

Opinion of the Scientific Panel on Contaminants in the Food Chain on a request of the Commission related to concentration limits for boron and fluoride in natural mineral waters

(Question N° EFSA-Q-2003-21)

Adopted on 22 June 2005

SUMMARY

The Panel has been asked to advise on maximum concentrations of boron and fluoride in natural mineral waters that will not pose a health risk to consumers. The Scientific Panel on Dietetic Products, Nutrition, and Allergies (NDA) recently issued two opinions on the tolerable upper intake level (UL) for boron and fluoride. The CONTAM Panel based its advice on these UL values and did not re-evaluate these.

High consumption of mineral water ranges from 0.5 up to about 2 litres per day, based on data from 3 EU countries. The CONTAM Panel noted that for mineral water, brand loyalty of consumers is a key element to be taken into consideration and it has to be assumed that always the same brand is consumed by the same individual. Therefore, even when a brand represents a limited percentage of the market share, this brand may be consumed by a limited number of consumers that will include individuals with a high intake according to the distribution of intake seen for mineral water generally.

Taking into account the UL values of 10 mg boron per day for adults and 3, 4, 5, 7 and 9 mg boron per day for children aged 1-3, 4-6, 7-10, 11-14 and 15-17 years, respectively, the CONTAM Panel concluded that it is very unlikely that intake by the general population including children older than 14 years would exceed these levels even at the highest reported levels in bottled water. For children from 1 to 14 years of age, a maximum limit of 1.5 mg boron/l in bottled water would protect these children from exceeding the UL.

Calculating the dietary exposure of fluoride by combining a realistic high intake of mineral water of 1 litre/day with the maximum reported fluoride concentration (8 mg/l), the CONTAM Panel noted that the estimated exposure would exceed the UL for adults of 7 mg/person. The UL for a child of 1 to 3 years of age (1.4 mg/day) would be reached with the consumption of 200 ml of mineral water containing 8 mg/l. The Panel described scenarios for maximum limits for fluoride in mineral water. When a maximum limit of 1 mg/l is chosen, exposure to fluoride from bottled water in the whole population including young children would be unlikely to reach the UL values. When 5 mg/l is chosen as a maximum limit for fluoride, only the population of 15 years and older would be protected from exceeding the UL and only if exposure from other sources for this population would be negligible.

KEY WORDS

Boron, fluoride, natural mineral water, exposure assessment

BACKGROUND

Constituents may be present in the natural state of certain natural mineral waters because of their hydrogeological origin and may present a risk to public health above a certain concentration. It is therefore deemed necessary to establish concentration limits for these constituents in natural mineral waters.

Article 11 of Directive 80/777/EEC¹ makes provision for adopting harmonised concentration limits for the constituents of natural mineral waters after consulting the EFSA, and for labelling requirements to indicate, where applicable, the presence of certain constituents at high concentrations.

Commission Directive 2003/40/EC of 16 May 2003² has laid down concentration limits for a number of constituents.

No concentration limit was however fixed for boron. The Scientific Committee for Food (EC, 1996) had indicated 0.3 mg/l as a guide value for boron in natural mineral waters, based on the World Health Organization (WHO, 1993) recommendations. However, the WHO (1998) and other internationally recognised scientific organisations have since then made new appraisals of boron's effect on public health and have recommended higher values. It was therefore decided that the European Food Safety Authority would be consulted about boron in natural mineral waters so that the new scientific appraisals available can be taken into account and a maximum limit for boron was not set in the meantime.

It is generally acknowledged that a low-level fluoride intake can have a beneficial effect on teeth. By contrast, excessive fluoride intake can have harmful effects on public health. The WHO recommended a guide value of 1.5 mg/l for fluoride for drinking water, which was supported for natural mineral waters by the Scientific Committee for Food (EC, 1996). In order to protect infants and young children, who are the most sensitive to the risk of fluorosis, Directive 2003/40/EC² provides for a mandatory warning on the label of natural mineral water where the fluoride content exceeds 1.5 mg/l. It was also felt appropriate to lay down a harmonised maximum limit for fluoride in natural mineral waters to provide sufficient protection for the population as a whole. In this respect, account was taken of the values adopted by the U.S. Food and Drug Administration (4 mg/l) and by AFSSA (3 mg/l). A maximum limit of 5 mg/l was laid down in Directive 2003/40/EC², and it was agreed that the European Food Safety Authority would be requested to review this limit.

¹ OJ No L 229 of 30.8.1980, p. 1

² OJ No L 126 of 22.05.2003, p. 34

Community interest

Harmonised concentration limits for the constituents of natural mineral waters are necessary for the protection of public health and for the functioning of the internal market.

TERMS OF REFERENCE

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002³, the European Food Safety Authority is requested to advise on maximum concentrations of boron and fluoride in mineral waters that will not pose a health risk to consumers.

