CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 10 **CX/CF 15/9/9**
February 2015

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

9th Session
New Delhi, India, 16 – 20 March 2015

PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATE SAMPLING PLAN

(Prepared by the Electronic Working Group led by India)

Codex Members and Observers wishing to submit comments at Step 3 on the proposed draft Maximum Level for Total Aflatoxins in Ready-to-Eat Peanuts and Associate Sampling Plan, including possible implications for their economic interests, should do so in conformity with the *Uniform Procedure for the Elaboration of Codex Standards and Related Texts* (Codex Alimentarius Commission Procedural Manual) before **28 February 2015**. Comments should be directed:	
to: Mrs Tanja Åkesson Codex Contact Point Ministry of Economic Affairs P.O. Box 20401 2500 EK The Hague The Netherlands E-mail: info@codexalimentarius.nl	with a copy to: Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy E-mail: codex@fao.org
Note: Data and information in support of the proposed ML and other recommendations put forward in paragraphs 4 and 5 are presented in Appendix I and are not subject to comments. Codex members and observers are kindly invited to consider supporting information in Appendices I and II and III when submitting comments on the recommendations in particular the proposed ML in paragraph 5.	

Introduction

1. The 8th Session of the Committee on Contaminants in Foods (April 2014) agreed to initiate new work on establishing maximum levels (MLs) for total aflatoxins (AFs) in ready-to-eat (RTE) peanuts. The Committee agreed to establish an electronic working group (EWG) led by India to prepare a proposal for MLs for Total AFs in RTE peanuts, for comments at Step 3 and consideration at the next session of the CCCF[1]. The 37th Session of the Codex Alimentarius Commission (July 2014) approved new work on establishing MLs of Total AFs in RTE peanuts[2].

2. Accordingly Codex members and observers were invited to participate in the EWG. The list of participant is attached as Appendix III.

[1] REP14/CF, paras 119 and 120
[2] REP13/CAC, Appendix VI

Background

3. At the 7th Session of CCCF (April 2013), a new work proposal was presented by India to establish MLs of total AFs in RTE peanuts and sampling plans. Many delegations supported the proposal and indicated that they would provide data to support this work. Some other delegations, while not opposed to the establishment of MLs, proposed that a discussion paper be developed to provide an overview of the concern with RTE peanuts and to assemble data on consumption and aflatoxin levels in RTE peanuts in international trade, to allow the Committee to make a more informed decision on new work. Such data would be useful for JECFA should they conduct a risk assessment. It was noted that countries should provide correct information on their MLs. Further proposals were made to consider Aflatoxin B_1 (AFB_1) rather than total aflatoxins as this aflatoxin was considered the most widespread and toxic compound among aflatoxins. The Committee agreed to establish an EWG lead by India to prepare a discussion paper for consideration at the 8th Session of CCCF that define the issue, identify the available data and specify data requirements for establishing MLs of AFs in RTE peanuts. A discussion paper was prepared by the EWG and presented to the 8th Session of CCCF.[3]

Discussion and Recommendations

4. Codex members and observer who participated in the EWG submitted data on MLs of total AFs in RTE peanuts. Hence draft MLs for total AFs at 10 µg/kg in RTE peanuts in line with tree nuts may be recommended by the EWG to the 9th CCCF. Existing Codex methods of sampling as given in the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995), Schedule-I, Annex-I currently being practiced may continue for the time being even for RTE peanuts, however, there will be a need to review the method of sampling of RTE peanuts traded in all packs. With regards to identification of requirements for expert scientific advice and risk assessment by JECFA; CCCF should consider requesting JECFA to perform an exposure assessment for health impact based on proposed MLs for total AFs in RTE peanuts.

5. The EWG recommends 10 µg/kg draft MLs of Total AFs in RTE peanuts in line with tree nuts for comments at Step 3.

6. Information and data in support of the proposed MLs and the recommendation on sampling plan is provided in Appendix I. Additional information on US consumption of peanuts and peanut butter from all sources is provided in Appendix II.

Request for comments

7. Codex members and international observer organizations are invited to submit comments on the proposed draft ML and the recommendation for the sampling plan as indicated in paragraphs 4 and 5 above.

