Analysis of Ethyl Carbamate Results from FY 1988 – 2021 Monitoring

Victoria Incorvati[+], Eileen Abt[+], Jesse Lunzer[+], Armen Mirzoian*, Angela Jefferson*, Lauren Posnick Robin[+]

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
College Park, MD, USA

[+] Contributing Author works at CFSAN
* Contributing Author works at TTB

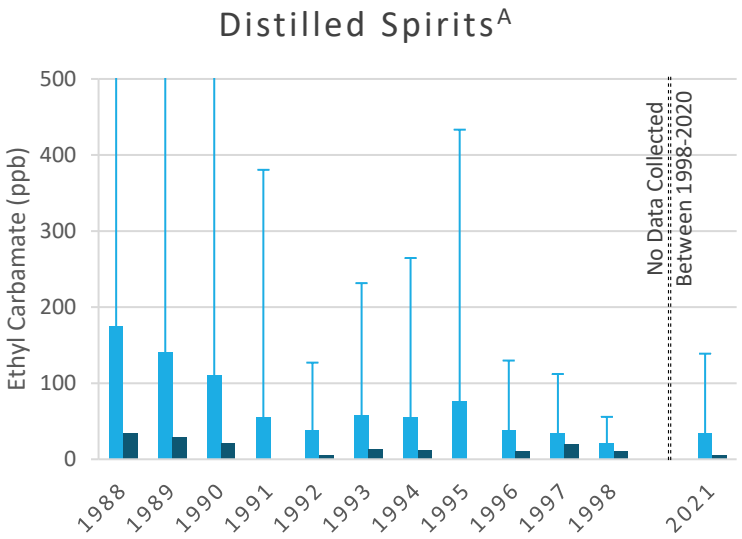
Introduction

- Ethyl carbamate is a process contaminant that can form during the fermentation and storage of foods and beverages containing nitrogen-rich compounds, such as urea, citrulline, and cyanate. The National Toxicology Program has classified ethyl carbamate as “reasonably anticipated to be a human carcinogen.”

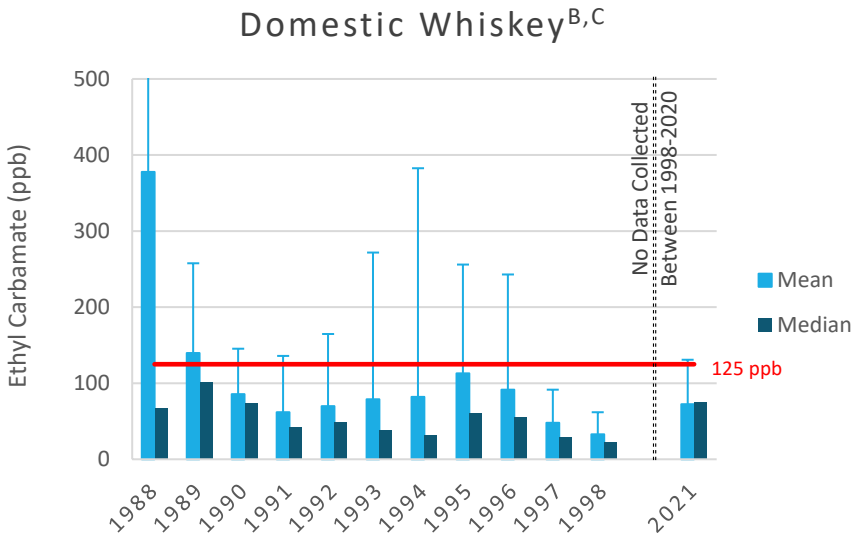
- The highest levels of ethyl carbamate occur in alcoholic beverages such as distilled spirits and wine. Consumers of alcoholic beverages are at the highest risk from ethyl carbamate. FDA has worked with other government agencies and domestic industry to develop voluntary programs and mitigation strategies to reduce ethyl carbamate in alcoholic beverages.

- FDA co-regulates alcoholic beverages with the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB).
  - Between 1988-1998, TTB monitored levels of ethyl carbamate in alcoholic beverages.
  - In 2020-2021, FDA and TTB cooperated on the sampling and analysis of 278 additional alcoholic beverages.

