

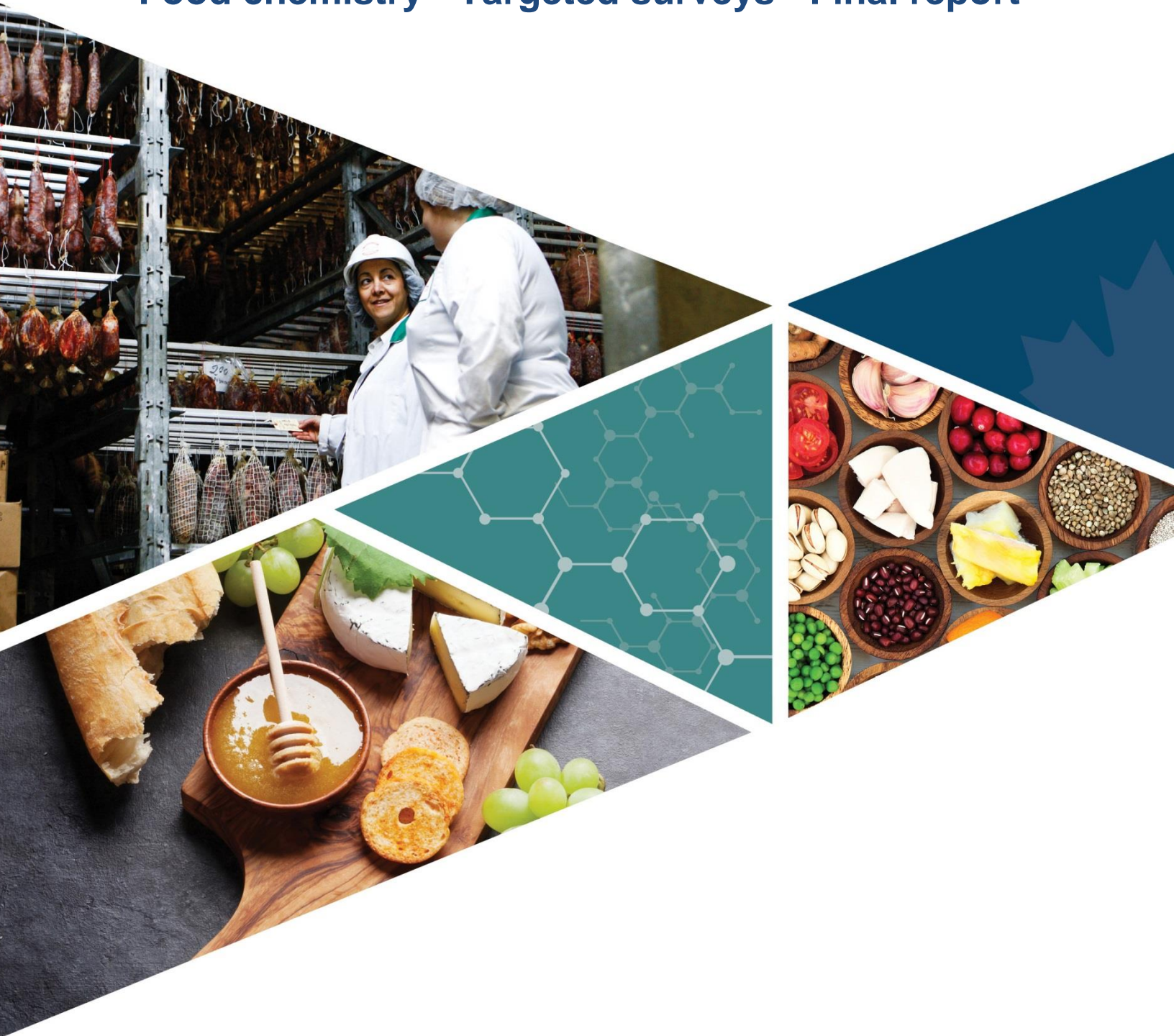


Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Ethyl Carbamate in Fermented Vegetables and Soy Products - April 1, 2019 to March 31, 2020

