TOX/2020/16

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Discussion paper on the potential risks from almond drink consumption in children aged 6 months to 5 years of age.

Background

1. The Department of Health and Social Care (DHSC), Public Health England (PHE) and the FSA are receiving an increasing number of enquiries regarding the use of plant-based drinks in the diets of infants and young children. Therefore, we are asking the COT to consider the potential health effects of almond drinks in the diets of these age groups.

2. Plant-based drinks are an increasingly popular replacement for dairy. In 2018, 114.5 million litres of plant-based drinks (rice, oat, almond, hazelnut and hemp) were sold in the UK whereas 127.5 million litres of plant-based drinks were sold in 2019. The main consumers of these products are those who have an intolerance to lactose or other components of cow's milk. Additionally, almond "milk" drinks may be used to replace dairy milk in vegan diets. Veganism is growing, with 600,000 vegans in the UK in 2019, up from 150,000 in 2014 (Vegan Society, 2016).

3. Currently the UK government advises that parents should only use infant formula as an alternative to breast milk in the first 12 months of a baby's life. It is also advised that whole cows' milk and unsweetened calcium-fortified milk alternatives, such as soya, almond and oat drinks can be given to children from the age of 1 as a part of a healthy, balanced diet[1].

Literature search

4. A literature search was conducted to identify any chemical contaminants found in almond drink that may be of toxicological concern. Based on the literature search, one relevant paper identified cyanide as a contaminant in almond drinks. Another two papers identified aflatoxin as a contaminant in almond nuts but not specifically in almond milks/drinks. The search terms 'almond milk and glycosides' and 'almond milk and aflatoxins' were used to identify these papers. No other relevant papers were found. A full list of all search terms can be found at the end of this paper in Annex A.

[1] NHS Choices (2018) available at: https://www.nhs.uk/live-well/eat-well/milk-and-dairy-nutrition/

5. Based on the literature search, limited occurrence data were identified in the published data. Occurrence data were identified in three published papers and are summarised below in paragraphs 6 - 8.

Occurrence data

6. Eleven drinks containing raw vegetables and fruit, flax seeds, whole apples with seeds, raw almond drink and pasteurised almond drink were analysed for total cyanide. Total cyanide levels of 9.6, 41,134 and 272 µg/L were detected in smoothies containing almond drink. The two smoothies with the highest levels also contained flaxseed which is also high in cyanide-containing molecules (Baker et al, 2018).

7. The secretariat was not able to find data for total cyanide in almond drinks alone. Therefore, occurrence data of total cyanide in sweet and bitter almonds were taken from EFSA's database which comprises of analytical samples from across the European Union (Table 1). EFSA (2016) noted that the concentration range of cyanogenic glycosides in almonds reported as sweet or bitter overlapped.

			Concentration (µg/kg)	**Concentration (µg/kg)**
Contamination	**Food commodity**	**Number of samples**	**Mean LB**	**Mean UB**
Total cyanide	Sweet almond	35	4500	4500
Total cyanide	Bitter almond	3	1437000	143700

LB: lower bound; UB: upper bound. EFSA 2019.

8. There were no data for aflatoxins in almond drinks. However, 40 nut samples (shelled almonds, pistachios, hazelnuts, peanuts and walnuts) taken from an Algerian market were tested for aflatoxigenic fungi and aflatoxin contamination. Out of the 40 nut samples, 8 were almond nut samples, all of which tested for aflatoxin B1 (AFB1) levels ranging from 1.65 - 4.00 µg/kg, the mean was reported to be 2.12 µg/kg AFB1 (Riba et al, 2018).

9. Twenty-one samples of Portuguese almond nuts were tested for aflatoxigenic fungi and aflatoxin contamination. Out of the 21 almond nut samples, AFB1 was detected in 1 sample at a concentration of 4.97 µg/kg. As AFB1 was only detected in one almond nut sample, this sample is unlikely to be representative of AFB1 levels in almond nuts. Therefore, this concentration will not be considered further.

10. Table 2 below contains information on the almond content of a variety of almond drinks sold in the UK.

Brand of almond drink	Almond content (% w/w)
Alpro	2.3
Almond breeze	2.5
Innocent	5.8
Rude	6

Table 2: Data on the almond content of a range of different almond drink brands sold in the UK.

