CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 13

CX/CF 24/17/13 February 2024

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

17<sup>th</sup> Session 15 – 19 April 2024 Panama City, Panama

DISCUSSION PAPER ON CADMIUM AND LEAD IN QUINOA

(Prepared by the Joint FAO/WHO JECFA Secretariats)

Codex members and observers wishing to submit comments on the recommendations in paragraph 29, of should do so as instructed in CL 2024/28-CF available on the Codex webpage<sup>1</sup>

# BACKGROUND

- 1. Noting that the existing maximum levels (MLs) for lead and cadmium in cereals in the *General Standard for Contaminants in Food and Feed* (CXS 193-1995) explicitly excluded quinoa, the 40th Session of the Codex Alimentarius Commission (CAC40, 2017) requested<sup>2</sup> that the Codex Committee on Contaminants in Foods (CCCF) consider including quinoa in the MLs for lead and cadmium in cereals in CXS 193.
- 2. CCCF12 (2018) considered<sup>3</sup> this request and noted that since quinoa was a pseudo-cereal and the growing conditions were different, it might be appropriate to consider quinoa separately and an ML for lead and cadmium in this commodity could be based on data specific to quinoa. The Committee agreed to consider whether the MLs for cadmium and lead for cereal grains in CXS 193 could be extended to quinoa or whether new/separate MLs for quinoa should be established based on a paper prepared by the Codex and JECFA Secretariats.
- 3. CCCF13 (2019) further considered<sup>4</sup> this matter and agreed that the JECFA Secretariat would issue a call for data on occurrence data for cadmium and lead in quinoa through the GEMS/Food database covering approximately the last 10 years. Based on the information collected, the JECFA and Codex Secretariats would finalize the discussion paper for consideration by CCCF14.
- 4. CCCF14 (2020) considered the discussion paper<sup>5</sup> and had a discussion<sup>6</sup> on whether it was necessary to establish MLs for cadmium and lead in quinoa. CCCF noted the diverse views expressed on whether to establish MLs, and if MLs were to be established, whether to extend the MLs for cadmium and lead in cereals to quinoa in CXS193 or whether to have separate MLs for quinoa. CCCF also noted the need to consider the different cultivars and growing conditions, and ongoing work on data generation. Noting the different views, CCCF decided to postpone the discussion on MLs for cadmium and lead in quinoa for three years to allow data generation and submission to the GEMS/Food database.

<sup>&</sup>lt;sup>1</sup> Codex webpage/Circular Letters: <u>http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.</u> Codex webpage/CCCF/Circular Letters:

http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF
REP17/CAC40, para. 81

<sup>&</sup>lt;sup>3</sup> REP18/CF12, paras. 11-14

<sup>&</sup>lt;sup>4</sup> REP19/CF13, paras. 97 - 103

<sup>&</sup>lt;sup>5</sup> CX/CF 21/14/13

<sup>&</sup>lt;sup>6</sup> REP21/CF14, paras. 173-180

- 5. CCCF16 (2023) recalled<sup>7</sup> the decision taken at CCCF14 and requested the JECFA Secretariat to review the paper presented at CCCF14 based on an analysis of the new data collected through a call for data on cadmium and lead in quinoa and quinoa-based products, including foods for infant and young children. The call for data should include a request for data on occurrence of lead and cadmium for the last 10 years, consumption data, and country of origin (if known) should be indicated in the remarks field in order to help assess the geographic representativity of the data. The data collected with methods with a limit of quantification (LOQ) of 0.4 mg/kg or below, would be helpful but not required, given the current MLs in CXS 193 for lead and cadmium in grains of up to 0.4 mg/kg.
- 6. The JECFA Secretariat issued a request for data on cadmium and lead in quinoa and quinoa-based products, including foods for infants and young children on 15 September 2023 with a deadline for submission of data on 15 December 2023.

# OCCURRENCE DATA

Data retrieved from the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food database).

