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Joan Claybrook, President

18 March 2003

Re: Standard's Committee Draft of the Guidelines for the Use of Irradiation as a Phytosanitary Measure

Dear Sir/Madam,

Public Citizen, on behalf of our 150,000 members worldwide, is pleased to submit this public comment on the Standard's Committee Draft of the Guidelines for the Use of Irradiation as a Phytosanitary Measure (Guidelines). Public Citizen is a non-profit, membership organization, established in 1971 that advocates for consumer protection, and for government and corporate accountability.

The Guidelines are listed as Item 5 on the Provisional Agenda for the Fifth Session of the Interim Commission on Phytosanitary Measures, 7-11 April 2003 in Rome. Public Citizen has concerns with specific points contained within the Guidelines, as well as overall concerns with the contents. Overall, the guidelines are very vague, with primary reliance on the National Pest Protection Organizations (NPPOs) and without any oversight.

The majority of the Guidelines are voluntary without a central gatekeeper for the information. Public Citizen urges you to ensure the Guidelines are mandatory with a central clearinghouse to maintain the information. In addition, the information that the clearinghouse holds should be made available to the public in order to allow for NPPO's accountability.

Below are specific concerns for specific Guidelines:

- **Guideline 2. Treatment objective:** It states that NPPOs should achieve certain responses in targeted pests, including mortality; preventing successful development of pests; the inability of pest(s) to reproduce; or inactivation.

However, nowhere in this item is it stated to what extent these responses or any other responses should or must be achieved. Without specific goals, member nations could establish any response level they see fit – for example, a 20 percent mortality response for *C. capitata*. Stating that response options must be implemented, without stating specific goals, is insufficient. Plainly, without the establishment of minimum response levels, Item 2 is flawed.

• **Guideline 2.1 Efficacy:** It states that NPPOs should specifically define the efficacy of treatments, by describing required responses and stating the statistical level of response required. Again, as in Item 2, nowhere in this item is it stated to what extent these responses or any other responses should or must be achieved. Stating that response options must be implemented, without stating specific goals, is insufficient. Further, several suggested options are listed, but these appear to be suggestions only. Plainly, without the establishment of minimum response levels, and without stating response option requirements, Item 2.1 is flawed.

• **Guideline 3. Treatment:** It includes cesium-137 as a type of ionizing radiation. Because of safety concerns and historical accounts, cesium-137 should be deleted from the Guidelines. It is a water-soluble by-product of nuclear weapons production and has a history of detrimental environmental impacts. It is not utilized anywhere in the world because of the high probability of environmental contamination.

In 1983, the United States Department of Energy (DOE) explained that utilization of radioactive materials in a civilian capacity would reduce the DOE's waste handling problem.¹ Five years later, cesium-137 was employed at a medical irradiation facility near Atlanta, Georgia, USA. One capsule of the water-soluble cesium-137 sprung a leak and radioactivity was spread throughout the community. It cost the US government \$30 million to clean up the accident.² Since then, cesium-137 has never been known to be used at any irradiation facility anywhere in the world, and there is no reason to endanger the public and the environment by allowing its use now. We urge you to oppose this unnecessary addition to the Standard's Committee Draft of the Guidelines for the Use of Irradiation as a Phytosanitary Measure.

Furthermore, Guideline 3 includes the statement, "The intended end use of the product should not be jeopardized by the irradiation treatment." When the end use of the product is food for nutritional value, then the irradiation process is jeopardizing the purpose of the product. Because the Guidelines contain no radiation cap, doses could exceed 1 kGy, the level at which various types of fruit, vegetable and meat sustain losses and disruption of vitamins, proteins, essential fatty acids and other nutrients.³ Irradiation itself does, in fact, jeopardize the end use if the plant product is intended for human consumption.

Furthermore, a paragraph has been added to the latest draft of the Guidelines (Standards Committee Draft, Publication No. 18, November 2002) since the prior draft (Standards Committee Draft, Country Consolation, May 2002) that raises profound concerns. The inserted paragraph states that "mortality will rarely be technically justified as the required response," and that "it is preferable that [live target pests] are unable to emerge from the commodity unless they can be practically distinguished from the non-irradiated pest(s)." This late-hour insertion is troubling on its face. First, there is no supporting evidence to indicate that mortality will rarely become a required response. Additionally, the prospect of monitoring live pests if and when they emerge from packaging material and determining – presumably in a very short period of time – whether they are irradiated or non-irradiated pests is, frankly, absurd. The Guidelines do not explain how, or even if, this can be accomplished. Plainly, a higher and more comprehensive standard for assuring the incapacitation of target pests can and must be attained.