[3] REP13/CF, paras 149-151

Appendix I

Proposal for establishment of MLs of total AFs in RTE Peanuts and associated sampling plan

Scope

1. The term RTE peanuts would be in accordance with as defined in the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF) (CODEX STAN 193-1995).

Definitions

2. The definition of RTE peanuts would be as defined in the GSCTFF (CODEX STAN 193-1995). RTE peanut includes several categories of peanuts, such as raw shelled peanuts, raw-in-shell peanuts, roasted in shell peanuts, roasted/blanched shelled peanuts, fried shelled peanuts with or without skin, coated peanuts in all types of packing (consumer or bulk), and any other products having preparation of more than 20% of peanuts.

Relevance

3. AFs are considered most important group of mycotoxins in the food supply and are known to be produced by at least 10 *Aspergillus* species. However, most are rare or rarely found in foods. The main fungi producing AFs remain *Aspergillus flavus* and *Aspergillus parasiticus*. Presently MLs of AFs established by Codex are only for further processing category of peanuts. Thus, there is a need to establish MLs of AFs in RTE peanuts. Establishment of Codex MLs of AFs in RTE peanuts will provide an internationally harmonized standard and will help to address the potential impediments to international trade of RTE peanuts as well as ensure fair practices in trade of these products.

4. Global trade in peanuts with a specific reference to RTE peanuts is increasing. According to International Nut & Dried Fruit Council (INC) world peanut production reached 36,523,000 metric tons in 2012 out of which 1,620,340 metric tons were exports/imports (the data does not differentiate between the intended uses). Trade statistical data from FAOSTAT do not differentiate between peanuts for further processing and RTE. International trade of RTE peanuts is facing difficulties due to different MLs of AFs fixed by various countries which results in trade barrier. Trade in peanuts and rejections have continuously increased during the past years.

Codex MLs of AFs in Peanuts

5. MLs of 15 µg/kg applies only to peanuts intended for further processing, there is no Codex standard for RTE peanuts. The current MLs of AFs for peanuts intended for further processing were adopted by 23rd session of the Codex Alimentarius Commission in 1999 (para 102 of the report).

Occurrence Data

6. Iran has reported 3 incidences of exceeding Iranian MLs of total aflatoxins 15 µg/kg and 9 incidences exceeding Iranian MLs of aflatoxin B_1 5 µg/kg out of 70 consignments analyzed during April 2010 to August 2012 imported from China and India. Similarly, Japan has reported exceeding MLs of 10 µg/kg of total aflatoxins in peanuts exported from India: 13 consignments in 2011, 6 consignments in 2012 and 4 consignments in 2013. Malaysia has also reported exceeding MLs of 15 µg/kg of total aflatoxins in peanuts exported from India: 15 consignments in 2013. The producing countries, exporting and importing countries do not specify RTE peanut rejection data vis-a-vis peanuts meant for other intended uses.

7. Presently, the official rejections reported due to exceeding MLs of AFs in peanuts traded under various categories including RTE peanuts are being conveyed to the producing and exporting countries by the importing countries. For example, the extracted rejection data due to exceeding MLs of AFs in various categories of peanut consignments reported by EU to the exporting countries is given in table-1.

Table 1: Peanuts and peanut products rejection due to exceeding MLs of AFs

Country	Year 2011	Year 2012	Year 2013	Year 2014 (up to Oct.)
Argentina	37	11	5	3
China	60	59	55	35
India	30	31	12	13
South Africa	12	3	2	0

Source: EU RASFF portal

8. MLs of AFS in RTE peanuts, consumption pattern and production/import/export data shared by Codex members and other interest parties is given in table-2.

