CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
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PROPOSAL FOR DISCUSSION PAPER ON OCHRATOXIN A IN DRIED FRUITS AS WELL AS A PROJECT DOCUMENT

(Submitted by Türkiye)

OBJECTIVE OF PROPOSAL

1. In the *General standard for contaminants and toxins in foods and feeds* (CXS 193-1995), maximum levels (MLs) for Ochratoxin A (OTA) are set for wheat, barley, rye, chilli pepper, paprika and nutmeg. There is no ML for dried fruits.

2. After the assessment made by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2007[1] and based on Provisional tolerable weekly intake (PTWI), the assessments made by other risk assessment organisations were made according to the margin of exposure (MOE) approach and not according to PTWI. In some countries and regions, the ML is regulated in the legislation for dried fruits.

3. The regulation[2], which entered into force in the European Union in 2022, sets MLs of 8 µg/kg for dried vine fruits (currants, raisins and sultanas) and dried figs and 2 µg/kg for other dried fruits. In Türkiye, a maximum limit of 10 µg/kg has been set for dried fruits in the regulation[3] that entered into force in 2023. In some other countries, such as Brazil (10 µg/kg), maximum limits have also been set for dried fruit.

4. The main objective of the proposal is to develop a code of practice (CoP) to prevent and reduce OTA in dried fruits and to initiate further processes, including sampling, methods of analysis and provision of data to the GEMS/Food Database, to enable the identification of MLs to facilitate fair practices in international food trade.

RECOMMENDATIONS

5. CCCF18 is invited to:

   a) consider the project document in Appendix II and make any necessary adjustments to ensure a robust rationale for the development of the CoP for the prevention and reduction of Ochratoxin A contamination in dried fruits, with a view to forward it to CAC48 (2025) for approval as new work; and

   b) establish an electronic working group (EWG), subject to CAC48's approval of the new work, to:

      a. develop the discussion paper in Appendix I and the CoP for consideration by CCCF19 (2026); and

      b. submit a new project document for consideration by CCCF19 to set maximum levels in dried fruits, including sampling plans, analytical method performance criteria, with a view to also request JECFA to initiate a call for data for the GEMS/Food database.

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[1] https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/1905

[2] EU. Commission Regulation (EU) 2022/1370 of 5 August 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of ochratoxin A in certain foodstuffs. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32022R1370

[3] Turkish Food Codex Regulation on Contaminants.
https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=40394&MevzuatTur=7&MevzuatTertip=5

APPENDIX I

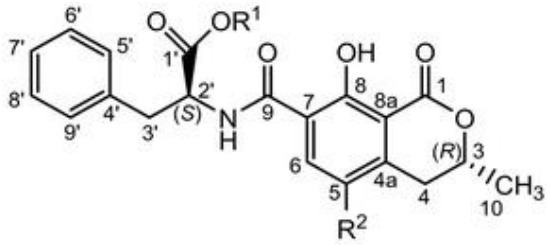
DISCUSSION PAPER ON OCHRATOXIN A IN DRIED FRUITS

(For consideration by CCCF)

BACKGROUND

Ochratoxin A

1. Ochratoxins are mycotoxins produced by various fungi of the genus *Aspergillus* and *Penicillium*, e.g. *A. ochraceus, A. carbonarius* and *P. verrucosum*. Their chemical structures contain the amino acid L-phenylalanine linked via an amide bond to a substituted dihydroisocoumaric acid.



Ochratoxin	Substituents	Molecular formula	Molar mass ($g \cdot mol^{-1}$)	CAS number
OTA	$R^1 = H$; $R^2 = Cl$	$C_{20}H_{18}ClNO_6$	403.8	303-47-9
OTB	$R^1 = H$; $R^2 = H$	$C_{20}H_{19}NO_6$	369.4	4825-86-9
OTC	$R^1 = C_2H_5$; $R^2 = Cl$	$C_{22}H_{22}ClNO_6$	431.9	4865-85-4

Figure 1. Chemical structure of ochratoxin A, B and C

2. The most prevalent and toxic ochratoxin is ochratoxin A (OTA). OTA is stable to moderate heating, but losses ranging up to 90% are observed at temperatures above 180°C. OTA is a toxic fungal metabolite classified by the International Agency for Research on Cancer as a possible human carcinogen (group 2B).

3. JECFA last evaluated Ochratoxin A (OTA) in 2007. The new data, including data on mode of action of OTA in the kidney, do not indicate any reason to modify the previous approach taken by JECFA with respect to setting a PTWI. The Committee therefore retained the previous PTWI of 100 ng/kg bw.

4. There is a code of practice (CoP)[4] on OTA for cereals, wine, coffee, cocoa and spices.

5. In the General Standard for Contaminants and Toxins in Foods and Feeds, maximum limits for OTA are set for wheat, barley, rye, chilli pepper, paprika and nutmeg.

6. There is no set maximum limit and CoP for dried fruits within the scope of CAC.

RISK EVALUATION

JECFA Evaluation

7. The JECFA has issued[5] several evaluations of OTA (FAO/WHO, 1991, 1996, 2001, 2007). In 1991, a provisional tolerable weekly intake (PTWI) of 112 ng/kg bw was established, based on an LOEL of 8 µg/kg bw per day for deterioration of renal function in pigs, and by application of an default uncertainty factor (UF) of 500. This UF was applied by the Committee because NOELs were frequently not demonstrated for OTA and the effects were observed already after a small proportion of a pig's lifetime and that consequently a 500-fold margin needs to be applied to the LOELs. In 1995, the PTWI was confirmed but rounded off to 100 ng/kg bw and was then retained in the JECFA evaluation that followed in 2002. In their most recent evaluation on OTA (FAO/WHO, 2007) in which new evidence and data becoming available since their last evaluation were considered, the JECFA again confirmed the PTWI of 100 ng OTA/kg bw. The estimates of dietary exposure to OTA using occurrence data (mainly from Europe) ranged from 8 to 17 ng/kg bw per week, and thus were well below the PTWI.

[4] Available at: https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-standards/en/?committee=CCCF
[5] Available at: https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/1905

Risk assessment by other scientific bodies[6]

8. In 2006, the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (EFSA) published[7] an opinion related to OTA in food. The CONTAM Panel concluded that there is a lack of convincing evidence that Balkan Endemic Nephropathy (BEN) is associated with OTA exposure. OTA is nephrotoxic in all animal species tested and there is evidence that these effects are associated with oxidative stress. It also causes immuno- and neurotoxicity and teratogenicity at higher doses. OTA accumulates in the kidneys and upon chronic exposure to doses toxic to the kidney it also induces kidney and liver tumours in rodents. The results from genotoxicity tests are inconsistent. The overall evidence supports the hypothesis that DNA damage is induced by oxidative stress rather than by direct interaction. The Panel identified the effects on the kidneys in rats and pigs as the critical endpoint for OTA and established a tolerable weekly intake (TWI) of 120 ng OTA/kg bw based on an LOAEL (lowest observed adverse effect level) of 8 µg/kg bw per day identified for early markers for renal toxicity in pigs and by applying a composite uncertainty factor (UF) of 450. This UF is composed of a default UF of 10 for intraspecies variability and a default UF of 2.5 for toxicodynamic and an OTA-specific UF of 6 for toxicokinetic interspecies variability (instead of the default 4.0) because the body burden resulting from the same external dose of OTA will be six times higher in humans than in pigs. An additional UF of 3 was used accounting for an LOAEL instead of an NOAEL (no observed adverse effect level). Main contributors to OTA dietary exposure were cereals and cereal products, wine, beer, grape juice, brewed coffee, cocoa and cocoa products and pork meat. Estimated exposure levels for average consumers varied between 15 and 20 ng/kg bw per week and for high consumers between 40 and 60 ng/kg bw per week and thus were below the TWI of 120 ng/kg bw. It was noted that these estimates are conservative for the adult population but that it cannot be excluded that infants and children and certain high consumers could have higher exposures.

