Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay - ProFume® Gas Fumigant

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Background

■ 2004 - Registration
  □ Grain Processing Facilities, Stored Cereal Grains, Dried Fruits and Tree Nuts
  □ First Establishment of Food Residue Tolerances

■ 2005 - Registration
  □ Food Processing Facilities
  □ Established Tolerances for food commodities in Food Processing Facilities
Background

Use pattern

- For control of rodent, insect, and other invertebrate pests.
- Sites to be fumigated: Non-residential structures, food handling establishments
  - pet food facilities, bakeries, food production facilities, mills, warehouses, etc.
  - stationary transportation vehicles (railcars, shipping containers, trucks, etc., excluding aircraft and passenger railcars)
  - temporary and permanent fumigation chambers, and storage structures.
Fluoride is a breakdown product of ProFume

- but is also widely used for public health purposes in water treatment, toothpaste and various dental applications.
Background

- As part of a larger government reevaluation of fluoride affecting drinking water standards and other sources of human exposure
  - EPA believes that certain segments of the public have too much fluoride (F) exposure and that excess F exposure can lead to “severe dental fluorosis” (SDF)
    - First time US Government identifies SDF is an “adverse health effect”
  - Based on EPA’s legal interpretation of the controlling federal statute, EPA believes it cannot legally grant/defend food tolerances under these conditions
  - EPA was compelled to make the proposal because activists have threatened to sue the Government to enforce their own interpretation of the law
On January 19, 2011, the U.S. Environmental Protection Agency (USEPA) issued a proposed order:

- Granting objections to tolerances
- Denying request for a stay of the tolerances

EPA proposal is a staged phase out of food tolerances for ProFume* over three years

- Agency believes that public exposure to **fluoride** is too high
- EPA acknowledges that the contribution of ProFume to total fluoride exposure in the U.S. is **negligible**.
Proposed Tolerances Withdrawal

- EPA is proposing to withdraw tolerances under the following schedule:
  - Immediate.
    - Tolerances for canceled uses: Dried eggs; powdered milk
  - 90 days.
    - Tolerances for all commodities
  - Three years.
    - Tolerances for cocoa, walnuts and dried tree fruits (other than raisins), and Tolerances for commodities receiving residues from incidental treatment during structural fumigation.
EPA’s Action

- EPA opened a public comment period to their proposal for phase out food tolerances for ProFume®
- The proposal from EPA was a proactive step on their part to prevent litigation
- EPA sought comments from stakeholders affected by the proposal (millers, food processors, pest control operators, etc.)
  - The public comment period ended July 5, 2011
EPA Assessment

- EPA acknowledges that
  - public exposures to fluoride resulting from the use of ProFume are a “tiny fraction” of much higher exposures from background levels in food, drinking water and toothpaste
  - greatest human fluoride exposure concern is for people living in areas of the U.S. with drinking water containing high, naturally occurring levels of fluoride
Impact of Sulfuryl Fluoride Phase-Out on Total Aggregate Fluoride Exposure for Children (1-4 years) in Areas with Drinking Water Containing 2.59 mg/L Fluoride

- Current
- Partial phase-out
- Complete phase-out

Chronic Exposure (mg/kg/d)

- Sulfuryl Fluoride
- Soil
- Tooth Paste
- Food (Background)
- Beverages
- Drinking Water

Always read and follow label directions.
ProFume Impact on Risk

- EPA’s concerns over fluoride exposure would be essentially the same if ProFume never existed. Cancelling food tolerances for ProFume will not resolve - or even significantly mitigate - EPA’s concerns over fluoride exposure.

- Phasing out food tolerances for ProFume offers no benefit to public health and, on the contrary, imposes significant - unnecessary - public health risks.
Public Comments

- 80 letters in support of food tolerances for SF.
  - 30 trade and commodity associations
  - 18 food and commodity processors
  - 22 fumigators,
  - 5 distributors
  - 3 University researchers
  - Natural Resources Defense Council
  - USDA
  - Sulfuryl Fluoride Agricultural Coalition (SFAC)
  - and Dow AgroSciences.
Public Comments

- Small number of submissions from organizations or individuals not involved in the post-harvest market
  - focused on fluoride in water as the issue of concern
Dow AgroSciences is working on a multifaceted strategy, which involves the following components:

- **Science** – evaluation of the actual science behind the F issue and any options
- **Regulatory** – evaluating the specific policies germane to this action and options
- **Legal** – evaluating the legal landscape and options
- **Legislative** – looking at the potential for legislative options that could change or impact the scenario
- **Advocacy** – ensuring stakeholders in the use of the product know how to effectively engage influencers
Looking Forward

- Finalization of any actions by the EPA are not likely to occur until all public comments have been considered by the Agency and all administrative remedies have been exhausted by adversely affected stakeholders.

- During this process, ProFume can continue to be used as it is currently labeled.
No Impact on the Vikane gas fumigant  Product Labeled Uses
Thank you for your time!