Table 2: MLs of AFS in RTE peanuts, consumption pattern and production/import/export data

Sr. No.	EWG participating Country	MLs of aflatoxins (μg/kg)		Legislation Reference No.	Methods of sampling	Consumption pattern	Production/ import/export data (MT)
		B_1	Total (Sum of $B_1+B_2+G_1+G_{2)}$				
1	Africa	Not given	Not given	Not given	Not given	Not given	Not given
2	Argentina	Not given	20	Argentine Legislation	FAO Food and Nutrition Paper 55, 1993	Below 200 grams per person per year	Argentine population consumes neither peanut butter nor peanut oil; therefore, 100% of the production of these foods is intended for foreign markets
3	Austria	2	4	EC Regulation 1881/2006 , EC Regulation 165/2010	EC Regulation 401/2006, EC Regulation 178/2010	School children (6 to 15 years): 9.7 g/d; Women (19 to 65 years): 52.6 g/d; Men (19 to 65 years): 92.2 g/d.	Not given
4	China	20	Not given	Chinese National Standard, GB 2761-2011	Not given	7g/person/day (not confirmed)	Annual production about 15 Import: none; export data about 0.7
5	Cuba	Not given	15	Cuba national legislation	Not given	Not confirmed the national consumption data but part of foods that are marketed in the ambulatory sale	Not given
6	ICMSF	Not given	Not given	Not given	Not given	Not given	Not given
7	India	Not availa ble	30	Food Safety and Standards (contaminant s, toxins and residues) Regulations, 2011	For exports country specific or Codex Stan 193-1995 Annex-I Codex General Standard for contaminant s and toxins in foods	Not available	Production: million MT 2009-10: 5.43 2010-11: 8.26 2011-12: 6.96 Export s: MT 2010-11: 4,33,753 2011-12: 8,32,617 2012-13: 5,35,661
8	Iran	5	15	ISIRI 5925, Iranian National Standard, 2002	ISIRI 6872, Iranian National Standard, 2004	Not given	Production: 2000 tons/year Import from India & China

Sr. No.	EWG participating Country	MLs of aflatoxins (μg/kg)		Legislation Reference No.	Methods of sampling	Consumption pattern	Production/ import/export data (MT)
		B_1	Total (Sum of $B_1+B_2+G_1+G_{2)}$				
9	Japan	Not given	10	Japanese legislation	Not given	2 g/capita/day (estimated value from import and domestic production volume of peanuts)	Domestic Production (ton/year, 2012) Shelled raw peanuts: 10895 Import (ton/year, 2012) Shelled raw peanuts: 26235 Roasted in-shell peanuts: 6348 Roasted shelled peanuts: 1933 Fried shelled peanuts: 42676 Peanut butter: 4887 RTE peanuts containing added sugar (ex. Peanut butter): 2248
10	Russia	5	Not given	Russian national legislation	Tutelyan V.A., Eller K.I., Sobolev V.S. A survey. USSR Food Additives & Contaminants 1989, Vol. 6, No. 4, p. 459-465	1.6 g/day '9 3.06 g/day '12 average intake according to the 5-years statistics is at 2.06 g/day	Import 2012: 159655 2011: 106391.1 2010: 94780.6 Export 2012: 180 2011: 204 2010: 172
11	Sudan	Not given	10	Sudanese Standards and Measurements Organization No 2839 /2004	Not given	30-40% of production	Production: 800000
12	Thailand	Not given	20	Notifications of the Ministry of Public Health No. 98/2529 (1986) (mandatory regulation)	Not given	0.83 g/person/ day for Thai age >3 years	Not given
13	Uganda	Not given	10	Not given	Not given	Scarce data	Not given

Sr. No.	EWG participating Country	MLs of aflatoxins (μg/kg)		Legislation Reference No.	Methods of sampling	Consumption pattern	Production/ import/export data (MT)
		B_1	Total (Sum of $B_1+B_2+G_1+G_{2)}$				
14	UK	2	4	EC Regulation 1881/2006 , EC Regulation 165/2010	Commission Regulation (EC) No 401/2006 as amended by Commission Regulation (EU) No 178/2010	Chronic consumption: 0.101 g/kg bw/d Acute consumption: 0.414 g/kg bw/d	Not given
15	USA	Not given	20	U.S. Federal Food, Drug, and Cosmetic Act	Not given	Attachment	Not given

9. The above data shows that there is no uniformity across the countries on MLs of AFs in RTE peanuts. It is observed from the data/information provided by countries/members those producing, exporting and importing countries have established MLs of AFB_1 and total aflatoxins in peanuts which also apply to RTE peanuts. As a result of which the peanut producing and exporting countries are facing rejections due to exceeding MLs of AFs.