Aflatoxin B1 (AFB1) in almonds

11. Aflatoxins are produced as a result of fungal contamination with *Aspergillus flavus* and *A. parasiticus* moulds under warm and humid conditions in tree nuts such as almonds, hazelnuts, brazil nuts, cashew nuts, walnuts and pecan nuts. The degree of contamination is dependent on temperature, humidity, soil and storage conditions.

12. Aflatoxins have been previously reviewed by the Scientific Committee for Food (SCF) in 1996, the European Food Safety Authority (EFSA) in 2007 and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1998, 2001 (AFM1) and 2017.

13. EFSA considered the chronic endpoint of liver carcinogenicity in a rat performed in a study by Wogan et al, 1974 to be the most sensitive and adequate study for dose response modelling.

14. Groups of male Fisher rats were administered diets containing 0, 1, 5, 15, 50, or 100 µg/kg diet of AFB1 (purity >95%) until clinical deterioration of animals was observed, at which time all survivors in that treatment group were killed. EFSA converted the dietary concentrations of AFB1 into daily intakes assuming that an average adult male rat consumed 40 g diet per kg body weight per day. EFSA also adjusted the daily intake to 104 weeks in order to compensate for the shorter study duration in some of the AFB1 groups. In the modelling of the results from the Wogan et al. (1974) study the highest dose was omitted because this dose resulted in a 100% tumour incidence.

15. US EPA BMD software (BMDS) was used (US EPA, 2006) for modelling the liver carcinoma dose-response in male Fisher rats and to calculate BMD and BMDL values for an extra 10% risk compared to the background.

16. The calculated BMD_{10} values ranged from 0.41 to 0.48 µg/kg b.w. per day and the $BMDL_{10}$ values from 0.17 to 0.34 µg/kg b.w. per day. In order to be prudent, the EFSA Panel used the lowest $BMDL_{10}$ of 0.17 µg/kg b.w. per day in the risk assessment.

17. In 2019, following a request from the European Commission, EFSA

released a draft opinion for public consultation on the risks to public health related to the presence of aflatoxins in food. The EFSA Panel proposed the use of a $BMDL_{10}$ of 0.4 µg/kg b.w. per day in the risk assessment.[2]

Cyanogenic glycosides in almonds

18. The almond can either be bitter or sweet. Bitterness in almonds is determined by a recessive gene whereas the sweetness in almonds is determined by a dominant gene. The bitterness in almond is also determined by the cyanogenic glycoside content (Sanchez-Perez et al, 2008).

19. Once macerated the almond the cyanogenic glycosides may interact with the enzyme ß-glucosidase. This enzyme hydrolyses the cyanogenic glycosides and can yield hydrogen cyanide, benzaldehyde, glucose and ketones (Haque, 2002).

20. Exposure to large amounts of the hydrogen cyanide component can lead to convulsions, loss of consciousness, dizziness, weakness, mental confusion and heart failure (Burns et al, 2012).

21. The sweet almond contains lower levels of total cyanide compared to bitter almond as seen in table 1.

22. Cyanogenic glycosides in bitter apricot kernels were previously reviewed by COT in 2006 where a nominal acute reference dose of 5 µg/kg was established. More recently, cyanogenic glycosides in raw apricot kernels. were reviewed by EFSA (EFSA, 2016). An acute reference dose (ARfD) of 20 µg/kg body weight was established for cyanide. In the most recent EFSA opinion (EFSA, 2019), the panel concluded that the ARfD of 20 µg/kg body weight is applicable for acute effects of cyanide regardless the dietary source.

Exposure Assessment

Aflatoxin

23. No relevant data on aflatoxin contamination in almond drink were identified from the literature search. However, aflatoxin concentrations had been measured in almond nuts (paragraph 8). The highest detected concentration of 4.00 µg/kg AFB1 (Riba et al, 2018) in almond nuts was used to estimate the amount of AFB1 that would be present in 1 litre of almond drink assuming 6% (w/w) almond nuts in the drink[3]. The value of 0.24 µg/kg aflatoxin was calculated.