9. Health Canada have re-evaluated[8] the appropriateness of the EFSA TWI to see if it would be applicable if OTA were to be regulated by a threshold approach and carried out a dietary risk assessment of OTA applying a non-threshold approach assuming that the compound is a genotoxic carcinogen. Using the data on decreases in TM (transport maximum) renal clearance expressed relative to body weight or to inulin clearance seen in a 90-day pig study, they have derived a BMD10 (a benchmark dose defined as a 10% increase over the background) of 1.56 µg OTA/kg bw per day). Applying a default UF of 10 for intra-species variability and a default UF of 2.5 for toxicodynamic and a specific UF of 10 for toxicokinetic inter-species variability (instead of the UF of 6 used by EFSA) and a factor of 2 for extrapolating from a subchronic study to a chronic health-based guidance value (HBGV), a tolerable daily intake (TDI) of 3 ng/kg bw per day (which would correspond to a TWI of 21 ng/kg bw) was considered appropriate instead of the 17 ng/kg bw per day (corresponding to 120 ng/kg bw per week) as previously established by EFSA. For their risk assessment of OTA, Health Canada used a negligible cancer risk intake (NCRI) that was defined as the exposure associated with a cancer risk of 1:100,000. This is equivalent in units to a TDI derived using a tumourigenic dose 5% (TD05, a 5% increase in incidence over background in the observable dose response curve) of 27.4 µg/kg bw per day from kidney tumours seen in a 2-year rat study. This value was corrected to 19.6 µg/kg bw per day considering that animals were dosed only 5 days per week. Applying a safety factor of 5,000 that results from dividing the TD05 by 5,000, which is equivalent to a 10−5 risk on a linear extrapolation to zero exposure, an NCRI of 4 ng OTA/kg bw per day resulted. Dietary exposures to OTA in a Canadian population were below the NCRI except for 1- to 4-year-old children.

10. In 2017, the UK Committee on Toxicity of Chemicals in Food Consumer Products and the Environment (COT) published[9] a review of potential risks from OTA in the diet of infants aged 0–12 months and children aged 1–5 years. The Committee evaluated all relevant in vivo studies published since the 2006 EFSA opinion and concluded that there is no new data available suggesting that the TWI of 120 ng/kg bw was established by EFSA in 2006, needs to be changed. Estimated exposure for breastfed infants ranged from 0.68 to 55 ng/kg bw per day for average consumers and from 1.02 to 82 ng/kg bw per day for high consumers. At low or average concentrations of OTA in breast milk exposures are below the TDI but at high concentrations infants estimated exposures exceeded the TWI by up to fivefold. The COT noted that such high exposures are unlikely to occur.

11. Mitchell et al. carried out[10] a risk assessment of dietary OTA in the United States. For the risk characterisation, calculated exposures for different age groups in the 'total population' and 'consumers' (individuals reporting consumption of specific foodstuffs prone to contain OTA) were compared either with the JECFA PTWI of 100 ng/kg bw or the Health Canada NCRI of 4 ng/kg bw per day (for both HBGV values see text above in this section) and a margin of safety (MOS) approach was applied. Overall, MOS was > 1 in all age groups (both total population and consumers) applying either

[6] Available at: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6113
[7] Available at: https://doi.org/10.2903/j.efsa.2006.365
[8] Available at: https://doi.org/10.1080/02652030903013278
[9] Available at https://cot.food.gov.uk/committee/committee-on-toxicity/cotstatements/cotstatementsyrs/cot-statements-2018/cot-statement-on-potential-risks-from-ochratoxin-a-ota-in-the-diet-of-infants-aged-0-to-12-months-and-children-aged-1-to-5-year
[10] Available at https://doi.org/10.1016/j.fct.2016.12.037

reference value. The only MOS ≤ 1 was seen when 95th percentile exposures of 'consumers' aged between 1 and 5 years were compared with the NCRI as established by Health Canada.

12. In 2020, EFSA CONTAM Panel published[11] its risk assessment opinion for OTA again. Since the previous EFSA assessment (2006), more recent studies have raised uncertainty regarding the mode of action for kidney carcinogenicity. Following respective EFSA guidance, the CONTAM Panel considered that it was not appropriate to establish an HBGV and concluded that for both non-neoplastic and neoplastic effects of OTA, an MOE approach needs to be applied for risk characterisation. As a consequence, the TWI of 120 ng/kg bw as established by the CONTAM Panel in 2006 is no longer valid. For characterisation of chronic non-neoplastic effects, an MOE of ≥ 200 between the selected non-neoplastic RP and calculated exposures was considered as being of low health concern. This MOE was derived by applying a default uncertainty factor (UF) of 100 for intra- and interspecies toxicokinetic and toxicodynamic differences combined with an additional UF of 2 to account for extrapolation of a 3-month study in pigs to a chronic situation in that species. For characterisation of chronic neoplastic effects, an MOE of ≥ 10,000 between the selected neoplastic RP and calculated exposures would be of low health concern. This MOE was derived following EFSA guidance for substances that are both genotoxic and carcinogenic. In the interpretation of the MOE for the neoplastic risks, the Panel considered that the MOE of 10,000 for substances that are genotoxic and carcinogenic could be particularly conservative in this case because the evidence for a direct interaction of OTA with the DNA is inconclusive. A total of 71,769 measurements of concentrations of OTA in food submitted within the last 10 years by 29 European countries and one Industry association were used for assessing dietary OTA exposures. The majority (about 55%) of the data came from Germany and the Netherlands. The proportion of left-censored data (results below the limit of detection (LOD) or limit of quantification (LOQ)) was 75%. The highest mean concentrations of OTA were recorded in the categories 'Plant extract formula', 'Flavourings or essences' (both containing liquorice extracts) and 'Chili pepper'. The most important contributors to the chronic dietary exposure to OTA were 'Preserved meat', 'Cheese' and 'Grains and grain-based products'. Dried and fresh fruits such as grapes, figs and dates as well as fruit juices and nectars were also contributing to the exposure of in some of the 'Toddlers' and 'Other children' groups, albeit, to a lesser extent than the three major categories. Non-chocolate confectionary was a significant source of exposure in countries where liquorice-based sweets are commonly consumed. For neoplastic effects of OTA, the CONTAM Panel emphasises, that it was not possible to make a clear distinction between a direct and an indirect mechanism of genotoxicity. As a result, the risk characterisation will be either not sufficiently cautious or overcautious depending on which MoAs actually take place. The Panel points out that the MOE of 10,000 is likely to be most conservative in this case as the evidence for a direct interaction of OTA with the DNA is inconclusive and alternative thresholded mechanisms may play a role in the formation of kidney tumours. Pending elucidation of the MoAs for the genotoxicity/carcinogenicity of OTA, the Panel concluded that an MOE of 10,000 to the neoplastic reference point is warranted for the risk characterisation of OTA, albeit being the most conservative approach until the MoAs are clarified. The overall uncertainty associated with the present assessment is considered as high. The assessment is more likely to overestimate than to underestimate the risk. The CONTAM Panel recommended that more studies elucidating the sequence of critical events at the carcinogenic target site in the kidney are needed as well as more data on the levels of OTA in human milk and the differential toxicokinetics of OTA in different species including transfer to the fetus.