- **Guideline 6.2 Labeling:** There is no requirement that irradiation dose or variety be included on labels. Further, there are no specific guidelines or oversight for *mandatory* label type, size, placement. Labeling specifications should be outlined.

- **Guideline 6.3 Verification:** Continuous supervision should be mandatory to ensure continued compliance of Guidelines. The IPPC should maintain the records and make them available to the public at all times to ensure compliance.

- **Guideline 7. Documentation by the treatment facility:** One year is an arbitrary number in keeping treatment records and may not be sufficiently long, as one of the very purposes of irradiation is to extend the shelf life of food. Some products may be able to be stored for longer than one year before they are consumed. For the sake of consumer safety and greater system accountability, documentation should be maintained for five years.

- **Guideline 7.1 Documentation of procedures:** Included in the minimum requirements should be the type of ionizing radiation utilized. In addition, the Guideline should specify that the information is available to the public.

- **Guideline 7.2 Facility records and traceability:** Again, maintaining records for one year is an arbitrary assignment. The records should be kept for five years. The “may be” in the sentence “Other information that may be required . . .” should be changed to “is” to ensure mandatory compliance. This information should be made available to the public to ensure accountability.

- **Guidelines 8.1 / 8.3 Export inspection / Import inspection:** These guidelines, added to the latest draft of the Guidelines (Standards Committee Draft, Publication No. 18, November 2002) since the prior draft (Standards Committee Draft, Country Consolation, May 2002), raise profound concerns that question the integrity of the entire program. Guideline 8.1 states: “Live target pests may be found after treatment but should not result in the certification being refused.” Overlooking live target pests would seem to invalidate the purpose and undermine the credibility of the entire program. Further, this statement is based on no evidence, whatsoever. The guideline also states that “Audit checks...be undertaken to ensure that the required response is achieved.” The word “may” should be changed to “should” or, preferably, “must.” Otherwise, such audits may never occur.

Similarly, Guideline 8.3 states that “the detection of live stages of target pests in import inspection should not be considered to represent treatment failure resulting in non-compliance... Where mortality is required, live target pests may be found when transport times are short, but should not result in the consignment being refused.” Again, overlooking live target pests would seem to invalidate the purpose and undermine the credibility of the entire program. And, similar to Guideline 8.1, Guideline 8.3 states: “Laboratory or other analyses may be performed on surviving target pest(s) to verify treatment efficacy.” The word “may” should be changed to “should” or, preferably, “must.” Otherwise, such analyses may never occur.

The late-hour inclusion of these two Guidelines is disturbing. We are puzzled as to why and how statements of such magnitude were not included in earlier drafts of the Guidelines. Among many problems, it would seem that adding these Guidelines so late in the ISPM-establishment process

robbed IPPC participants an opportunity to fully discuss them. These Guidelines should be removed and only returned if, following comprehensive scientific review and discussion, they are deemed appropriate. Plainly, given the lack of sufficient discussion and given the implications of these late-hour additions, these Guidelines should not be included in any document approved at the April ICPM meeting.

- **Annex 1:** This is incomplete, therefore, Public Citizen urges the IPPC to not pursue ratification of the Guidelines for the Use of Irradiation as a Phytosanitary Measure until this Annex is complete.

- **Annex 2:** Included in the Checklist for Facility Approval should be a full contingency plan in place if a large-scale accident should occur at the facility in order to protect the environment and community.

- **Appendix 1:** Estimated Minimum Absorbed Doses for Certain Responses for Selected Pest Groups lists minimum radiation doses to achieve various responses for various plant pests. The minimum radiation dose range for seed weevils (70-100 Gy) is below the dose needed to sterilize the mango seed weevil. The appropriate dose is 300 gray.^{4,5} Additionally, the minimum radiation dose range for all fruit flies (50-150 Gy) is below the dose range needed to prevent adult emergence from the 3rd instar. For *B. dorsalis*, the minimum dose has been reported to be 250 Gy,⁶ which is the dose adopted recently by the United States Department of Agriculture (USDA).⁷ For *C. capitata*, a recent article cited studies indicating a minimum dose ranging 50 Gy to approximately 500 Gy, with the approximate average being 224 Gy.⁸ The USDA has adopted a dose of 225 Gy.⁹ For *B. cucurbitae*, the minimum dose has been reported to be 209 Gy.¹⁰ The USDA has adopted a dose of 210 Gy.¹¹ Plainly, the minimum dose range expressed in the Appendix is flawed and simply maintains the existence of irradiation facilities, rather than addresses a purposed problem with pest infestation.