[2] EFSA draft opinion available at: https://www.efsa.europa.eu/sites/default/files/consultation/consultation/Aflatoxins_Draft_Opinion_for_public_consultation.pdf
[3] Rude Health (2018) available at: https://rudehealth.com/product/ultimate-almond-drink/

24. The mean detected concentration of 2.21 µg/kg AFB1 in 8 almond nuts was used to estimate the amount of AFB1 that would be present in 1 litre of almond drink assuming 6% (w/w) almond nuts in the drink (Riba et al, 2018). The value of 0.13 µg/kg AFB1 was calculated.

25. No almond drink consumers in infants between the ages of 6 to 18 months were reported in the DNSIYC survey. A small number of almond drink consumers between the ages of 18 months to 5 years (n=4) were reported in the NDNS survey. The mean and maximal AFB1 exposures estimated for these consumers (n=4) of almond drink ranged from 0.000047 – 0.00011 µg/kg bw/day. These estimates are uncertain as they are based on only 4 consumers of almond drink. Therefore, consumption data for cows' milk were used as a proxy, assuming that all cows' milk will be replaced with almond drink.

26. Table 2 gives the chronic exposure estimates for AFB1 in children between the ages of 6 months and 5 years, with the assumption that all cows' milk would be replaced with almond drink in a diet. Potential chronic AFB1 exposures were calculated using the estimated maximal AFB1 value of 0.24 µg/kg and estimated mean AFB1 concentration of 0.13 µg/kg AFB1 combined with consumption data from the UK Dietary and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013) and the National Diet and Nutrition Survey (NDNS) (Bates et al, 2014; 2016; Roberts et al, 2018) for children aged 6 to 18 months of age and those between 18 months and 5 years, respectively.

Chronic AFB1 exposure from cows' milk (excluding infant formula) µg/kg bw/day

		0.13 µg/kg AFB1 (mean concentration)	0.13 µg/kg AFB1 (mean concentration)	0.24 µg/kg AFB1 (maximal concentration)	0.24 µg/kg AFB1 (maximal concentration)
Age group	Number of consumers	Mean	97.5th Percentile	Mean	97.5th Percentile
6 - 18 months	1826	0.0027	0.0087	0.0052	0.016
18 months – 5 years	1053	0.0023	0.0069	0.0044	0.013

Table 2: Estimated chronic AFB1 exposures (µg/kg bw/day) of children aged 6 months to 5 years based on an assumption that all cow milk would be replaced with almond drink in diet (excluding infant formula) (using estimated mean and maximal AFB1 concentrations)

Cyanogenic Glycosides

27. No relevant data for total cyanide contamination in almond drink alone were identified from the literature search. Therefore, occurrence data of total cyanide in sweet and bitter almond kernels were taken from EFSA's database which comprises of analytical samples from across the European Union as

seen in table 1.

28. The sweet almond mean upper bound and lower bound concentration of 4500 µg/kg was used to estimate the amount of cyanide that would be present in 1 litre of almond drink assuming 6% (w/w) almond nuts in the drink. The value of 270 µg/kg was calculated.

29. The bitter almond mean upper bound and lower bound concentration of 1,437,000 µg/kg was used to estimate the amount of cyanide that would be present in 1 litre of almond drink assuming 6% (w/w) almond nuts in the drink. The value of 86,220 µg/kg was calculated.

30. No almond drink consumers in infants between the ages of 6 to 18 months were reported in the DNSIYC survey. A small number of almond drink consumers between the ages of 18 months to 5 years (n=4) were reported in the NDNS survey. The sweet almond mean LB and UB cyanide exposures estimated for these consumers (n=4) of almond drink ranged from 0.08 – 0.12 µg/kg bw/day. The bitter almond mean LB and UB cyanide exposures estimated for these consumers (n=4) of almond drink ranged from 25.71 – 38.75 µg/kg bw/day. These estimates are uncertain as they are based on only 4 consumers of almond drink. Therefore, consumption data for cows' milk were used as a proxy, assuming that all cows' milk will be replaced with almond drink.