13. In the EFSA assessment 2020, dried and fresh fruits such as grapes, figs and dates as well as fruit juices and nectars were also contributing to the exposure of in some of the 'Toddlers' and 'Other children' groups, albeit, to a lesser extent than the three major categories.

14. In 2022, a Technical Opinion was prepared for different maximum limit scenarios (2, 8, 10, 15 µg/kg) for some dried fruits (grapes, figs, apricots, mulberries) in Türkiye. Using the minimum, average and maximum daily consumption amounts in Türkiye and European Union sources, an evaluation was made according to the MOE (10.000) approach for different age groups. Only for the high consumption data at the maximum level of 15 µg/kg, the risk of health concern in the 1-3 age group was calculated, while low health concern was found in all other scenarios.

METHODS OF ANALYSIS

15. The analysis of OTA in food relies on well-established methods, and reliable results generally are obtained as evidenced by the results from proficiency testing. Due to the chemical nature of the molecule, acid or alkali extraction from the matrix is commonly used. In general, alkaline extraction provides better recoveries; however, in the case of complex matrices (i.e. meat or sausages), an alkali–acid liquid–liquid partition can be used to increase selectivity. Extraction[12] of OTA from dried fruits is usually carried out using a mixture of methenol or acetonitrile and water in certain proportions.

16. Over the years, many methods have been developed for the determination of mycotoxins in dried fruits. Due to the diverse physicochemical properties of mycotoxins, the extraction, clean-up, chromatographic separation, and detection

[11] Available at: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6113
[12] Available at: https://pubmed.ncbi.nlm.nih.gov/18348046/

procedures of conventional enzyme-linked immunosorbent assay (ELISA), thin layer chromatography (TLC), or liquid chromatography coupled to ultraviolet or fluorescence detector (LC-UV/FLD) methods were only suited for the analysis of a single mycotoxin or single class of mycotoxins. As different mycotoxins are often present in the same dried fruit product, analytical methods that can simultaneously determine different mycotoxins are seen as more efficient. With advances in LC-MS instrumentation, LC-MS-based, especially liquid chromatography with tandem mass spectrometry (LC-MS/MS)-based, analysis has received increasing attention since the early 2000s. Compared to ELISA, TLC, or LC-UV/FLD, LC-MS/MS methods not only offer superior sensitivity and specificity, but also can simultaneously determine multiple mycotoxins in a single analysis[13].

17. An interlaboratory study[14] was carried out for Ochratoxin A in Currants, Raisins, Sultanas, Mixed Dried Fruits and Dried Figs. Based on results for 5 naturally contaminated test samples (blind duplicates) the relative standard deviation for repeatability (RSDr) ranged from 4.9 to 8.7%, and the relative standard deviation for reproducibility (RSDR) ranged from 14 to 28%.

18. In Regulation 2023/2782[15] of the European Union, the analysis performance criteria for mycotoxins are set as follows. The rules in Türkiye[16] are the same as in the EU.

- Recovery : the average recovery should be between 70 and 120 %. In exceptional cases, average recoveries outside the above range can be acceptable but shall lie within 50-130 %, and only when the precision criteria for RSDr and RSDwR are met.
- Precision:

  RSDr (repeatability relative standard deviation) shall be ≤ 20 %.

  RSDwR (within-laboratory reproducibility relative standard deviation) shall be ≤ 20 %.

  RSDR (reproducibility relative standard deviation) should be ≤ 25 %.
- LOQ: hall be ≤ 0,5*ML and should preferably be lower (≤ 0,2*ML).

19. There are no analysis performance criteria for foods for which a maximum limit is set in the General Standard for Contaminants and Toxins in Foods and Feeds. The analysis performance criteria for total aflatoxins in dried figs are given in the table below.

Table 2. Specific requirements with which methods of analysis should comply with

Criterion	Concentration range (ng/g)	Recommended value	Maximum permitted value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 100%	n/a
	> 15	80 to 110%	n/a
Precision or relative standard deviation RSD_R (Reproducibility)	1 to 120	Equation 4	2 x value derived from Equation 4
	> 120	Equation 5	2 x value derived from Equation 5
Precision or relative standard deviation RSD_r (Repeatability)	1 to 120	Calculated as 0.66 times Precision RSD_R	n/a
	> 120	Calculated as 0.66 times Precision RSD_r	n/a

n/a = not applicable

42. The detection limits of the methods used are not stated. Only the precision values are given at the concentrations of interest. The precision values (expressed as a%) are calculated from equations 4 and 5.

Equation 4: $RSD_R = 22.0$

Equation 5: $RSD_R = 45.25C^{-0.15}$

where:

[13] Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC8954288/
[14] Available at: https://academic.oup.com/jaoac/article-abstract/86/6/1164/5657078?redirectedFrom=fulltext&login=false
[15] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R2782&qid=1748200010307
[16] Available at (Turkish): https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=42345&MevzuatTur=9&MevzuatTertip=5

SAMPLING

20. There is no sampling plan for foods for which a maximum limit is set in the General Standard for Contaminants and Toxins in Food and Feed. There is a sampling plan for total aflatoxins in dried figs. In summary, the following sampling procedure for dried figs is applied in the Standard.

- For dried figs (≤ 15 tonnes): 10-100 incremental samples of 300 g, resulting in an aggregate sample of 3-30 kg. Aggregate samples over 10 kg are divided into two or three laboratory samples.

21. The sampling plan outlined paragraph 20 for aflatoxins in dried figs in the CODEX Standard is applied for OTA in dried figs in the EU and Türkiye. There is legislation in the EU and Türkiye that includes a sampling plan for OTA in dried fruits other than dried figs. The sampling plan for these dried fruits is summarised below.

- For dried fruits other than dried figs in bulk (> 15 tonnes): 100 incremental samples of 100 g, resulting in an aggregate sample of 10 kg. For smaller lots (≤ 15 tonnes), less incremental samples (10-100) are to be taken.

CODE OF PRACTICE

22. Codex Alimentarius does not have a CoP for the prevention and reduction of OTA in dried fruits. There are 5 CoPs for the prevention and minimisation of OTA in other foods (cereals, wine, coffee, cocao and spices). The existing CoP (CXC 63-2007) for wine includes recommendations on practices for harvest and wine grapes cultivation in vineyards. The occurrence data used for wine in the risk assessment by EFSA and JECFA in different years before and after the publication of the CoP for wine are given in Table 1.

Table 1. Occurrence data for wine

	JECFA (2001)		SCOOP (EC, 2002)		EFSA (2020)		
Wine	n	mean (µg/kg)	n	mean (µg/kg)	n	Mean (LB/UB) (µg/kg)	P95 (LB/UB) (µg/kg)
	1828	0.32	1470	0.36	5692	0.06/0.25	0.39/0.84
Note: The maximum limit for wine in the European Union and Türkiye is 2 µg/kg.							

