

inhabits the root system of plants and acts as an antifungal agent. Review of the available toxicology data submitted in support of registration indicate that it is non-toxic and non-pathogenic to animals and humans. In its proposed use as a soybean seed treatment, it is not foreseen to contribute any or more than a negligible amount of dietary exposure.

1. *Food.* The product is used only as a seed treatment and the organism inhabits the roots of the plants, in this case the soybean plant roots. The use of products which contain *B. pumilus* GB 34 is not anticipated to result in more than negligible, if any, any dietary exposure from food for humans. To date there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions in humans resulting from exposure to *B. pumilus* GB 34.

2. *Drinking water exposure.* There is expected to be only insignificant or minimal human exposure to the organism in drinking water from its use in the treatment of seeds, its only use proposed. The treatment of seeds is expected to take place in a commercial seed treatment facility. The farmer then plants the seeds in the soil. Since the organism is non-toxic and non-pathogenic to humans, even if small amounts would seep into the ground water, there is expected to be no adverse effect on humans.

B. Other Non-Occupational Exposure

The possibility for non-dietary exposure to residues of this *B. pumilus* pesticide for the general population, including infants and children, is unlikely because the only proposed use site is in an agricultural setting, as a treatment on soybean seeds. Since the seed treatment is to take place in a commercial seed treating facility where mechanical treating equipment is used, it is not expected that dermal or inhalation exposure to residues will occur in the general population, including infants and children. *Bacillus pumilus* GB 34 is a ubiquitous bacterium commonly found in soil, water, air and decomposing plant tissue and which acts as an antifungal agent. The bacteria typically occur at 106 to 107 colony forming units (CFU's) per gram of soil. It is not known to be pathogenic or toxic to any animal or plant species. The added soil density from the proposed seed treatment use rates represents a very small proportion of the naturally occurring bacilli in the soil and therefore is not expected to add substantially to the effects of the naturally occurring *Bacillus*.

VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *B. pumilus* GB 34 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *B. pumilus* does not appear to be toxic or pathogenic to humans. Thus, there is no indication that the bacteria we consider here share any common mechanisms of toxicity (metabolic mechanisms) with other substances.

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

There is reasonable certainty that no harm will result from aggregate exposures to residues of *B. pumilus* GB 34, in its use as a seed treatment, to the U. S. population, including infants and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there is probably no potential for harm, from this bacterium in its use as a seed treatment via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity (no toxicity at the maximum doses tested, Toxicity Categories III and IV). Moreover no inhalation or dermal exposure is expected. FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold 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 unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that the bacterium, *B. pumilus* GB34, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *B. pumilus* GB 34.

VIII. Other Considerations

A. Endocrine Disruptors

EPA is required under FFDCA section 408(p) to develop a screening process to determine whether pesticide chemicals (and any other substance that may have

an effect that is cumulative to an effect of a pesticide chemical) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effects effect as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the 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 the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been determined, *B. pumilus* GB 34 may be subjected to additional screening and/or testing to better characterize any effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for *B. pumilus* GB 34.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation. Accordingly, the Agency has concluded that analytical methods are not needed for enforcement purposes related to *B. pumilus* GB 34.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels nor any tolerances or exemptions issued for *B. pumilus* GB 34 outside the United States.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue