

OCT 28, 1999

MEMORANDUM

SUBJECT: Classification of Seed Treatments as Food or Nonfood Uses.

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

TO: HED Chemistry Interest Group

In response to questions from registrants involved in seed treatments, the Chem SAC has discussed the determination of such uses as food versus nonfood based on the results of radiolabeled studies. This memorandum details the decisions made in this area.

Seed treatments are addressed in guideline 860.1000 (page 3): AIn order for a seed treatment to be considered a nonfood use, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop. If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances. The guideline does not specify in quantitative terms what is meant by Ano uptake of residues. The SAC has concluded that this phrase means that the total radioactive residue (TRR) needs to be less than the limit of quantitation (LOQ) or minimum quantifiable limit (MQL) for all raw agricultural commodities (RAC=s) of concern for the crop as delineated in Table 1 of guideline 860.1000. Furthermore, the LOQ/MQL needs to be 5 ppb (0.005 ppm) or lower to establish Ano uptake of residues and thus have the use be considered nonfood.

It should be emphasized that the requirement for the TRR to be <5 ppb in all RAC=s is more stringent than the guideline in that the latter refers to only the aerial portion of the crop. In the case of a root crop like radishes the portion of the plant in the soil is a food item; therefore, the TRR in the root also needs to be <5 ppb for the seed treatment use to be considered nonfood. In some cases the TRR may be <5 ppb in one crop part, but >5 ppb in another. For example, it would not be unusual for quantifiable residues to be seen in wheat or soybean forage, but at the same time the grain/seeds have residues below the LOQ. In these instances the use is classified as a food use requiring tolerances. Guidance on crop field trials for some scenarios with the TRR greater than 5 ppb is presented below.

One scenario that could be encountered for seed treatments is TRR=s >5 ppb, but <10 ppb. The nature of the residue guideline (860.1300) indicates that no characterization or identification of radioactivity is required when the TRR is <10 ppb (unless there are toxicological concerns with residues at lower levels). Thus, if the TRR is >5 ppb but <10 ppb, it is a food use but no characterization of the radioactivity is normally required. In these cases, the residue of concern will be considered to be the parent compound. It may also be possible to reduce the

number of field trials significantly from that normally required in 860.1500 for the crop. If three trials conducted at a 5x rate show residues of parent less than the LOQ of the analytical method in all RAC=s of concern, additional trials are not needed and tolerances can be set at the LOQ of the method. If residues are above the LOQ in one or more of the RAC=s in the 5x studies, additional field trials up to the usual requirements of 860.1500 will be needed. These additional trials should preferably be done at a 1x rate. In the 1x rate trials, only those RAC=s with residues >LOQ from a 5x rate need to be analyzed.

When TRR=s exceed 10 ppb, guideline 860.1300 instructs one to attempt extracting, characterizing, and identifying the activity. It is possible the residue of concern will include metabolites in addition to parent. This memorandum does not address the various situations which might follow in these cases.

Special situations may arise with respect to seed treatment uses on soybeans and peanuts due to our accepting feeding restrictions for soybean forage/hay and peanut hay. In those instances where there is uptake of activity >5 ppb in those commodities, the uses are classified as food uses and field trials required regardless of the TRR=s in the soybean seeds or peanut nutmeats. However, the petitioner may choose to restrict feeding of the foliage parts of these crops. This would eliminate the need for crop field trials on the foliage, but at a minimum the three 5x rate trials would still be needed for the seeds or nutmeats along with a tolerance on these RAC=s.

Questions have also been posed on the use of representative crops and crop groups in these food/nonfood determinations. Specifically, it was asked whether all small grains could be covered by a radiolabeled study on wheat. The SAC agreed to this concept. Therefore, if the TRR=s in wheat forage, hay, grain and straw are all <5 ppb, the seed treatment can be considered nonfood for the following crops: wheat, barley, oats, rye, triticale, buckwheat, and millet. It was further concluded that if <5 ppb total activity is found in all wheat and corn RAC=s, uses on all cereal grains except rice and wild rice can be classified as nonfood uses.

If a registrant is interested in establishing that seed treatment uses on all crops should be considered nonfood, it would need to be shown that the TRR=s are <5 ppb in five representative crops. The suggested crops are a small grain (e.g., wheat, barley, oats), radish (analyze both root and tops), leaf lettuce, soybeans, and a short season fruiting or cucurbit vegetable (e.g., pepper, cucumber). It is again emphasized that all RAC=s of the small grain and soybeans should be analyzed for total radioactivity.

Another topic to be addressed in this document concerns the possibility of establishing a nonfood use without radiolabeled data. There may be cases where it can be shown that the maximum theoretical residue in harvested crop parts will be <5 ppb. If verifiable information can be provided on the minimum theoretical dilution factor (i.e., weight of harvested RAC divided by weight of seed planted) and applying that dilution to the starting residue on the treated seed results in <5 ppb, the use can be considered nonfood in the absence of a radiolabeled study.

On a case-by-case basis we may be willing to call theoretical residues above 5 ppb a non-food use. This would be possible in cases where there are radiolabeled seed treatment data with the same active ingredient on other crops to get some idea on the degree of transfer from seed to harvested RAC. If the data on these other crops show the actual dilution factor is well above the theoretical one, some leeway would be permitted in cases where the calculated residue exceeds 5 ppb.

Finally, there is at least one crop where no data or calculations are needed to establish the nonfood nature of the use. In the case of coffee, three years elapse from the time of planting the seed until harvested beans are produced. In this instance the SAC believes it is reasonable for any seed treatment to be considered a nonfood use.