Ethyl Carbamate Levels in Distilled Spirits from 1988-2021

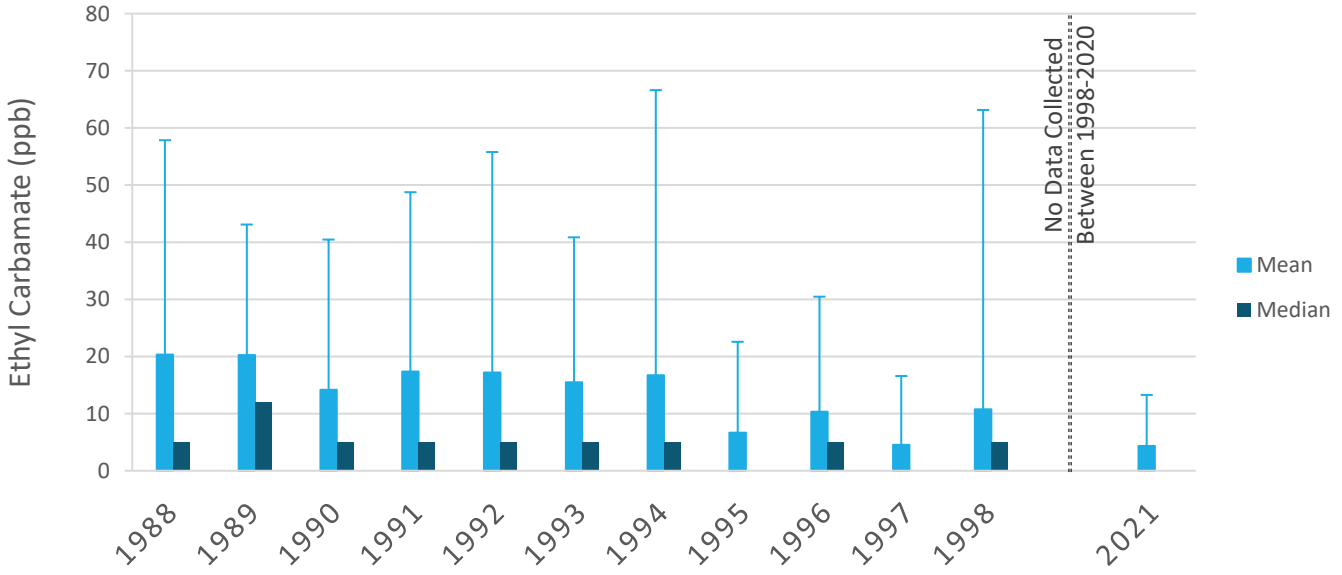


[A] Between 80 – 710 samples were analyzed each year. The median level of ethyl carbamate in distilled spirits was 0 ppb in 1991 and 1995.



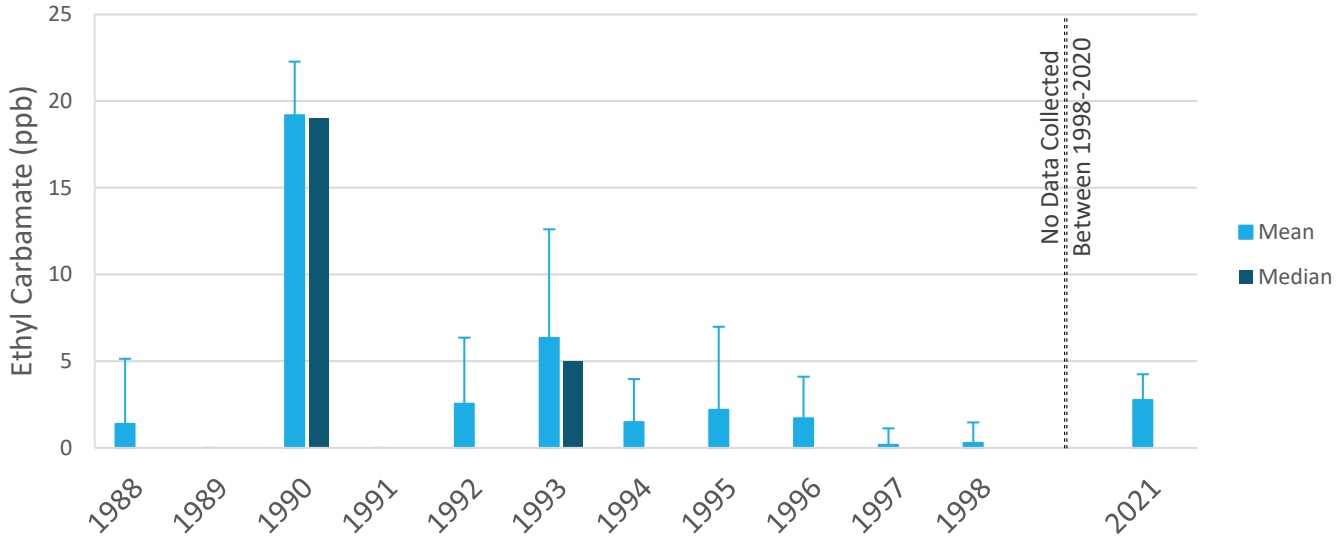
[B] Between 10 – 200 samples were analyzed each year.
[C] Whiskey is the only distilled spirit mentioned in the Memorandum of Understanding (MOU) between the Distilled Spirits Council of the United States (DISCUS) and FDA. The target level set by the MOU is 125 ppb.