23. Control of ochratoxin A formation in dried vine fruits is less easy, because any preharvest infection with *A. carbonarius* will continue to develop during the early stages of drying. In addition, any damage to grapes during harvest and the commencement of drying can lead to new *A. carbonarius* infections. Although the hot, high sunlight levels that occur during drying are not favourable to the growth of *A. carbonarius*, this fungus is less inhibited than almost any other species, and so ochratoxin A production can continue until the water activity of the drying grapes has been reduced substantially (JECFA 2007).

24. Achieving OTA-free food and food products presents several challenges. However, mitigating mould and subsequent mycotoxin contamination in the various agricultural food items is both feasible and serve as an effective control measure. These challenges occur at different stages: pre-harvest (including crop production and growth) and post-harvest (encompassing harvest, transport, storage, and processing). Notably, addressing mould infestation and detoxification of the toxin before harvest has significant potential[17].

25. The implementation of advanced agricultural technologies and good agricultural, manufacturing, and storage practices can mitigate OTA contamination. To prevent fungal growth in plants, employing good agricultural practices like proper soil cultivation, crop rotation, efficient irrigation in drought conditions, accurate use of fungicides and fertilizers, timely harvesting, and adopting fungus-resistant crop varieties is vital. Maintaining product quality during harvest necessitates using dry containers to manage agricultural produce and prevent fungal growth. Inadequate preharvest methods can lead to fungal contamination and the build-up of OTA mycotoxin in stored agricultural products, particularly due to fungi like P. verruca sum and A. flavus infiltrating plants preharvest. Postharvest techniques are essential for addressing OTA mycotoxin post-formation[19].

26. The control of postharvest OTA contamination revolves around two key strategies, as follows: firstly, the eradication of fungus-infected items, and secondly, the application of a spectrum of treatment methods to the products. These essential practices are incorporated into the storage and distribution phases of the food and feed supply chain. Additionally, this approach extends to the implementation of antagonistic microorganisms such as yeast, fungi, and bacteria, which serve as a shield against OTA production within consumables. Notably, the mere presence of fungus-infected items does not necessarily indicate the concurrent presence of OTA. Instead, the emergence of OTA hinges on a specific set of conditions encompassing nutrient availability, temperature, O2 levels, moisture, and time, all of which must coexist[19].

27. In the literature, there are physical, chemical and biological methods studied for the prevention and control of OTA.

[17] Available at: https://www.sciencedirect.com/science/article/pii/S2405844024153443

28. Physical control strategies encompass a range of measures aimed at mitigating mycotoxin contamination of crops and products. These strategies include mould prevention, decontamination, detoxification, cleaning, sorting, and toxin monitoring. Various chemical agents have shown efficacy in decontaminating and mitigating the physiological effects of mycotoxins. Acids such as citric, lactic, tartaric, acetic, hydrochloric, and succinic acids have been employed in the food production industry. Alkaline substances such as ammonia and sodium bicarbonate, as well as salts (sodium bisulfite and sodium chloride) and oxidizing agents (sodium hypochlorite and hydrogen peroxide), have also been utilized, achieving an approximate 90 % decontamination rate. Biological control strategies are employed to inhibit fungal growth and ochratoxin A (OTA) formation in food commodities[18].

29. The methods used to decontaminate mycotoxins in food products should not only inactivate, destroy, or eliminate the toxin but also maintain the nutritional quality of the food, which should be acceptable for both human and animal consumption and should not significantly alter the technological properties of the product[18]. Chemical decontamination for OTA in food is banned in some countries.

30. It is possible to develop a CoP for the prevention and reduction of OTA contamination in dried fruits based on the available literature information and the experience of the countries.

PROCESSING

31. Adhering to good manufacturing practices during the processing and storage of dried fruits is crucial for minimizing mycotoxin contamination. This includes maintaining cleanliness, regularly inspecting and cleaning storage areas and equipment, and following proper hygiene practices. Proper handling and storage techniques can help prevent cross-contamination and minimize the risk of mycotoxin development[19].

32. In dried fruits such as figs, aflatoxin-contaminated fruits can be manually separated using the Bright Greenish Yellow Fluorescence (BGYF) method under ultraviolet (UV) light. However, no such separation method has yet been defined for OTA.

33. In this research[20], the effects of washing treatments (potassium carbonate (PC), potassium hydroxide (PH), peracetic acid (PA), alkaline hydrogen peroxide (AHP)), ultrasound (US) and high-intensity pulsed light (HIPL) technologies on the removal of ochratoxin A (OTA) residues in raisins were investigated. PC at 5 min (66.60%), PH at 10 min (65.25%), alkaline hydrogen peroxide at 5 min (63.30%) and HIPL at 12 J cm−2 (62.50%) were found to be the most successful applications in OTA degradation, respectively. Although the OTA degradation rate was high after chemical washing for 10 min, the raisins had a chemical odour. The results show that HIPL effectively reduces OTA levels in raisins without causing any quality loss.

34. The effects of various food processes, including both nonthermal and thermal methods, on the reduction in OTA were summarized in this review, with emphasis on the toxicity of residual OTA as well as its known and unknown degradation products. Since complete removal of OTA from foodstuffs is not feasible, additional strategies that may facilitate the reduction in OTA in food, such as adding baking soda and sugars, was also discussed, so that the industry may understand and apply practical measures to ensure the safety of its products destined for human consumption[21].

35. The extensive exposure of OTA and environmental factors necessitates the development of effective mitigation strategies to protect public health and food security. This review explores OTA's occurrence, toxicity, and health impacts in food systems, highlighting the limitations of conventional decontamination methods. Moreover, it examines innovative strategies like irradiation, cold plasma (CP), adsorbents, ozone (O3), and bacterial and fungal treatments, emphasizing their potential to reduce OTA contamination effectively. These methods are critically evaluated for their efficacy, impact on food safety, nutritional quality preservation, sensory attributes, and overall consumer acceptance. By integrating insights from recent advancements, the review offers a comprehensive understanding of OTA mitigation, promoting the development of sustainable, scalable, and safe decontamination technologies for improved food safety and public health protection[22].

LEGISLATION FOR MAXIMUM LEVEL

36. The countries and maximum limits for OTA in dried fruits are given in Table 2. In the legislation, the maximum limit for OTA in dried fruits is regulated as maximum 10 µg/kg. However, in recent years in Türkiye, there have been more than 10 µg/kg occurrence data in P95 for dried figs and dried mulberries.

[18] Available at: https://www.mdpi.com/2304-8158/13/8/1184
[19] Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10537527/
[20] Available at: https://academic.oup.com/ijfst/article/59/12/9170/7932941
[21] Available at: https://pubmed.ncbi.nlm.nih.gov/38276534/
[22] Available at: https://www.preprints.org/manuscript/202412.2214/v1

Table 2. Regulatory limits for the presence of OTA in Dried Fruits

Region/ Country	Food commodity	OTA limit (µg/kg)
EU	Dried vine fruits (currants, raisins and sultanas) and dried figs	8
	Other dried fruits	2
Türkiye	Dried fruits	10
Brazil	Dried fruits	10
Egypt	Dried fruits	10

37. In Türkiye, the statistical information of the data obtained from the official control results and food establishments are given for dried figs in Table 3. Similar situation is valid for dried mulberry and P95 level of the occurrence data is above 10 µg/kg. Dried apricots are traded both with and without sulphur. The P95 level of occurrence data in sulphur-free dried apricots traded commercially is well above 2 µg/kg.

