

July 27, 2005

Public Information and Records Integrity Branch (PIRIB)  
Office of Pesticide Programs (OPP)  
Environmental Protection Agency (7502C)  
1200 Pennsylvania Ave, NW  
Washington, DC 20460-0001

**RE: Proposed Rule on Revocation of Tolerance Exemptions; 70 FR 31401; June 1, 2005; Docket Number OPP-2005-0069**

Dear Sir or Madam:

Monsanto is pleased to offer comments on the above proposal concerning the revocation of Tolerance Exemptions for 31 pesticide chemicals.

Monsanto's Confidential Statements of Formula (CSFs) for our pesticide products do not list any of the specific chemicals, which are the subject of this Proposed Rule, as intentionally added pesticide chemicals. Therefore, we have no fundamental basis for objection to the proposed revocations.

However, in the course of investigating these chemicals, five questions arose, enumerated below. It would be helpful to Monsanto and other interested parties if the Agency clarified their policy on these matters, in order that this proposed rule can be evaluated from a more fully informed position. In addition to making the present proposal clearer, the answers will no doubt assist both registrants and EPA staff in consistently evaluating the acceptability of pesticide chemicals in pesticide products going forward.

**1. Ingredients in non-food use pesticide products.** Monsanto believes that food / feed tolerances, or exemptions from them, are only necessary for chemicals included in pesticide products whose labels include application to food or feed crops or livestock. Pesticides used for landscaping or other non-food pest control treatments are not subject to requirements for tolerances or exemptions from tolerances. Could the Agency please reconfirm this policy?

**2. Impurities in technical grade active ingredients.** Monsanto believes that impurities that occur in active ingredients as a result of their manufacture, which are not intentionally added, do not require separate individual tolerances or exemptions. According to the regulations specified in 40 CFR 158 Subpart C "Product Chemistry Data Requirements", impurities need to be identified based on their toxicological relevance and content level as part of the data set that supports the TGAI registration. When registrants comply with those requirements, impurities in TGAIs that might occur as residues in foods or feeds as a result of the legal use of that TGAI are then covered by tolerance regulations that pertain to that active ingredient, and all of its known components. This fundamental paradigm applies regardless of the chemical composition of the specific TGAI impurity, which may be structurally identical to

inert chemical ingredients that do require tolerance exemptions when intentionally added to pesticides. While this seems logical and consistent with the intent of the regulations, a short statement summarizing the Agency's treatment of this matter would be helpful.

**3. Impurities in inert ingredients.** From time to time, Monsanto receives inquiries from EPA's Product Chemistry reviewers seeking information on impurities in proposed inert ingredients; the identities and percentage amounts of each impurity are requested. Based on this experience, we believe that some Agency personnel are evaluating inert ingredient impurities against unspecified acceptance criteria, possibly tolerance exemptions; if not, why is the information sought? Like impurities in TGAIs, Monsanto believes that impurities, which are present in technical grades of inert ingredients as a result of manufacture, do not require separate individual tolerance exemptions when those inert ingredients are used in the formulation of food-use pesticides. However, since the composition of inert ingredient chemicals is not as closely regulated as for TGAIs, such a direct extension of the TGAI policy to inert ingredients could potentially be subject to some limitations. It would be valuable information for registrants, inert manufacturers, and EPA personnel if the Agency would state how impurities in inert ingredients are to be evaluated, if at all, in the future. Monsanto believes that some of the 31 chemicals proposed for tolerance exemption revocation may be impurities in other inert ingredients whose exemptions remain in place. In order to evaluate the acceptability of the proposed revocations, the Agency's treatment of inert impurities is a key piece of information.

**4. Salts of common strong acids and bases.** Present Agency practice is somewhat unscientific and inconsistent regarding the requirements for tolerance exemptions for ionic inert ingredients in pesticide formulations. The present practice seems to be that inert ingredients as added to the formulation require tolerance exemptions before EPA will approve a formulation. However, the relevant FFDC A statute pertains to pesticide chemical residues that may occur in commodities after treatment. For ionic substances, chemical principles dictate that the cations and anions may re-aggregate in solution, so that the predominant salt form(s) at time of pesticide treatment and beyond may not be those that were added to the formulation. In addition to the legal discontinuity resulting from EPA's current approach, the requirement for each salt form to have a separate tolerance exemption leads to a very long list of tolerance exemptions for different salts that are nothing more than 10 to 20 common ions in nearly all possible pairings.

Monsanto advocates a better approach. We propose that EPA establish an exemption for each ion only once, in such a way that all possible salts are simultaneously exempted, so long as they involve only the subject ion combined with any otherwise exempted counterion(s). In doing so, it would be convenient to use the acid or base form of an ion as the foundation exemption. For example, the exemption for sulfuric acid could read "Sulfuric acid and any of its salts formed by combination with ions that are otherwise exempted from tolerances in this Part." This would include sodium, potassium, ammonium, calcium, etc. sulfate materials, no matter the ratio of ions or hydration state of the salts involved. Similar exemptions could be established for all common mineral acids, alkali and alkaline earth hydroxides, etc.

A response on this proposal is sought, so that Monsanto can evaluate the proposal for revocation of the present tolerance exemption for sulfurous acid. Sodium sulfite is one salt

form of sulfurous acid, for which a separate tolerance exemptions exists. Only one of these two exemption listings would be needed in Monsanto's proposal.

**5. Reactive intermediates or reagents.** Monsanto notes that the Agency proposes to revoke the tolerance exemption for phosphorous oxychloride. This reactive chemical is an unlikely component of a pesticide formulation as sold. It is a very likely reagent used in the preparation of active ingredients and inert ingredients, and fragments from it, such as inorganic phosphate and inorganic chloride ions, may occur in technical materials produced through its use. It may even be included in pesticide formulation manufacture where polymeric materials such as encapsulating shell walls are formed *in situ*. In a related question to those numbered 2 and 3 above, where is the requirement for a tolerance exemption incurred? Is it for reagents that are employed but consumed in the manufacture of a pesticide, or only for the impurities resulting from use of these materials during production and present when the formulation is sold, or neither? Monsanto would be better able to evaluate the advisability of a revocation of the phosphorous oxychloride tolerance exemption if the Agency's policy on this matter was clearly stated.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schnieder (202-383-2866) or by direct phone (314-694-1582), fax (314-694-4028), or electronic mail at [stephen.j.wratten@monsanto.com](mailto:stephen.j.wratten@monsanto.com).

Sincerely,

Stephen J. Wratten  
Manager, Registrations

cc: R. P. Schneider  
Comments Inert Ingredients.doc