Consumption Data

10. Consumption pattern of countries/members is given in above table. Peanuts are widely consumed and the international market potential has been increasing. Peanut producing countries have established MLs of AFs between 10 μg/kg to 30 μg/kg which applies to all categories of peanuts. According to the WHO Global Environment Monitoring System **(**GEMS) program, average daily per capita consumption of shelled peanuts varied from 0.7gm to 21.8gm. The extent of aflatoxin exposure from peanuts is observed to be relatively less when compared to cereals as the consumption of peanuts is lower. For example, average daily consumption of shelled peanuts and maize in EU countries is 4.0g & 33.3g, respectively. Amounts of maize, peanuts and other nuts consumed in each GEMS/Food Consumption Cluster Diet is given in table-3.

Table 3: Consumption (g/day) of maize, peanuts and other nuts in each GEMS/Food Cluster Diet

Cluster Diet (g/day)	A	B	C	D	E (EU)	F	G	H	I	J	K	L	M (USA)
Tree nuts	4.2	21.5	3.9	3	5.5	10.2	16.3	15.7	9.7	1.9	19.1	29	5.6
Almonds	0	1.9	1	0	1	0.8	0	0.1	0	0	0	0.3	0.3
Brazil nuts	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1
Hazelnuts	0.0	2.1	0.0	0.1	1.3	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.1
Pistachios	0.0	0.7	0.5	0.9	0.3	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.2
Walnuts	0.0	1.3	0.0	0.1	0.3	0.1	0.2	0.0	0.0	0.0	0.0	0.1	0.4
Peanuts in shell	7.6	4.3	3	1	5.6	2	10.6	2.9	6.6	30.5	1.3	1	9.7
Peanuts shelled	5.2	3.1	2.1	0.7	4	1.4	7.6	2.1	4.7	21.8	0.9	0.7	6.9
Maize	82.7	148.4	135.9	31.8	33.3	7.5	35.2	298.6	248.1	57.4	63.1	58.6	85.5

Source: GEMS/Food Consumption Cluster Diet WHO 2006

A = Mauritius; B = Cyprus, Greece, Israel, Italy, Portugal, Spain, Turkey; C = Algeria, Egypt, Jordan, Morocco, Syrian Arab Republic, Tunisia; D = Armenia, Belarus, Bosnia and Herzegovina, Bulgaria, Iran, Macedonia, Moldova, Romania, Russian Federation, Serbia and Montenegro, Ukraine; E = Austria, Belgium, Croatia, Czech Republic, Denmark, France, Germany, Hungry, Ireland, Luxembourg, Malta, The Netherland, Poland, Slovakia, Slovenia, Switzerland, United Kingdom; F = Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Sweden; G = China, India, Indonesia, Malaysia, Nepal, Sri Lanka, Thailand, Viet Nam; H = Guatemala, Honduras, Mexico, Paraguay, Peru, El Salvador; I = Kenya, Malawi, Mozambique, South Africa, Tanzania, United Republic of Zimbabwe; J = Nigeria, Sudan; K = Barbados, Belize, Brazil, Colombia, Costa Rica, Cuba, Dominican Republic, Jamaica, Surinam, Venezuela; L = Japan, Republic Korea, The Philippines; M = Argentina, Australia, Canada, Chile, New Zealand, United States of America, Uruguay.

Toxicological Aspects

11. Aflatoxins were evaluated by JECFA at several meetings. The 49th meeting in 1998 performed a comprehensive risk assessment including an exposure assessment that applied different hypothetical maximum levels to existing contamination patterns of food commodities (WHO TRS 884; pp. 69 – 77). The meeting agreed that aflatoxins are considered to be human liver carcinogens, AFB_1 being the most potent one. Maize and groundnuts were identified as main contributors of dietary intake of aflatoxins. According to JECFA the roasting of groundnuts reduces aflatoxin levels by 50-80% (49th meeting). Based on the comparison of two hypothetical standards of aflatoxin contamination in food (10 µg/kg or 20 µg/kg) the Committee concluded that their impact on public health depends on the fraction of samples to be rejected for human consumption. If the fraction of samples to be excluded under the two standards is similar, the higher standard would yield essentially the same risk of liver cancer as the lower standard.