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 and fermented foods such as bread, yogurt, soy products and fermented vegetables^{1,2,3}. EC levels in these products can be affected by a wide range of factors, including processing and storage temperature, strain of yeast used, crop fertilization and exposure to sunlight^{2,3,4,5,6}. This compound is classified as 'probably carcinogenic to humans' by the International Agency for Research on Cancer (IARC)⁷, 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 300 fermented products, including 200 vegetable samples and 100 soy samples. EC was detected in 3% of the samples tested, with levels ranging from 4 parts per billion (ppb) to 217 ppb. The highest levels of EC were reported in bean curd samples. 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.

Health Canada 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 fermented vegetables and soy products 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}. EC levels in foods can be affected by a wide range of factors, including processing and storage temperature, strain of yeast present, crop fertilization and exposure to sunlight^{2,3,4,5,6}.

EC is classified as 'probably carcinogenic to humans' by the International Agency for Research on Cancer (IARC)⁷. As such, Health Canada has set in place Maximum Levels (ML) for EC in various alcoholic beverages including sake, spirits, liqueurs and wine⁸. Due to this potential health risk, the CFIA considered it important to examine EC levels in other fermented foods available on the Canadian retail market.

What did we sample

A variety of domestic and imported fermented products including fermented vegetables (kimchi, pickles/gherkins, sauerkraut) and soy products (tofu/bean curd, tempeh, miso, soybean paste, etc.) were sampled between April 1, 2019 and March 31, 2020. Samples of products were collected from local/regional retail locations located in 11 major cities across Canada. These cities encompassed 4 Canadian geographical areas:

- Atlantic (Halifax and Moncton)
- Quebec (Montreal and Quebec City)
- Ontario (Toronto and Ottawa)
- West (Calgary, Saskatoon, Vancouver, Victoria and Winnipeg)

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 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
Fermented vegetables	49	143	8	200
Soy products	16	69	15	100
Total	65	212	23	300

^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 Health Canada. 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 Health Canada 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 300 samples tested, most (97%) did not have detected levels of EC. 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)
Fermented vegetables	200	3 (1.5)	4	9	6.3
Soy products	100	6 (6)	7	217	108
Total	300	9 (3)	4	217	74

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

Of 200 fermented vegetables samples tested, EC was detected in only 3 samples at low levels. Of the positive samples, 2 were samples of the same brand of sauerkraut and 1 was a sample of kimchi.

Most (93%) soy products sampled did not have detected levels of EC. EC was detected in 5 bean curd samples and 1 miso sample. The average level of EC in soy product was 108 ppb with a maximum of 217 ppb.

What do the survey results mean

The main objectives of this targeted survey were to expand upon the baseline data regarding the levels of EC in selected fermented foods on the Canadian retail market. The detection rates and the levels recorded for EC in the products tested in this targeted survey were comparable to those previously found in similar product types in previous surveys and in the scientific literature (Table 3)^{9,10,11,12,13}. Some differences observed may be due to the specific type of product tested or sample size.

There was limited literature available for comparison of the survey results on EC in fermented vegetables. The levels of EC observed in this survey were within the range reported in the literature in similar products^{10,11,12,13}. The larger sample size in this survey confirms that the occurrence of EC in fermented vegetable product available on the Canadian market is low.

The range of the EC levels observed in soy products was comparable to that found in previous survey years and closely matched the average level of EC in soy products reported in the literature^{9,10}. The low detection rate in this survey (6%) was also in close agreement with that previously reported in 2016 (11%)⁹. The highest levels of EC reported in this survey were in bean curd, which is within the range reported in the literature^{10,11}.

