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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: July 13, 2005

Subject: HED Response to Comments Received Regarding the Notice of Filing for Petition
3F6573--Use of Sulfuryl Fluoride in Food Processing Facilities.

DP Number: 316783

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Following please find HED responses to comments submitted in regard to the Notice of Filing for sulfuryl fluoride that appeared in the March 4, 2005 issue of the Federal Register. The Registration Division has requested that HED respond, in particular, to items 2.6.1, 3.2.1, 3.2.2, 3.2.3, 3.3.3, 3.3.5, 3.3.6, 3.6, and 3.9.

2.6.1. "What levels of fluoride in blood and/or urine in workers using sulfuryl fluoride as a food fumigant would trigger EPA's Concern?"

HED Response: We would be concerned about fluoride levels in blood and/or urine that result from occupational exposure to sulfuryl fluoride that are in excess of that which would be equivalent to oral exposures greater than the reference dose (RfD) for sulfuryl fluoride and/or the maximum contaminant level (MCL) for fluoride, expressed on an exposure basis. Risk estimates from OPP are based on a coupling of exposure estimates to hazard estimates. Those exposure estimates are typically in terms of environmental concentrations (i.e., how much pesticide is in food, water, air, etc.). While concentrations of fluoride in blood and/or urine serve as measures of internal dose, EPA does not have

reliable quantitative data relating environmental exposure levels to internal dose (blood or urine levels) nor internal dose to health effects. Therefore, HED has not examined how internal levels of fluoride can be used to characterize the risk posed by fluoride.

- 3.2.1. “Dow states that ‘the highest fluoride levels were 754 ppm in powdered eggs.’ Why is DOW requesting such a significant increase in the tolerance for egg – from 754 ppm to 850 ppm?”

HED Response: A tolerance is meant to serve, among other things, as an indicator of misuse (i.e., uses that are not made in compliance with the labeled use pattern). Therefore, tolerances should be set within bounds that protect legal uses of a pesticide (lower bound) and that capture potential misapplication (upper bound). Given the variability in the residue data, HED presumes that the tolerance proposed by Dow is designed to fall within those bounds.

- 3.2.2. “Would EPA identify for the public the exact uses, or intended uses, of these eggs (for example, baby food, processed food, bakeries, restaurants, animal feed, List 4 Inerts, food to foreign countries, non-food products, etc.) and the population subsets that will be most exposed to these eggs (prisons, schools, military bases, organic consumers, export market, etc.). EPA might consider this request unreasonable; however, because fluoride accumulates in the body, people have the right to know where they can expect to find this intolerable level of fluoride in their food.”

HED Response: Typically, powdered eggs serve as a recipe component in products such as cakes and brownies (either in their final form or as a box mix); they may also be reconstituted and used for making egg-based foods such as scrambled eggs or omelets. EPA does not have information regarding what subset of the population that is most likely to consume powdered eggs. The dietary model used by the Office of Pesticide Programs (Dietary Exposure Evaluation Model; DEEM, version 2.03) breaks the general U.S. population in to subgroups based on age and gender, and does not address the specific groups mentioned in the comment. Exposure estimates for the subgroups addressed by the model will be included in HED’s forthcoming human health risk assessment for Petition 3F6573.

- 3.2.3. “If a person ate 1 powdered egg, what would be the milligrams of fluoride consumed?”

HED Response: If a person were to consume the equivalent of a powdered egg, the exposure to fluoride would depend on the concentration of fluoride in the powdered egg. Assuming a worst-case, tolerance-level residue of fluoride (900 ppm—which exceeds Dow’s requested level for the reasons cited under 3.2.1 above), the dietary exposure can be estimated based on the reconstitution factor for powdered eggs (2 teaspoons/egg), the bulk density of powdered egg (0.35 g/mL), and the number of teaspoons per mL (0.20288):

$$0.35 \text{ g/mL} \times 2 \text{ tsp} \div 0.20288 \text{ tsp/mL} \times 900 \text{ } \mu\text{g/g} \approx 3100 \text{ } \mu\text{g} = 3.1 \text{ mg.}$$

As noted in 3.2.1, a tolerance value is intended to represent an upper-bound residue level that could occur as a result of a legal use of a pesticide. As such, use of tolerance-level residues results in a very high-end estimate of exposure since actual residues are likely to be lower than the tolerance.

- 3.3.3. “There are many scenarios in which some people might reuse retail packing materials. For example, they may use them to store food or allow their children to play with, etc. What are the fluoride levels a young child would receive in hand-to-mouth exposure after they handle a food package fumigated with sulfuryl fluoride.”

HED Response. Data are not available reflecting the levels of either sulfuryl fluoride or fluoride in packaging materials. Food residue studies with sulfuryl fluoride indicate that substances with high fat content are the most likely to retain residues of sulfuryl fluoride following post-fumigation aeration and that substances with high protein content are more likely to have higher fluoride concentrations. HED believes that the packaging materials that might be present during fumigation are most probably polymer film and/or cardboard products. Since these have neither a high fat nor a high protein content, it is probable that there would be very little retention of either sulfuryl fluoride or fluoride ion. Given that, HED has not done a hand-to-mouth exposure analysis and believes that any such exposures would be very small, especially in light of the other sources of fluoride exposure.

- 3.3.5. “What percentage of this packaging will be incinerated on a yearly basis? Has EPA calculated the levels and the fate of the fluoride emissions when disposed by incineration on a yearly basis? If it has, would EPA please provide the details.”

HED Response: See response to 3.3.3, above.

- 3.3.6. “Several states allow ‘burn barrels’ or ‘open burning’ of garbage. For example, New York State allows ‘open burning’ in communities with a population less than 20,000 people (EPA has estimated that this is a major source of dioxin entering the US environment.) What are the levels of fluoride emissions estimated to be from ‘burn barrels’ when retail packaging fumigated with sulfuryl fluoride is burned?”

HED Response: See response to 3.3.3, above.

- 3.6. “Dow states, ‘1. Acute toxicity. The acute LC50 for sulfuryl fluoride is 642 ppm 1,088 milligram/kilogram body weight (mg/kg/bwt) [sic] for CD-1 mice exposed for four hours.’ Is this oral or inhalation exposure? Is this the most sensitive acute toxicity data available? Is the mouse the most sensitive species for acute toxicity data?”

HED Response: The LC_{50} reflects an inhalation exposure. Acute inhalation toxicity data are available from mice and rats. Of these, the mouse appears to be the more sensitive species. Data from other species are not available; therefore, the mouse is the most sensitive species based on the available data.

- 3.9. “Dow is requesting a tolerance for ‘Processed Food.’ Would EPA provide a definition of ‘Processed Food’ and also provide examples so that the public will know more definitively what this term covers.”

HED Response: According to the Federal Food, Drug, and Cosmetic Act, which is the statute under which tolerances are set, processed foods are “...any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.” For conventional agricultural pesticide tolerances, this typically means a raw agricultural commodity that is processed into another form of that commodity (e.g., apples to apple juice, wheat to flour, mint to mint oil, etc.). As relates to Dow’s current petition, HED has taken the term to mean any commodity that is the output from a food processing facility (e.g., chips, cookies, cake mixes, etc.). A processed food tolerance is therefore being proposed because it would be impractical to establish individual tolerances on the myriad of such finished foods.



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