12. For groundnuts JECFA verified this result using limited available data (Europe, US) if “all groundnuts are included, the average aflatoxin concentration would be 15 µg/kg. The average aflatoxin concentration would be 0.6 µg/kg if all samples with levels above 20 µg/kg were excluded and 0.5 and 0.4 µg/kg if all samples with levels above 15 and 10 µg/kg, respectively, were excluded.” (WHO FAS 40). More detailed assessment using monitoring data from Europe and the US and applying those to five regional diets confirmed that the main impact on aflatoxins intake from groundnuts was whether a maximum level, was applied rather than whether the maximum levels was 10 µg/kg, 15 µg/kg, or 20 µg/kg. JECFA at the 68th meeting of the Committee confirmed the hazard characterization of aflatoxins as genotoxic carcinogens that induce tumours in the liver of animals and humans and for which no tolerable levels can be established (WHO TRS 947, pp. 159-169; WHO FAS 59, pp. 305-356).

13. In response to a request from CCCF, the Committee assessed the impact of different MLs of AFs exposure on data provided by producing countries, noting that these better represent the materials in commerce and result in a robust estimate of aflatoxins dietary exposure from the tree nuts. Consumption of almonds, Brazil nuts, hazelnuts, pistachios, and dried figs contributed greater than 5% of the total aflatoxin dietary exposure in only five of the 13 GEMS/Food cluster diets. If fully enforced, an ML at 20 µg/kg in hazelnuts, almonds, pistachios, Brazil nuts, and dried figs would only have an impact on the relative contribution to AFs dietary exposure in these clusters, including high-level consumers of tree nuts (due solely to high level contamination reported for pistachios). For tree nuts other than pistachios, the presence of an ML has no effect on AFs dietary exposure. Moreover, the Committee concluded that enforcing an ML of 15, 10, 8, or 4 µg/kg, would have little further impact on the overall dietary exposure to AFs in all five of the highest exposed population groups compared to setting an ML of 20 µg/kg.

14. As part of its reply to the specific request from CCCF on tree nuts JECFA did also assess the contribution of various commodities including groundnuts to overall aflatoxin intake. The JECFA noted at several occasions that the reduction of AFs in dietary exposure is an important public health goal; particularly in populations who consume high levels of any potentially AFs contaminated food. The risks arising from the exposure to AFs were evaluated through potency estimates for human liver cancer derived from epidemiological and toxicological studies. The potency of AFs was defined by the JECFA to be 30 times higher in carriers of hepatitis B virus (HBsAg+; about 0.3 cancers/year/100000 individuals) than in non-carries of hepatitis B virus (HBsAg-; about 0.01 cancers/year/100000 individuals). Thus, reduction of AFs intake in populations with a high prevalence of hepatitis B carriers will have a greater impact on reducing liver cancer rates than in populations with a low prevalence of carriers.

15. At its 64th meeting, the JECFA (FAO/WHO, 2005) decided that evaluations on compounds that are both genotoxic and carcinogenic, such as AFs, should be based on the estimation of Margins of Exposure (MOE). The MOE is defined as the ratio between a toxicological threshold (such as the BMDL3-benchmark dose lower confidence limit) and the intake. MOE lower than 10000 may indicate a public health concern (EFSA, 2005).

Methods of Sampling

16. Currently, Codex General Standard for Contaminants and Toxins in Food and Feed (Codex STAN 193-1995) and Code of practice for the prevention and reduction of aflatoxin contamination in peanuts (CAC/RCP 55-2004) are available. Aflatoxins in peanuts are heterogeneously distributed, which makes representative sampling extremely difficult. Therefore, considerable care and planning are needed in sampling to ensure the accuracy of the estimated levels of aflatoxins. Currently non-destructive methods are not available for measuring aflatoxin contents in peanuts. A typical analytical method for the determination of aflatoxins in peanut kernels includes sampling, milling and homogenization. Therefore, for a precise determination of representative (average) value of aflatoxin load in an individual consignment/lot, the entire consignment/lot needs to be ground for analysis which is impractical. The existing Codex methods of sampling currently being practiced is comprehensive hence may continue for RTE peanuts. Method of sampling could be reviewed for RTE peanuts traded in all packs, if required, in due course.

