



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Ethyl Carbamate in Alcoholic Beverages and Vinegars - April 1, 2018 to March 31, 2019

Food chemistry - Targeted surveys - Final report



Summary

Targeted surveys provide information on potential food hazards and enhance the Canadian Food Inspection Agency's (CFIA's) routine monitoring programs. These surveys provide evidence regarding the safety of the food supply, identify potential emerging hazards, and contribute new information and data to food categories where it may be limited or non-existent. They are often used by the Agency to focus surveillance on potential areas of higher risk. Surveys can also help to identify trends and provide information about how industry complies with Canadian regulations.

Ethyl carbamate (EC) is a chemical that unintentionally forms during the fermentation process. It can be found in alcoholic beverages such as wine, beer, spirits, and fermented foods such as bread and yogurt¹. EC levels in alcoholic beverages and vinegars can be affected by a wide range of factors, including storage temperature, strain of yeast used, crop fertilization and exposure to sunlight^{2,3,4,5,6,7}. This compound is classified as 'probably carcinogenic to humans' by the International Agency for Research on Cancer (IARC)⁸, and therefore may pose a health risk to the consumer.

This targeted survey generated further baseline surveillance data on the occurrence of EC in domestic and imported products on the Canadian market. The CFIA sampled and analyzed 390 products, including 125 beer, 17 sake, 117 spirit and liqueur, 125 vinegar and 6 wine samples. EC was detected in 9.5% of samples tested, with levels ranging from 4 ppb to 135 ppb. Comparison of the survey results to previous surveys and scientific literature showed that the levels of EC in Canadian retail products are similar to those reported in a variety of scientific studies.

In all sake, wine, spirit and liqueur samples, the levels of EC met Maximum Limits (MLs) established by Health Canada (HC)⁹. There are no regulations in Canada for EC levels in beer and vinegar, so levels were assessed by HC on a case-by-case basis using the most current scientific data. HC determined the levels of EC in food observed in this survey are not expected to pose a concern to human health, therefore there were no follow-up actions resulting from this survey.

What are targeted surveys

Targeted surveys are used by the CFIA to focus its surveillance activities on areas of highest health risk. The information gained from these surveys provides support for the allocation and prioritization of the Agency's activities to areas of greater concern. Originally started as a project under the Food Safety Action Plan (FSAP), targeted surveys have been embedded in our regular surveillance activities since 2013. Targeted surveys are a valuable tool for generating information on certain hazards in foods, identifying and characterizing new and emerging hazards, informing trend analysis, prompting and refining health risk assessments, highlighting potential contamination issues, as well as assessing and promoting compliance with Canadian regulations.

Food safety is a shared responsibility. We work with federal, provincial, territorial and municipal governments and provide regulatory oversight of the food industry to promote safe handling of foods throughout the food production chain. The food industry and retail sectors in Canada are responsible for the food they produce and sell, while individual consumers are responsible for the safe handling of the food they have in their possession.

Why did we conduct this survey

The main objectives of this targeted survey were to generate further baseline surveillance data on the level of EC in alcoholic beverages and vinegars available on the Canadian retail market, and to compare the prevalence of EC in foods targeted in this survey with that of similar products in other targeted surveys and scientific literature.

EC is formed unintentionally during fermentation by the spontaneous reaction of urea and ethanol. During fermentation, some strains of yeast naturally produce urea and ethanol, which can react together to form EC^{3,4}. Excessive fertilization with urea and other nitrogen fertilizers has also been linked to higher concentrations in fermented products made from grapes⁵. Other factors that can affect EC levels include cooling time during the fermentation process as well as temperature and exposure to ultra-violet (UV) light during storage^{2,6}.

EC is classified as 'probably carcinogenic to humans' by the International Agency for Research on Cancer (IARC)⁸. As such, Health Canada (HC) has set in place Maximum Levels (ML) for EC in various alcoholic beverages including sake, spirits, liqueur and wine⁹. Due to this potential health risk, the CFIA considered it important to examine EC levels in alcoholic beverages and vinegars available on the Canadian retail market.

What did we sample

A variety of domestic and imported alcoholic beverages and vinegars were sampled between April 1, 2018 and March 21, 2019. Samples of products were collected from local/regional retail locations located in 6 major cities across Canada. These cities encompassed 4 Canadian geographical areas: Atlantic (Halifax), Quebec (Montreal), Ontario (Toronto, Ottawa) and the West (Vancouver, and Calgary). The number of samples collected from these cities was in proportion to the relative population of the respective areas. The shelf life, storage conditions, and the cost of the food on the open market were not considered in this survey.

Table 1. Distribution of samples based on product type and origin

Product type	Number of domestic samples	Number of imported samples	Number of samples of unspecified ^a origin	Total number of samples
Beer	54	49	22	125
Sake	0	17	0	17
Spirits and liqueurs	36	63	18	117
Vinegar	12	64	49	125
Wine	1	5	0	6
Grand total	103	198	89	390

^a Unspecified refers to those samples for which the country of origin could not be assigned from the product label or available sample information

How were samples analyzed and assessed

Samples were analyzed by an ISO 17025 accredited food testing laboratory under contract with the Government of Canada. The results are based on the food products as sold and not necessarily as they would be consumed.

Chemical contaminants in foods have regulatory MLs established by HC. Compliance is assessed against the established ML available when the survey was carried out. In the absence of a specific ML, the levels of EC may be assessed by HC on a case-by-case basis using the most current scientific data. Any high results of EC are reviewed by Health Canada's Bureau of Chemical Safety to determine if the levels are harmful to consumers.