ASSESSMENT

Dietary exposure assessment

The Scientific Panel on Contaminants in the Food Chain (CONTAM) has been asked by the European Commission to advise on the maximum concentrations of boron and fluoride in mineral waters that will not pose a health risk to consumers. The Scientific Panel on Dietetic Products, Nutrition, and Allergies (NDA) recently issued two opinions on tolerable upper intake level (UL) for boron (EFSA, 2004) and fluoride (EFSA, 2005). The CONTAM Panel has based its advice on these UL values and did not re-evaluate these.

Bottled water consumption

The distribution of individual consumption of bottled water was extracted from national food consumption surveys in 3 Member States (Table 1), namely Italy (Turrini *et al.*, 2001), France (Volatier, 2000) and Sweden (Becker and Person, 2002). Those surveys are based on 7 days record for individuals. The average consumption of subjects having consumed bottled water during the survey (“consumers only”) was taken into account.

The CONTAM Panel noted that for mineral water, brand loyalty of consumers is a key element to be taken into consideration and that it has to be assumed that always the same brand is consumed. Therefore, even when a brand represents a limited percentage of the market share, this brand may be consumed by a limited number of consumers that will include individuals with a high intake according to the distribution of intake seen for mineral waters generally. The following exposure assessments will be conducted simulating alternatively 100 % of brand loyalty (a consumer is consuming always the same brand) and 50 % of brand loyalty (half of the consumption for a given consumer is of the same brand) in order to follow previous recommendations (Arcella *et al.*, 2003). Those two levels should be considered as the medium and upper bounds of the exposure because the assumption of 50 % of brand

³ OJ No L 031 of 01.02.2002, p. 16

loyalty assumes that the other 50 % of bottled water are not contributing at all to the total exposure.

Table 1: Consumption of bottled water (ml/day) for 3 countries (n = number of consumers over the considered percentile)

Country	Number of consumers	Mean (ml/day)	SD	90 th %tile (ml/day)	95 th %tile (ml/day)	97.5 th %tile (ml/day)	99 th %tile (ml/day)
France >15 years	1298	408	± 372	914 (n=129)	1109 (n=64)	1376 (n=32)	1672 (n=12)
France 3 to 15 years	771	273	± 260	583 (n=77)	783 (n=38)	939 (n=19)	1164 (n=7)
Italy	971	487	± 341	840 (n=97)	1000 (n=48)	1344 (n=24)	1938 (n=9)
Sweden	393	184	± 217	429 (n=39)	640 (n=19)	792 (n=9)	1029 (n=3)

Boron

The CONTAM Panel noted that the NDA Panel derived following UL values: 10 mg boron/person/day for adults based on the most sensitive end-point detected in animal studies, i.e. the NOAEL for decreased foetal body weight in rats following maternal exposure during pregnancy, and 3, 4, 5, 7 and 9 mg boron/day for children aged 1-3, 4-6, 7-10 11-14 and 15-17 years of age, respectively, derived by extrapolating from the UL for adults on a body surface area basis (EFSA, 2004). These UL values apply to the intake of boron in the form of boric acid and borates.

The highest percentile of bottled water consumption reported in Table 1 (1938 ml per day in Italy at the 99th percentile) was combined with the maximum reported level in mineral water (i.e. 4.3 mg/l) for boron assuming 100 % of brand loyalty. Even under those very conservative assumptions, the estimated exposure would not reach the UL of 10 mg/person/day for adults and of 9 mg/person/day for children older than 14 years. The CONTAM Panel concluded that it is very unlikely that for those populations, the dietary exposure to boron from bottled water and food will exceed the UL values.

For the population of children between 1 and 14 years of age for whom the UL ranges from 3 to 7 mg boron/day, different scenarios can be proposed: i) when assuming a similar consumption as adults (1938 ml per day) and 100 % of brand loyalty, a maximum limit of 1.5 mg per litre would protect all children (1 to 14 years of age) against exceeding the UL. ii) when assuming more realistically a consumption of 1 litre per day (95th percentile in Italy for adults + children and 97.5th percentile in France for children only) and a brand loyalty of

50%, a maximum concentration of 4.3 mg/l ($0.5 \text{ l} \times 4.3 \text{ mg/l} = 2.1 \text{ mg/day}$) would be unlikely to lead to exceed even the lowest UL value if the other sources of boron are not taken into account.

Fluoride

The CONTAM Panel noted that the NDA Panel derived following UL values: 5 mg fluoride/day for children 9-14 years of age and 7 mg fluoride/day for the population 15 years and older (adults), based on the most critical endpoint, bone fracture. An UL of 1.4 mg fluoride/day was established for children 1-3 years of age and 2.2 mg fluoride/day for children 4-8 years of age, based on the critical endpoint, moderate dental fluorosis (EFSA, 2005).

