Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Ethyl carbamate in fermented soy products and cooking wine – April 1, 2022, to March 31, 2023

Food chemistry – Targeted surveys – Final report

Canada

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 275 samples, including 181 fermented soy products and 94 cooking wine samples. EC was detected in 34% of the samples tested, with levels ranging from 4 parts per billion (ppb) to 824 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 targeted surveys are

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 we conducted this survey

The main objectives of this targeted survey were to generate further baseline surveillance data on the level of EC in selected products likely to contain EC. In this survey, soy products (bean curd etc.) with high likelihood of containing EC were targeted. Cooking wine was tested for the first time.

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 wine[8]. 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 we sampled

A variety of domestic and imported fermented soy products (fermented tofu/bean curd, tempeh, miso, soybean paste, etc.) and cooking wine samples were collected between April 1, 2022 and March 31, 2023. 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
Cooking wine	23	70	1	94
Soy products	63	112	6	181
Total	**86**	**182**	**7**	**275**

Table notes

[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 samples were 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 levels established by Health Canada. Currently, these have been established for the presence of EC in certain types of alcoholic beverages. Health Canada has determined a maximum level (ML) of 35 ppb for EC in table wine, 100 ppb in fortified wines, 150 ppb in distilled spirits, 400 ppb in fruit brandies and liqueurs and 200 ppb in sake (rice wine)[8]. 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. Note that there are no Canadian regulatory limits for the remaining categories of products included in the survey.

Results of the survey

Of the 275 samples tested, most (66%) 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

Product type	Number of samples	Number of samples (%) with detected levels	Minimum (ppb)	Maximum (ppb)	Average[b] (ppb)
Cooking wine	94	74 (79)	5	578	78
Soy products	181	19 (11)	4	824	134
Total	**275**	**93 (34)**	**4**	**824**	**89**

Table notes

[b] Only positive results were used to calculate the average (hazard) levels.

Of 94 cooking wine samples tested, EC was detected in 74 samples at levels up to 578 ppb. The detection rate observed (79%) in cooking wine is one of the highest compared to other product types tested to date[9,11,12,13]. Although sometimes large variance between the same products with different lot numbers was observed, products of certain brands had consistently higher levels of EC.

Most (89%) soy products sampled did not have detected levels of EC. Of the positive samples, 10 were samples of bean curd, 5 were samples of miso, 3 were samples of soybean paste and 1 was a sample of tempeh. The average level of EC in soy product was 134 ppb with a maximum of 824 ppb. Elevated levels of EC (above 30ppb) were only observed in the bean curd sub-category of soy products.

What 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 products 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)[9,11,12,13,9,14]. 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 cooking wine. The levels of EC in cooking wines observed in this survey were above the range reported

in the literature, with 7 samples exceeding the maximum numbers previously reported[9]. The difference may be due to larger sample size collected in this survey. Nevertheless, the average level of EC closely matched that reported in literature[9].

The EC levels observed in soy products were comparable to that found in previous survey years [9,11,12,13]. The low detection rate in this survey (11%) was also in close agreement with that previously reported (1 to 15% in various surveys years)[9,11,12,13]. The highest levels of EC reported in this survey were in bean curd, as observed in previous surveys and reported in the literature[9,14]. Two samples of the same bean curd product had levels of EC higher than those reported to date. It should be re-iterated that soy products sampled in this survey were selected due to their high likelihood of containing EC, contributing to higher average and maximum levels when compared to some other survey years.

Table 3. Minimum, maximum and average concentration of ethyl carbamate in cooking wine and soy products across various studies

Product type	Study	Number of samples	Minimum (ppb)	Maximum (ppb)	Average (ppb)
Cooking wine	CFIA survey, 2022	94	5	578	78[c]
Cooking wine	Wu et al., 2012	20	5	206	87
Soy products	CFIA survey, 2022	181	4	824	134[c]
Soy products	CFIA survey, 2021	156	5.5	100	52.8[c]
Soy products	CFIA survey, 2020	73	16.5	520	145[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]

Table notes

[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.

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