National Food Processors Association and other food and grower trade associations. That petition sought the repeal or revision of several EPA policies and interpretations related to how EPA coordinated actions under its various statutory authorities over pesticide residues in food. EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act and sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act. Although EPA has not resolved all of the policy questions raised by the NFPA petition, EPA has concluded that changes are warranted to its policy concerning when FFDCA section 409 is applicable to a pesticide use and several related legal interpretations.

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I. Introduction

In *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), *cert. denied*, 113 S.Ct. 1361 (1993), the Ninth Circuit U.S. Court of Appeals held that the Delaney anti-

cancer clause in the food additives provision of the Federal Food, Drug, and Cosmetic Act was not subject to an exception for pesticide uses which pose a *de minimis* cancer risk. Prior to the decision becoming final, food processors and growers filed a petition with EPA challenging a number of policies and interpretations relating to how EPA implements its authority under the FFDCA. The petition proposes policies and interpretations that would reduce the impact of the *Les* decision. This notice responds to the petition in part.

II. Background

A. Statutory Background

Pesticide residues in human and animal food in the United States are regulated under provisions of the Federal Food, Drug and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The interplay between sections 402, 408 and 409 of the FFDCA and, to a more limited extent, between the FFDCA and FIFRA, have created a complex, and sometimes contradictory, statutory framework underlying residue regulation in food.

Before a pesticide may be sold or distributed, it must be registered under the FIFRA. 7 U.S.C. 136 et seq. To qualify for registration, a pesticide must, among other things, perform its intended function without causing "unreasonable adverse effects on the environment." 7 U.S.C. 136a(c)(5). The term "unreasonable adverse affects on the environment" is defined as "any unreasonable risk to man or the environment taking into account the economic, social and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). The FFDCA, 21 U.S.C. 301 *et seq.*,

authorizes the establishment by regulation of maximum permissible levels of pesticides in foods. Such regulations are commonly referred to as "tolerances." Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342. EPA was authorized to establish pesticide tolerances under Reorganization Plan No. 3 of 1970. 5 U.S.C. App at 1343 (1988). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA).

The FFDCA has separate provisions for tolerances for pesticide residues on

raw agricultural commodities (RACs) and for residues on processed food. For pesticide residues in or on RACs, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408. 21 U.S.C. 346a. EPA regulates pesticide residues in processed foods under section 409 which pertains to "food additives." 21 U.S.C. 348. Maximum residue regulations established under section 409 are commonly referred to as food additive tolerances or food additive regulations (FARs). Section 409 FARs are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, a pesticide residue in processed food generally will not render the food adulterated if the residue results from application of the pesticide to a RAC and the residue in the processed food when "ready to eat" is below the RAC tolerance set under section 408. This exemption in section 402(a)(2) is commonly referred to as the "flowthrough" provision because it allows the section 408 raw food tolerance to flow through to the processed food form. Thus, a section 409 FAR is only necessary to prevent foods from being deemed adulterated when the concentration of the pesticide residue in a processed food when "ready to eat" is greater than the tolerance prescribed for the RAC, or if the processed food itself is treated or comes in contact with a pesticide.

To establish a tolerance regulation under section 408, EPA must find that the regulation would "protect the public health." 21 U.S.C. 346a(b). In reaching this determination, EPA is directed to consider, among other things, the "necessity for the production of an adequate, wholesome, and economical food supply." Id. Prior to establishing a food additive tolerance under section 409, EPA must determine that the "proposed use of the food additive [pesticide], under the conditions of use to be specified in the regulation, will be safe." 21 U.S.C. 348(c)(3). Section 409 specifically addresses the safety of carcinogenic substances in the so-called Delaney clause which provides that "no additive shall be deemed safe if it has been found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *." Id. Although EPA has interpreted the general standard under section 408 to require a balancing of risks and benefits, where a pesticide which is an animal or human carcinogen is involved, the section 409