The maximum level for maize grain should be 10 µg/kg instead of 15 µg/kg for Total Aflatoxins and also limit for Aflatoxin B1 should be considered which should not exceed 5 µg/kg as this the most important toxin of concern. 2. Also the maximum levels for Infant based cereals should be reduced from 5 µg/kg to lower levels, limit for Aflatoxin B1 also should be considered for compliance. 3. The test portion may vary from 25g to 100g depending on the Technique used LC/MS and HPLC, respectively. 4. Decision rule should include Measurement Uncertainty component also.	**United Arab Emirates**
• The United States thanks Brazil for their work on this agenda item. • The United States supports the adoption of 5 kg as laboratory sample size and 25 g as test portion size for maize grain, destined for further processing. • The United States can support the alignment of the sampling plans for sorghum, husked rice, and polished rice with the proposed sampling plan for aflatoxins in maize grain, if a 1 kg laboratory sample size is used. Based on the small particle size for these product categories, a 1 kg laboratory sample size would be adequate. • The United States does not object to the alignment of the sampling plans for flour meal, semolina and flakes derived from maize and cereal-based foods for infant and young children with the DON and fumonisins sampling plans. • The United States supports a 70:30 ratio of aflatoxin isomers (7:1:1:1) for performance criteria. At the proposed ratio of 50:50 (3:1:1:1), the bias would be 17% if one of the minor isomers is slightly below the method LOQ. A ratio of 70:30 would yield a smaller bias of 10%. A ratio of 70:30 does not require as low an LOQ (i.e., a more sensitive method) for B2, G1, and G2 as 90:10 or 80:20; e.g., for maize, the required LOQ is 0.6 µg/kg (for 70:30) versus 0.4 µg/kg for 80:20 or 0.2 µg/kg for 90:10. • The phrase “approaches zero” should be replaced with “is minimized” in paragraph 18 of Appendix I, CX/CF 23/16/7, “Complete homogenization implies that particle size is extremely small, and the variability associated with sample preparation (Annex I) approaches zero.” • Paragraph 19 of Appendix I, CX/CF 23/16/7, should be deleted because the particle size has been defined in the Tables. • The U.S. does not object to advancing this sampling plan for final adoption by the CAC if our concerns are addressed.	**USA**

SPECIFIC COMMENTS

COMMENT	MEMBER/ OBSERVER
Planes de muestreo y criterios de rendimiento para las aflatoxinas (AFB1+AFB2+AFG1+AFG2) en harina, sémola, semolina y hojuelas de maíz En cuanto a otros comentarios, Chile quisiera mencionar que, ha detectado un error en la función decisoria expuesta en las tablas a continuación descritas, expuestas en el apéndice I del documento CX/CF 23/16/7. - Planes de muestreo y criterios de rendimiento para las aflatoxinas (AFB1+AFB2+AFG1+AFG2) en harina, sémola, semolina y hojuelas de maíz: Función decisoria indica que "Si la suma de los resultados del análisis de AFB1, AFB2, AFG1 y AFG2 de la muestra de laboratorio es igual o inferior a 15 µg/kg, se acepta el lote. De lo contrario, se rechaza", en circunstancias que el nivel máximo es 10 µg/kg.	**Chile**
Planes de muestreo y criterios de rendimiento para las aflatoxinas (AFB1+AFB2+AFG1+AFG2) en arroz descascarillado En cuanto a otros comentarios, Chile quisiera mencionar que, ha detectado un error en la función decisoria expuesta en las tablas a continuación descritas, expuestas en el apéndice I del documento CX/CF 23/16/7. - Planes de muestreo y criterios de rendimiento para las aflatoxinas (AFB1+AFB2+AFG1+AFG2) en arroz descascarillado: Función decisoria indica que "Si la suma de los resultados del análisis de AFB1, AFB2, AFG1 y AFG2 de la muestra de laboratorio es igual o inferior a 15 µg/kg, se acepta el lote. De lo contrario, se rechaza", en circunstancias que el nivel máximo es 20 µg/kg.	
Planes de muestreo y criterios de rendimiento para las aflatoxinas (AFB1+AFB2+AFG1+AFG2) en arroz pulido En cuanto a otros comentarios, Chile quisiera mencionar que, ha detectado un error en la función decisoria expuesta en las tablas a continuación descritas, expuestas en el apéndice I del documento CX/CF 23/16/7. - Planes de muestreo y criterios de rendimiento para las aflatoxinas (AFB1+AFB2+AFG1+AFG2) en arroz pulido: Función decisoria indica que "Si la suma de los resultados del análisis de AFB1, AFB2, AFG1 y AFG2 de la muestra de laboratorio es igual o inferior a 15 µg/kg, se acepta el lote. De lo contrario, se rechaza", en circunstancias que el nivel máximo es 5 µg/kg.	
Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in cereal-based food for infants and young children destined for food aid programs Objected and refused because infant and young children weak and sensitive and MRL of aflatoxin shall be the same in food for infants and young children and food destined for aid programs	**Iraq**
Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in flour meal, semolina and flakes derived from maize In the row 'decision rule' of the table, it is needed to be modify, 15 ug/kg → 10 ug/kg	**Republic of Korea**

COMMENT	MEMBER/ OBSERVER
Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in husked rice In the row 'decision rule' of the table, it is needed to be modify, 15 ug/kg → 20 ug/kg	
Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in polished rice In the row 'decision rule' of the table, it is needed to be modify, 15 ug/kg → 5 ug/kg	
Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in sorghum In the row 'decision rule' of the table, it is needed to be modify, 15 ug/kg → 10 ug/kg	
Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in cereal-based food for infants and young children In the row 'decision rule' of the table, it is needed to be modify, 15 ug/kg → 5 ug/kg	
Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in cereal-based food for infants and young children destined for food aid programs. In the row 'decision rule' of the table, it is needed to be modify, 15 ug/kg → 10 ug/kg	
Table 2. Subdivision of cereal grains sublots according to lot size - flour meal, semolina, and flakes derived from maize and cereal based food for infants and young children and cereal based food for infants and young children destined for food aid programs WFP appreciates the concrete steps taken by the EWG to further the guidance on the topic. Additionally, WFP would like to seek clarifications on the proposed amount of incremental samples for cereal-based food for infants and young children. Referred text: Table “sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in cereal-based food for infants and young children” stipulates increments 10*100g, while Table 2 “Subdivision of cereal grains sublots according to lot size - flour meal, semolina, and flakes derived from maize and cereal based food for infants and young children and cereal based food for infants and young children destined for food aid programs” stipulates the number of incremental samples as 100. Clarification required: WFP employs 1.5kg packages for cereal based food for infants and young children, engages inspection companies to sample and test the products upon delivery. Does this proposal imply that inspection companies must open 100 packages of 1.5kg for each lot exceeding 50 metric tons? Considering the potential food loss and supply chain delays, it would be appreciated if EWG can provide guidance on sampling for such retail products which are produced in accordance with international food safety and quality standards.	**WFP**