

SULFURYL FLUORIDE
US EPA's response to Objections and request for an evidentiary hearing
submitted by Fluoride Action Network and Beyond Pesticides
on the Final Rule for the first-time use of sulfuryl fluoroide as a food fumigant.

United States Environmental Protection Agency
Washington DC 20460

Office of Prevention, Pesticides
and Toxic Substances

June 2, 2005

Fluoride Action Network
82 Judson Street
Canton, New York 13617

Jay Feldman
Executive Director
Beyond Pesticides/National Coalition Against the Misuse of Pesticides
701 E Street, SE
Washington, DC 2003

Re: Objections and Request for a Hearing Concerning Sulfuryl Fluoride Tolerances

Dears Sirs and Madam:

This letter relates to the objections and request for a hearing that were filed by the Fluoride Action Network ("FAN") and Beyond Pesticides/National Coalition Against the Misuse of Pesticides [For the sake of brevity the objecting parties are referred to throughout the balance of this letter as "FAN."] with EPA on March 23, 2004, in regard to the establishment of various pesticide tolerances for sulfuryl fluoride under section 408 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), § 346a. In your Objection/Hearing Request, you listed numerous issues on which you seek an administrative hearing. Although EPA is still considering whether to grant your hearing request, EPA can identify, at this point, several issues included in the hearing request that either appear not to meet regulatory requirements or are not even phrased as issues but rather as questions to EPA. The purpose of this letter is

(1) to provide you with notice of the issues we have preliminarily determined not to meet the requirements for a hearing so that you may cure any deficiency, if you so choose;

(2) to alert you to the requirement to submit reports and articles relied upon in your hearing request; and

(3) to provide answers to questions you have raised. We ask that you respond to this letter within 90 days from receipt.

Pursuant to section 408(g)(2) of the FFDCA, any person may file an objection to EPA establishment of a pesticide tolerance, so long as that objection is filed within 60 days of issuance of the tolerance, and request a public evidentiary hearing on the objection. EPA regulations prescribe the form and manner of hearing requests. According to 40 C.F.R. § 178.27, hearing requests must:

(1) be submitted in conjunction with an objection to a tolerance;

(2) include a statement of the factual issues on which a hearing is requested and the requestor's

contentions on these issues;

(3) include a copy of any report, article, survey, or other written document upon which the objector relies to justify an evidentiary hearing;

(4) include a summary of any evidence not covered by paragraph (3); and

(5) include a discussion of the relationship between the factual issues and the relief requested by the objection.

EPA is directed to hold an evidentiary hearing "if and to the extent [EPA] determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." 21 U.S.C. § 346a(g)(2)(B). EPA regulations further describe those issues that are appropriate for review at a public evidentiary hearing. According to 40 C.F.R. § 178.32(b), a hearing will only be granted if the material submitted by the requestor shows that all of the following three conditions are met:

(1) There is genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.

(2) There is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary. An evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions, nor if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determinations urged.

(3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issues were resolved in the manner sought.

40 C.F.R. § 178.32(b)(1b) - (3).

As noted above, several of the issues for which a hearing is requested are framed as questions to EPA, not as disputed matters of fact. The purpose of a hearing is to resolve genuine and substantial issues of fact that are disputed by the parties, not to discover if such issues exist. To clarify whether a disputed factual issue exists, EPA has attempted below to answer FAN's questions with this letter. In its reply, FAN can indicate whether it believes there is a disputed matter with regard to the issue that meets the criteria for a hearing stated above. In addition to answering FAN's questions, EPA has also identified those issues that, while presented as a disputed matter, appear not to be appropriate for a hearing either because they do not concern a genuine and substantial issue of fact or because FAN has not shown that there is a reasonable possibility that available evidence identified by the FAN would, if established, resolve one or more such issues in FAN's favor. Finally, EPA also calls to FAN's attention the requirement in 40 C.F.R. § 178.27(c) that the requestor of a hearing submit a copy of "any report, article, survey, or other written document" upon which the requestor relies.

To date, no determination has been made that a hearing is appropriate as to any issue. These matters are still under consideration.

FAN Questions

1. Use of Fluoride as an Inert Ingredient. (FAN Objection No. 8). FAN has stated that sodium fluoride is approved for use in pesticides as a "List 4-B Inert." FAN has identified 198

pesticides that have tolerances on commodities that may be treated with sulfuryl fluoride and asks:

(a) Is sodium fluoride approved for use as a List 4-B inert in any or all of these 198 pesticides?

EPA Response: Sodium fluoride is not an approved inert ingredient in any pesticide product containing the 198 pesticides listed by FAN. Sodium fluoride does appear as an impurity in two pesticide products and exposure to fluoride as a result of use of these pesticide products has been taken into account by the aggregate exposure assessment for sulfuryl fluoride. Because issues involving impurities may involve Confidential Business Information (CBI), EPA cannot release any more information without ascertaining whether any CBI claims are involved.

(b) Has EPA calculated the levels of fluoride that may result in food from use of sodium fluoride as a List 4-B inert?

EPA response: See response to (a) above.

