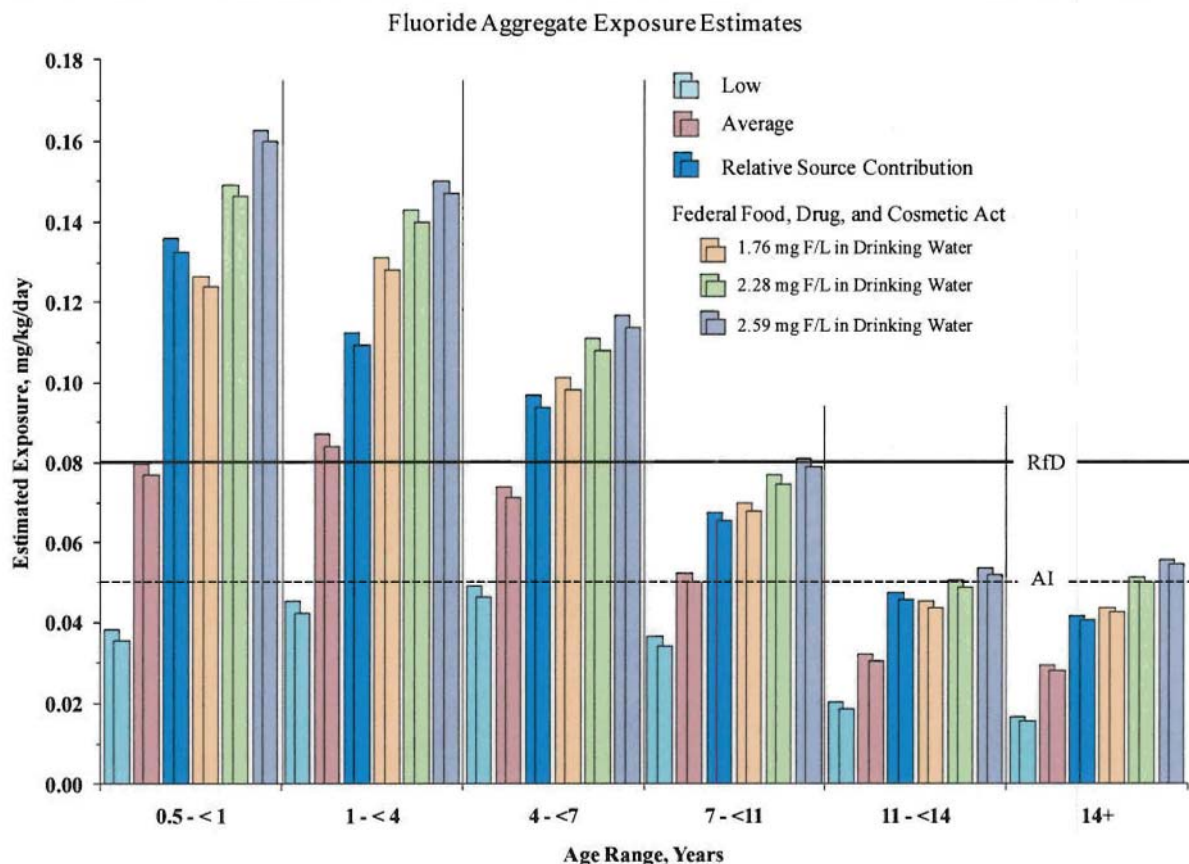


## **Proposed EPA Action on Food Tolerances for ProFume<sup>®</sup> gas fumigant**

- EPA has issued a **proposal** to phase out food tolerances for ProFume over the next three years. To view this proposed action in detail go to <http://www.epa.gov/pesticides/sulfuryl-fluoride>
- **What EPA has announced is a proposal, for public comment – not a final action.** Accompanying this proposal is a public comment period (90 days from the official publication in the Federal Register) offering the opportunity for stakeholder input.
- Finalization of this proposal **will not** occur until all public comment has 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.**
- This proposal is 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), a condition potentially involving pitting of the teeth. For the first time EPA now believes SDF is an “adverse health effect”.
  - Based on EPA’s legal interpretation of the controlling federal statute, the Agency believes it cannot legally grant/defend food tolerances under these conditions.
  - EPA feels compelled to do this now because activists have threatened to sue the Government in an attempt to enforce their own interpretation of the law.

