

## SUPPLEMENTARY INFORMATION:

## I. Introduction

EPA is proposing two separate actions in this document. First, EPA proposes to revoke the food additive regulations (FARs) for residues of the herbicide trifluralin in or on peppermint oil and spearmint oil (40 CFR 185.5900). Second, EPA proposes to withdraw its Order dated July 14, 1993 (58 FR 37862) to the extent that it revoked the food additive regulations for trifluralin in or on peppermint oil and spearmint oil.

## A. Statutory Background

The Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., authorizes the establishment by regulation of maximum permissible levels of pesticides in foods. Such regulations are commonly referred to as "tolerances." Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342. EPA was authorized to establish pesticide tolerances under Reorganization Plan No. 3 of 1970. 5 U.S.C. App. at 1343 (1988). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA). EPA can establish a tolerance in response to a petition (FFDCA 408(d)(1), 409(b)(1)), or on its own initiative (FFDCA 408(e), 409(d)).

The FFDCA has separate provisions for tolerances for pesticide residues on raw agricultural commodities (RACs) and tolerances on processed food. For pesticide residues in or on RACs, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408 of the act. 21 U.S.C. 346a. EPA regulates pesticide residues in processed foods under section 409, which pertains to "food additives." 21 U.S.C. 348. Maximum residue regulations established under section 409 are commonly referred to as food additive regulations (hereinafter referred to as "FARs"). Section 409 FARs are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, a pesticide residue in processed food generally will not render the food adulterated if the residue results from application of the pesticide to a RAC and the residue in the processed food when ready to eat is below the RAC tolerance. This exemption in section 402(a)(2) is commonly referred to as the "flow-through" provision because it

allows the section 408 raw food tolerance to flow through to the processed food forms. Thus, a section 409 food additive regulation is only necessary to prevent foods from being deemed adulterated when the concentration of the pesticide residue in a processed food when ready to eat is greater than the tolerance prescribed for the RAC, or if the processed food itself is treated or comes in contact with a pesticide.

## B. Regulatory Background

On July 14, 1993, EPA issued a final order, subject to objections and requests for a hearing, revoking the trifluralin FARs for peppermint oil and spearmint oil (58 FR 37862, hereinafter referred to as "1993 Order"). This Order was issued in response to the decision by the U.S. Court of Appeals, Ninth Circuit, in the case of *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), cert. denied, 113 S.Ct. 1361 (1993). DowElanco, the manufacturer of trifluralin, filed objections to the revised Order, as well as requests for a hearing on and a stay of, the revocation Order. On June 30, 1994, EPA issued a final order denying DowElanco's objections and requests for a hearing and a stay of the revocation (59 FR 33684, hereinafter referred to as "1994 Order"). On July 14, 1994, DowElanco filed an action in the U.S. Court of Appeals, D.C. Circuit for review of EPA's 1993 Order, and moved for summary reversal or, in the alternative, an emergency stay of the revocation. *E.I. DuPont DeNemours and Co., et al. v. EPA*, Civ. Action No. 94-1504 (D.C. Cir.). On August 24, 1994, the Court denied DowElanco's motion for summary reversal, but issued an emergency stay of the revocation. In the **Federal Register** of September 12, 1994 (59 FR 46768), EPA reinstated the FARs for trifluralin (as well as for the other pesticides involved in the litigation), and they are currently in effect.

On September 11, 1992, the National Food Processors Association (NFPA) and other organizations filed a petition with EPA challenging, among other things, EPA's interpretation of the phrase "ready to eat" in the Delaney Clause. (Petition to the Environmental Protection Agency, Office of Pesticide Programs, Concerning EPA's Pesticide Concentration Policy (1992)) (hereinafter cited as "NFPA petition"). The petition requested that EPA apply the term "ready to eat" in the flow-through provision according to what NFPA asserts is its plain meaning. EPA sought public comment on the petition (**Federal Register** of Feb. 5, 1993 (58 FR 7470)). In the **Federal Register** of June 14, 1995 (60 FR 31300), EPA issued a partial response to the NFPA petition,

addressing the "ready to eat" policy. In that response, EPA agreed that the term "ready to eat" food has a common-sense meaning of food which is consumed without further preparation and stated its intention to apply that interpretation in future actions.

## II. Revocation of the Food Additive Regulations for Trifluralin in Peppermint Oil and Spearmint Oil

EPA has reviewed the trifluralin FARs for peppermint oil and spearmint oil. EPA has determined that no section 409 tolerance is necessary for mint oils because they are not "ready to eat" processed foods, and because ready to eat foods containing mint oils are unlikely to have trifluralin residues greater than the RAC tolerances for peppermint hay and spearmint hay.

As noted above, under FFDCA section 402(a)(2), processed foods containing pesticide residues are not deemed adulterated if the level of pesticide residues in the processed food "when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity." EPA believes that the common-sense meaning of the term "ready to eat" food is food ready for consumption without further preparation. Mint oils are not consumed "as is" but are used as a flavoring in other foods. As such, peppermint oil and spearmint oil are not "ready to eat."

Mint oils are used as flavoring agents in foods such as beverages, ice cream, candy and chewing gum. The maximum amounts used are listed in a February 1965 article in *Food Technology* ("Recent Progress in the Consideration of Flavoring Ingredients Under the Food Additives Amendment, III. GRAS Substances," Richard L. Hall and Bernard L. Oser). The highest concentrations of peppermint oil and spearmint oil in foods are in chewing gum at 8,300 ppm and 6,200 ppm, respectively. These equate to dilution factors of 120 and 160, respectively. Using these dilution factors and the mint oil tolerances of 2 ppm or the maximum levels observed from a 1 x rate (i.e., about 1.2 ppm), maximum residues of trifluralin in the ready-to-eat food will be on the order of 0.010 to 0.02 ppm. These are lower than the RAC tolerances of 0.05 ppm. Thus, no section 409 tolerances are needed for peppermint oil and spearmint oil, and EPA proposes to revoke the existing food additive regulations.

## III. Withdrawal of the July 14, 1993 Order With Respect to Trifluralin

EPA proposes to withdraw those aspects of EPA's July 1993 Order and EPA's June 1994 Order revoking the