- 7. Following the call for data on cadmium and lead in quinoa, the JECFA Secretariat received through the GEMS/Food database, 529 results for quinoa products for lead and 516 results for cadmium (1045 data points in total). This dataset excludes foods for infants and small children in ready to eat meals or in mix cereals-based products which include quinoa. To avoid introducing any confounding bias in the interpretation of the data, it was decided to present in this discussion paper the data on cereals and cereals-based products that contain only quinoa as such (grain, seed, flour).
- 8. Sampling period ranged from 2013 to 2023. The individual food samples were collected randomly. Submitted data for cadmium were from Argentina (15) Canada (n=138), Ecuador (n=6), EU (n=270), Peru (n=25), USA (61) and Singapore (n=1). Submitted data for lead were from Argentina (n=13), Brazil (n=2), Canada (n=158), Ecuador (n=13), EU (n=246) Peru (n=25), USA (n=77) and Singapore (n=1). Limit of detection (LOD) and Limit of quantification (LOQ) for cadmium ranged from 0.001 to 0.132 mg/kg and from 0.001 to 0.44 mg/kg respectively. For lead, LOD and LOQ were ranged from 0.0001 to 0.128 mg/kg and from 0.0004 to 0.427 mg/kg, respectively. While less than 8% of censored data (all below LOD) were noted from the cadmium dataset, 59% of the lead data were non detected (ND). According to the JECFA procedure, non-detected (ND) data were assumed to be equal to the LOD, however it should be highlighted that in the case of lead that this approach leads to an uncertainty of the mean occurrence level, which can be highlighted in this case by a 2.5 ratio between the lower bound (ND=LOD) scenarios.
- 9. Tables 1 and 2 provide the distribution of concentration levels in cereals and cereals-based products for cadmium and for lead respectively. The proportion of rejected samples based on proposed ML of 0.1 and 0.2 mg/kg were estimated and provided for the purpose of CCCF discussion.
- 10. The concentration levels of cadmium in quinoa cereals and quinoa cereals-based products ranged from <LOD to 0.59 mg/kg with a mean content of 0.05 mg/kg. Table 1 shows that the distribution of concentration levels of cadmium with no ML is following a normal distribution (Mean = P50) and that some samples exceed the ML of 0.1 mg/kg set in the Codex standard for cereal grains whole commodity. In terms of trade, the impact of applying an ML of 0.1 mg/kg would be a rejection rate of 4.7% for quinoa cereal grains at the global level while applying an ML of 0.2 mg/kg would have a lower rejection rate of 0.2%.

ML (mg/kg)	No. of individual samples	% <lod< th=""><th>Mean</th><th>P50</th><th>P75</th><th>P95</th><th>P97.5</th><th>Max</th><th>Proportion of quinoa grains rejected (%)</th></lod<>	Mean	P50	P75	P95	P97.5	Max	Proportion of quinoa grains rejected (%)
No ML	516		0.05	0.05	0.06	0.09	0.13	0.59	0
ML= 0.2	515	7.9	0.05	0.05	0.06	0.09	0.13	0.19	0.2
ML=0.1	492		0.04	0.04	0.06	0.08	0.09	0.10	4.7

Table 1: distribution of concentration levels of cadmium in quinoa (in mg/kg)

<sup>7</sup> REP23/CF16, para. 10

## CX/CF 24/17/13

11. The concentration levels of lead in quinoa cereals and quinoa cereals-based products ranged from <LOD to 0.24 mg/kg with a mean content of 0.02 mg/kg. Table 2 shows that the distribution of concentration levels of lead with no ML is following a lognormal distribution (Mean > P50). Few samples exceed the ML of 0.2 mg/kg set in the Codex standard for cereal grains whole commodity. In terms of trade, the impact of applying an ML of 0.2 mg/kg would be a rejection rate of 0.4% of quinoa cereal grains at the global level while applying an ML of 0.1 mg/kg would have an impact of 3.8% rejection rate.

ML (mg/kg)	No. of individual samples	% <lod< th=""><th>Mean</th><th>P50</th><th>P75</th><th>P95</th><th>P97.5</th><th>Max</th><th>Proportion of quinoa grains rejected (%)</th></lod<>	Mean	P50	P75	P95	P97.5	Max	Proportion of quinoa grains rejected (%)
No ML	529		0.02	0.01	0.03	0.08	0.13	0.24	0
ML=0.2	527	59	0.02	0.01	0.03	0.06	0.13	0.15	0.4
ML=0.1	509		0.02	0.01	0.03	0.04	0.05	0.10	3.8

Table 2: distribution of concentration levels of I	lead in	quinoa	(in ı	mg/kg)
--	---------	--------	-------	--------

#### CONSUMPTION DATA

Consumption data of quinoa from the GEMS/Food cluster diet

12. Currently there is no food item related to quinoa consumption as such identified in the GEMS/Food classification in cluster diets.

### FAO/Stat Food Supply Utilization Accounts

13. Two countries (Bolivia and Peru) have reported food availability exceeding 1g/capita/day and average 6.34 g/capita/day and 2.53 g/capita/day respectively, over the period spanning from 2017 to 2021.

