

without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

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I. Legal Authorization

The Federal Food, Drug, and Cosmetic Act (FFDCA) [21 U.S.C. 301 et seq.] authorizes the establishment of tolerances (maximum legal residue levels) and exemptions from the requirement of a tolerance for residues of pesticide chemicals in or on raw agricultural commodities pursuant to section 408 [21 U.S.C. 346(a)]. Without such tolerances or exemptions, a food containing pesticide residues is considered to be "adulterated" under section 402 of the FFDCA, and hence may not legally be moved in interstate commerce [21 U.S.C. 342]. To establish a tolerance or an exemption under section 408 of the FFDCA, EPA must make a finding that the promulgation of the rule would "protect the public health" [21 U.S.C. 346a(b)]. For a pesticide to be sold and distributed the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA, 7 U.S.C. 136 et seq.].

In 1988, Congress amended FIFRA and required EPA to review and reassess the potential hazards arising from currently registered uses of pesticides registered prior to November 1, 1984. As part of this process, the Agency must determine whether a pesticide is eligible for reregistration and if any subsequent actions are required to fully attain reregistration status. EPA has chosen to include in the reregistration process a reassessment of existing tolerances or exemptions from the need for a tolerance. Through this reassessment process, EPA can determine whether a tolerance must be amended, revoked, or established, or whether an exemption from the requirement of one or more tolerances must be amended or is necessary.

The procedure for establishing, amending, or repealing tolerances or exemptions from the requirement of tolerances is set forth in the Code of

Federal Regulations 40 CFR parts 177 through 180. The Administrator of EPA or any person may initiate an action proposing to establish, amend, revoke, or exempt a tolerance for a pesticide registered for food uses. The proposal must explain the grounds for such a proposed action and will be published as a public notice. Each petition or request for a new tolerance, an amendment to an existing tolerance, or a new exemption from the requirement of a tolerance must be accompanied by a fee or a request for a waiver of such fee. Current Agency policy on tolerance actions identified during the reregistration process is to administratively process without requiring payment of a fee tolerance actions for revision or revocation of an established tolerance, or if the proposed exemption from the requirement of a tolerance requires the concurrent revocation of an approved tolerance. Comments submitted in response to the Agency's published proposals are reviewed; the Agency then publishes its final determination regarding the specific tolerance actions.

II. Chemical-Specific Information and Proposed Actions

A. Methoprene: Amendment to 40 CFR 180.1033 and Revocation of Exemption under 40 CFR 185.4150

1. Regulatory background.

Methoprene was first registered under FIFRA in 1975; a Registration Standard was issued in February 1982. Subsequent to the issuance of the Registration Standard, methoprene was reclassified by EPA from a conventional to a biochemical pesticide based on its mode of action and chemical structure. The Reregistration Eligibility Document (RED) for methoprene was issued in March 1991. At the time of the RED, a number of sites were registered for mosquito control. For these sites, which included both food and non-food, exemptions from the requirement of tolerances had been established. In the RED, the Agency recommended that these exemptions be revoked based on the following rationale:

The mosquito vector control uses that were exempt from the requirement of a tolerance under 40 CFR 180.1033 and 185.4150 are now considered non-food uses. Thus, the exemptions are no longer applicable and will be revoked.

Subsequent to the issuance of the RED, other mosquito vector control uses were added to the methoprene label; these included vineyards, date palm orchards, nut orchards, berry orchards, and fruit orchards. No tolerances or

exemptions from the requirement of tolerances were established.

2. *Proposed action.* Amendment to 40 CFR 180.1033. The 1991 RED document erroneously reclassifies many of the mosquito vector control uses for food sites as non-food, and recommends that the exemptions from the requirements of a tolerance be revoked because they are unnecessary. The Agency has reviewed its position and determined that the exemptions for all food sites should remain or be established. Because methoprene exhibited low toxicity and showed no oncogenic potential in chronic feeding studies (Ref. 1), and because methoprene has low potential for exposure when used as a mosquito larvae control, the Agency is proposing that methoprene be exempt from the requirement of a tolerance in or on all raw agricultural commodities, including pastures, rice fields, vineyards, date palm orchards, nut orchards, berry orchards, and fruit orchards, when used to control mosquito larvae.

With this proposal, the Agency is acknowledging its error in the RED and is also amending the RED determination that the mosquito vector control uses are non-food. The Agency believes that these uses are indeed food uses, and as such, should have the appropriate clearances for residues on food under the Federal Food, Drug, and Cosmetic Act.

Revocation of exemption under 40 CFR 185.4150(a). Revoke this exemption, deleting paragraph (a), because the Agency no longer requires tolerances for potable water.

B. Sodium Propionate: Revocation of Exemptions under 40 CFR Sections 180.2(a) and 180.1015

1. *Regulatory background.* EPA first registered propionic acid-containing products in the early 1970's. The currently registered products are used as fungicides and bactericides, and have been used for both human food and animal feed. In 1975, EPA exempted sodium propionate from tolerances for residues following post-harvest application in grains or hays (40 CFR 180.1023). Sodium propionate is also exempt from the requirement of a tolerance when applied (as an inert ingredient) to growing crops or to raw agricultural commodities after harvest as described in 40 CFR 180.1001(c). Sodium propionate is Generally Recognized As Safe (GRAS) (21 CFR part 1081), by the Food and Drug Administration (FDA) for use in food.

The Reregistration Eligibility Document (RED) was issued for propionic acid and its salts in 1991. The