What were the survey results

Of the 390 samples tested, most (90.5%) did not have detected levels of EC. Among all alcoholic beverages sampled in this survey, there did not appear to be any relationship between alcohol content by volume (ABV) and EC level. Table 2 illustrates the range of concentrations detected in the survey samples by product type.

Table 2. Summary of targeted survey results on ethyl carbamate in selected fermented foods

Product type	Number of samples	Number of samples (%) with detected levels	Minimum (ppb)	Maximum (ppb)	Average ^b (ppb)
Beer	125	2 (1.6)	4	4	4
Sake	17	3 (18)	7	33	15.7
Spirits and liqueurs	117	23 (20)	4	42	12.3
Vinegar	125	6 (5)	6	135	29.5
Wine	6	3 (50)	17	86	40
Grand Total	390	37 (9)	4	135	17.2

^bOnly positive results were used to calculate the average (hazard) levels

Of 125 beers sampled, only 2 had detected levels of EC, the lowest detection rate of product types included in this survey. Wines sampled in this survey had the highest detection rate (50%) compared to other product types (5-20%), although the sample size was small.

Most (95%) sampled vinegars did not have detected levels of EC. One apple cider vinegar sample contained 135 ppb, the highest in this survey. Although the reported average among vinegar samples was 29.5 ppb, when the single 135 ppb sample is excluded, all other vinegar samples contained 13 ppb or less.

What do the survey results mean

For some product groups, the results from this survey were comparable to those found in previous surveys and in scientific literature (Table 3).

Beers sampled in this survey and in the literature had a detection rate of less than 10%. It was also common among surveys included in Table 3 for average EC levels in beer to be less than those of other product types tested.

Among sakes sampled in the CFIA's 2017 to 2018 and 2018 to 2019 targeted surveys, only 10% and 18% had detected EC levels¹³. In other surveys, all sake samples had detected levels of EC^{7,12,14}. The average concentration in sakes in this survey was similar to that of the previous year's survey, and lower than that of other surveys. Spirits and liqueurs sampled in this survey reported a lower detection rate than that of the previous year and other studies in the literature. Among sampled wines, the detection rate in this survey was higher than the 2017 to 2018 survey, but lower than other studies in the literature^{7,11,12,13,14}.

Table 3. Minimum, maximum and average concentration of alcoholic beverages and vinegars across various studies

Product type	Study	Number of samples	Minimum (ppb)	Maximum (ppb)	Average (ppb)
Beers	CFIA survey, 2018 to 2019	125	4	4	4 ^d
Beers	Hong Kong CFS (2009a)	15	0	5.8	1.13
Beers	EFSA survey (2007)	1208	0	33	5 ^e
Beers	Bondu et al. (2004)	9	0	0	0
Sake	CFIA survey, 2018 to 2019	17	7	33	15.7 ^d
Sake	CFIA survey, 2017 to 2018	10	19	19	19
Sake	Hong Kong CFS (2009a)	9	2	330	74.7
Sake	Bondu et al. (2004)	2	81	164	123
Sake	Chung et al. (2000)	9	2	330	74.7
Spirits and liqueurs	CFIA survey, 2018 to 2019	117	4	42	12.3 ^d
Spirits and liqueurs	CFIA survey, 2017 to 2018	57	4	84.5	16.8 ^d
Spirits and liqueurs	EFSA survey (2007)	2318	0	1060	32 ^e
Spirits and liqueurs	Bondu et al. (2004)	9	12	6131	724 ^d
Vinegars	CFIA survey, 2018 to 2019	125	6	135	29.5 ^d
Vinegars	Hong Kong CFS (2009a)	18	0	37	9.32
Vinegars	Bondu et al. (2004)	10	33	33	33
Vinegars	Chung et al. (2000)	5	0.3	2.5	1.2
Wine	CFIA survey, 2018 to 2019	6	17	86	40.0
Wine	CFIA survey, 2017 to 2018	28	7	35	21 ^d
Wine	Hong Kong CFS (2009a)	23278	0	180	7 ^e
Wine	Bondu et al. (2004)	13	11	24	-
Plum Wine	Chung et al. (2000)	5	0.4	230	110

^dOnly positive results were used to calculate the average (hazard) levels

^eSamples with no detectable levels set to LOD for calculation of average.

In this survey and other surveys, a wide variety of EC levels were observed within wines, spirits and liqueurs. Among wines, this variance might be due to differences in crop fertilization⁵, strain of yeast used for fermentation⁴, storage time, storage temperature or cooling time after fermentation². Among spirits and liqueurs, differences in EC levels could be due to the quality of the raw material; hygiene during fermentation, distillation or storage; and exposure to ultra-violet light during storage^{6,10}.

A single sample of apple cider vinegar had the highest EC level of all products sampled in this survey. However, another sample of the same product with a different lot number did not contain a detectable level. The variance between these 2 lots could be due to slight differences in manufacturing or storage.

In all sake, wine, spirit and liqueur samples, the levels of EC met MLs established by HC. There are no regulations in Canada for EC levels in beer and vinegar. All levels of EC found in the products tested in this survey were deemed safe for consumption by Canadians and no product recalls were required. Future EC surveys will look to broaden the CFIA's baseline knowledge on the levels present in fermented vegetable products and fermented soy products.

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