

For propanoic acid and its calcium and sodium salts a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given their low toxic potential for the oral route of exposure, that humans of all ages are highly exposed to propanoic acid from natural sources, and the human body has a known pathway for metabolizing propanoic acid.

V. Cumulative Effects

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify or revoke a tolerance or tolerance exemption, the Agency considers "available information" concerning the cumulative effects of a particular chemical's residues and other substances that have a common mechanism of toxicity." Propanoic acid and its calcium and sodium salts are lower toxicity chemicals. EPA does not have, at this time, available data to determine whether propanoic acid and its calcium and sodium salts have a common mechanism of toxicity with other substances or how to include these pesticide chemicals in a cumulative risk assessment.

VI. Determination of Safety for U.S. Population, Infants and Children

Based on the available data, the lower toxicity of propanoic acid and its calcium and sodium salts, and considering the FDA affirmed GRAS uses and the JEFCA finding of the unlimited ADI, EPA concludes that propanoic acid and its calcium and sodium salts do not pose a dietary risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to propanoic acid and its calcium and sodium salts. For propanoic acid and its calcium and sodium salts, due to the expected low oral toxicity, a safety factor analysis has not been used to assess the risk. For the same reasons and especially considering the available developmental toxicity information, the additional tenfold safety factor for the protection of infants and children is unnecessary.

VII. Other Considerations

1. *Endocrine disruptors.* FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), may have an effect in humans that is similar to an effect produced by a naturally occurring

estrogen, or such other endocrine effect. EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing propanoic acid and its calcium and sodium salts for endocrine effects may be required.

2. *Analytical enforcement methodology* An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

3. *Existing exemptions* Several tolerance exemptions for the residues of propionic acid, have been established in 40 CFR 180.1023. Under 40 CFR 180.1023(a) propionic acid or a mixture of methylene bispropionate and oxy(bismethylene) bispropionate is exempted from the requirement of a tolerance when used as a fungicide on 22 commodities. In addition exemptions from the requirement of tolerances from residues of propionic acid (see 40 CFR 180.1023(b)) have been established in or on meat and meat byproducts of cattle, sheep, hogs, goats, horses, and poultry, milk, and eggs when applied as a bactericide/fungicide to livestock drinking water, poultry litter, and storage areas for silage and grain. The two above exemptions are only being modified for the nomenclature change from propionic to propanoic acid.

The current exemption under 40 CFR 180.1023(c) will be replaced by a new tolerance exemption which covers the existing exemptions under (c), but is broader and will also include the calcium and sodium salts of propanoic acid.

Exemptions from the requirement of a tolerance have been established in 40 CFR 180.1001(c) for sodium propionate with a use as a preservative and for propionic acid with a use as a catalyst in the pesticide formulation. These exemptions are now duplicative and will be removed.

D. International Residue Limits

The Agency is not aware of any country requiring a tolerance for propanoic acid and its calcium and sodium salts nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

VIII. Conclusion

Based on the information in the record, summarized in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate

exposure to residues of propanoic acid, calcium propionate, and sodium propionate. Accordingly, EPA finds that exempting propanoic acid; propanoic acid, calcium salt; and propanoic acid, sodium salt from the requirement of a tolerance will be safe. With the establishment of this tolerance exemption in 40 CFR 180.1023(c), the existing tolerance exemptions for inert ingredients in 40 CFR 180.1001(c) are duplicative and can be removed.

IX. Regulatory Assessment Requirements

This proposed rule establishes a consolidated and expanded exemption from the requirement for a tolerance under section 408(d) of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant impact on a substantial