U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

June 30, 2020

Ms. Rebecca Coates
Executive Director
Ontario Ginseng Growers Association
Box 587, 1283 Blueline Rd.
Simcoe, Ontario N3Y 4N5 Canada

Re: Docket No. FDA-2019-P-5069

Dear Ms. Coates:

This responds to your citizen petition requesting that the U.S. Food and Drug Administration (FDA or we) establish a dichloro-diphenyl-trichloroethane (DDT) action level of 3 parts per million (ppm) for ginseng (see Citizen Petition from Rebecca Coates, Executive Director, Ontario Ginseng Growers Association, to the Commissioner, Food and Drug Administration, dated October 4, 2019 ("petition") at page 1).

In accordance with 21 CFR § 10.30(e)(3), and for the reasons stated below, we are denying your petition.

I. Background

Pesticides are used to treat fruits, vegetables, grains, and other foods, and may be present in small amounts, as pesticide chemical residues, after treatments. Before a pesticide may be sold or distributed in the United States, the Environmental Protection Agency (EPA) evaluates the pesticide and determines whether to grant a registration that permits its sale and distribution.

Before allowing the use of a pesticide chemical on food crops, the EPA, under section 408 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishes a tolerance (maximum residue level), which is the amount of residue allowed to remain in or on each treated food commodity, or it establishes an exemption from the requirement of a tolerance for the pesticide chemical. Without a tolerance or exemption from a tolerance for the pesticide chemical residue, food containing a pesticide chemical residue is considered adulterated under section 402(a)(2)(B) of the FD&C Act and may not be introduced or delivered for introduction into interstate commerce (which includes importation into the U.S.).

FDA has the responsibility to enforce EPA-established pesticide tolerances in most foods imported into the United States and domestic foods shipped in interstate commerce. We recognize that food may contain a pesticide chemical residue from sources of contamination that cannot be avoided by good agricultural or manufacturing practices, such as contamination by a pesticide that persists in the environment. In the absence of an EPA tolerance, or tolerance

exemption, we may establish an action level for such unavoidable pesticide chemical residues. FDA action levels are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable. Further, we note that an action level is not legally binding, and FDA may take enforcement action on a case-by-case basis whether a contaminant is below, at, or above an action level.[1]

EPA banned all agricultural use of the pesticide DDT in 1972 because of its adverse environmental effects and possible human health risks.[2] However, DDT residues persist in the environment. We published action levels for DDT in various crops,[3] and did not include an action level for DDT in ginseng.

EPA's Health Effects Division (EPA/HED) prepared an internal memorandum recommending that FDA use the FDA action level for DDT in/on carrots (3 ppm) as a "surrogate FDA action level" for ginseng (see United States Environmental Protection Agency, Chemistry and Exposure Branch, Health Effects Division Memorandum: Translation of Carrot DDT FDA Action Levels to Ginseng Root, dated February 26, 2018 ("memorandum") at page 1). You provided this memorandum to support your petition.

II. Specific Response to the Request in your Petition

Your petition requests that the FDA now adopt the EPA/HED recommendations and implement a 3 ppm DDT action level for ginseng.

Based on the review of the evidence, a 3 ppm DDT action level is not appropriate because it does not represent a level of contamination that is unavoidable for ginseng. As discussed above, action levels are established at levels based on unavoidability. We are not aware of any evidence indicating that the proposed surrogate action level of 3 ppm represents a level of contamination that is unavoidable in ginseng. Based on data collected under FDA's Pesticide Residue Monitoring Program[4] between fiscal year 2009 and 2017, only 9 of 112 (or 8 percent of) ginseng root samples (including fresh, dried, and powdered ginseng root) tested positive for DDT, and those had levels between 0.013 ppm and 0.650 ppm. The 50th and 95th percentiles of the 112-sample dataset were non-detect[5] and 0.117 ppm, respectively. Therefore, 3 ppm does not represent a level of contamination that is unavoidable.

In addition, FDA notes that in the memorandum, EPA/HED does not recommend that FDA establish an action level for DDT in/on ginseng. The memorandum instead recommends using

---

[1] *See* Pesticide Residue Monitoring Program Questions and Answers, available at https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-questions-and-answers (accessed June 2, 2020).
[2] *See* Consolidated DDT Hearings, Opinion and Order of the Administrator, 37 FR 13369 (July 7, 1972).
[3] *See* Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed (August 2000), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed (accessed February 26, 2020).
[4] Available at https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-reports-and-data.
[5] < 0.010 milligram per kilogram limit of quantitation

the FDA action level for DDT in/on carrots (3 ppm) as a "surrogate FDA action level" for ginseng for the following reasons:

1. Ginseng and carrot are both members of EPA Crop Subgroups 1A and 1B (40 CFR 180.41).
2. When establishing EPA tolerances for those subgroups, carrot is one of the representative commodities for required field sampling (EPA/OPP/HED SOP 2000.1).
3. Radish is also a member and representative commodity of crop group 1A and 1B although carrot is more similar to the growth and structure of ginseng therefore EPA recommends using carrot to represent ginseng.[6]

Memorandum at pages 1-2.

EPA/HED's memorandum does not provide sufficient evidence to support FDA establishing an action level of 3 ppm for DDT in ginseng. Specifically, EPA has stated that in recommending an action level to FDA, EPA would include an analysis of the limit of action level, review of surveillance data, crop grouping assessments, and any Codex recommendations (47 FR 42956 (1982)).[7] EPA/HED's memorandum does not address several of these factors that EPA stated it would consider in recommending an action level, including analysis on the limit of action level, review of surveillance data, or Codex review. In addition, while the memorandum compares ginseng to carrot based on crop group overlap, it does not include a crop grouping assessment, in which action levels are set on crop groups rather than on individual crops, whenever possible. Instead, EPA/HED based its recommendation for using the FDA action level for DDT in/on carrots (3 ppm) as a "surrogate FDA action level" for ginseng based primarily on two factors: (1) the inclusion of both ginseng and carrots in the same crop subgroups, and (2) the growth and structure of ginseng being close to carrot (memorandum at pages 1-2).

If FDA were to set an action level for DDT in ginseng, we would do so in consultation with EPA. Without EPA's analysis of factors such as those discussed above, and since 3 ppm DDT does not represent a level of contamination that is unavoidable for ginseng, FDA declines to set

---

[6] The memorandum says that EPA "recommends using carrot to represent ginger" (emphasis added). Because this matter involves ginseng and not ginger, we assume the intended word was "ginseng."

[7] In the *Federal Register* of September 29, 1982, EPA explained that in determining what action level should be used, the level must be sufficient to protect the public health, while also taking into account the extent to which the contaminant is unavoidable. In making a recommendation, EPA articulated the following as factors it would consider during its deliberations on recommending action levels:

1. Limit of action level. Action levels will be set limiting the quantity of a pesticide in or on food commodities to the extent necessary to protect the public health. Consideration will be given to the extent to which the pesticide cannot be avoided in the production of such commodities.
2. Review of surveillance data. Surveillance data on pesticide residues collected by, among others, FDA, or any other monitoring data available will be reviewed by EPA to determine the current anticipated unavoidable residue levels for a cancelled pesticide. EPA will also review available toxicology data to determine if these residue levels would be unsafe.
3. Crop grouping assessments. Action levels will be set on crop groups rather than on individual crops, whenever possible.
4. Codex review. Consideration will be given to harmonizing EPA recommended action levels with those pesticide residue limits recommended by the Codex Alimentarius Commission. (47 FR 42956 at 42957).

an action level of 3 ppm for DDT in ginseng.[8]

III. Conclusion

For the reasons stated above, we are denying your petition to establish a DDT action level of 3 ppm for ginseng.

Sincerely,

Mark A. Moorman, Ph.D.
Director
Office of Food Safety
Center for Food Safety
and Applied Nutrition

[8] FDA sets action levels for residues of cancelled pesticide chemicals that persist in the environment and that were considered to be unavoidable in food and feed in consultation with EPA. We also note with the passage of the Food Quality Protection Act of 1996 (Pub. L. 104-170), FDA, in consultation with EPA, may at a future date determine on a case-by-case basis that it is appropriate to withdraw an action level because EPA has elected to issue a tolerance for residues of the pesticide chemical in food, under section 408(1)(4) of the Act (21 U.S.C. 346a(1)(4)), or because EPA has determined that the residues of the pesticide chemical are no longer expected to be unavoidably present in food. *See* Draft Guidance for FDA Staff, Compliance Policy Guide, CPG Sec. 575.100 Pesticide Chemical Residues in Food - Enforcement Criteria (CPG 7141.01), January 2008, at page 10. Available at https://www.fda.gov/media/77986/download (accessed April 3, 2020)).