Table 3. Dried fig OTA results in Türkiye.

Years	N	LOQ (µg/kg)	<LOQ (N)	Mean LB (µg/kg)	Mean UB (µg/kg)	P95	> 8 µg/kg (N)	> 10 µg/kg (N)
2019-2021	153	0.50	126	2.35	2.76	8.32	8	5
2022	307	0.50	197	2.50	2.82	11.44	32	22
2023	169	0.50	100	2.27	2.56	10.27	17	13
2024	348	0,50	268	2.73	3,12	14.85	20	19

38. Occurrence data for dried fruits in the EFSA 2020 risk assessment are given in Table 4.

Table 4. Dried fruits OTA results (EFSA 2020).

Foods	N	<LOQ (N)	Mean LB (µg/kg)	Mean UB (µg/kg)	P95 LB	P95 UB
Dried Figs	1936	1448	3.63	4.12	8.5	8.9
Dried apricot	319	300	0.28	1.12	0.3	2
Dried vine fruits (currants, raisins and sultanas)	4070	2206	1.86	2.44	8.6	8.6
Dried dates	347	335	1.83	2.27	0	2
Dried mulberry	0					
Dried prunes	253	248	0.02	0.71	0	2

39. Review articles on studies conducted on OTA in dried fruits in the literature contain formation data.

Table 5. Dried dates OTA in review articles[23] (2023)

Country	N	<LOQ (N)	Mean (µg/kg)	Range (µg/kg)
Brazil	10	8	-	0.1-5
China	40	31	-	LOD-61.4
Egypt	28	25	-	1.48-6070
Iran	10	8	2.5	1.4-3.6
Iran	22	17	1.2	0.5-2.1
Tunisia	48	30	1.26	0.57-3.34

[23] Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10537527/

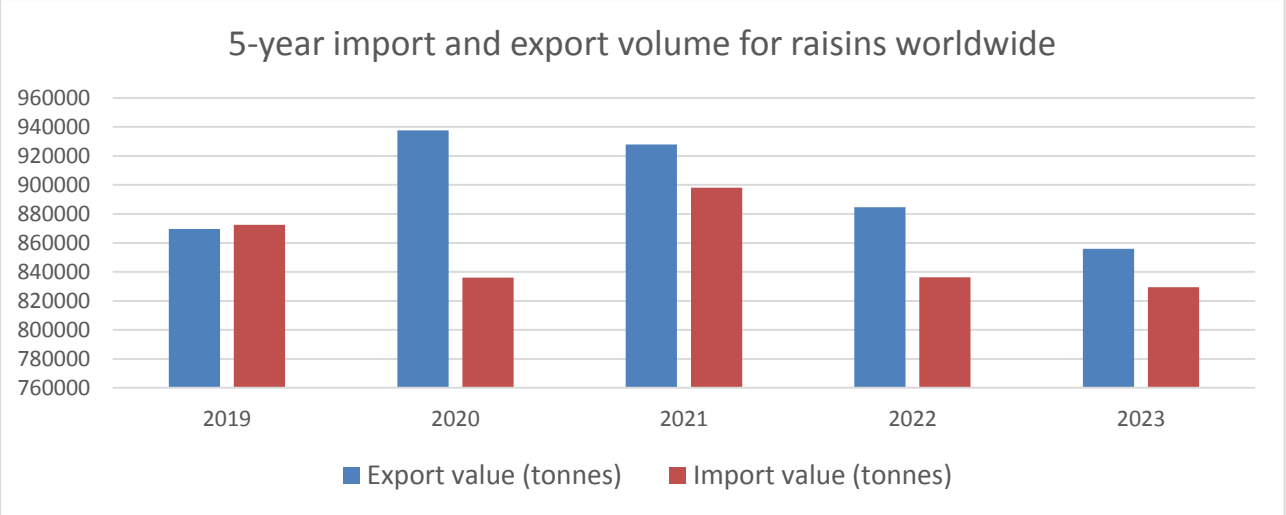
Table 6. Dried vine fruits OTA in review articles[24] (2023)

Country	N	<LOQ (N)	Mean (µg/kg)	Range (µg/kg)
Argentina	50	13	-	1.4-14
Brazil	43	14	-	0.1-33.9
Canada	153	45	2,74	0.1-26.6
China	56	22	0.99	0.07-12.83
Cyprus	43	13	2.2	0.2-13.7
Czech Republic	48	30	11.5	1.6-63.6
Czech Republic	12	7	0.46	0.1-2.17
Greece	81	21	2.6	0.6-13.8
Greece	41	11	-	0.1-98.2
Greece	26	0	47.2	2.8-138.3
Iran	66	27	2.98	0.16-8.4
Iran	38	19	7.0	2.9-18.2
Italy	35	17	2.6	0.05-12.61
Pakistan	17	13	5.6	0.18-18.5
Sweden	118	22	-	0.1-34.6
Türkiye	1885	172	1.36	0.3-100
United Kingdom	60	7	6.4	0.3-53.6
United States	109	61	2.26	0.28-15.34

