gum. These foods are not generally available to consumers in grocery stores and, even if a consumer could purchase such a food, it would not be consumed "as is" but would be further processed (e.g., dried hops used in brewing beer) or used as an ingredient in a food product. Other foods for which EPA has set food additive regulations, such as raisins, olives, and potato chips, clearly are "ready to eat."

EPA generally believes that foods that are mixed prior to consumption are not "ready to eat." Mixing generally involves the combining of foods with the intent of creating a different food product. For example, combining a tea bag with hot water is intended to create a new food product, the beverage tea. Thus, the dried tea in the tea bag would not be considered "ready to eat." On the other hand, EPA does not believe this mixing principle applies to condiments. Condiments are consumed as a supplement to other "ready to eat" food. A condiment is also consumed "as is."

There remain, however, many commodities for which EPA has traditionally set food additive regulations which are not so easily characterized under the "ready to eat" standard and which will require a caseby-case inquiry. One of the reasons for the fact-intensive nature of this inquiry is that foods have many uses and eating habits vary widely in the United States. Thus, determining whether a food is "ready to eat" involves identifying all significant uses of a food and then determining if any of those uses meets the definition of "ready to eat." For example, perhaps the most common use of vegetable oil is as a cooking medium or as an ingredient in baked products. However, another use of vegetable oil is as a "dressing" for a green salad. When used in this manner, oil is directly added to the salad as a condiment, and thus oil generally would qualify as "ready to eat." Additionally, EPA will need to explore whether some foods which have traditionally not been consumed without further preparation, are actually being consumed on an "as is" basis. Comments submitted by DuPont Agricultural Products support this approach:

We appreciate that some concentrated products can be consumed without mixing. The likelihood of occurrence of this consumption pattern is a factor which should be considered in determining which form is best viewed as the ready-to-eat stage. In our view, a reasonable approach would be to weigh such a consumption pattern based on the frequency of occurrence. If the consumption of the concentrate occurs with great infrequency, the appropriate ready-toeat food would still be the diluted product. (Comments of DuPont Agricultural Products at 8).

In circumstances where EPA's revised approach to the term "ready to eat" results in particular food forms of a commodity being dropped from the category of "ready to eat," EPA will need to explore whether there is a possibility of concentration of residues above the section 408 tolerance in any other, ready-to-eat forms of that commodity. In many instances further preparation of a not-ready-to-eat commodity will so significantly reduce residues that, even if the not-ready-toeat precursor processed food contained residues over the section 408 tolerance, the ready-to-eat commodity will not. Use of citrus oil as a flavoring in ice cream may be an example of this phenomenon. Citrus oil may be such a small proportion of the total product that any residues over the section 408 tolerance in the oil would be diluted below the section 408 tolerance in the ice cream. However, in other instances, the dilution involved in further preparation of a not-ready-to-eat processed food is not so dramatic. For example, flour, assuming it is found to be a not-ready-to-eat food, is prepared into commodities such as crackers or tortillas in which the dilution factor may be fairly modest. In situations such as this, EPA will have to determine whether it should be setting section 409 FARs on different commodities than has been EPA's traditional practice

2. Enforcement approach. EPA's revised approach to the term "ready to eat" will make enforcement of the FFDCA more challenging as regards foods no longer considered "ready to eat." EPA does not view as satisfactory NFPA's suggestion that for enforcement purposes EPA should develop dilution tables and from such tables promulgate action levels to evaluate the legality of not-ready-to-eat processed food. Although this is a possibility, EPA regards it as cumbersome and lacking the enforcement ease of binding tolerances. An action level is not binding on anyone and thus even though use of a dilution table may suggest that a food is adulterated, FDA could only successfully proceed against the food if it could prove in court that the level of residue found in the notready-to-eat food would render ready-toeat food adulterated.

Instead, EPA has decided to use its general rule-writing authority under FFDCA section 701 to establish maximum residue levels for not-readyto-eat processed food. Section 701 grants EPA the authority "to promulgate regulations for the efficient enforcement of this Act." 21 U.S.C. 371. These maximum residue levels would be set no higher than the levels which could result in the processed food assuming legal residues in the raw food and that good manufacturing practices were followed.

EPA's authority to set such maximum residue levels arises from the flowthrough provision. The flow-through provision does not legalize residues in ready-to-eat processed food unless three criteria are met: (1) the residues are at or below the applicable section 408 tolerance; (2) the precursor raw food had residues within the section 408 tolerance; and (3) good manufacturing practices were followed in preparing the processed food. The maximum residue levels set under section 701 would establish binding regulations as to when the two latter criteria of the flowthrough provision are met for a specific pesticide use. If such a maximum residue level were exceeded in a processed food, then as a matter of law the flow-through provision would not apply to the food (whatever the residues in the food when it is "ready to eat"), and thus the food would be adulterated as a matter of law under FFDCA section 402(a)(2)(C)

3. Animal feeds. As noted, a number of commenters claimed that food processing byproducts such as grape pomace, soybean hulls, etc. are not 'ready to eat" either because they are unpalatable or nutritionally deficient or because they are not a significant portion of the diet of animals. EPA generally intends to apply a similar approach to processing byproducts used as animal feeds as it will to human foods in determining whether the byproducts are "ready to eat" and will also use section 701 maximum residue levels, as described above, where appropriate. Determinations on specific processing byproducts will have to be made on a case-by-case basis. To the extent it can be shown that any individual processing byproduct is unpalatable when fed "as is" or that for other reasons the processing byproduct is generally not fed absent further processing or mixing, EPA would not categorize that particular byproduct as "ready to eat." EPA believes this showing probably can be made for a substantial number of processing byproducts.

In response to comments stating that EPA required examination of processing byproducts not currently used as animal feeds (e.g., apple pomace), EPA would note that it has recently revised its guidelines on what processing byproducts are used as animal feeds. This revision followed a comprehensive survey of animal feed practices. EPA has