

QUILLAIA EXTRACT TYPE 1 (addendum)

First draft prepared by

Dr P. Verger¹ and Dr M. DiNov²

¹Institut National de la Recherche Agronomique, Paris, France; and

²US Food and Drug Administration, College Park, Maryland, USA

Background	63
Proposed use	64
New information submitted	64
'Frozen novelties' as surrogates for frozen carbonated beverages	64
Frequency and amount of frozen carbonated beverages purchased	64
Assessment of dietary exposure	65
Assessment based on model diets	65
Assessment based on probabilistic approach	65
References	66

1. BACKGROUND

Quillaia extracts can be used as foaming agents in soft drinks and cocktail mixes and as emulsifiers in foods such as baked goods, sweets, frozen dairy products, gelatine and puddings. Their main food use is in soft drinks. The Codex Alimentarius has adopted a recommendation for use of quillaia extract as a foaming agent at a level of 100 mg/kg in food category 14.1.4, 'water-based flavoured drinks'. The exposure estimates considered previously by the Committee did not explicitly consider use of quillaia extract in semi-frozen carbonated and non-carbonated beverages; therefore, the Codex Committee on Food Additives and Contaminants requested information on use of concentrations up to 500 mg/kg in these products.

Quillaia extracts were considered previously by the Committee, at its 26th, 29th, 57th and 61st meetings (Annex 1, references 59, 70, 154 and 166). At its 57th meeting, the Committee assessed all relevant information on toxicity with information on dietary intake and allocated a temporary ADI of 0–5 mg/kg bw for the unpurified extract, pending clarification of the specifications. At its sixty-first meeting, the Committee reviewed new information relating to the chemical characterization of quillaia extracts and further information on the specifications. The Committee agreed that separate specifications were needed for the two forms of quillaia extract, type 1 ('unpurified') and type 2 ('semi-purified') and also concluded that the data submitted for toxicological and dietary exposure assessment were specific to material described as type-1 extract. The 'temporary' assignment to the ADI of 0–5 mg/kg bw was therefore removed. The Committee at its fifty-seventh meeting estimated dietary exposure to quillaia extracts by a stepwise procedure, assuming a concentration of 500 mg in all water-based flavoured drinks. On the basis of this use level, the Committee concluded that exposure at the 95th percentile of the distribution of consumption of soft drinks, particularly by children, could exceed the ADI. Estimates

of exposure based on consumption of soft drinks in the USA likely to contain quillaia extracts at a level of 100 mg/kg were below the ADI.

2. PROPOSED USE

The composition of semi-frozen carbonated and non-carbonated beverages is essentially similar to that of the corresponding unfrozen beverages, except for the addition of foaming agents and of carbonation or air to increase the volume, thus reducing the specific gravity of the dispensed beverage. They are made in retail establishments from beverage concentrates with unique equipment that resembles ice-cream machines, which inject water and CO₂ or air. Quillaia extract is added to create a soft or creamy-textured beverage that is light and fluffy. It is the key factor in the proper mixing of ingredients, in the formation of the foam and in dispersion of the foam throughout the beverage. Furthermore, quillaia helps to keep the beverage from forming a solid block of ice in the machine and in maximizing the smooth texture of the ice crystals in the beverage. Carbonation or air increases the volume of the original unfrozen beverage up to 180%, essentially doubling the melted volume. The typical density provided by the petitioner for the final beverage ranges from 530 to 590 g/l.

Frozen carbonated beverages are offered for sale in the same range of container sizes as those used for dispensed unfrozen beverages (e.g. soft drinks) in the same establishments. Therefore, the volume purchased is similar to that of unfrozen beverages, but the amount of dried quillaia extract present in the product as consumed is lower owing to expansion. As the volume expansion is somewhat variable because of differences among machines, the petitioner conservatively used the upper end of the range of typical density values for frozen carbonated beverages in this exposure assessment, i.e. 0.590 kg/l. Therefore, a use level of 500 mg/kg in unexpanded frozen carbonated beverages corresponds to 295 mg quillaia extract per litre of frozen carbonated beverages as consumed.

3. NEW INFORMATION SUBMITTED

3.1 'Frozen novelties' as surrogates for frozen carbonated beverages

The petitioner provided data on consumption of 'frozen novelties' in the USA (Table 1). Frozen novelties differ from frozen carbonated beverages in that they are denser, i.e. contain less air. The average daily exposure to quillaia extracts is based on 2-day individual dietary records for consumption of frozen novelties. The amount of surrogate frozen novelties consumed per eating occasion was also provided (United States Department of Agriculture, 2000).

3.2 Frequency and amount of frozen carbonated beverages purchased

The petitioner submitted information from a market survey in the USA on the frequency of purchase and consumption of frozen carbonated beverages. The two surveys were too dissimilar to be merged. In particular, the first (Table 2) was performed in November 2002, while the second (Table 3) was conducted in spring 2002. In addition, the amount of quillaia ingested per eating occasion was estimated

Table 1. Distribution of amount of frozen carbonated beverages surrogate 'frozen novelties' consumed per eating occasion in the total population of the USA

Amount frozen carbonated beverages consumed (g per eating occasion)	Percentile
97.1	10
145.2	20
190.6	25
192	30
193.9	40
276.4	50
289.5	60
384	70
385	75
387	80
524	90
719	95
963	98
1062	99
1066	99.5
1158	99.9

From United States Department of Agriculture (2000). The unweighted total number of eating occasions and associated person-days of consumption were 253 and 244, respectively

from container sizes, which range from 8 to 64 fluid ounces, corresponding to 240–1900 ml. These amounts correspond to 70–558 mg of quillaia or 23–186 % of the current ADI per eating occasion.