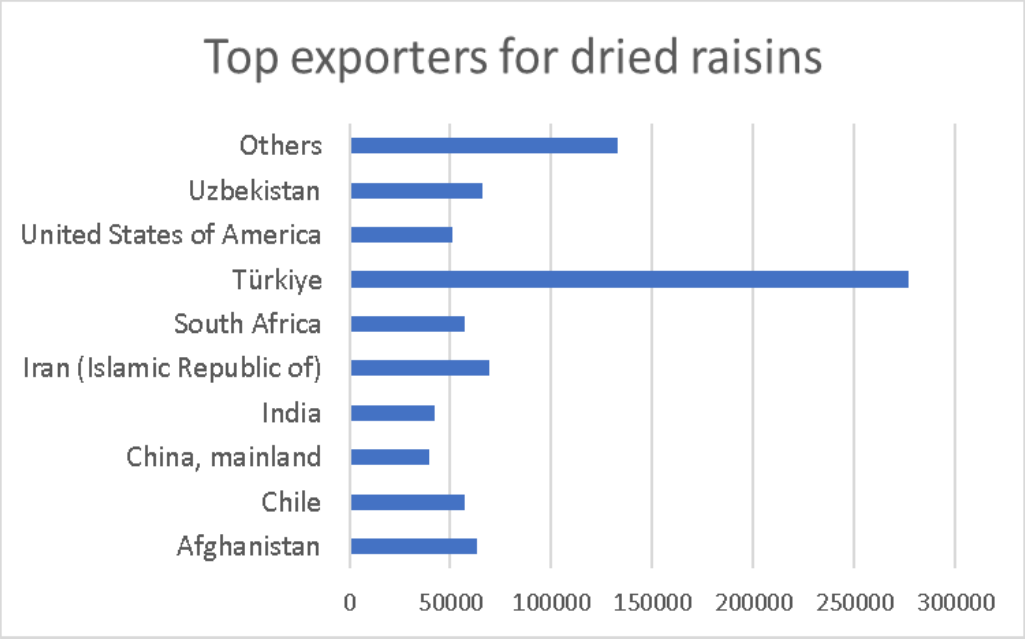
TRADE VOLUME OF DRIED FRUITS

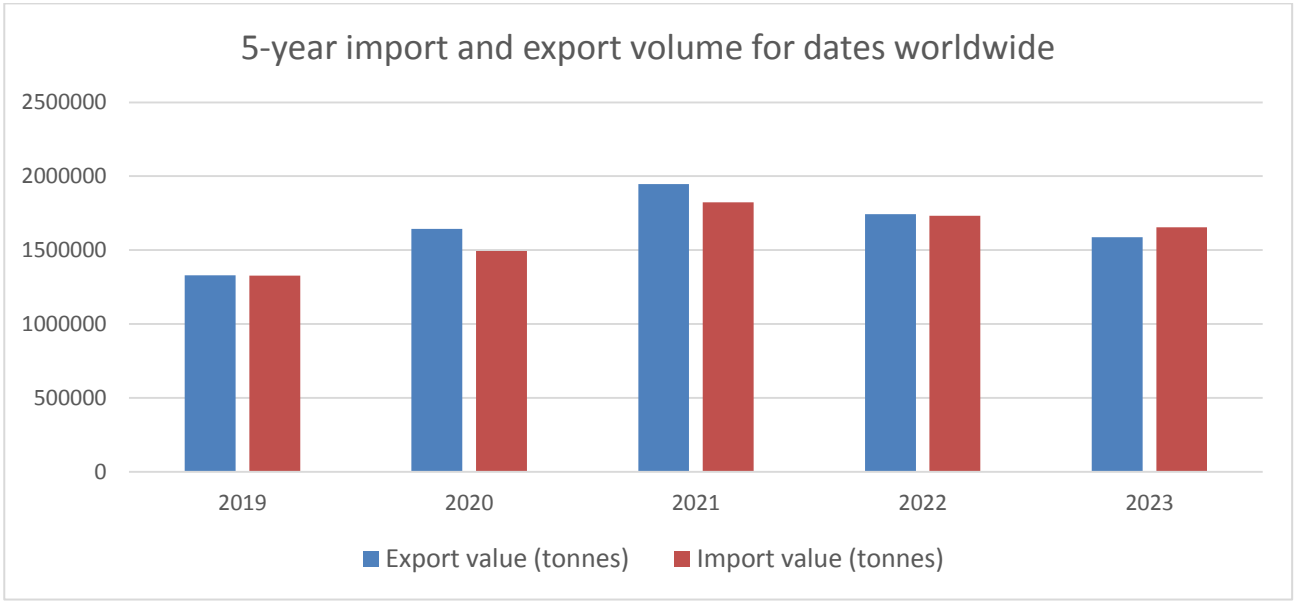
40. Definitions for dried fruits have been established in the General Standard[25] for Dried Fruits, and specific provisions have been determined for dried apricots, dried dates, raisins, dried longans, and dried persimmons.

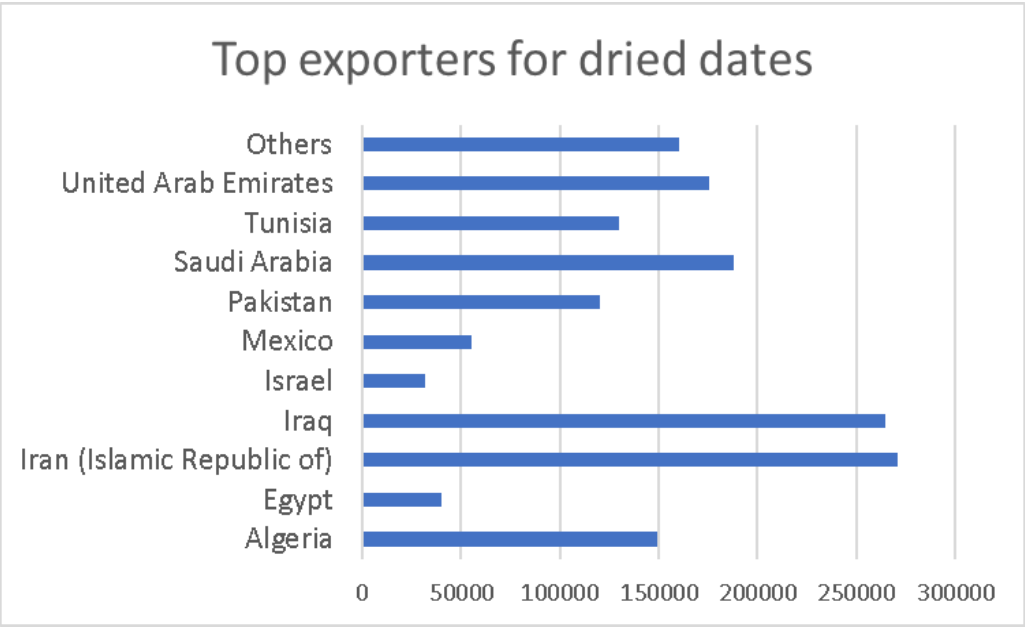
41. FAOSTAT[26] provides export and import statistics for raisins, dates, dried apricots, dried figs, dried plums and other dried fruits.

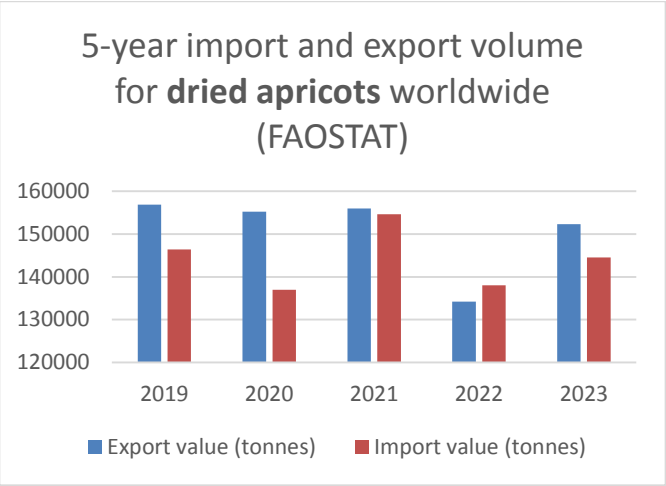


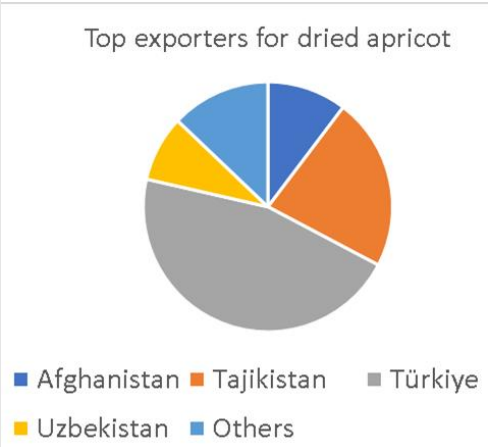
[24] Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10537527/
[25] Available at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B360-2020%252FCXS_360e.pdf
[26] Available at: https://www.fao.org/faostat/en/#home

