

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Spinosad is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for spinosad.

Using the exposure assumptions described in Unit IV. B. for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 600 for the U.S. population, 260 for all infants less than 1-year old, 190 for children 1–6 years old (greatest risk subpopulation) and 250 for children 7–12 years old. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to

food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of spinosad in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's LOC, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO SPINOSAD

| Population Subgroup | Aggregate MOE (Food + Residential) | Aggregate LOC | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Short-Term DWLOC (ppb) |
|---------------------------|------------------------------------|---------------|-------------------------|------------------------|------------------------|
| U.S. population | 600 | 100 | 2.3 | 0.037 | 1,400 |
| All infants (<1 year old) | 260 | 100 | 2.3 | 0.037 | 300 |
| Children (1–6 years old) | 190 | 100 | 2.3 | 0.037 | 230 |
| Children (7–12 years old) | 250 | 100 | 2.3 | 0.037 | 290 |
| Female (13–50) | 760 | 100 | 2.3 | 0.037 | 1,300 |

4. *Intermediate-term risk.*

Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

Though residential exposure could occur with the use of spinosad, the average aerobic soil metabolism half-life of spinosad (containing factors A and D) is 13–14 days. For the intermediate-term duration, typical lawn maintenance practices, such as mowing and watering, are expected to expedite the dissipation of spinosad on turfgrass. Since residue on turf that is available for transfer after day 30 is expected to be negligible, intermediate-term post-application incidental oral exposures were not assessed.

5. *Aggregate cancer risk for U.S. population.* Spinosad has been classified as “not likely to be carcinogenic in humans” based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, spinosad is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to spinosad residues.

V. Other Considerations

A. *Analytical Enforcement Methodology*

Adequate enforcement methodology using high pressure liquid chromatography with ultraviolet detector (HPLC/UV) is available to enforce the tolerances in plants. Adequate livestock methods are available for tolerance enforcement. Method RES 94094 (GRM 95.03) is an HPLC/UV method suitable for determination of spinosad residues in ruminant commodities. Method GRM 95.03 has undergone successful independent laboratory validation (ILV) and EPA laboratory validation, and has been forwarded to FDA for inclusion in PAM Volume II. Method GRM 95.15 is another HPLC/UV method suitable for determination of spinosad residues in poultry commodities. This method has been forwarded to FDA for inclusion in PAM Volume II. Method RES 95114, an immunoassay method for determination of spinosad residues in ruminant commodities, underwent a successful ILV and EPA laboratory validation. It has been submitted to FDA for inclusion in PAM Volume II. The methods may be requested from: Paul Golden, U.S. EPA/OPP/BEAD/ACB, Environmental Science Center, 701 Mapes Road, Fort Meade, MD 20755–5350; telephone number: (410) 305–2960; FAX (410) 305–3091; e-mail address: RAM Mailbox.

B. *International Residue Limits*

There are no Codex, Canadian or Mexican maximum residue limits

established for spinosad in/on root and tuber vegetables. Therefore, no compatibility problems exist for the proposed tolerances.

VI. Conclusion

Therefore, the tolerance is established for residues of spinosad in or on onion, dry bulb at 0.10 ppm.

VII. 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) of the FFDCA, 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