Discrepancy in existing MLs

17. Information gathered from the CRDs of agenda item 20 of 7th CCCF Session 8-12 April 2013 Moscow Russian Federation, the MLs of AFs in RTE peanuts/peanuts established by Thailand: 20 μg/kg total aflatoxins; Kenya: 10 μg/kg total aflatoxins; Malaysia: 10 μg/kg total aflatoxins; Russia: 5 μg/kg AFB_1, EU: 2 μg/kg AFB_1 and 4 μg/kg total aflatoxins; USA: 20 μg/kg total Aflatoxins; China: 20 μg/kg AFB_1. Korea has proposed 10 μg/kg AFB_1 and 15 μg/kg total aflatoxins, African Union and Ghana have proposed MLs between 4 μg/kg and 15 μg/kg total aflatoxins. Apparently, this shows that there is a great disparity.

18. Discrepancy in fixing MLs of same foodstuff by different countries or diet clusters, however, is often discussed on the basis of wide differences in per capita consumption of various foodstuffs in different countries/diet clusters. Even though this sounds logical, the calculations clearly indicate that the wide difference in total possible intake of aflatoxins from various sources (nuts and maize) across the countries/diet clusters. The discrepancy is that in spite of fact that per day consumption of peanuts (4 g/day) is 1/8th of the per day consumption of maize quantity (33.3 g/day), the MLs of aflatoxins kept 4 μg/kg for both these commodities. Thus there are lot of inconsistencies in fixing MLs of aflatoxin in various foodstuffs by different countries which is considered to be neither logical nor scientific. Comparative data of peanuts and various foodstuffs is available for EU and USA and is given in table-4.

Table 4: Consumption of peanuts and various foodstuffs in EU and USA

Foodstuff	EU		USA	
	Per capita consumption	MLs	Per capita consumption	MLs
	(g/day)	(ng/g)	(g/day)	(ng/g)
Peanuts	4	4	6.9	20
Tree nuts	5.5	4	5.6	20
Almonds	1	10	0.3	20
Brazil nuts	0.1	10	0.1	20
Hazelnuts	1.3	10	0.1	20
Pistachios	0.3	10	0.2	20
Walnuts	0.3	4	0.4	20
Nuts (total)	12.5	Not applicable	13.6	Not applicable
Maize	33.3	4	85.5	20
Nuts + Maize	45.8	Not applicable	99.1	Not applicable

Source: FAO 1998 Mycotoxin Prevention and Control in Food Grain Food and Agricultural Organization of the United Nations Rome.

19. Adoption of draft MLs 10 µg/kg of total AFs in RTE peanuts in line with MLs of AFs in tree nuts will enable smooth trade of RTE peanuts as well as provide opportunity to compile data which will substantiate adoption of MLs of AFs in RTE peanuts by the CCCF.

Appendix II

US Consumption of peanuts and peanut butter from all sources

Data of analysis: 13 August 2013

Basis for consumption estimate: 2-day average

Software program: FARE, Access

DRF file: PEANUTING

					Peanut intake			Peanut intake per kg bw		
					Per capita	Per user		Per capita	Per user	
Population group	NHANES Survey	total n (unwgtd)	n eaters (unwgtd)	% eaters	Mean	Mean	90th%ile	Mean	Mean	90th%ile
					g/day			g/kg bw/day		
MF Total Population	2009-10	8,219	2,768	37.5	4.5	12.1	30.1	0.077	0.204	0.512
	2003-10	31,788	10,672	38.3	4.9	12.8	30.4	0.084	0.220	0.540

NOTES: All estimates exclude pregnant women and breastfeeding children

Appendix III

List of EWG participants

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