

“concerning aggregate exposure levels of consumers.” Further, Congress expressly recognized in the FQPA that this type of information is relevant and appropriate to a FQPA safety analysis. The statute, as amended by the FQPA, contains special provisions placing certain requirements upon EPA when it relies upon percent crop treated data in chronic risk assessments or anticipated residue data. (21 U.S.C. 346a(b)(2)(E) and (F)). Anticipated residue data is a term of art encompassing, among other things, data on the effect food processing has on pesticide residue levels. (70 FR at 46731–46732; Ref. 9) This term was in use by EPA well before such language was adopted in the FQPA. (Ref. 10; see, e.g., 54 FR 33044, 33045, August 11, 1989).

Given this clear legal authority, the States’ vague allegations that the use of percent crop treated data or processing factors runs counter to the intent of the FQPA are meritless.

3. *Use of percent crop treated data and individual exposure.* The States’ claim that EPA’s use of percent crop treated data is not protective of individuals appears to be based on a lack of understanding of (1) the differences between acute and chronic risks and (2) the different techniques EPA uses for incorporating percent crop treated information into risk assessments. At times, EPA uses percent crop treated data in estimating exposure for both chronic and acute risk assessments. Such data, however, is used in a different manner in these assessments due to the differences in how acute and chronic exposures may result in harm. Moreover, as to both acute and chronic risk, EPA is concerned with the risk to an individual within major, identifiable population subgroups and incorporates percent crop treated data in a manner consistent with that concern. Further explanation of this approach is provided below.

With a chronic risk, EPA is concerned with adverse effects that occur from the cumulative effect of repeated exposures over an extended time period (i.e., generally a period of 1 year or more for dietary exposure). The focus for a chronic exposure assessment is not on the level of any one exposure or even the variation in exposure from day-to-day so much as the general level of the continuing exposure. Thus, in estimating chronic pesticide exposure, EPA uses average daily pesticide exposure over the appropriate time period. In estimating average daily pesticide exposure, EPA takes into account that, given the national distribution of food in the United States, over a chronic timeframe a person will

consume food from a mixture of sources—regional, national, and international—as well as food grown at different times of the growing season. It is likely, therefore, that to the extent a food commodity is not uniformly treated with a given pesticide, the consumer will over time be exposed to a fairly representative sample of treated and untreated commodities.

Accordingly, in refined exposure estimates for chronic pesticide exposures, EPA generally averages dietary pesticide exposure from a food based on the percentage of that food that has been treated with the pesticide. For example, if the estimated residue value for a pesticide on treated blueberries is 1 part per million (ppm) and half of the blueberry crop is treated, EPA would estimate the chronic pesticide exposure level from blueberries using the assumption that all blueberries contain 0.5 ppm of the pesticide (i.e., treated blueberries bear 1 ppm pesticide residues and over time a person gets an equal mixture of treated and untreated blueberries). EPA has long used percent crop treated data in this manner in chronic risk assessments and Congress explicitly recognized the appropriateness of this method of estimating pesticide exposure in the FQPA. (21 U.S.C. 346a(b)(2)(F)).

With acute hazards, EPA is concerned with an adverse effect that can result from a single pesticide exposure or pesticide exposure over a single day to an individual. Thus, acute pesticide exposure assessments are designed to measure or estimate the maximum amount of residue that may be present in a single commodity serving or meal. EPA’s traditional method of using percent crop treated data in chronic risk assessments is problematic for acute risk assessments because it masks the highest levels of pesticide residues expected in food by averaging residue values from treated and untreated commodities in estimating pesticide exposure. For this reason, EPA, up until the mid-1990’s, did not use percent crop treated data in acute risk assessments. Instead, for acute risk assessments, EPA assumed that all commodities for which a pesticide had a tolerance contain residues at the tolerance level. That changed, however, with the introduction in the last decade of probabilistic risk assessment analysis.

Probabilistic analysis, when used in pesticide exposure/risk assessment, is “a statistical method where the range of exposures to pesticide residues and the probability of exposure to any particular level is quantified.” (Ref. 3 at 22). Probabilistic exposure assessments are particularly helpful in realistically

estimating pesticide exposure levels from short-term exposures (e.g., a single meal) where there are multiple variables affecting pesticide exposure levels. For pesticide exposures from food these variables can include:

i. Several different foods may be consumed in differing amounts;

ii. The consumed foods may or may not have been treated with the pesticide in question; and

iii. Foods that are treated may have a wide range of residue levels. Integral to probabilistic analysis of pesticide exposure is information on differing consumption patterns among individuals, the range of the levels of pesticide residue in treated food, and the percent of food that has been treated with a pesticide. Importantly, information on percent crop treated is not used in a probabilistic analysis to average residue levels between treated and untreated crops but rather solely to determine “the probability of [an individual] encountering a treated commodity.” (Ref. 11 at 14). Thus, percent crop treated information is used in a fundamentally different fashion in probabilistic acute risk assessments than in non-probabilistic chronic risk assessments. (The Agency currently does not use probabilistic techniques for chronic risk assessment due to limitations in its food consumption database.)

The States’ challenge to EPA’s use of percent crop treated data for metribuzin is flawed because the States attack the appropriateness of the exposure estimate for a chronic risk assessment based on concerns more applicable to acute risk. The States argue that the adjustment of residue values by the percentage of the treated crop understates exposure of individual children because “if a child is eating treated carrots, he or she is consuming carrots that all contain pesticide residues . . .” (Ref. 2 at 5). EPA generally agrees that if the concern is acute risk, it would be inappropriate to estimate acute exposure for non-blended commodities by multiplying the expected residue value in a food (e.g., carrots) by an estimate of the percent of carrots treated with the pesticide. Acute exposure assessments should be designed to identify actual exposures that can occur to an individual at a single meal or in a single day. For metribuzin (and alachlor and chlorothalonil as well), however, EPA used percent crop treated data only for estimating chronic pesticide exposure and risk. For chronic dietary risk, it is generally exposure over a period of at least 1 year that matters and over such a time period a person is likely to