*Consumption data of quinoa from the FAO/WHO Chronic Individual Food Consumption database (CIFOCOss)* 

- 14. Limited number of countries (16) with few consumers have reported consumption of quinoa grain in the CIFOCOSs database. The overall mean consumption was estimated by weighting each of the mean values by the number of subjects/consumers. Total mean consumption (consumers and non-consumers) from all countries can be estimated at 0.58 g/d. This is reflecting the fact that quinoa consumption is not widely distributed within the population. For consumers only, the mean consumption is 0.65 g/kg bw/d in adult population corresponding to 21.5 g/day. Considering the low number of consumers (<25 at the P90), it is not possible to calculate a statistically robust high percentile.
- 15. According the JECFA procedure, high percentile (P95) can be estimated by multiplying the mean by a factor of two. In doing so, a high 95th percentile consumer is estimate at 1.30 g/kg bw/d in adult population corresponding to 43 g/day.
- 16. In children, level of consumption is (13.3 and 26.5 g/day for mean and 95<sup>th</sup> percentile respectively), the mean consumption is 0.73 g/kg bw/d and the 95<sup>th</sup> percentile would be 1.45 g/kg bw/d.

#### DIETARY EXPOSURE ESTIMATES

#### Cadmium

17. Table 3 presents the estimates of dietary exposure and the risk characterization to cadmium for consumers of quinoa grain. Impact of different proposed MLs for quinoa grain on the dietary exposure and risk characterization is provided for discussion at CCCF.

Table 3: Dietary exposure to cadmium from the consumption of quinoa grain in adults and children's consumers, risk characterization and impact of different proposed MLs.

Cadmium: PTMI JECFA82 (25 µg/kg/bw/month)	Population	mean consumer of quinoa grain (g/kg bw/d)	P95 consumer of quinoa grain (g/kg bw/d)	mean exposure to lead from quinoa (μg/kg bw/d)	P95 exposure to lead from quinoa (μg/kg bw/d)	Risk characterization of lead from quinoa: mean (% PTMI)	Risk characterization of lead from quinoa: P95 (% PTMI)
	Adult	0.65	1.30	0.98	1.95	4%	8%
	Children	0.73	1.45	1.09	2.18	4%	9%
MI - 0.2	Adult	0.65	1.30	0.98	1.95	4%	8%
WIL - 0.2	Children	0.73	1.45	1.10	2.18	4%	9%
MI = 0.1	Adult	0.65	1.30	0.78	1.56	3%	6%
IVIL = 0.1	Children	0.73	1.45	0.88	1.74	4%	7%

- 18. Mean concentration values reported in Table 1 in quinoa cereals and quinoa cereals-based products from all the available GEMS/Food data are combined with the consumption data of consumers of quinoa grains reported in FAO/WHO CIFOCOss individual food consumption data. The resulting dietary exposure estimates to cadmium in adult consumers are estimated at 0.98 µg/kg bw/month in mean and at 1.95 µg/kg bw/month at the P95. For children, the mean consumer can be estimated at 1.09 µg/kg bw/month and at 2.18 µg/kg bw/month at the P95.The last JECFA assessment (JECFA 82, 2021) maintained the PTMI of 25 µg/kg bw/month (Adults/mean), 6.9-12.1 µg/kg bw/month (Adults/high level). Children 0.5–12 years of age: 3.9-20.6 µg/kg bw/month. Vegetarians: 23.2 µg/kg bw/month
- 19. The dietary exposure from the consumption of quinoa grains in population groups could represent approximately 4% of the PTMI in mean and up to 9% at the P95.
- 20. Moreover, Table 3 shows that enforcing a maximum limit of 0.1 or 0.2 mg/kg for cereal grains quinoa would have little impact on dietary exposure to cadmium for the general population, compared with the current situation with no Codex ML, while Table 1 indicates that the proportion of rejected quinoa cereal grains from the world market would be approximately of 5% with an ML of 0.1 mg/kg and 0.2% with an ML of 0.2 mg/kg.
- 21. Table 4 presents the estimates of dietary exposure and the risk characterization to lead for consumers of quinoa grains. The impact of different proposed MLs for quinoa cereal grains on the dietary exposure and risk characterization is provided for discussion at CCCF.

# Table 4: Dietary exposure to lead from the consumption of quinoa grain in adults and children's consumers, risk characterization and impact of different proposed MLs.