31. Table 3 gives the acute exposure estimates for total cyanide in children between the ages of 6 months and 5 years, with the assumption that all cows' milk would be replaced with almond drink in a diet. Potential acute cyanide exposures were calculated using the estimated total cyanide concentrations of 4500 µg/kg (sweet almond) and 86,220 µg/kg (bitter almond) combined with consumption data from the UK Dietary and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013) and the National Diet and Nutrition Survey (NDNS) (Bates et al, 2014; 2016; Roberts et al, 2018) for children aged 6 to 18 months of age and those between 18 months and 5 years, respectively.

Acute total cyanide exposure from cows' milk (excluding infant formula) µg/kg bw/day

		4500 µg/kg CN (sweet almond)	4500 µg/kg CN (sweet almond)	86,220 µg/kg CN (bitter almond)	86,220 µg/kg CN (bitter almond)
Age group	Number of consumers	Mean	97.5th Percentile	Mean	97.5th Percentile
6 - 18 months	1826	7.73	23.79	2469.55	7595.83
18 months – 5 years	1053	6.98	18.83	2228.03	6012.47

Table 3: The acute exposure estimates of for total cyanide in children between the ages of 6 months and 5 years, with the assumption that all cows' milk would be replaced with almond drink in a diet.

Risk characterisation

Aflatoxin

Margin of Exposure (MOE)

32. The updated EFSA opinion on aflatoxins has not been released yet. Therefore, the current EFSA approach was used for risk characterisation.

33. Numerous studies have shown AFB1 to be both genotoxic and carcinogenic in animal studies, the margin of exposure (MOE) approach was used to characterise aflatoxin exposure risk in food by EFSA.

34. A margin of exposure (MOE) calculation can be carried out, as below: MOE = ($BMDL_{10}$ (µg per kg per day) / Exposure value (µg/kg bw/day))

35. Estimated AFB1 MOEs for infants and young children aged 6 months to 5 years were calculated using a $BMDL_{10}$ of 0.17 µg/kg b.w. per day (EFSA, 2007) and the estimated aflatoxin chronic exposures (Table 4).

Estimated AFB1 MOEs

		4500 µg/kg CN (sweet almond)	4500 µg/kg CN (sweet almond)	86,220 µg/kg CN	86,220 µg/kg CN
Age group	Number of consumers	Mean	97.5th Percentile	Mean	97.5th Percentile
6 - 18 months	1826	7.73	23.79	2469.55	7595.83
18 months – 5 years	1053	6.98	18.83	2228.03	6012.47

Table 4: Estimated AFB1 exposure (µg/kg bw/day) of children aged 6 months to 5 years based on an assumption that all cows' milk would be replaced with almond drink in diet (excluding infant formula) (using estimated mean and maximal AFB1 concentrations)

Cyanogenic glycosides

Acute reference dose (ARfD)

36. In the most recent EFSA opinion, (EFSA, 2019) the panel concluded that the ARfD of 20 µg/kg body weight was applicable for the acute effects of cyanide regardless the dietary source. No chronic health-based guidance has been established for cyanide.

37. The estimated acute exposures in Table 4 (µg/kg bw/day) were used to calculate the health risks as percentages of the ARfD (20 µg/kg body weight) These percentages are shown below in Tables 5 and 6.

Sweet almond (270 µg/kg HCN)

	6 to <18 month-olds (n = 1826)	6 to <18 month-olds (n = 1826)	18 month- to <5 year olds (n = 1053)	18 month- to <5 year olds (n = 1053)
Calculation of health risk	Mean	97.5th Percentile	Mean	97.5th Percentile
Acute risk (% ARfD)	39	119	35	94

Table 5: Calculation of acute risk from estimated dietary exposure to total cyanide in almond drink in infants and young children aged 6 months to 5 years (using estimated mean LB and UB concentration from the sweet almond)

Bitter almond (86,220 µg/kg HCN)

	6 to <18 month-olds (n = 1826)	6 to <18 month-olds (n = 1826)	18 month- to <5 year olds (n = 1053)	18 month- to <5 year olds (n = 1053)
Calculation of health risk	Mean	97.5th Percentile	Mean	97.5th Percentile
Acute risk (% ARfD)	12348	37979	11140	30062

Table 6: Calculation of acute risk from estimated dietary exposure to total cyanide in almond drink in infants and young children aged 6 months to 5 years (using estimated mean LB and UB concentration from the bitter almond)

Conclusions

38. There are very few data available on contaminants in almond drinks.

39. This risk assessment for AFB1 is based on a worst-case scenario as it is assumed that almond drink will be consumed in the same way as cows' milk since there are very few almond drink consumers (aged 6 months to 5 years according to DNSIYC and NDNS surveys) to provide data for almond drink. A high level of AFB1 has been assumed, and the drink is assumed to contain the highest proportion of almonds.

