

Ethyl Carbamate in Wine

Wine Institute Technical Committee Summary Background Document

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There have been recent concerns expressed by officials in other countries about the levels of ethyl carbamate in wine. Countries like Korea, for example, are requesting information from U.S. wineries regarding the U.S. wine industry response to ethyl carbamate. Fortunately, there is a large body of scientific data on this subject. This document is intended to provide some definitive background on this issue and will refer to recent findings by respected organizations and agencies regarding ethyl carbamate in wine.

What is ethyl carbamate?

Ethyl carbamate is a substance that is unintentionally produced as a trace byproduct of natural processes and is present in all foods (such as bread, wine, beer, distilled spirits, instant soup, sauerkraut, soy sauce, some cheeses and yogurt) that are made by fermentation processes. Ethyl carbamate is classified internationally as a probable human carcinogen. It is not an additive to wine. Substances such as urea can be produced naturally by the yeasts that turn grape juice into wine. Over time, urea and other compounds such as citrulline can react with some of the alcohol in the wine to produce minute amounts of ethyl carbamate. Industry research has identified some known factors, such as climate, soil conditions, vine variety, vineyard fertilization, strains of microorganisms used in fermentation, temperature, and duration of storage prior to consumption, that affect the presence and levels of ethyl carbamate in wine.

What has the U.S. wine industry done about ethyl carbamate?

1988 FDA Voluntary Agreement

With the discovery of minute levels of ethyl carbamate in wine in early 1988, the industry immediately began working diligently in conjunction with the United States Food and Drug Administration (FDA) to reduce levels as far as technologically possible. The U.S. wine industry consulted with FDA and agreed to a voluntary monitoring program that set as a goal that, for table wines (wines containing 14% or less alcohol by volume) produced from the 1988 harvest/crush, and for subsequent years, the weighted average of American table wines will not exceed 15 parts per billion of ethyl carbamate; and for dessert wines (wines containing over 14% alcohol by volume) produced from the 1989 harvest/crush, and for subsequent years, the weighted average will not exceed 60 parts per billion. In 1994, the agreement between the U.S.

wine industry and the FDA was amended, maintaining the voluntary levels established in 1988 and also including a provision that no more than 1% of table wine volume will have ethyl carbamate levels above 25 ppb and no more than 1% of dessert wine volume will have ethyl carbamate levels above 90 ppb.

The 1988 agreement included a commitment by the U.S. wine industry to additional research. Studies involving the University of California at Davis, Cornell University, and research conducted by Wine Institute members, included the following:

- radioisotope studies to elucidate the precursors and pathways of ethyl carbamate formation;
- studies on the effects of enological and viticultural parameters on ethyl carbamate formation;
- the possible use of urease to reduce ethyl carbamate levels;
- preparation of a database of ethyl carbamate test results from approximately 2,000 samples produced under known enological and viticultural conditions and statistical analysis of the data to determine the correlation of those conditions with ethyl carbamate formation;
- practical experimentation with and empirical tests of potential methods to reduce levels of ethyl carbamate.

1997 Ethyl Carbamate Preventative Action Manual

The wine industry's intensive research into the field resulted in the publication of the ETHYL CARBAMATE PREVENTATIVE ACTION MANUAL, authored by Christian E. Butzke & Linda F. Bisson, Department of Viticulture & Enology University of California, Davis. This manual has served as an invaluable guide to wine producers both in the U.S. and other countries, and is available in both English and Italian on the FDA's website at <http://www.cfsan.fda.gov/~frf/ecaction.html>.

JECFA Review - 2005

In 2004, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) published a call for data on ethyl carbamate for its 64th meeting to be held in Rome on 09-17 February 2005. Wine Institute responded to JECFA. A copy of our responses can be found at <http://www.box.net/shared/njtejlx5w0>. Accompanying Wine Institute's submission were analytical results from the Liquor Control Board of Ontario (LCBO), which consisted of well over 60,000 determinations. The Wine Institute has maintained close contact over the years with the Liquor Control Board of Ontario (LCBO). This organization performs analyses on all

imported wines entering Ontario, as a means of enforcing the Canadian ethyl carbamate limits. The data the LCBO has amassed over the years represent the most comprehensive body of data concerning the levels of ethyl carbamate in wine globally and the trends in those levels over time. **The LCBO data clearly shows that ethyl carbamate levels in wine have been progressively and significantly decreasing over time.**

Following the 2005 JECFA meeting, a brief Summary and Conclusion document was published and can be found at

http://www.who.int/ipcs/food/jecfa/summaries/summary_report_64_final.pdf In that report, JECFA states:

Data on concentrations of ethyl carbamate in foods and beverages were submitted by the US Food and Drug Administration, the UK Food Standards Agency and the Wine Institute of the USA. The alcoholic beverages considered in these reports originate from many countries throughout the world. *For alcoholic beverages, only recent data were included because concentrations have been reduced considerably over time as a result of the application of mitigation measures.* (emphasis added)

EFSA Review - 2007

More recently, the European Food Safety Authority issued a call for submission of data on levels of ethyl carbamate in food and beverages in late September, 2006. Seven EU Member States, the Liquor Control Board of Ontario and the Wine Institute of California responded to EFSA's call for data on ethyl carbamate and submitted results covering analyses from 1998 to 2006. EFSA's summary and scientific opinion of the Panel on Contaminants was published in September, 2007 and can be retrieved from http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178655060600.htm .

EFSA raised concerns about stone-fruit brandies and tequila, and made only two recommendations - both addressing such beverages and not wine:

RECOMMENDATIONS

- Mitigation measures should be taken to reduce the levels of ethyl carbamate in certain alcoholic beverages such as fruit brandies. Such measures should include focus on hydrocyanic acid and other precursors of ethyl carbamate to prevent the formation of ethyl carbamate during shelf-life of these products.
- Measures should be introduced to reduce concentrations of hydrocyanic acid in certain types of beverages

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Still operating under the FDA voluntary goals to this day, the U.S. wine industry continues to address ethyl carbamate in wine production. Since the discovery of minute levels of ethyl carbamate in wine, the industry has worked in conjunction with FDA to reduce the levels as far as technologically possible. Since early 1988, voluntary limits have been in place and the industry has been monitoring ethyl carbamate. In addition, the industry has conducted and funded extensive research on the mechanisms that produce ethyl carbamate. The findings have been used in the vineyard and winery to continually reduce ethyl carbamate levels as far as possible. The recent reviews of data and science from JECFA and EFSA and the data from the LCBO show that the wine industry is successfully reducing ethyl carbamate levels in wine and that ethyl carbamate levels have been progressively and significantly decreasing over time.