(c) Has EPA ever tested crops treated with pesticide containing sodium fluoride as a List 4-B inert ingredient for fluoride residues?

EPA Response: See response to (a) above.

(d) Has EPA ever tested crops treated with cryolite for fluoride residues? If so, has EPA released the results to the public?

EPA Response: EPA has extensive data on fluoride residues resulting from treatment of crops with cryolite. Cryolite residues on crops are measured as fluoride and these levels of fluoride are used in estimating aggregate fluoride exposure. These issues are discussed in the following enclosed memoranda. [See Enclosures 1 at pp. 18-26 and pp. 45-48; 2 at pp. 4-13; 3 at pp. 7-10; and 4 at pp. 26-28].

(e) Does EPA know whether fluoride residues can result from fluorinated pesticides (FAN identifies 31 of the 198 pesticides as fluorinated)?

EPA Response: Generally speaking, EPA believes that fluoride residues are unlikely to result from the use of fluorinated pesticides due to the nature of the covalent carbon-fluorine bond that occurs in most fluorinated pesticide molecules. A review of the metabolism studies that have been submitted for the fluorinated pesticides in question would be required to definitively determine whether or not residues of fluoride *per se* might result from the use of fluorinated pesticides. Further data review would be required to then determine if any fluoride residues occur at biologically significant levels. As a screen to estimate the exposure to fluoride that may occur from fluorinated pesticides, scientists in the Health Effects Division of the Office of Pesticide Programs ("OPP") have searched the toxicology databases in OPP for references to a finding of fluorosis. The only compounds for which fluorosis is noted are sulfuryl fluoride and cryolite. Since toxicology studies typically include exposure levels that are far in excess of that which would be experienced by humans, EPA is confident that the lack of findings of fluorosis provides strong evidence that any fluoride residues occurring from the use of these pesticides are insignificant in comparison to exposure from sulfuryl fluoride or cryolite. The fungicide tolyfluanid provides an example of this. Studies with tolyfluanid show that fluoride may be released during the metabolism of the parent compound and toxicology studies show that fluoride levels do, in fact, increase in the teeth and bones of test organisms. However, the increase is well below levels that are known to cause fluorosis. Fluorosis was looked for in these studies and was not observed (Joint FAO/WHO Meeting on Pesticide Residues, 2002 - Tolyfluanid). If FAN has further questions regarding potential fluoride exposure from fluorinated pesticides, EPA can make available metabolism studies for these pesticides.

2. Corn Grits Tolerance Level. (FAN Objection No. 8). Is the 15.0 ppm tolerance for sulfuryl fluoride on "corn, field, grits, postharvest" an error?

Response: The tolerance petition requested a tolerance for processed corn, field, grits at 0.01 ppm. Upon re-examination of the data, it is apparent that the 15.0 ppm tolerance value is an error. The residue study lists a maximum residue of 14.4 ppb (parts per billion). [See Enclosures 5 at p 9; 6 at p 9; and 7 at p. 9] This value was mistakenly carried forward in the review process as 14.4 ppm. The data support a tolerance of 0.02 ppm and the tolerance for corn, field, grits will be corrected as part of EPA's response to the objections filed by FAN. [See Enclosure 5].

3. Sorghum Grain Tolerance. (FAN Objection No. 8). Will sulfuryl fluoride be used on "Sorghum, grain" only, or will it be used also on the category: "Sorghum, grain, grain?"

Response: The tolerance regulation is imprecise here and will be corrected as part of EPA's response to the objections filed by FAN. Grain sorghum (or sorghum, grain) is the overall crop under EPA's commodity definitions. Grain sorghum is divided into four raw agricultural commodities: forage (sorghum, grain, forage); aspirated grain fractions (sorghum, grain, aspirated grain fractions); stover (sorghum, grain, stover); and grain (sorghum, grain, grain) [See Enclosure 8 at p. 30, Table 1]. Sulfuryl fluoride is only registered as a fumigant on the commodity grain produced from grain sorghum and thus the tolerance should have read "sorghum, grain, grain." [See Enclosure 9, Proposed Label at p. 5].

4. Use of Cryolite on Grapes. (FAN Objection No. 9). How many times can various cryolite products be applied to grapes?

Response: The label allows up to 5 applications per year and states that the total application rate cannot exceed 20 lb ai/A/year. The maximum single application rate is 9.6 lb ai/A. [See Enclosure 10 at p. 8].

5. Cryolite Grape Tolerance and Multiple Cryolite Applications. (FAN Objection No. 9). Does each application of cryolite to grapes have an individual tolerance of 7 ppm or is 7 ppm the legal limit no matter how many applications of cryolite?

Response: The legal limit for cryolite on raisins is 7 ppm. Although EPA through use of crop field residue trials considered the number of applications and application amount, as specified on the label, in approving the tolerance level, the established level defines what amount of residue may remain in food regardless of what application pattern is followed.

6. Use of Sulfuryl Fluoride on Raisins. (FAN Objection No. 9). How many times can sulfuryl fluoride be applied to raisins?

