

purpose of this study group was to identify areas of quality regulation that would elicit consensus and support among industry producers and handlers. Record evidence also states that the proposed regulatory provisions are based on current industry practices and are substantiated by a wide body of scientific research and data.

Record testimony ties the industry's concern over the regulation of aflatoxin in pistachios to the protection of consumer interests by preventing the sale of contaminated nuts. Witnesses repeatedly cited evidence demonstrating consumers' reluctance to buying defective or damaged pistachios contaminated with mold. Consumer concerns about the presence or threat of aflatoxin in pistachios makes the regulation of aflatoxin bearing molds important.

Moreover, witnesses testified that if there were an outbreak of aflatoxin contamination in pistachios, widespread consumer reluctance to buy pistachios could result, even if the contamination was limited and quickly remedied. Witnesses feared that a single occurrence of aflatoxin contamination in pistachios could devastate the California pistachio industry and create effects that could take years and substantial financial resources to overcome.

Record evidence demonstrates the importance of regulating quality (including size) in tandem with aflatoxin, as research suggests a strong correlation between some sub-quality characteristics (for example, "early-split" pistachio nuts) and the propensity for aflatoxin contamination.

Evidence presented at the hearing suggests that aflatoxin contamination first occurs in the field and can continue to occur until pistachios are dried to a level where mold cannot grow. Industry research shows that most of the aflatoxin occurs in early split nuts or pistachios where the hull is damaged prior to harvest. A high percentage of small pistachios have a tendency to split early compared to larger pistachios. Accordingly, witnesses explained that there is a strong correlation between smaller, lighter pistachios with staining on the shell and the presence of aflatoxin.

Record evidence presented on the basis of research conducted by Mark A. Doster and Themis J. Michailides ("Characteristics of Pistachio Nuts with *Aspergillus* Molds," 1991) delineates a positive correlation between early split pistachios and aflatoxin. A witness citing this study quoted, "Early splits (ES) are pistachio nuts that have both hull and shell split and frequently have

moldy and/or insect-infested kernels. The hulls of ES nuts split over a several week period prior to harvest. Those ES that split earlier than two weeks before harvest had four times greater *Aspergillus* mold contamination compared with ES that split within two weeks of harvest. Both older ES and ES with moldy kernels had very different physical characteristics compared to normal nuts: fruits and kernels weighed less, hulls were more shriveled, and shells were smaller and stained * * *. In a typical orchard approximately 1 to 4% of the nuts are ES at harvest time. Molds in the genus *Aspergillus* are frequently found in ES nuts."

According to other studies cited at the hearing, 90 percent of aflatoxin is contained in 4.6 percent of low-quality pistachios. Witnesses citing these studies further stated that removal of low-quality product, defined as smaller, lighter, stained-shell nuts typically found in "early splits", would reduce the average presence of aflatoxin in pistachios from 1.2 to 0.12 nano-grams/gram (ng/g) for all product sold for human consumption.

Furthermore, drawing from a study on the distribution of aflatoxin in processed and unprocessed pistachios, witnesses cited the study's conclusion that, "all aflatoxin found here arises in the orchard; none is produced under normal processing conditions."

Record evidence demonstrated that aflatoxin occurs rarely in a very small number of nuts, it originates in the field, and it is predominantly found in early split or damaged pistachios which have very different physical characteristics than higher quality pistachios.

Due to the exceptional physical characteristics of the infected nuts, witnesses explained that these nuts should be removed as part of the industry's handling procedures. As such, witnesses advocated the implementation of mandatory regulations that would not only set a maximum level of aflatoxin, but also, through quality and size specifications, encourage the removal of those nuts that both have the least consumer acceptance and are most likely to harbor aflatoxin.

Marketing Policy

Proposed § 983.37 would require that the committee prepare and submit to USDA prior to August 1st of each year an annual marketing policy. The marketing policy would serve as the basis for any committee recommendations for revisions in quality regulations for the upcoming crop year. Record evidence explained that in developing its marketing policy,

the committee should consider production, harvesting, processing and storage conditions, as well as current and prospective prices.

Proposed Aflatoxin Provisions

According to testimony presented by Dr. Al Eaton, Director of the Center for Ecogenetics and Environmental Health, and the Department of Environmental Health, School of Public Health and Community Medicine, both of the University of Washington, aflatoxin is a known contaminant in pistachios. Dr. Eaton's testimony outlined the scientific arguments behind regulating aflatoxin as a known human carcinogen. Other witnesses argued that regulation of aflatoxin is an important factor contributing to the quality of pistachios. Witnesses testified that regulation of aflatoxin is crucial to positive acceptance of pistachios among consumers and growth of consumer demand.

As stated by Dr. Eaton, the U.S. and international scientific communities have reviewed the significance of aflatoxin in human food and animal feed extensively. Dr. Eaton referred to studies by Eaton and Groopman, 1994, as well as the Food and Agriculture Organization and World Health Organization's Joint Expert Committee on Food Additives (JECFA), 1998. Dr. Eaton stated that limiting aflatoxin in affected commodities is important in regard to these concerns.

Proposed § 983.38(a) would provide for a maximum aflatoxin level for pistachios shipped for domestic human consumption. The level supported by record evidence is 15 parts per billion (ppb). Under this provision, no pistachios with an aflatoxin level greater than 15 ppb could be shipped for domestic human consumption. Witnesses testifying at the hearing stated that the 15 ppb threshold is an appropriate level to ensure the quality of pistachios. Witnesses also explained that 15 ppb is the maximum level of aflatoxin allowed in peanuts, another commodity known to be affected by aflatoxin-bearing molds (7 CFR part 996).

The United States Food and Drug Administration (FDA) currently employs an aflatoxin tolerance level in pistachios of 20 ppb. Thus, this proposal would be more restrictive than what is currently accepted by the FDA. Witnesses explained that the 15 ppb was selected as the proposed maximum threshold to ensure that sampling procedures would result in aflatoxin tolerances below the current FDA level.

Proposed § 983.38(a) also provides that an aflatoxin inspection certificate