

and pest pressures it is unrealistic to assume that no grower will treat his or her crop with a pesticide in the manner that yields the highest lawful residues.

Moreover, where residues do concentrate during processing, EPA questions the ability of the processor or grower to manage pesticide residue levels so as not to produce over-tolerance residues in processed food. Although processors may know the concentration factor of residues from processing studies, the concentration factor does not suggest with any precision how processors could instruct growers to change their pesticide application procedures so that residues over the section 408 tolerance will not result in processed food. Levels of residues in raw crops are dependent not only on how much pesticide is applied but on when and how the pesticide is applied. Little data exist that describe the effect of varying any of these procedures on residue levels. Similarly, EPA believes little information is available concerning how changes in their manufacturing processes affect residue levels in processed food. Finally, as discussed below, the comments received on the NFPA petition reinforce EPA's experience that farmers often do not know the ultimate destination of their crop. Therefore, EPA believes it would be very difficult for growers or processors to manipulate residue levels in processed food.

EPA would be open to considering further industry proposals laying out a potential policy framework that more specifically delineates how processor practices could be taken into account in determining the likelihood that residues in processed food would exceed the applicable section 408 tolerance. It would be helpful if such policy proposals contained criteria for evaluating whether specific processor claims regarding pesticide/commodity combinations are reasonable. Among other things, these criteria should address (1) what data would be submitted to EPA to verify residue levels, (2) how the practicality of the proposed scheme would be evaluated (e.g., degree of concentration of processing operations and ability to separate raw food streams), and (3) whether processor control of residue levels for a specific pesticide/commodity combination could be feasibly enforced. If such further policy proposals are received, EPA would seek public input before making any decision on the merits of the proposals and using the proposed criteria in evaluating specific pesticide uses.

*Mixing and blending.* EPA believes that in many instances it would be

appropriate to take into account mixing and blending in determining the likelihood that residues over the section 408 tolerance could result. This change in practice is warranted, EPA believes, because EPA's prior assumption, i.e., that all raw food have the potential to have residues at or near the section 408 tolerance level, does not adequately take into account the realities of food processing. Because of the way EPA sets section 408 tolerances, individual raw commodities do have the potential of having residues at or near the tolerance level. The data from field residue trials show, however, that residue values even from a single field can vary significantly. When individual raw commodities are mixed in processing operations, it is realistic to expect that there will be an averaging effect on the residues in the processed food.

Accordingly, if EPA determines that there is a sufficient degree of mixing or blending during processing such that the normal variation among individual samples from a field will be substantially evened out, EPA will consider comparing some "average" residue value from field trials times the concentration factor to the RAC tolerance level in determining the likelihood of residues over the section 408 tolerance. EPA generally believes that the most relevant "average" residue value from crop field trials is the highest average residue value from the series of individual field trials. Using an average of all samples from all field trials in all regions of the U.S. would tend to suppress the variability in residue values to a greater extent than can be expected by mixing or blending. Generally, crops grown in different regions of the U.S. are not mixed prior to processing. Rather, crops are often processed field-by-field as they are harvested by the grower.

There are a number of constraints EPA thinks are critical here. First, considering average field trial residues is only appropriate where the values being averaged are from field trials involving maximum treatment rates. In other words, averaging may be used to take into account the variation in residues which occurs in crops receiving maximum treatment and minimum preharvest intervals but not residue variations as result of different levels of treatment. As laid out above, EPA has no basis on which to make assumptions about whether crops in specific instances would be treated at rates lower than the maximum permitted on the pesticide label or what residues those lower rates would produce. Second, whether considering blending would be appropriate would

depend on the quality of the data base. Consideration of any "average value" would be less appropriate where adequate data from all representative regions of the country are not available. Finally, even where it would be appropriate to consider average residues, EPA believes a simple calculation showing that the average residue multiplied by the concentration factor from a processing study is less than the RAC tolerance alone may not conclusively show that residues over the section 408 tolerance could not result. In appropriate circumstances, EPA may need to consider a number of other factors, such as the variability in the field trial data, in determining the likelihood of residues over the section 408 tolerance.

*Degradation of residues.* Although EPA recognizes that degradation of residues frequently occurs, it is not apparent how EPA could take that phenomenon into account in its concentration policy other than to the extent the effects of degradation are captured in processing studies. EPA would need detailed data on the degradation rates of pesticides as well as on the minimum time between the harvesting of crops and when such crops are manufactured into ready-to-eat processed foods. Without such information, it would be difficult to establish a tolerance level that would assure that legally treated crops did not result in illegal food.

Some comments filed in response to the NFPA petition suggest that marketplace survey or FDA monitoring data would be relevant to whether there is a likelihood of residues over the section 408 tolerance. Certainly, data from marketplace studies have some degree of relevance to the question of whether residues in processed food may exceed the section 408 tolerance. The relevance of marketplace studies, however, depends on how the marketplace study was performed. For example, the principal reason marketplace studies have been conducted in the past is to obtain better data concerning actual residue values close to the point at which food is consumed. Thus, marketplace studies generally involve sampling commodities in retail grocery stores. A tolerance for processed food would not only apply to food in retail stores but at all prior points at which the food moved in interstate commerce. This fact would have to be taken into account in assessing the relevance of a marketplace study in determining the likelihood of residues in processed food in excess of the section 408 tolerance. Monitoring data can also be relevant to determining