OCT. 30, 1997

MEMORANDUM

SUBJECT: Determining the Need for Tolerances in Livestock Commodities.

FROM: Chemistry Science Advisory Council
Health Effects Division (7509C)

TO: HED Chemistry Interest Group

This memorandum addresses the process for deciding whether tolerances are required for residues of a pesticide in livestock commodities (meat, milk, poultry, eggs [MMPE]) when residues occur in raw agricultural commodities fed to animals. As described in 40 CFR 180.6, tolerances may or may not be needed depending upon the level of certainty of the presence of finite residues in the animal products If it is concluded that finite residues will be incurred (180.6(a)(1)) or there is a reasonable expectation of finite residues (180.6(a)(2)), tolerances will be established for MMPE. On the other hand, if there is no reasonable expectation of finite residues in MMPE (180.6(a)(3)), tolerances for residues in those commodities are not required.

The necessity for MMPE tolerances is determined by the results of livestock metabolism and/or feeding studies. As discussed in pages 15-16 of guideline 860.1300 (Nature of the residue-plants, livestock), in some cases it is possible to determine that a feeding study and MMPE tolerances are not needed based on the residues in feed items and the results of the livestock metabolism study. The example cited there has a dietary burden of 0.01 ppm for livestock, a 10 ppm radiolabeled dose in the metabolism study, and total radioactivity <0.1 ppm in animal tissues, milk and eggs. Assuming a linear relationship between dose and residues, expected residues in animal commodities in this instance would be on the order of 0.1 ppb. As this value is an order of magnitude or more below the limit of detection for methods used to measure residues in livestock

products, a conclusion can be made that there is no reasonable expectation of finite residues in MMPE. Tolerances in such commodities would not be required.

In borderline cases using the concept described above, reviewers should keep in mind the species used in the metabolism study and the duration of the dosing period. In the case of ruminants, the metabolism study is normally conducted with a goat and the dosing period is often only three days. The feeding study used to determine residues in a more quantitative manner is required on dairy cattle with a dosing period of at least 28 days. Therefore, some caution is required when contemplating waiving the cattle feeding study and the need for tolerances. With poultry, the species is virtually always the same for the metabolism and feeding studies. Therefore, there may be less difficulty in making the decision on the need for poultry commodity tolerances based on just the radiolabeled study.

The above process wherein livestock feeding studies and animal tolerances are not required has been used often in recent years for certain classes of pesticides. In particular, the sulfonylurea and imidazolidone herbicides often fit into this category as they produce low residues in feed items and show minimal transfer to animal products. For most classes of chemicals, however, the livestock metabolism studies do not permit a conclusion of no reasonable expectation of residues in animal products. Livestock feeding studies as described in guideline 860.1480 are required in such cases.

Livestock feeding studies are normally conducted with three dosing levels (1x, 3x, 10x) where 1x represents the highest expected dietary burden for the animals when tolerance level residues are present on all potentially treated feed items. The studies are typically conducted using lactating dairy cattle and laying hens. Refer to 860.1480 for details on how to calculate the dietary burden and other specifics for conducting such studies. The general rule for determining the need for MMPE tolerances based on the feeding study is as follows. If quantifiable residues of concern are found in milk, eggs or edible tissues (muscle, fat, liver, kidney [ruminants only]) from any dosing level less than or equal to 10x, our conclusion will normally be that there is a reasonable expectation of finite residues and tolerances will be required for animal products. In order to conclude that there is no reasonable expectation of residues in MMPE, there would need to be a lack of quantifiable residues in all samples from a dosing level of at least 10x.

When residues are quantifiable in milk, eggs or tissues from a dose of 10x or less, tolerances will normally be set on all

products related to the animal of interest. In other words, if a cattle feeding study shows quantifiable residues, tolerances will be set on cattle meat, fat and meat byproducts as well as milk. [The three tissue tolerances would be set for goats, hogs, horses and sheep as well.] On a case-by-case basis, however, tolerances may be set on only one or two of the animal products. For example, if no quantifiable residues are observed in muscle, fat and milk at a 10x feeding level, but residues are found in liver and kidney at 10x as well as the lower doses, a tolerance would only be needed on meat byproducts (of cattle, goats, hogs, horses, sheep) to cover residues in liver and kidney. In other words, in some instances the conclusion of “no reasonable expectation of finite residues” may be made for just a portion of the animal products on which we set tolerances.