The Development of Regulatory Policies for the Use of Irradiation as a Phytosanitary Treatment

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The Animal and Plant Health Inspection Service (APHIS) has taken a number of positive steps to speed expansion of the role of irradiation as an alternative technology for phytosanitary treatments. Recent efforts have been directed toward the rapid development of positions leading to a comprehensive framework for regulatory acceptance and operational implementation. At least three current initiatives are moving quickly into formal regulatory processes.

Position Discussion Documents (versions I - V) have served as an informal vehicle for accomplishing these objectives over the past year. The initial draft was first introduced at the Annual Meeting of the North American Plant Protection Organization (NAPPO) in October 1994. Since then, an ever-widening circle of reviewers has included subject matter experts, state and foreign regulatory officials, other federal and state agencies, industry, and the general public.

The overall reaction to these discussion documents has been positive, based on several hundred responses received by APHIS. Most issues involve technical concerns and other comments are editorial in nature. Nonetheless, additional review and further comment is welcome and still greater distribution is encouraged as APHIS accelerates toward formalizing the document by publishing in the Federal Register.

The Agency has chosen not to take a piecemeal approach or to be swayed to become either a proponent or opponent of irradiation technology. Instead, the strategy has been to move as quickly as possible to build a degree of internal expertise and to design a long-term, comprehensive approach that includes overarching policies and an defined regulatory framework. The establishment of this infrastructure is seen as providing a clear understanding of the path to treatment approval, thereby adding long-term efficiency to the regulatory process.

A key part of this strategy involves the elements of communication, education, and openness. This is believed to be especially critical with irradiation because of the general lack of understanding about the technology and because of its association with the negative aspects of nuclear energy issues in general. The series of Position Discussion Documents have been specifically designed to help promote this understanding and bring the technology into focus in a phytosanitary sense. The goal is to bring issues of concern to the forefront in an informal and technical forum prior to the formal regulatory proposal.

Another element of the discussion document design involves current regulatory initiatives and their direction as the result of surfacing during the assembly of a larger policy framework. Two closely related initiatives involve the adoption of generic doses for fruit flies and the modernization/modification of the irradiation treatment currently approved for papaya from Hawaii. Both of these efforts are based on well researched positions concerning the state of irradiation treatments for fruit flies. This has the potential to open new doors for a very large number of commodities previously unauthorized because other treatments were not suitable. There is a particularly high level of interest in exploring the possibilities with exotic fruits for which there is a high demand, and consequently greater smuggling. Providing a legitimate, plentiful, and quality supply of such fruit is believed to be key to reducing the load of illegal fruit.

The third initiative under consideration at this time involves developing irradiation treatments for raw logs from Russia. Research is underway in Russia to determine the dose required for complete mortality of all quarantine significant organisms on or in logs from Russia. APHIS and ARS are working closely with Russian scientists to design appropriate research protocols and to evaluate the results. Studies are slated to be complete within a few months.

APHIS hopes that sharing perspectives on these and other pertinent issues related to irradiation as a phytosanitary treatment will result in critical consideration of the developing positions by a broad base of reviewers, and timely input will be offered to further improve the potential for quickly adopting new irradiation treatments for phytosanitary problems.