

4. If you estimate potential burden or costs, explain how you arrived at your estimate.

5. Provide specific examples to illustrate your concerns.

6. Offer alternatives.

7. Make sure to submit your comments by the comment period deadline identified.

8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

## II. Background

In the **Federal Register** of April 12, 2000 (65 FR 19759) (FRL-6498-8), EPA issued a notice pursuant to section 408 for the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 6E4705) by LignoTech USA, Inc., 100 Highway 51 South, Rothschild, WI 54474-1198. This notice included a summary of the petition prepared by the petitioner LignoTech USA, Inc. This petition requested that 40 CFR 180.1001(c) and (e) be amended by establishing an exemption from the requirement of a tolerance for residues of humic acid, sodium salt.

Subsequently, the petitioner revised the petition to request the establishment of an exemption from the requirement of a tolerance for residues of humic acid, sodium salt under 40 CFR 180.1001(c) only. There were no comments received in response to the Notice of Filing. In the **Federal Register** of July 18, 2000 (65 FR 44469) (FRL-6595-9), the Agency established an exemption from the requirement of a tolerance for residues of humic acid, sodium salt when used as an inert ingredient (adjuvant, UV protectant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

In the **Federal Register** of March 6, 2002 (67 FR 10203) (FRL-6825-9), the Agency published a Notice of Filing to amend the above pesticide petition 6E4705 from Arctech, Inc. located at 14100 Park Meadow Drive, Chantilly, VA 20151, to amend the existing exemption from the requirement of a tolerance to include residues of humic acid, potassium salt when used as an inert ingredient in pesticide formulations applied to growing crops, raw agricultural commodities (RAC) after harvest, or to animals. The notice included a summary of the petition prepared by the petitioner, Arctech, Inc.

There were no comments received in response to this Notice of Filing.

## III. What Action is the Agency Taking?

EPA on its own initiative, under section 408(e) of the FFDCA, 21 U.S.C. 346a, is proposing to establish an unlimited exemption from the requirement of a tolerance for residues of humic acid, sodium salt (CAS Reg. No. 68131-04-04); humic acid, potassium salt (CAS Reg. No. 68514-28-3); and humic acid (CAS Reg. No. 1415-93-6) when used as an inert ingredient in pesticide formulations that are applied to growing crops under 40 CFR 180.1001(d).

The Agency has not issued a final rule on the petition seeking the establishment of a tolerance exemption for humic acid, potassium salt, but rather is issuing this proposed rule to amend the existing tolerance exemption for humic acid, sodium salt to also include humic acid, potassium salt; and humic acid. Based on a review and evaluation of the available data, which includes a 90-day toxicity study using humic acid, the Agency believes that the tolerance exemption should also include humic acid, not just the two salts, as requested by the petitioners. The existing tolerance exemption for humic acid, sodium salt will also be shifted from 40 CFR 180.1001(c) to 40 CFR 180.1001(d). Given that the nature of the substances considered are naturally occurring materials, and ubiquitous in the environment, but essentially, a component of soil, the Agency believes that 40 CFR 180.1001(d), i.e., application to growing crops to be more appropriate. The Agency has determined that there are no existing products containing humic acid, sodium salt having post-harvest uses. Therefore, this action will not have an effect on any currently registered pesticide product.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the

pesticide chemical residue in establishing an exemption from the requirement of a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for the establishment of an exemption from the requirement of a tolerance for humate materials. EPA's assessment of exposures and risks associated with establishing the exemption from the requirement of a tolerance follows.

## IV. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by humate materials are discussed in this unit.

Humate materials or humic substances occur naturally in the environment. They are part of the environment in which we grow our food. The use of the term humus is said to have occurred when Rome was an empire. The term has also been found in 18th century writings. Humic substances are used as soil conditioners to increase the amount of organic matter in the soil; thus, increasing the workability of the soil. They are widely regarded as being beneficial to plants.

The formation of humic substances is not completely understood. It is known that humic substances arise during the decay of organic materials, which is the reason that humic substances are often associated with coal, lignite, and mudstones. There are several theories as to possible formation pathways (lignin theory, polyphenol theory, and sugar-amine condensation). Generally, humic substances can be further subdivided into three categories: humic acids, fulvic acids, and humins. Humic acid is the major extractable component. With humates being natural substances, there is some variation in composition of the various materials.

There is some confusion as to an exact definition of humic acid. According to