LCBO

Discover the World

December 19, 2006

Mr. John Manfreda
Administrator
Alcohol and Tobacco Tax and Trade Bureau
U.S. Treasury
650 Massachusetts Avenue, NW
Washington, DC 20226

Dear Mr. Manfreda,

Re: Comments in Response to Notice No. 62 71 FR 42329 – July 26, 2006

We appreciate the opportunity to comment on the proposed regulations on "Major Food Allergen Labeling for Wines, Distilled Spirits and Malt Beverages".

As the importer of record of beverage alcohol in the province of Ontario, we are concerned that the proposed regulations could mislead the consumer and will not provide the consumer with adequate information as to the correct identity and quality of the products.

The proposed labeling requirement for allergens is mandated of the fact that processing aids are used and designed to be absent from the final product, and if used and removed according to good manufacturing practice, the final concentration of these substances in the wine, if present at all, is likely to be extremely low due to the removal of precipitates through the clarification process.

There is no published literature available on the concentration of these proteinaceous fining agents in the finished wine; however, there are commercially available assays to measure their concentration in foods – ELISA and PCR. Unfortunately the lower level of sensitivity of both of these assays is generally at the mg/L level, which is approximately 100-fold higher than the likely level of processing aid residue in wine when GMP is adopted.

Furthermore, there is no reliable scientific data on the human threshold limits to sensitivity of these potential allergens, other than the study published by J. M. Rolland, et. al., *Nutrition* 22 (2006), 882-885 from Monash University, Melbourne, Australia.

The justification for your proposed regulations relies heavily on anecdotal evidence of adverse allergic reactions. In this respect, we believe that we can provide you with substantial, objective information from our consumer complaint database regarding whether wine that we import poses an allergen risk.

The LCBO is a provincial government enterprise reporting to the Minister of Infrastructure Renewal. It is one of the world's largest retailers of beverage alcohol, importing products from over sixty countries world wide with a retail network of more than 800 stores in the province of Ontario, Canada. Net sales in 2005/06 were at $3.68 billion CDN which represented 51.2% of the Ontario beverage market share. Total volume sales for the same year were 388,733,000 litres of which 14% represented spirits, 29% wine, 49% beer and 8% ready to drink beverages. During this same period, more than $240 million of revenue was due to USA beverage alcohol sales, of which approximately 46% was from wine.

On a given year the LCBO retails either through its stores or through private stock/direct delivery/virtual offer programs more than 12,000 brands of beverage alcohol products of which approximately 75% represents wines, 10% spirits and the balance beer and ready-to-drink products. One of the primary reasons of this amazing selection of products is the demographics of our consumer base, which represents a multicultural society of more than 100 nationalities.

The LCBO is committed to retailing products of good quality, authentic and free of any contaminants, and as such all products listed by the LCBO are stringently evaluated for taste and appearance and chemically tested by its state-of-the-art Quality Assurance testing facilities.

Quality Assurance is also responsible for monitoring and investigating all customer complaints.

LCBO classifies customer complaints into two categories; complaints of a general nature and complaints requiring investigation. Complaints of a general nature are open bottles returned to an LCBO retail outlet for reasons of off taste, off odour, off colour, foreign matter or other, e.g., faulty package. The customer is issued a refund for their purchase and the complaint information is keyed into our Point of Sale (POS) system. Complaint data is transmitted nightly to our corporate mainframe and reconciled on a weekly basis. Statistical reports comparing the ratio of total complaints received, by Stock Keeping Unit (SKU), to the actual sales are generated and reviewed to identify possible product quality problems.

Complaints requiring investigation are complaints of alleged illness, personal injury or property damage. Retail staff notifies Quality Assurance immediately upon receipt of the complaint and arrangements are made to have the customer's sample forwarded for investigation. The steps taken to investigate the complaint are dependent on the nature of the complaint and the condition of the sample. Sensory evaluation, laboratory and packaging testing may be conducted. The customer is provided with a written report at the conclusion of the complaint.

In reviewing our Customer Complaint data base year-to-date since the year 2000, we have recorded 486,535 customer complaints. Of the total number of complaints, 1,344 (0.28%) were investigated by QA, of which 337 (0.07%) were of an alleged illness related nature.

One (1) complaint was specifically identified as an allergic reaction confirmed by a physician at a hospital emergency. The product consumed was a liquor type (Amaro Feltsina Ramazzotte). This product contains a mixture of several herbs, including "chinarinde", a source of quinine.

The possible side effects of quinine are well documented. The symptoms described by this customer, swelling of the lips & face and hives, are the classic symptoms of an allergic reaction to quinine.

Considering our total volume sales, the demographics of our customer base and the large selection of products we retail, we can postulate that the lack of any substantiated adverse allergic reactions to wine products in the last approximately six years, provides strong evidence that legally permitted additives and processing aids for wine-making, present virtually no risk of severe adverse reaction such as anaphylaxis.

As a consequence of the lack of data available on the residual of processing aids in wine and the inability to accurately and sensitively measure the residual at present as well as the lack of data on harm (human threshold limits to sensitivity), such regulations would be technically of no additional value to consumers and practically impossible to enforce at any level.

In order to avoid unnecessary expenses at all levels, we would suggest a delay in the implementation of such legislation until all of the above concerns are reasonably addressed.

Thank you for allowing us to submit our comments and we appreciate the granting of the extension on the comment period.

We would be happy to respond to any questions you may have as related to our comments.

Sincerely yours,

George Soleas, M.Sc., Ph.D., MCIC
Vice President, Quality Assurance