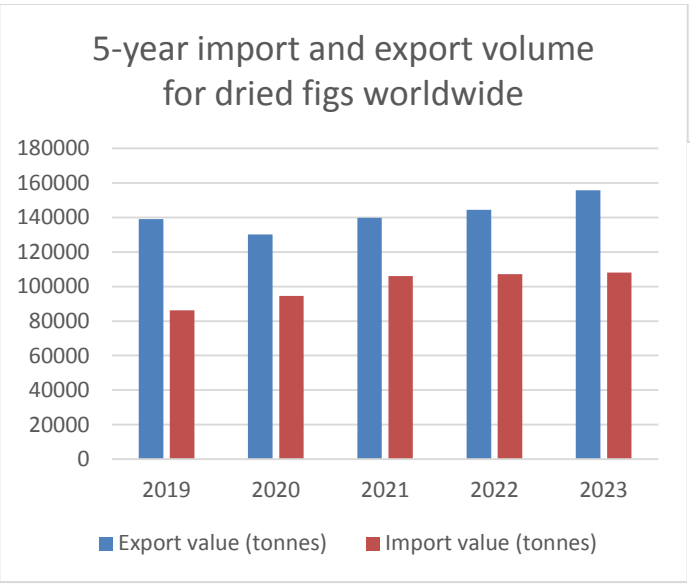

Top exporters for dried raisins
Others
Uzbekistan
United States of America
Türkiye
South Africa
Iran (Islamic Republic of)
India
China, mainland
Chile
Afghanistan
0
50000
100000
150000
200000
250000
300000

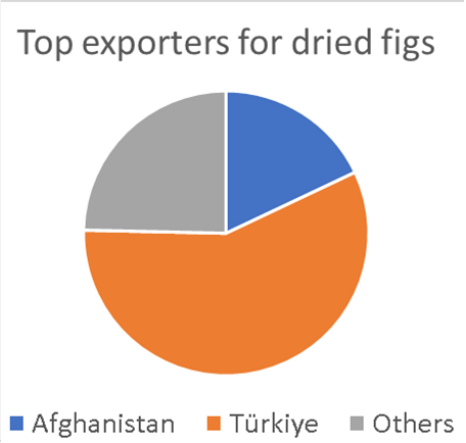

5-year import and export volume for dates worldwide
2500000
2000000
1500000
1000000
500000
0
2019
2020
2021
2022
2023
Export value (tonnes)
Import value (tonnes)

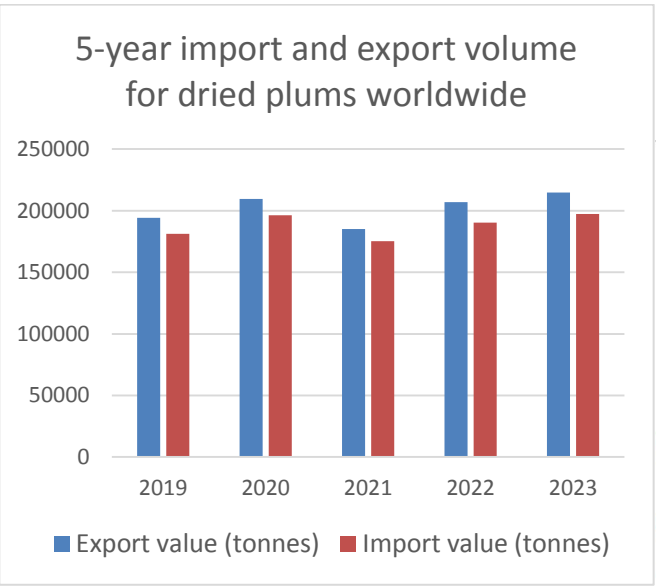

Top exporters for dried dates
Others
United Arab Emirates
Tunisia
Saudi Arabia
Pakistan
Mexico
Israel
Iraq
Iran (Islamic Republic of)
Egypt
Algeria
0
50000
100000
150000
200000
250000
300000

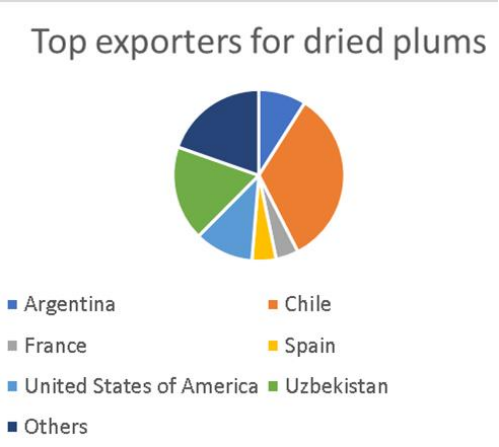

5-year import and export volume for dried apricots worldwide (FAOSTAT)
160000
150000
140000
130000
120000
2019
2020
2021
2022
2023
Export value (tonnes)
Import value (tonnes)

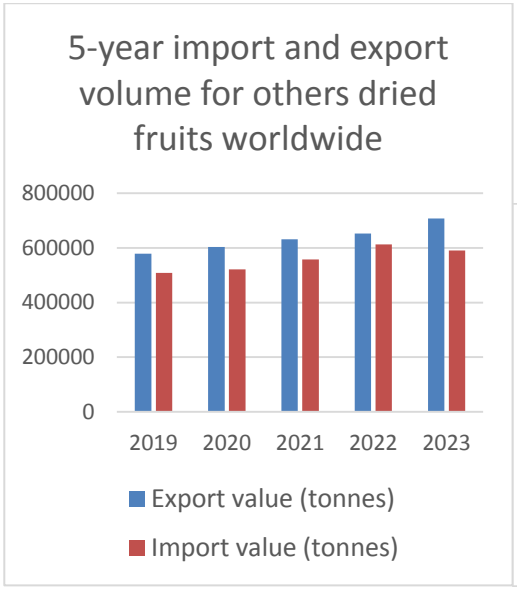

Top exporters for dried apricot
Afghanistan
Tajikistan
Türkiye
Uzbekistan
Others

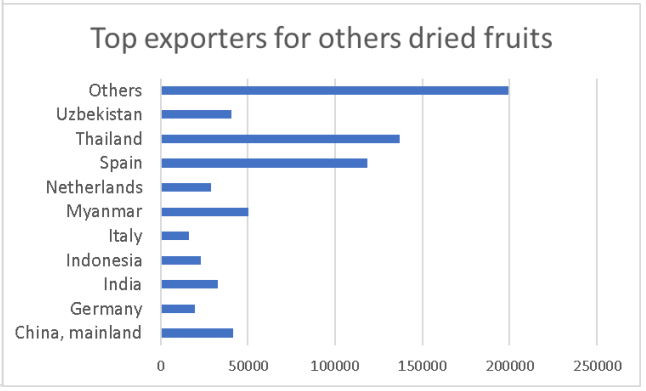

5-year import and export volume for dried figs worldwide
180000
160000
140000
120000
100000
80000
60000
40000
20000
0
2019
2020
2021
2022
2023
Export value (tonnes)
Import value (tonnes)


