Delaney clause, in contrast to section 408 and FIFRA, explicitly bars such balancing no matter how infinitesimal the potential human cancer risk. *Les* v. *Reilly*, 968 F.2d at 989.

B. EPA Coordination of the Statutory Provisions Governing Pesticides

In its administration of FIFRA and FFDCA sections 408 and 409, EPA has specified that FIFRA registrations for food-use pesticides will not be approved until all necessary tolerances and food additive tolerances have been obtained. 40 CFR 152.112(g). As a policy matter, EPA has taken a similar approach to FFDCA sections 408 and 409, not granting section 408 tolerances until needed section 409 FARs have been granted.

This linkage of its statutory authorities has been described by EPA as its coordination policy. Basically, EPA's coordination policy is an expression of EPA's intent to take into account all of the applicable provisions governing pesticides in taking action under any one of the three. EPA's view has been that it should not be approving pesticide uses under one of the three provisions if an approval needed under one of the other provisions cannot be obtained.

EPA's concentration policy establishes the criterion as to when approval is needed for food-use pesticides under FFDCA section 409, and hence when the Delaney clause applies. Generally, EPA has used a ''concentration in fact'' standard as the test of whether a use needs a section 409 FAR. The concentration in fact standard focuses on the level of the pesticide residue in the processed food, measured on a weight to weight basis, compared to the level of the residue in the precursor raw agricultural commodity. If a processing study shows that the level of pesticide residue in the processed food exceeds the level of residue in the precursor raw agricultural commodity, EPA would conclude there has been a concentration in fact of the pesticide residues in the processed food.

EPA believes the concentration in fact test is relevant to the inquiry of whether a section 409 FAR is needed because residues in the raw crop may be at or near the section 408 tolerance level. Residues in the raw crop may be close to the section 408 tolerance level because section 408 tolerance levels are established based on actual field trials and designed to be set no higher than necessary given approved usage directions for the pesticide established in the FIFRA registration. Under EPA regulations, the section 408 tolerance level should ''reasonably reflect the amount of residue likely to result when the pesticide chemical is used in the manner proposed.'' 40 CFR 180.4. If residue levels in the raw crop are at or near the section 408 tolerance level and concentration in fact occurs during processing, the residue level in the processed food is likely to exceed the section 408 tolerance. The National Academy of Sciences (NAS) has acknowledged the logic behind EPA's reliance on a concentration in fact standard:

> In determining whether a section 409 food additive tolerance is required, the EPA focuses on whether residues in any processed product exceed those found on the unprocessed crop, not whether residues concentrate above some hypothetical section 408 tolerance.
>
> The logic of the EPA's practice is clear. A section 408 tolerance represents a residue level that may in some cases be realized. A section 409 tolerance must reflect the possible residue levels in processed foods derived from that raw commodity.

National Research Council, Regulating Pesticides in Food: Delaney Paradox 28 (1987).

III. The NFPA Petition

On September 11, 1992, the National Food Processors Association (NFPA), the United Fresh Fruit and Vegetable Association, the Florida Fruit and Vegetable Association, the Northwest Horticultural Council, and the Western Growers Association filed a petition with EPA challenging the policies followed by EPA in linking its regulatory activities under the various pesticide provisions of FIFRA and FFDCA. (Petition to the Environmental Protection Agency, Office of Pesticide Programs, Concerning EPA's Pesticide Concentration Policy (1992)) (hereinafter cited as ''NFPA petition''). The NFPA petition explicitly attacks what it calls EPA's ''concentration policy.'' In actuality, the petition is a challenge to two interrelated policies described by EPA as its coordination and concentration policies. The NFPA petition argues that the coordination and concentration policies are both unlawful and unnecessary. The petition requests that the EPA coordination policy be repealed so that section 408 tolerances can remain in effect (or can be established) for pesticide uses even if, under the *Les* decision, the associated section 409 FARs have to be revoked (or cannot be established). The petition asks that the concentration policy be modified so that it takes into account factors beyond the concentration in fact test. Additionally, the petition requests that EPA apply the term ''ready to eat'' in the flow-through provision according to what NFPA asserts is its plain meaning.

EPA sought public comment on the petition (58 FR 7470, Feb. 5, 1993). Extensive public comment was received, and significant comments are discussed in this notice. Several more narrowly focused comments are discussed in a separate document that has been included in the docket.

IV. Summary of EPA's Partial Response to NFPA Petition

Sections V through VII below set forth EPA's partial response to the NFPA petition. EPA has not reached a decision on NFPA's challenge to the coordination policy. EPA, however, has completed evaluation of NFPA's contentions regarding the concentration policy and EPA's interpretation of the term ''ready to eat.'' This document responds to the NFPA petition on these two issues. In brief, EPA agrees with NFPA and many of the commenters that modifications should be made to its concentration policy so that it is a better predictor of the likelihood that residues in processed food may exceed the applicable section 408 tolerance. EPA, however, cannot accept all of NFPA's suggested changes to the concentration policy. As to interpretation of the phrase ''ready to eat,'' EPA agrees that such term must be given its common-sense meaning.

V. Concentration Policy

A. General Issues

EPA's concentration policy is the trigger for when a pesticide use needs a section 409 FAR. EPA has treated a pesticide use as needing a section 409 FAR generally whenever a processing study shows that pesticide residues are greater in the processed food than in the raw agricultural commodity before processing. In other words, EPA looks to see if the pesticide ''concentrates in fact.'' EPA has used concentration in fact as the trigger for when a food additive regulation is needed because, in theory, RAC tolerances are set at levels no higher than necessary to cover maximum legal usage under the FIFRA registration. RAC tolerances are established based on field trial data showing the range of residues likely to result from maximum legal application of the pesticide. Generally, the RAC tolerance level is set just slightly above the maximum residue value found in the field trials. Thus, if concentration in fact occurs during processing, overtolerance residues in processed food can result if the RACs used for processing contain pesticide residues reflecting maximum legal usage.