40. The EFSA Scientific Committee stated that an MOE of 10,000 or higher, if based on the $BMDL_{10}$ from a carcinogenicity study, would be of low concern from a public health point of view (EFSA, 2005).

41. Based on the maximal and mean AFB1 concentration values, calculated MOEs are significantly lower than 10,000 (Table 3), which have the potential to be a health concern. The MOEs range from 20 to 63 and 11 to 39 for mean and high-level consumers at exposures of 0.13 and 0.24 µg/kg bw/day AFB1 respectively.

42. However, given the conservative nature of the risk assessment, it is unlikely that this age group would be exposed to AFB1 levels as high as 0.13 – 0.24 µg/kg bw/day in almond drinks so the MOEs would also be higher in practice, although the MOEs would still be likely to be < 10,000.

43. Using the mean consumption rates, estimates of acute exposure to cyanide via the consumption of almond drink assuming sweet almonds were used to make the drink do not exceed the ARfD for infants and young children aged 6 months to 5 years. Using the 97.5th consumption rate, an estimate of acute exposure to cyanide levels in almond drink assuming sweet almonds were used to make the drink slightly exceed the ARfD for children aged 6 to 18 months. However, using the 97.5th consumption rate, an estimate of acute exposure to cyanide levels in almond drink assuming sweet almonds were used to make the drink do not exceed the ARfD for infants aged 18 months to 5 years.

44. Using the mean and 97.5th percentile consumption rates, estimates of

acute exposure to cyanide levels in almond drink assuming bitter almonds were used to make the drink exceed the ARfD for children aged 6 to 18 months. These cyanide levels would be severely toxic or fatal.

45. The risk assessment for cyanide is based on a worse-case scenario as it is assumed that both sweet and bitter almond would be used to make almond drink. In practice, bitter almonds would not be deliberately used in almond drinks as they would be unpalatable. However, contamination with bitter kernels or the presence of almond kernels could occur[4]. It is also assumed that almond drink will be consumed in the same way as cows' milk since there are very few almond drink consumers (aged 6 months to 5 years according to DNSIYC and NDNS surveys) to provide data for almond drink.

Questions for the Committee:

i). Do the Committee consider that, based on the available data, intakes of aflatoxins from the consumption of almond drink are of concern to the health of children ages 6 months to 5 years of age?

ii). Do the Committee consider that, based on the available data, intakes of cyanide from the consumption of almond are of concern to the health of children ages 6 months to 5 years of age if both sweet and almonds are used in almond drinks?

iii). Do the Committee consider the current government advice to be appropriate?

iv). Do the Committee have any other comments?

Secretariat
March 2020

[4] The Secretariat is in contact with almond drink manufacturers to establish whether routine monitoring is conducted and whether manufacturing methods would reduce the glycoside content.

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Discussion paper on the potential risks from almond drink consumption in children aged 6 months to 5 years of age.

Search strategy

Pubmed (2009 - current), google scholar (2009 – current) using the following search terms:

Search terms	Number of relevant hits from google scholar	Number of relevant hits from pub med
“Almond milk and glycosides”	1	0
“Almond milk and amygdalin”	0	0
“Almond drinks and glycosides”	0	0
“Heavy metals in almond milk”	0	0
“Pesticides in almond milk”	0	0
“chemical contaminants in almond milk”	0	0
“Almond milk and benzaldehyde”	0	0
“Almond milk and Propylene oxide”	0	0
“Almond milk and Aflatoxins”	2	0
“Almond milk and Carrageenan”	0	0
“Almond milk and Glyphosate”	0	0
“Almond milk and Cyanide toxicity”	0	0
“Almond milk and Polycyclic aromatic hydrocarbon”	0	0
“Almond milk and 7-methylbenzo(a)pyrene”	0	0