

# Journal of Agricultural and Food Chemistry

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Irvin E. Liener, *Editor*

Dockets Management Branch (HFA-305)  
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5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Dec. 31, 1998

To whom it may concern:

Reference is made to Docket No. 98P-0683, entitled "Food Labeling: Health Claims: Soy Protein and Coronary Heart Disease", which appeared in Federal Register, Nov. 10, 1998, (Volume 63, Number 217, pages 62977-63015).

I would like to take issue with the information found on pg. 62979 as it pertains to the risk of human exposure to trypsin inhibitors. The impression one gets from reading this section is that there is little cause for concern as far as the human exposure to soybean trypsin inhibitors is concerned. What is particularly disturbing is the fact that no reference is made to any of the articles which I have published which questions the safety of soybean trypsin inhibitors in the human diet. These are the following:

Liener, I.E., Trypsin Inhibitors: Concern for Human Nutrition or Not? *Journal of Nutrition* 116, 920, 1986.

Liener, I.E., et al., Effect of a Trypsin inhibitor from Soybeans (Bowman-Birk) on the Secretory Activity of the Human Pancreas, *Gastroenterology* 94, 419, 1988.

Liener, I.E., Possible Adverse Effects of Soybean Anticarcinogens, *Journal of Nutrition* 125, 744S, 1995.

Liener, I.E., Soybean Protease Inhibitors and Pancreatic Carcinogenesis, *Journal of Nutrition* 126, 582, 1996.

Copies of these papers are enclosed for your convenience.

In the interests of a balanced treatment of the subject, I trust you will give due consideration to the opposing view that the soybean trypsin inhibitors do in fact pose a potential risk to humans when soy protein is incorporated into the diet. Your response to the issue which I have raised would be greatly appreciated.

Sincerely yours

Irvin E. Liener  
Editor and Professor Emeritus