The various 97.5th percentiles⁴ reported in Table 1 were used assuming a similar water consumption across age groups. Two hypothesis of brand loyalty were applied namely 50 and 100 %. Under those assumptions, the daily consumption of bottled water ranges from 396 ml (97.5th percentile in Sweden with 50 % of brand loyalty) to 1376 ml (97.5th percentile in France with 100 % of brand loyalty). Those levels were combined with several concentrations for fluoride namely 1 mg/l, 1.5 mg/l (WHO guide value), 3 mg/l (AFSSA proposed value), 4 mg/l (FDA established value), 5 mg/l (EU maximum limit) and the maximum reported level in mineral water (i.e. 8 mg/l).

Results are summarised in Table 2 and show on the one hand that a limit of 5 mg/l would protect 97.5 % of the adult population 100 % brand loyal against exceeding the UL of 7 mg/day, if the exposure from other sources is not taken into account. On the other hand, a maximum limit of 1 mg/l would protect 97.5 % of the whole population including young children 100 % brand loyal against exceeding the UL of 1.4 mg fluoride/day if the exposure from other sources is not taken into account.

Table 2: Exposure assessment scenarios for fluoride from bottled water (in mg/day/person) using 97.5th percentile for bottled water consumption in 3 EU countries (see Table 1), two levels of brand loyalty and 6 levels of fluoride in water.

Consumption (ml/day)	Fluoride content (mg/l)					
	1	1.5	3	4	5	8
396	0.4	0.6	1.2	1.6	2	3.2
1376	1.3	1.9	3.8	5.2	6.5	10.4

⁴ The 97.5th percentile was chosen because there were enough consumers to allow a statistical analysis.

The CONTAM Panel noted several exposure scenarios to ensure not to exceed the UL values depending on the population considered and the context these mineral waters are consumed:

Scenario 1: The CONTAM Panel concluded that a maximum limit of 5 mg fluoride/l in bottled water would protect only the population over 15 years old and only if there was no exposure to fluoride from other sources.

Scenario 2: Based on the most critical endpoint (bone fracture) for the population of 9 years and older consuming regularly the same brand (or type) of mineral water, the CONTAM Panel noted that a maximum limit of 3 mg fluoride/l in mineral water would lead to an exposure to fluoride from bottled water below 4 mg/day and, therefore, would allow for exposure to fluoride from other sources, e.g. 1 mg fluoride/day for the age group 9 to 14 years and 3 mg fluoride/day for the population of 15 years and older, respectively.

Scenario 3: The CONTAM Panel concluded that a maximum limit of 1.5 mg fluoride/l in bottled water would protect only children older than 3 years old and only if there was no exposure to fluoride from other sources.

Scenario 4: Considering the population of children below 3 years of age for whom an UL of 1.4 mg/day was established based on the critical endpoint of moderate dental fluorosis and assuming that this population is consuming regularly the same brand (or type) of mineral water, the CONTAM Panel concluded that a maximum limit of 1 mg fluoride/l in mineral water would lead to an exposure to fluoride from bottled water around the UL. Considering the conservative assumptions made to build the model, the total exposure to fluoride from all food sources would be unlikely to reach the UL.

The CONTAM Panel noted that with scenario 1 and 2, children of 1 to 8 years of age will exceed the UL values. When drinking such mineral water on a regularly basis these children will have a risk of developing moderate dental fluorosis.

CONCLUSIONS

High consumption of mineral water ranges from 0.5 up to about 2 litres per day based on data from 3 EU countries.

The CONTAM Panel noted that for mineral water, brand loyalty of consumers is a key element to be taken into consideration and that it has to be assumed that always the same brand is consumed by the same individual. Therefore, even when a brand represents a limited percentage of the market share, this brand may be consumed by a limited number of consumers that will include individuals with a high intake according to the distribution of intake seen for mineral water generally.

For boron, the CONTAM Panel concluded that it is very unlikely that the general population including children older than 14 years are exceeding their respective UL values even at the

highest reported boron concentrations in bottled water. For children from 1 to 14 years of age, a maximum limit of 1.5 mg boron/l would protect these children from exceeding the UL values.

For fluoride, the CONTAM Panel noted that the estimated exposure would exceed the UL for adults of 7 mg/person when calculating the dietary exposure of fluoride by combining a realistic high intake of mineral water of around 1 litre/day with the maximum reported fluoride concentration (8 mg/l). The UL for a child of 1 to 3 years of age (1.4 mg/day) would be reached with the consumption of 200 ml of mineral water containing 8 mg/l. The Panel further noted that this calculation does not take into account exposure from other sources. The Panel described 4 scenarios for setting maximum limits for fluoride in mineral water. When a maximum limit of 1 mg/l is chosen, exposure to fluoride in the whole population including young children from all sources would be unlikely to reach the UL values while when 5 mg/l is chosen as a maximum limit for fluoride, only the population of 15 years and older would be protected from exceeding the UL and only if exposure from other sources for this population would be negligible.

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