

experimental product would be negligible due to the lack of residue in comparison with the toxicity NOAELs.

## V. Cumulative Effects

The Agency has considered the cumulative effects of 6-benzyladenine 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. Based on the available information and data for 6-benzyladenine, no mammalian toxicity is expected at the proposed experimental use rates. Therefore, no cumulative effects are expected.

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

1. *U. S. population.* The analysis estimated that the chronic exposures for the overall U.S. population was 0.000014 mg/kg/day (0.03% of the chronic population adjusted dose (cPAD)). The acute dietary estimated exposure was 0.000069 mg/kg/day (0.01% of the acute population adjusted dose (aPAD)) for the overall U.S. population. Critical exposure commodity analysis showed that apple juice contributed the most to dietary exposure for the overall population. Due to the low anticipated dietary intake of 6-benzyladenine residues relative to the chronic and acute population adjusted doses, and the fact that actual exposure will probably be considerably less because the dietary exposure analysis was made based on worst-case assumptions, it is likely that the proposed new uses of 6-benzyladenine on apples and pistachios will not result in adverse effects to human health.

2. *Infants and children.* The analysis estimated that the chronic exposures for the most highly exposed subgroup, non-nursing infants, was 0.000085 mg/kg/day (0.2% of the cPAD). The acute dietary estimated exposure was 0.000361 mg/kg/day (0.07% of aPAD) for the most highly exposed subgroup, non-nursing infants. Critical exposure commodity analysis showed that apple juice contributed the most to dietary exposure for all infants. Due to the low anticipated dietary intake of 6-benzyladenine residues relative to the chronic and acute PAD, and the fact that actual exposure will probably be considerably less because the dietary exposure analysis was made based on worst-case assumptions, it is likely that the proposed new uses of 6-benzyladenine on apples and pistachios will not result in adverse effects to human health.

## VII. Other Considerations

### A. Endocrine Disruptors

EPA is required under 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 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 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 EDSP have been developed, 6-benzyladenine may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of 6-benzyladenine. To date, there is no evidence to suggest that 6-benzyladenine affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

### B. Analytical Method

The Agency is establishing a temporary exemption from the requirement of a tolerance for the reasons stated above. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purposes for 6-benzyladenine.

### C. Codex Maximum Residue Level

Currently, there are no Codex, Canadian or Mexican maximum residue levels for residues of 6-benzyladenine in/on apples or pistachios.

## VIII. Conclusions

Based on the toxicology information submitted and reviewed previously, and summarized in the June 1994 N6-Benzyladenine RED (Ref. 1), there is a reasonable certainty that no harm will result from aggregate exposure of residues of 6-benzyladenine to the U.S. population, including infants and children, under reasonably foreseeable circumstances, when the biochemical pesticide is used in accordance with good agricultural practices under the conditions of the 2-year experimental program. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the data submitted previously and summarized in the RED, as well as that data submitted to support the temporary tolerance exemption and Experimental Use Permit applications, demonstrating negligible dietary exposure in comparison with the toxicity NOAELs. As a result, EPA establishes a temporary exemption from the tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of 6-benzyladenine in or on apples and pistachios.

## 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 to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0308 in the subject line on the first page of your submission. All