



SEP 15 2017

John Kidder
Vice President
Monterey Mushrooms
260 Westgate Drive
Watsonville, CA 95076

Re: Citizen Petition FDA-2006-P-0142

Dear Mr. Kidder:

This responds to your petition, dated May 4, 2006, which requested that “the Commissioner of Food and Drugs amend the packaging recommendations for mushrooms as put forth in 1978 by D.A. Kautter et al (Journal of Food Protection Vol, 41, No.2, pages 120-121) of the Food and Drug Administration, recommending that each package of mushrooms contain (2) 1/8 inch holes.” (See Citizen Petition submitted by John Kidder, Vice-President, Monterey Mushrooms, to the Division of Dockets Management, Food and Drug Administration (“Petition”), at page 1.) You also asked that the Commissioner amend the recommendation to state that:

The recommendation by the FDA to provide 2 – 1/8 inch holes in all PVC over wrapped tills does not apply to other forms of packaging. In the event that mushrooms are packaged in other forms packaging such as micro perforated films it will be the producer’s responsibility to demonstrate that there is an adequate supply of air to prevent the mushrooms from becoming anaerobic under normal shipping and distribution conditions.

Petition at page 1. Your petition also discusses the use of micro perforated films and asks that FDA “recognize the safety of mushroom packaging in poly bags with adequate open area” as described in your petition (Petition at page 8).

Your petition concerns a recommendation in an approximately one page article published in the Journal of Food Protection nearly 40 years ago. In the article, the FDA authors state that “since our experiments showed that inoculated mushrooms occasionally became toxic (14 in 250 packages) when only one 1/8 inch hole was made in the wrapper, it seems prudent to recommend that PVC-wrapped tills of mushrooms have two unblocked holes in the wrapper.”

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
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We note that the article predates FDA's Good Guidance Practices (GGPs) (21 CFR 10.115), which are FDA's policies and procedures for developing, issuing, and using documents that describe the agency's interpretation or policy on a regulatory issue. The recommendation in the article is not stated as a requirement and is not contained in a regulation. Further, you do not assert that FDA has treated the statement as a requirement. Regarding your request to explicitly state that the recommendation does not apply to other forms of packaging, that statement itself is limited to "PVC-wrapped tills."

Under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 371(h)) and FDA's GGPs, FDA has discretion as to whether to issue or revise guidance. In light of the age of the article, the limited scope of the statement you identify, and its nonbinding nature, FDA is not persuaded of the need to issue the guidance requested in your petition regarding the statement in the article.

We further note that, since the article's publication in 1978, we have issued new regulations pertaining to food safety. For example, pursuant to the FDA Food Safety Modernization Act, we issued a final rule titled, "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" ("CGMP & PC rule"). The CGMP & PC rule establishes measures to ensure that hazards requiring a preventive control will be minimized or prevented (21 CFR Part 117). The required hazard evaluation must consider, among other things, the effect of packaging activities on the safety of the finished food (21 CFR 117.130(c)(2)(vi)). We published the final rule in the Federal Register on September 17, 2015 (see 80 Fed. Reg. 55907). Information regarding the final rule, along with related guidance documents, can be found at our website at <https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm>. Given the framework of the CGMP & PC rule, we find it unnecessary to grant your request to "recognize the safety of mushroom packaging in poly bags with adequate open area."

Therefore, in accordance with 21 CFR 10.30(e)(3) and for the reasons stated above, we are denying your petition.

Sincerely,

A handwritten signature in blue ink, appearing to read "Nega Beru", is written over a horizontal line.

Nega Beru, Ph.D.
Director
Office of Food Safety
Center for Food Safety
and Applied Nutrition