In addition, if a minimum does level is assigned, as too should a maximum does level to prevent the over-irradiation of plant products.

Above and beyond these shortcomings, Appendices to the Guidelines are not officially considered part of the Guidelines.¹² Thus, by its nature, Appendix 1 is meaningless. We urge you to include it into the Guidelines proper and the make the appropriate adjustments to the radiation dose.

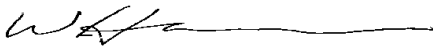
Appendix 2: Prior to the latest draft (Standards Committee Draft, Country Consolation, May 2002), and after the draft previous to this draft (Standards Committee Draft, Publication No. 18, November 2002), this section was re-classified from an Annex to an Appendix. Thus, Appendix 2 is not officially considered part of the Guidelines and, by its nature, Appendix 2 is meaningless. This is most unfortunate, because this section spells out a research protocol that includes, among other initiatives, archiving samples of the different developmental stages of the pests studied in order to, among other reasons, resolve possible future disputes on identification; calibrate, certify and use dosimetry systems according to recognized international standards; estimate the dose required to ensure quarantine security; confirm if the estimated minimum dose to provide quarantine security is valid; and keep test records and data in order to validate the data

requirements, and make these records available to interested parties. We urge you to include this critical section into the Guidelines proper.

We strongly urge the Interim Commission on Phytosanitary Measures to take our comments into account at its Fifth Session in Rome next month. Most importantly, as Annex 1 is incomplete, the Guidelines should not be ratified until they are complete, otherwise the various NPPO's will be left to their own discretion, and the purpose of the Guidelines will be null and void.

Thank you for your attention to this comment. If you have any questions, please feel free to contact me.

Sincerely,



Wenonah Hauter
Director,
Critical Mass Energy and Environment Program

Notes

¹ "Hearings on H.R. 2496, Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1984." Before the Procurement and Military Nuclear Systems Subcommittee of the Committee on Armed Services, House of Representatives, Congress of the United States. March 1-2, 1983. Washington, D.C.

² "Radiation accident spurs new NRC regulations." States News Service, Dec. 21, 1990.

³ Murray, D.R. *Biology of Food Irradiation*. Staunton, UK: Research Studies Press Ltd., 1990.

⁴ Heather, N.W., and Corcoran, R.J. "Effects of ionizing energy on fruit flies and seed weevil in Australian mangoes." Proceedings of the IAEA/FAO Research Coordination Meeting on the Use of Irradiation as a Quarantine Treatment of Food and Agricultural Commodities, Kuala Lumpur, Malaysia, August, 1990.

⁵ Jessup, A.J., and Rigney, C.J. "Gamma irradiation as a commodity treatment against *Dacus tryoni*, Queensland fruit fly, in fresh fruit." Proceedings of the IAEA/FAO Research Coordination Meeting on the Use of Irradiation as a Quarantine Treatment of Food and Agricultural Commodities, Kuala Lumpur, Malaysia, August, 1990.

⁶ Seo, S.T. et al. "Hawaiian fruit Bies in papaya, bell pepper, and eggplant: quarantine treatment with gamma irradiation. *Journal of Economic Entomology*, 66: 937-939, 1973.

⁷ 67 Federal Register 65016, 23 October 2002.

⁸ Hallman, G.J. and Loaharanu, P. "Generic Ionizing Radiation Quarantine Treatments Against Fruit Flies (Diptera: Tephritidae) Proposed." *Journal of Economic Entomology*, 95(5):893-901, 2002.

⁹ Note 4, Op. cit.

¹⁰ Note 3, Op. cit.

¹¹ Note 4, *Op. cit.*

¹² Personal communication with Nancy Klag, Plant Protection and Quarantine, APHIS, USDA. March 13, 2003.