Table 2. Frequency of consumption of frozen carbonated beverages

Frequency (eating occasions/year)	% of consumers
≥ once a day	15
4–6 times per week	9
1–3 times per week	13
Once a week	12
2–3 times a month	23
≤ once a month	28

Dataset 1; n = 463; International Council of Beverages Associations (2002a)

Table 3. Frequency of consumption of frozen carbonated beverages

Frequency (eating occasions/year)	% of consumers
> once a week	10
Once a week	14.8
Once per 2–3 weeks	19
Once a month	26.8
< once a month	29.5

Dataset 2; n = 400; International Council of Beverages Associations (2002b)

4. ASSESSMENT OF DIETARY EXPOSURE

4.1 Assessment based on model diets

The conclusions of the previous assessment were considered still valid in principle. Nevertheless, for the current assessment and as mentioned above, the concentration of quillaia considered was 295 mg/l in ready-to-drink frozen carbonated beverages. In addition, it was assumed that frozen carbonated beverages are drunk in the same volume as other beverages, even if they are less dense.

The consumption figures used previously for all soft drinks ranged from 640 ml/day for adults at the 97.5th percentile in the United Kingdom to 1600 ml/day for the whole population of Australia and New Zealand at the 95th percentile. The 97.5th percentile consumption for children in the United Kingdom was 800 ml/day. These figures were not updated for the current report as they are consistent with recently reported 97.5th percentile levels in Europe and for consumers only in Italy (Turrini et al., 2001), France (Volatier, 2000) and Sweden (Becker & Pearson, 2002), which are 446 ml/day, 556 ml/day and 946 ml/day, respectively. In the USA, dietary exposure to quillaia extracts was estimated by using frozen novelties as a surrogate for frozen carbonated beverages. Consumption of these beverages is 524 and 719 g/day, equivalent to a similar volume in millilitres at the 90th and 95th percentiles of consumers only. In view of the differences in the methods used, all the reported figures were considered to be consistent. The range would therefore be 0.5–1.5 l/day per high consumer around the world.

If it is assumed that there are 295 mg/l of quillaia extract in the final product, consumption of 446, 524, 556, 640, 719, 800, 946 and 1600 ml would correspond to exposure to quillaia extract of 131–472 mg/day, i.e. 44–157 % of the current ADI of 0–5 mg/kg bw.

In this assessment, we assumed that frozen carbonated beverages are the only source of quillaia extracts, as no data were submitted about concentrations in solid foods. It is unlikely that a high consumer of frozen carbonated beverages would also consume other beverages containing the same additive, but no data were available.

4.2 Assessment based on probabilistic approach

The previous estimate indicates that, independently of the surrogate used for the assessment, high consumers drink similar amounts of soft drinks. The probabilistic approach is the best means of estimating the number of consumers highly exposed to a specific beverage. The petitioner combined the frequency of consumption of frozen carbonated beverages with the amounts of frozen carbonated beverages and frozen novelties consumed, using a Monte Carlo simulation. In this exercise, the petitioner assumed that frequency and amount are independent variables and combined the two distributions randomly. The highest percentile reported was the 90th, which is adequate from a statistical point of view, considering the number of persons in each study (244 consumers of frozen novelties and 463 for the frequency of consumption of frozen carbonated beverages). Under those conditions, dietary exposure to quillaia extracts would be below the ADI of 0–5 mg/kg bw.

The hypothesis of independence between the amount consumed and the frequency of consumption cannot be verified from the available information. Therefore, a scenario in which a high consumer is also a frequent consumer cannot be excluded. The largest amount of frozen carbonated beverages that could be consumed on one eating occasion is 1900 ml. With the surrogate approach of frozen novelties, the highest reported consumption would be 524, 719, 963 and 1062 ml at the 90th, 95th, 98th and 99th percentiles, respectively, while consumption of 1 l of beverage would be necessary to reach the ADI for a person weighing 60 kg bw.

If 100% dependency is assumed between the frequency and the amount consumed, it is possible to estimate the number of consumers likely to be at risk for overstepping the current ADI of 0–5 mg/kg bw. Frozen carbonated beverages are consumed in the USA by 1–7% of the total population, corresponding to 10 000–70 000 consumers per million. Of those consumers, 15% regularly consume frozen carbonated beverages at least once a day, which corresponds to 1500–10 500 persons per million, and 1% drink more than 1 l/day, which corresponds to 15–100 persons per million in the entire population.

5. REFERENCES

- Becker, W. & Pearson, M. (2002) [*Dietary habits and nutrient intake in Sweden 1997–98*]. Uppsala, Livsmedelsverket (in Swedish).
- International Council of Beverages Associations (2002b) Unpublished document.
- International Council of Beverages Associations (2002b) Unpublished document.
- Turrini, A., Saba, A., Perrone, D., Cialfa, E. & D'Amicis, A. (2001) Specific elaboration of the data derived from the food survey INN-CA96-98: Food consumption patterns in Italy: the INN-CA Study 1994–1996. *Eur. J. Clin. Nutr.*, **55**, 571–588.
- United States Department of Agriculture (2000) *CSFII Data Set and Documentation: The 1994–96, 1998 Continuing Surveys of Food Intakes by Individuals*, Food Surveys Research group, Beltsville, Human Nutrition Research Center, Agricultural Research Station
- Volatier, J.-L. (2000) [*Individual, national enquiry on food consumption*]. Paris, Editions TEC et DOC (in French).