

buildings (residential and other indoor uses).

A. Dietary Exposure

Humans and animals are commonly exposed to *Bacillus pumilus*, a ubiquitous microorganism that inhabits soil. No toxicological endpoints were identified for *Bacillus pumilus* strain QST2808. The low toxicity and non-pathogenicity/infectivity of *Bacillus pumilus* strain QST2808 is demonstrated by the data summarized in Unit III of this action.

1. *Food.* While the proposed use pattern may result in dietary exposure with possible residues in or on agricultural commodities, negligible to no risk is expected for the general population, including infants and children, or animals because *Bacillus pumilus* strain QST2808 technical demonstrated no pathogenicity or oral toxicity at the maximum doses tested, as noted above in (Unit III).

2. *Drinking water exposure.* Most importantly, there is no evidence of adverse effects from oral, dermal, or inhalation exposure to this microbial agent. (See "Unit III. Toxicological Profile" above.) In addition, the potential for transfer of *Bacillus pumilus* strain QST2808 to surface or ground water during run-off associated with intended use applications is considered minimal to non-existent, due in part to its percolation through and resulting capture in soil. Accordingly, the use of this microbial pest control agent on terrestrial plants is not anticipated to negatively impact the quality of drinking water.

B. Other Non-Occupational Exposure

Based on the proposed use patterns, the potential of non-dietary exposures to *Bacillus pumilus* strain QST2808 pesticide residues for the general population, including infants and children, is unlikely. Accordingly, the Agency believes that the potential aggregate non-occupational exposure, derived from dermal and inhalation exposure through the application of *Bacillus pumilus* strain QST2808, should fall well below the currently tested microbial safety levels.

1. *Dermal exposure.* The potential for dermal exposure to *Bacillus pumilus* strain QST2808 pesticide residues for the general population, including infants and children, is unlikely because potential use sites are agricultural and horticultural. However, since *Bacillus pumilus* strain QST2808 is a naturally occurring bacteria in soil, there is a great likelihood of prior exposure for most, if not all individuals. Accordingly, the increase in exposure due to this

proposed product would be negligible. Furthermore, and as demonstrated in Unit III of this action, the organism is of low dermal toxicity, the acute lethal dose (LD₅₀) is greater than 2,000 mg/kg, and the QST2808 Technical was essentially non-irritating (Toxicity Category IV). Accordingly, the risks anticipated for this route of exposure are considered minimal.

2. *Inhalation exposure.* The potential for inhalation exposure to *Bacillus pumilus* strain QST2808 pesticide residues for the general population, including infants and children is unlikely because potential use sites are agricultural and horticultural. However, since *Bacillus pumilus* is a natural occurring bacteria in soil, there is a great likelihood of prior exposure for most, if not all individuals. Accordingly, the increase in exposure due to this proposed product would be negligible. Furthermore, and as demonstrated in Unit III of this action, the acute pulmonary toxicity/pathogenicity testing performed on the technical formulation did not demonstrate pathogenicity or toxicity of *Bacillus pumilus* strain QST2808. (See Unit III above.) Accordingly, the risks anticipated for this route of exposure are considered minimal.

V. Cumulative Effects

The Agency has considered the potential for cumulative effects of *Bacillus pumilus* strain QST2808 and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *Bacillus pumilus* strain QST2808 is practically non-toxic to mammals. Because no mechanism of pathogenicity or toxicity in mammals has been identified for this organism (see Unit III above), no cumulative effects from the residues of this product with other related microbial pesticides is anticipated.

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

There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of *Bacillus pumilus* strain QST2808 due to its use as a microbial pest control agent. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, *Bacillus pumilus* strain QST2808 is not pathogenic or infective and is practically non-toxic to mammals. (See Unit III above.) Accordingly, exempting *Bacillus pumilus* strain QST 2808 from the

requirement of a tolerance should be considered safe and pose no significant risk.

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are incorporated into EPA risk assessments either directly through the use of a margin of exposure analysis or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. Due to the ubiquitous nature of *Bacillus pumilus*, residues of this microbial pesticide in or on agricultural commodities are not expected to significantly increase exposure to the U.S. population, including infants and children. Here, EPA concludes that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of *Bacillus pumilus* strain QST2808 and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to *Bacillus pumilus* strain QST2808 residues.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the screening program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone