NFPA challenges EPA's concentration policy on two grounds. First, NFPA claims that all available data support the view that food additive regulations are unnecessary to avoid adulterated processed food. Second, NFPA argues that EPA has ignored the ''ready to eat'' requirement in the flow-through provision. EPA's interpretation of the term ''ready to eat'' will be addressed in the following section.

B. Monitoring Data and the Concentration Policy

NFPA cites various data sources which it claims show residues on both raw and processed foods generally to be well below the level of the RAC tolerance. NFPA argues that residues in processed foods generally fall below RAC tolerances because of the careful attention paid to the flow-through provision by food processors.

> When the flow-through provision was adopted and as it operated for a number of years, processors clearly understood that it was their obligation to produce a processed product that stayed within the raw product tolerance. This obligation could be met through any number of steps, including supervision of growers' pesticide practices, careful and informed buying practices, analysis of raw product, handling, cleaning and treatment of the raw product, and testing of the finished produce to assure that it would be in compliance with the Act * * *. [T]hey recognized that if their process involved some degree of concentration [and the food is consumed in the concentrated form], they were well advised to use raw product that at the time of processing was below the prescribed tolerance levels, and that failure to take such steps could possibly result in adulteration and a costly enforcement action.

(Comments of NFPA at 37–38).

NFPA asserts that the steps taken by processors to avoid overtolerance residues show that EPA's reliance on processing studies to require food additive regulations is unwarranted.

The data relied upon by NFPA do show that pesticide residues in raw and processed food generally are below section 408 tolerance levels. On the other hand, EPA is often presented with processing studies by pesticide manufacturers that demonstrate that particular pesticides concentrate in processed food to levels 2 times, 10 times, or even 50 times above the level found in the raw crop. EPA has examined carefully the factors cited by NFPA and commenters as an explanation for the low levels of residues to determine whether any adjustments to the concentration policy are appropriate. Although EPA has concluded that some adjustment to the concentration policy is warranted, EPA believes that the basic rationale of the concentration policy with its focus on concentration in fact is sound. As the National Academy of Sciences has found:

> The logic of 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 commodity.

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

At the same time, EPA recognizes that reliance solely on processing studies may not, in some circumstances, accurately ''reflect the possible residue levels in processed foods.''

In challenging the concentration policy, some commenters argue that EPA's policy is a theoretical exercise with no basis on actual data and that this is confirmed by EPA's description of its policy in its request for comment on the NFPA petition. EPA did not mean to suggest in that notice that its concentration policy focuses on theoretical possibilities. EPA's policy has always sought to determine whether residues greater than the section 408 tolerance can occur in processed food. EPA makes this determination based on hard data— actual processing studies involving, in most cases, the pesticide and crop in question. EPA's revisions to its policy do not change the basic focus of the concentration policy. Rather, as explained below, EPA has expanded the range of data and other information it will consider in determining whether residues greater than the section 408 tolerance can occur in processed food.

It is worth noting that the same data relied upon by NFPA to show that most food, whether raw or processed, is well below section 408 tolerance levels also reinforces EPA's judgment that many section 408 tolerances may currently be set higher than necessary and may need to be lowered so that they reasonably reflect actual residues. If section 408 tolerances are lowered, the chances of residues over the section 408 tolerance in processed foods where residues concentrate in fact would be greater.

C. Revisions to the Concentration Policy

1. *Introduction and summary.* EPA's concentration policy is designed to evaluate when residues in processed food may exceed the raw food tolerance due to concentration during processing. Generally, in implementing its concentration policy, EPA has used a test of concentration in fact as an indicator that residues over the section 408 tolerance may occur because residue levels in the RAC may exist at the tolerance level. EPA, however, also has historically considered, to a limited extent, at least two other factors in evaluating whether a processing study showing concentration of residues indicates there is a real possibility of residues over the section 408 tolerance. Below, EPA discusses those factors and other factors that may prevent the occurrence of residues over the section 408 tolerance.

EPA concludes that it has too rigidly applied its concentration in fact test. EPA continues to believe that information from processing studies is generally the most important single piece of information is assessing the likelihood that residues in processed food could exceed the section 408 tolerance. EPA will also continue to consider factors such as the variability of the analytical method and the degree of rounding used in establishing the section 408 tolerance. In a departure from past practice, EPA will, as explained below, take into account, where appropriate, information pertaining to the averaging of residues during processing. EPA will also, where appropriate, consider information obtained from properly designed market basket surveys. EPA, however, is not convinced at this time by the NFPA suggestion that, despite data showing residues concentrate during processing, processors can insure residue levels stay below section 408 tolerance levels.

2. *Factors relied upon by EPA in determining whether a pesticide which concentrates in fact is likely to produce residues in exceedance of the section 408 tolerance.* As noted, EPA follows a concentration in fact test to determine if section 409 FARs are necessary. For the most part, EPA's concentration in fact test is applied based on the results from data from processing studies. Historically, EPA has also occasionally considered two other factors in determining whether a processing study which shows concentration in fact does show that residues in processed food can exceed the appropriate section 408 tolerance.

The first of these factors is the degree of rounding that was used in setting the RAC tolerance. To a limited extent, EPA has considered the degree of rounding in past decisions on whether a section 409 FAR is needed. Generally, the highest value obtained from field trials is rounded up in selecting the tolerance level. For example, if the highest value from field trials was 8 parts per million (ppm), that data point might be rounded to 10 ppm for the tolerance value. Where rounding increases the observed residue level by 25 percent, the pesticide would have to concentrate by