

irradiation indicators. Also, another commenter raised concerns about including mangoes on the list of fruits approved for movement from Hawaii if treated with irradiation. These comments are discussed below by topic.

### Irradiation Indicators

We proposed to amend the irradiation provisions in § 318.13–4f to require cartons of fruits and vegetables being moved interstate in accordance with the regulations to be marked with irradiation indicators. Specifically, we had proposed to add a new § 318.13–4f(b)(7) to read as follows: “*Indicators.* Each carton of fruits and vegetables must bear an indicator device, securely attached prior to irradiation, that changes color or provides another clear visual change when it is exposed to radiation in the dose range required by this section for the pests for which the articles are being treated.” Four commenters opposed this proposed requirement for numerous technical, operational, and cost-benefit reasons.

One commenter referred to several studies that deal with the limitations of available radiation-sensitive indicators.<sup>1</sup> Specifically, the commenter stated that dose fluctuations resulting from density variations caused by the arrangement, size, and weight of individual fruit within the subunits of a pallet would make irradiation indicators impractical and unreliable.

Another commenter stated that the indicators that are currently available have not undergone adequate testing and standard development, and, therefore, their reliability is questionable. In addition, the commenter suggested that the added labor costs for the additional handling must be taken into account, offsetting the low cost of the production of the indicators themselves.

One comment, which was reviewed and submitted by several researchers, offered detailed discussion of several issues related to the use of irradiation indicators. The comment referred to American Society for Testing and Materials (ASTM) Standard E 1539–98, “Standard Guide for the Use of

Radiation-Sensitive Indicators.” Section 7.3 of that document states: “Some irradiation or storage conditions may result in false positive or negative observations. For these reasons, indicators should not be used as a criterion for product release. Also, external environmental influences may make the interpretation of the indicators meaningless outside the irradiation facility unless appropriate controls are used.” The commenter indicated that, for several technical reasons, irradiation indicators can only be used effectively to show that products have been exposed to “some” radiation, and not to show the exact dose of radiation that a product has received.

We have carefully analyzed all the data and opinions submitted recommending against the proposed indicator requirement and have decided to omit that requirement from this final rule. While we believe that an indicator could be employed as a useful “cross check” when Animal and Plant Health Inspection Service (APHIS) inspectors are correlating the required interstate movement certificates with the cartons referred to in those documents to offer additional protection against the introduction of plant pests into the mainland United States from Hawaii, apparently there is no such indicator that is: (1) Currently available at low cost; (2) validated to be sensitive and reliable in the appropriate dose ranges; and (3) validated to be resistant to false positives and false negatives caused by environmental effects. Therefore, we have omitted proposed § 318.13–4f(b)(7) from this final rule.

### Dosage Recommendations

One commenter noted that there are only two studies to date that examine the relationship between radiation dose and fertility in the adult mango seed weevil (*Sternonchus mangiferae* (Fabricius), formerly known as *Cryptorhynchus mangiferae*). The commenter stated that these studies do not provide adequate support for the proposed dose of 100 Gy (10 krad), which was recommended by ARS research findings as a sufficient quarantine treatment for mango seed weevil. The commenter suggested that, based on the limited amount of research that has been done, Hawaiian mangoes should be subjected to higher doses of radiation than 100 Gy (10 krad). We had proposed a minimum ionizing irradiation dose of 250 Gy (25 krad) for mangoes, which we indicated would be effective in eliminating both fruit flies and the mango seed weevil.

We have carefully analyzed the data and conducted a review of the available

literature on this topic and have determined that a higher dose of irradiation for mango seed weevil is appropriate. Based on research by ARS (Follett, 1999) and by the International Consultative Group on Food Irradiation of the Food and Agriculture Organization of the United Nations,<sup>2</sup> we are setting an irradiation dose level of 300 Gy (30 krad) for mango seed weevil in this final rule. We believe that there is enough research and evidence to support this dose level as an effective quarantine treatment for mango seed weevil.

The same commenter also stated that a dose of 250 Gy is excessive for fruit flies. He indicated that “recent research and analyses have demonstrated that studies finding that doses >150 Gy were needed most likely are in error,” but did not identify specific studies or analyses. He asked when APHIS would consider lower doses.

The research supporting this comment may have merit, but such research must be carefully evaluated and verified before we lower doses below the proposed level, which we know is effective. APHIS, in cooperation with ARS and others, will evaluate the lower doses recommended by this commenter. If we determine that lower doses are effective for fruit flies, we will initiate rulemaking in the future to reduce the doses. However, this evaluation process will take time, so in this final rule we are utilizing the dose of 250 Gy for fruit flies so that irradiation treatments may occur while this evaluation is underway.

The same commenter also stated that there should be a range of time given for irradiation treatment the way that a time range is given for vapor heat treatment in the comparison table (see Table 3) in the proposed rule. The commenter also asked if the comparison table compared values for the same amount of fruit in both treatments.

The comparison table was offered in the proposed rule’s economic analysis to illustrate the relative cost and time-saving benefits of irradiation treatments when compared to the presently available vapor heat treatment, not to set specific values for the two treatments. Although the same amount of fruit was used in both treatments, it was not possible to give a time range for irradiation treatment comparable to the time range given for the heat vapor treatment because of the number of

<sup>1</sup> Ehlermann, D.A.E. (Federal Research Centre for Nutrition, Karlsruhe (Germany). Inst. of Process Engineering), “Validation of a label dosimeter for food irradiation applications by subjective and objective means,” Appl. Radiat. Isot.; v. 48(9), p. 1197–1201; 1997.

International Atomic Energy Agency, “Standardized methods to verify absorbed dose in irradiated food for insect control,” IAEA, Vienna, 2001, IAEA–TECDOC–1201.

Razem, D. (Ruder Boskovic Inst., Zagreb (Croatia)), “Dosimetric performance of and environmental effects on sterin irradiation indicator labels,” Radiat. Phys. Chem.; v.49(4), p. 491–495.

<sup>2</sup> “Irradiation as a Quarantine Treatment of Fresh Fruits and Vegetables,” ICGFI, 1991. This publication also cited two other studies, (Heather and Corcoran, 1990) and (Jessup and Rigney, 1990), that supported an irradiation dose level of 300 Gy (30 krad) for mango seed weevil.