Lead JECFA 73 Point of Departure: Children 1 IQ point loss 0.6 µg/kg/bw/d Adults 1mm Hg increase in blood pressure 1.3 µg/kg/bw/d	Population	mean consumer of quinoa grain (g/kg bw/d)	P95 consumer of quinoa grain (g/kg bw/d)	mean exposure to lead from quinoa (μg/kg bw/d)	P95 exposure to lead from quinoa (μg/kg bw/d)	Risk characterizati on of lead from quinoa: mean (% PoD)	Risk characterizati on of lead from quinoa: P95 (% PoD)
No ML	Adult	0.65	1.30	0.01	0.03	0.4%	0.9%
	Children	0.73	1.45	0.01	0.03	2.4%	4.8%
MI = 0.2	Adult	0.65	1.30	0.01	0.03	0.4%	0.9%
WIL = 0.2	Children	0.73	1.45	0.01	0.03	2.4%	4.8%
ML = 0.1	Adult	0.65	1.30	0.01	0.03	0.4%	0.9%
	Children	0.73	1.45	0.01	0.03	2.4%	4.8%

22. Mean concentration values reported in Table 2 in quinoa cereals and quinoa cereals-based products from all the available GEMS/Food data are combined with the consumption data of consumers of quinoa grains reported in FAO/WHO CIFOCOss individual food consumption data. The resulting dietary exposure estimates to lead of adult consumers can be estimated at 0.01 µg/kg bw/day in mean and at 0.03 µg/kg bw/day at the P95. For children, the mean consumption is also estimated at 0.01 µg/kg bw/day and at 0.03 µg/kg bw/day at the P95.

- 23. The last JECFA assessment (JECFA73, 2010) has established a Point of departure (PoD) of 0.6 μg/kg/d for loss of intelligence quotient of 1 IQ point in children and of 1.3 μg/kg bw/d for 1 mmHg increase in blood pressure in adults. The overall dietary exposure to lead was estimated by JECFA to be: Adults: 0.02-3 μg/kg bw/d (mean), 0.06-2.43 μg/kg bw/d (90th to 97.5th percentile). Children: 0.03 to 9 μg/kg bw/d (mean), 0.2 to 8.2 μg/kg bw/d (90th to 97.5th percentile). The dietary exposure from the consumption of quinoa cereal grains could represent at the P95 up to 1% of the PoD in adults and 5% in children.
- 24. Moreover, Table 4 shows that enforcing a maximum level of 0.1 or 0.2 mg/kg for cereal grains quinoa would have little impact on dietary exposure to lead for the general population, compared with the current situation with no Codex ML while the Table 2 indicates that the proportion of rejected quinoa cereal grains from the world market would be approximately 4% with an ML of 0.2 mg/kg and 0.4% with an ML of 0.2 mg/kg.

## **CONCLUSIONS – JECFA Secretariat**

- 25. Data on cadmium in quinoa submitted through GEMS/Food indicate that no significant differences were noted in concentrations levels observed between quinoa cereal grains and quinoa cereal grain-based products.
- 26. The concentration levels of cadmium in quinoa cereals and quinoa cereals-based products are up to 0.59 mg/kg with a mean content of 0.05 mg/kg. The concentration levels of lead in quinoa cereals and quinoa cereals-based products are up to 0.24 mg/kg with a mean content of 0.02 mg/kg.
- 27. The analysis performed by the JECFA Secretariat indicate that, in term of consumer protection and trade, enforcing a maximum level of 0.1 or 0.2 mg/kg for cadmium in cereal grains quinoa would have little impact on dietary exposure to cadmium for the general population, compared with the current situation with no Codex ML, while the proportion of rejected quinoa cereal grains would be approximately 5% with an ML of 0.1 mg/kg and 0.2% with an ML of 0.2 mg/kg.
- 28. As for lead in quinoa cereal grains, the analysis performed by the JECFA Secretariat indicate that in terms of consumer protection and trade, enforcing a maximum level of 0.1 or 0.2 mg/kg for lead in cereal grains quinoa would have also little impact on dietary exposure to lead for the general population, compared with the current situation with no Codex ML while the proportion of rejected quinoa cereal grains would be approximately of 4% with an ML of 0.1 mg/kg and 0.4% with an ML of 0.2 mg/kg.

#### RECOMMENDATIONS

- 29. Based on the assessment of the JECFA Secretariat, CCCF is invited to consider whether:
  - a. There is enough evidence indicating there is no need to establish MLs for lead and cadmium in quinoa; or
  - b. There is enough evidence to either:
    - i. extend the MLs for cadmium and lead in cereal grains to quinoa; or
    - establish separate MLs for cadmium and lead in quinoa, and if in the affirmative, which MLs proposed by the JECFA Secretariat would be most appropriate as described in paragraphs 27 and 28; or
  - c. Further investigation of the evidence for (i) the extension of the current MLs for cadmium and lead in cereal grains to include quinoa or (ii) the establishment of separate MLs for cadmium and lead in quinoa is required for consideration by CCCF17 (2024).