Top exporters for dried figs
Afghanistan
Türkiye
Others

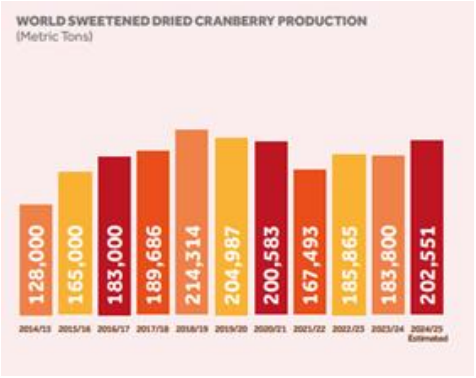

5-year import and export volume for dried plums worldwide
250000
200000
150000
100000
50000
0
2019
2020
2021
2022
2023
Export value (tonnes)
Import value (tonnes)

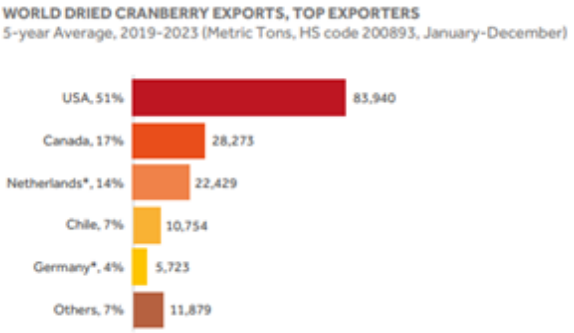

Top exporters for dried plums
Argentina
Chile
France
Spain
United States of America
Uzbekistan
Others

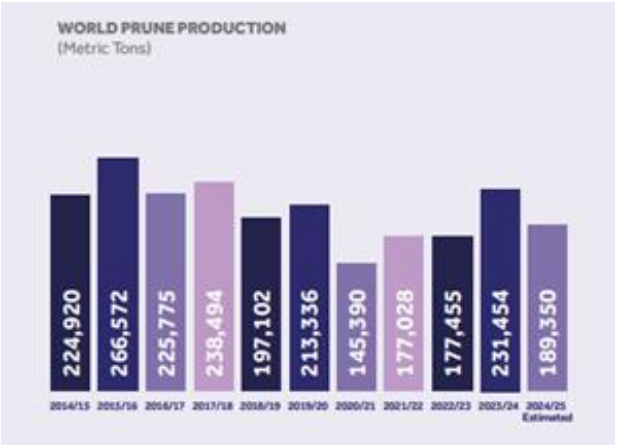




42. The International Nut and Dried Fruit Council (INC) publishes an annual report containing production, import, export and consumption data for dates, dried apricots, dried cranberries, dried grapes, dried figs and prunes. The figures for dried cranberries and prunes included in the INC 2024[27] report are shown below.







[27] Available at: https://api.iib.org.tr/files/anc_rapor1735025254995.pdf

APPENDIX II

PROPOSAL FOR NEW WORK ON THE DEVELOPMENT OF A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF OCHRATOXIN A CONTAMINATION IN DRIED FRUİTS

PROJECT DOCUMENT

(For consideration by CCCF)

1) Purpose and scope of the project

The new work aims to develop a Code of practice (CoP) for the prevention and reduction of ochratoxin A (OTA) contamination in dried fruits.

The scope of this new study is to provide recommendations for primary production, storage, processing, distribution, consumption and other stages of the food supply chain in order to guide producers, the food industry and consumers on the prevention and reduction of OTA in dried fruits, another food group at risk of OTA contamination.

2) Relevance and timeliness

OTA has been classified as Group 2B (possible human carcinogen) by the International Agency for Research on Cancer (IARC). The contamination of foods and animal feeds with OTA is a worldwide problem. In the *General standard for contaminants and toxins in foods and feeds* (CXS 193-1995), maximum limits for OTA are set for wheat, barley, rye, chilli pepper, paprika and nutmeg. At the same time, CoPs have been developed for these foods, for which maximum limits have been set in the Contaminants Standard[28].

Human exposure to OTA may be high due to the fact that they are present in a wide variety of foodstuffs, such as spices, cereals, oilseeds, some fruits and vegetables, nuts, coffee, wine, etc. Besides their presence in food, they are stable compounds and therefore they cannot be removed completely from those foodstuffs. Thus, it is important to maintain the level of contamination of mycotoxins in food at the lowest achievable level (ALARA principle).

It was recognized by FAO that the most efficient way to approach the problem of mycotoxins contamination in foodstuffs is the prevention or minimization of their concentrations by means of following a code of good practice.

3) Main aspects to be covered

The proposed new work will focus on good practices that will prevent or reduce contamination of dried fruits with OTA. The CoP will cover Good Agricultural Practices, Good Manufacturing Practices and Good Storage practices, since OTA contamination can develop during any of these steps.

4) Assessment against the criteria for the establishment of work priorities

(a) **Consumer protection from the point of view of health and fraudulent practices**. The CoP will provide additional guidance for countries in order to prevent and reduce OTA contamination of dried fruits and consequently minimize consumer dietary exposure to OTA.

(b) **Diversification of national legislations and apparent resultant or potential impediments to international trade. Currently, the best practices and legislations.** The CoP would provide internationally recognized scientific and technical guidance in order to improve the enhancement of international trade.

(c) **Scope of work and establishment of priorities between the various sections of the work.** The CoP will address all relevant measures for preventing or reducing OTA at different steps in the dried fruits chain: production, harvest, storage, processing, and distribution.

(d) **Work already undertaken by other international organizations in this field.** There is no guidance document developed by other international organisations on reducing and preventing OTA contamination in dried fruits. Reviews of scientific articles reveal physical, chemical and biological techniques for preventing and reducing OTA contamination in dried fruits.

5) Relevance to Codex Strategic Goals

(a) **Goal 1: Address current, emerging, and critical issues in a timely manner.** CoP for prevention or reduction of OTA in dried fruits will address the need for guidance to ensure consumers' health.

(b) **Goal 2: Develop standards based on science and Codex risk-analysis principles.** This work will apply risk

[28] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B193-1995%252FCXS_193e.pdf

analysis principles in developing the CoP by using scientific data and recommendations from FAO/WHO and other recognized expert bodies to support a reduction in consumers' exposure to OTA.

(c) **Goal 3: Increase impact through the recognition and use of Codex standards.** The proposed CoP ensures that information on recommended practices to prevent and reduce the presence of OTA consists of current best practices and will be available to all member countries, especially those with fewer resources to devote to this topic.

(d) **Goal 4: Facilitate the participation of all Codex Members throughout the standard-setting process.** All Codex members will be notified of the development of the CoP through the Codex Step process.

(e) **Goal 5: Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals.** The development of the CoP will provide essential guidance to countries and producers on keeping dried fruits that are highly contaminated with OTA out of the market, thereby helping to develop and implement effective and efficient business management systems and practices.

6) Information on the relationship between the proposal and other existing Codex documents

The CoP is concerned with the prevention and reduction of OTA contamination in products defined in the *General standard for dried fruits* (CXS 360-2020).

7) Identification of any requirement for any availability of expert scientific advice

The Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) has issued several evaluations of OTA (FAO/WHO, 1991, 1996, 2001, 2007).

8) Identification of any need for technical input to the standard from external bodies

There is no identified need for additional technical input from external bodies.

9) Timeline for completion of the new work

Work will commence following the recommendation by CCCF and approval by CAC. Completion of work is expected by 2028.