Table 3. Minimum, maximum and average concentration of fermented vegetables and soy products across various studies

Product type	Study	Number of samples	Minimum (ppb)	Maximum (ppb)	Average (ppb)
Fermented vegetables	CFIA survey, 2019	200	4	9	6.3 ^c
Kimchi	Kim et al., 2000	5	ND ^d	3.8	0.96 ^e
Sauerkraut	Hasnip et al., 2007	1	29	29	29
Pickled vegetables	Lei et al., 2012	5	40	96	71 ^c
Soy products	CFIA survey, 2019	100	7	217	108 ^c
Soy products	CFIA survey, 2016	92	7	328	89 ^c
Soy products	Kim et al., 2000	20	ND ^d	650	121 ^e

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

^d ND: non-detect

^e The value of 1/2 LOD was assigned to non-detects (results below limit of detection) for the calculation of mean levels

Health Canada 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. Future EC surveys will look to broaden the CFIA's baseline knowledge on the levels present in fermented soy products, vinegars and beverages.

References

1. [Archived – Food and Manufactured Food Program Inspection Manual. Chapter 4: Food Safety Hazards.](#) (2014). Canada. Canadian Food Inspection Agency.
2. [Opinion of the Scientific Panel on Contaminants in the Food Chain on a Request from The European Commission on Ethyl Carbamate and Hydrocyanic Acid in Food and Beverages.](#) (2007). The EFSA Journal, 551, pp. 1-44.
3. [Ethyl Carbamate in Local Fermented Foods.](#) (2009a). Hong Kong. Centre for Food Safety.
4. Crowell, E.A., Mooney, L.A., Ough, C.S. (1988). [Formation of Ethyl Carbamate Precursors During Grape Juice \(Chardonnay\) Fermentation. I. Addition of Amino Acids, Urea, and Ammonia: Effects of Fortification on Intracellular and Extracellular Precursors.](#) American Journal of Enology and Viticulture, 39, pp. 243-249.
5. Cui, K., Lin, J., Wu, Q., Xu, Y., Zhu, Y. (2017). [Urea production by yeasts other than Saccharomyces in food fermentation.](#) FEMS Yeast Research, 17(7).
6. Zhou, K., Siroli, L., Patrignani, F., Sun, Y., Lanciotti, R., Xu, Z. (2019). [Formation of Ethyl Carbamate during the Production Process of Cantonese Soy Sauce.](#) Molecules, 24(8), pp. 1474.
7. [Alcohol Consumption and Ethyl Carbamate.](#) (2010). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, 96.
8. [Health Canada's Maximum Levels for Chemical Contaminants in Foods.](#) (2018). Canada. Health Canada.
9. 2016-2017 Ethyl Carbamate in Alcoholic Beverages and Fermented Soy Products. [unpublished results]. Canada. Canadian Food Inspection Agency.
10. Kim, Y.-K.L., Koh, E., Chung, H.-J., Kwon, H. (2000). [Determination of ethyl carbamate in some fermented Korean foods and beverages.](#) Food Additives & Contaminants, 17(6), pp. 469-475.
11. Tang, A.S.P., Chung, S.W.C., Kwong, K., Xiao, Y., Chen, M.Y.Y., Ho, Y.Y., Ma, S.W.Y. (2011). [Ethyl carbamate in fermented foods and beverages: dietary exposure of the Hong Kong population in 2007–2008.](#) Food Additives & Contaminants: Part B, 4(3), pp. 195-204.
12. Hasnip, S., Crews, C., Potter, N., Christy, J., Chan, D., Bondu, T., Matthews, W., Walters, B., Patel, K. (2007). [Survey of ethyl carbamate in fermented foods sold in the United Kingdom in 2004.](#) J. Agric. Food Chem., 55(7), pp. 2755-2759.
13. Lei, F.F., Zhang, X.N., Gao, Y.L. (2012). [Multiple headspace solid-phase microextraction using a new fiber for avoiding matrix interferences in the quantitative determination of ethyl carbamate in pickles.](#) J. Sep. Sci., 35, pp. 1152-1159.