### Here are some important facts to keep in mind.

- By worst-case estimate the contribution from all food-related uses of ProFume<sup>®</sup> combined is negligible (i.e., no more than two to three percent of total human fluoride exposure). As noted in the EPA quote that follows, if the Agency hoped to reduce fluoride exposures, no regulatory decision related **solely** to ProFume could credibly advance that goal. *“Use of sulfuranyl fluoride is responsible for a tiny fraction of aggregate fluoride exposure... Elimination of sulfuranyl fluoride does not solve, or even significantly decrease, the fluoride aggregate exposure problems identified earlier.”* EPA Public Announcement January 10, 2011.
- EPA acknowledges that public exposures to fluoride resulting from the use of ProFume are negligible compared to much higher exposures from drinking water and toothpaste; its greatest concern over human exposure to fluoride is for people living in areas of the U.S. with drinking water containing high, **naturally occurring** levels of fluoride. As a result, cancelling food tolerances for ProFume will not resolve - or even significantly mitigate - EPA’s concerns over fluoride exposure.
- Food contaminated by insects, rodents and related pests poses a clear threat to public health. Fumigation is the most cost-effective, reliable and rapid means of eliminating these pests from food and the facilities where food is processed or stored. Phasing out food tolerances for ProFume offers no benefit to public health and, on the contrary, imposes significant - unnecessary - public health risks.
- As EPA makes any announcements related to ProFume<sup>®</sup>, we will keep you updated and involved. We are prepared to exhaust every remedy at our disposal to ensure that our customers retain access to this vital means of protecting our nation’s food supply. We have worked with EPA in addressing issues related to stored food in the past and will continue to work with the Agency – and with you – on this issue.



**Figure 1. Range of fluoride exposure estimates.** Estimates include fluoride from foods, commercial beverages, drinking water, incidental ingestion of fluoride toothpaste, and average incidental ingestion of soil. Within each grouping of paired columns, the higher column reflects the aggregate estimate including the average contribution from the use of sulfonyl fluoride whereas the lower column does not include the contribution from sulfonyl fluoride.

**Legend:** **Low** = Average consumption of food, commercial beverages and drinking water containing 0.1 mg F/L and no contribution from toothpaste.  
**Average** = Average consumption of food, commercial beverages and drinking water containing 0.87 mg F/L and one brushing per day with fluoride toothpaste.  
**OW RSCA** = 90<sup>th</sup> percentile consumption of drinking water (consumers only) containing 0.87 mg F/L + average exposure from food and commercial beverages (literature-reported values) + 1 brushing/day with fluoride toothpaste + average exposure estimates from soil + average exposure estimates from sulfonyl fluoride.  
**Federal Food, Drug, and Cosmetic Act** = Three sets of estimates are provided. All assume average consumption of food, commercial beverages and drinking water, and two brushings per day with fluoride toothpaste. The concentrations of fluoride in drinking water are 1.76 mg/L, 2.28 mg/L or 2.59 mg/L which are the average from systems reporting at least one sample  $\geq 2$  mg/L,  $\geq 3$  mg/L, or  $\geq 4$  mg/L, respectively.  
**RfD** = Reference dose protective for development of severe dental fluorosis = 0.08 mg/kg/day.  
**AI** = Adequate intake established by the Institute of Medicine = 0.05 mg/kg/day.

Source: USEPA, *Sulfonyl fluoride- Revised Human Health Assessment*, January 7, 2011, EPA-HQ-OPP-2005-0174-0109 (Docket ID)