



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUN 12 2007

• The Honorable Rosa L. DeLauro  
Chairwoman  
House Appropriations Subcommittee on Agriculture,  
Rural Development, Food and Drug Administration,  
and Related Agencies  
United States House of Representatives  
Washington, D.C. 20515-0703

Dear Chairwoman DeLauro:

Thank you for your letter of May 7 concerning the designation of diacetyl as "generally regarded as safe" (GRAS). Your letter urges the Food and Drug Administration (FDA) to consider revoking diacetyl's GRAS status for use as a flavoring agent and removing it from the market until further testing is completed. I appreciate your interest in this issue and your concern for consumers.

Your request is based largely on recent findings by the National Institute for Occupational Safety and Health (NIOSH). The NIOSH findings state that exposure to vapors containing diacetyl in a manufacturing environment has the potential to cause serious lung damage and the condition known as bronchiolitis obliterans. Diacetyl was codified as GRAS in 1983 in Title 21 of the Code of Federal Regulations, Subpart 184.1278, for general use as a flavoring agent and adjuvant. Your letter states that the more recent safety information comprises compelling scientific evidence that diacetyl poses a real threat to exposed workers, and also raises the possibility of harm to consumers of microwave popcorn. You believe that this information is sufficient to cause a reconsideration of the GRAS status of diacetyl, and that until further studies are conducted to examine the safety of diacetyl, it should be removed from the market.

FDA received a citizen petition (Docket Number 2006P-0379/CP1) that also requests revocation of diacetyl's GRAS status based on similar grounds. At this time, the agency does not have evidence that would cause it to take immediate action with respect to diacetyl.

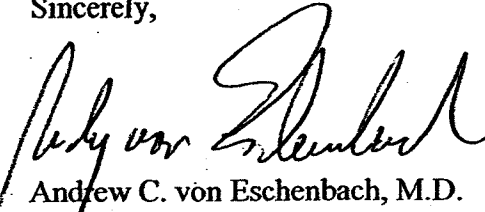
However, FDA is evaluating this citizen petition and considering the safety and regulatory issues that it raises. At the same time, FDA continues to monitor the scientific literature for studies conducted to define and clarify the dangers associated with exposure to diacetyl vapors. The agency will continue to monitor the applicability, if any, of those dangers to the safety of diacetyl at typical consumer inhalation exposure levels, as well as to ingestion of diacetyl as a flavoring agent or adjuvant. FDA also continues to monitor the diacetyl-related activities and scientific findings of other Federal agencies. If FDA

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concludes that the health of consumers is at risk through diacetyl exposure from food uses, it will take regulatory actions available to it under its authority to protect the public health.

Thank you for contacting us concerning this matter and please let us know if you have any further questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew C. von Eschenbach". The signature is fluid and cursive, with a large initial "A" and "E".

Andrew C. von Eschenbach, M.D.  
Commissioner of Food and Drugs

Document Name: G:\Wp\KRISTY\Letters\DeLauro Diacetyl GRAS 07-3195 June 2007  
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Trac # 2007-3195 (logged-in by OES)

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