Ethyl Carbamate Levels in Wine from 1988 to 2021[A]



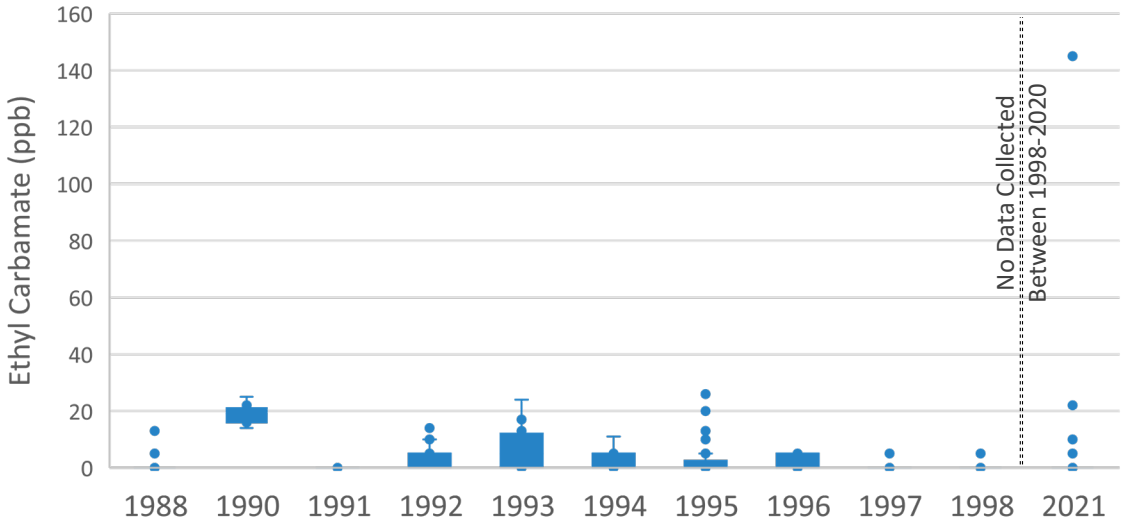
[A] Between 40 – 650 samples were analyzed each year. The median level of ethyl carbamate in wine was 0 ppb in 1995, 1997, and 2021.

Ethyl Carbamate Levels in Malt Beverages from 1988 to 2021[A]



[A] No samples were collected in 1989 or between 1998 and 2020.
The median level of ethyl carbamate in malt beverages was 0 for all other years besides 1990 and 1993.

Ethyl Carbamate Levels in Malt Beverages from 1988 to 2021[A, B, C]



[A] No samples were collected in 1989 or between 1998 and 2020.

[B] Each dot represents a single data point.

[C] Lower and upper ends of the box represent the 25th and 75th percentiles and the whiskers represent the minimum and maximum, excluding outliers (shown as dots).

Conclusions

- Levels of ethyl carbamate have decreased in distilled spirits and wine sampled in the United States from 1988 to 2021.
  - Mean and median levels of ethyl carbamate found in 2021 domestic whiskey samples are below the target level (125 ppb) set in the Memorandum of Understanding between the Distillers Council of the United States (DISCUS) and FDA.

- Levels of ethyl carbamate in malt beverages have remained low; however, one new malt beverage product on the market in 2021 appears to have higher levels of ethyl carbamate than previously seen in this product category.

Acknowledgements

- Eileen Abt
- Jesse Lunzer
- Lauren Posnick Robin
- Armen Mirzoian
- Angela Jefferson
- Betty Admasu