Response: The label permits sequential fumigations but limits the maximum cumulative dosage to 1500 oz-h/1000 cu ft. If fumigations are made with the commodity under reduced pressure, the total rate cannot exceed 200 mg hr/L (200 oz hr/1000 ft³). [See Enclosure 9, Proposed Label at pp. 6 and 10].

7. Total Fluoride Residue on Raisins. (FAN Objection No. 9). What is the total fluoride residue that EPA has calculated for raisins? If fluoride residues on grapes from cryolite can be 7 ppm, residues would be expected to be 2X to 6X greater.

Response: The current tolerance for cryolite on grapes is 7 ppm. 40 CF.R. § 180.145. That tolerance would apply to raisins produced from treated grapes. See 21 U.S.C. § 346a(a)(2). In the Reregistration Eligibility Decision (RED) for cryolite, EPA determined that fluoride residues from cryolite did have the potential to concentrate in raisins produced from cryolite-treated grapes [See Enclosure 1 at p. 26]. The RED found the concentration factor to be 10X and recommended a

raisin tolerance of 55 ppm. EPA's current view is that this concentration factor is in error because it exceeds the maximum theoretical concentration factor in producing raisins of 4.5X. Maximum theoretical concentration factors are calculated by dividing the mass of the processed product into the mass of the raw agricultural commodity. Assuming that all of the pesticide on the treated raw agricultural commodity remains in the processed food, the actual degree of concentration of the pesticide in the processed food cannot be higher than the maximum theoretical concentration factor. EPA plans to correct the cryolite tolerances in the future.

Additionally, EPA did not include the higher levels of fluoride that may be in raisins as a result of treatment with cryolite in the fluoride risk assessment prepared for the sulfuric fluoride tolerance action. [See Enclosure 4 at p. 27, Table 4.2.1.3]. To correct this error, EPA has recalculated exposure expected from fluoride from cryolite in raisins using a residue level for raisins that reflects both the concentration of fluoride that may occur upon drying (4.5X) and the removal that results from washing (0.3X). [See Enclosure 11 at p. 7]. This reanalysis yields chronic dietary exposure estimates for fluoride from cryolite that are, at most, 6.7% higher for all population subgroups. [See Enclosures 3 & 11 (compare results in Table 8 of each memorandum)]

8. Fluoride Residues on "Dried Fruits." (FAN Objection No. 9). Do the following fruits fall into the category of "Dried fruit (except raisin)": apricot, blackberry, blueberry, boysenberry, cherry, sweet and tart, cranberry, dewberry, kiwi fruit, loganberry, melon, nectarine, peach, plum, prune, dried, raspberry, strawberry, youngberry, figs, dates? Are there any others? (These fruits have fluoride residue tolerances of 7 ppm on the RAC, except kiwi fruit which is 15 ppm from the use of cryolite.) Has EPA calculated total fluoride residues from both cryolite and sulfuric fluoride? Has EPA taken into account that fluoride residues on dried fruit would concentrate between 2X and 6X?

Response: Any commodity that meets the common meaning of the term "fruit" and has been dried would qualify under EPA regulations as a "dried fruit." In conducting its dietary exposure assessment, the Agency included residues for all dried fruit commodities in the dietary exposure modeling software. These are the commodities with reported consumption in the Continuing Surveys of Food Intakes by Individuals (CSFII) and include apricot, cranberry, currant, raisin, peach, and plum. [See Response in No. 9 *infra* for further information concerning the CSFII]. Since this food survey is designed to be a comprehensive examination of food consumption, the fact that a particular food form is not captured in the survey suggests that consumption of the food form is, at most, a very minor component of the diet.

Further, EPA calculated fluoride residues resulting from use of cryolite and sulfuric fluoride. [See Enclosure 2 at 20-29]. As to potential concentrations of fluoride in dried fruit from treatment of the raw commodity with cryolite, EPA included concentration factors of 6X for dried apricots, 7X for dried peaches, and 5X for dried plums (prunes). [See Enclosure 11 at p. 9, Table 3]. No concentration factors were used for the dried commodities cranberry and currant. Concentration factors were not available for these two commodities. Within the CSFII database for the general U.S. population, dried cranberry accounts for less than 0.3% of the total dried fruits consumption and dried currant for less than 0.02%. In terms of the total diet, these percentages of consumption would be significantly less than that. Given the low consumption of these dried fruits, EPA believes that the lack of a processing factor for them does not result in any meaningful effect on the estimation exposure to fluoride.

For sulfuric fluoride the application is to the dried fruit, not the fruit prior to drying, so concentration is not an issue.

9. High End Consumers of Dried Fruit. (FAN Objection No. 9). Has EPA factored into its assessment high end users of dried fruit such as outdoor enthusiasts and school children?

Response: In conducting its dietary assessment, the Agency has used the Food Commodity Intake Database version of the Dietary Exposure Evaluation Model (DEEM-FCID). This model

uses the food consumption information contained in the CSFII databases from surveys conducted in 1994, 1995, 1996, and 1998. That survey is under the administration of the U.S. Dept. of Agriculture, Agricultural Research Service. The surveys included a target population of noninstitutionalized individuals from all 50 states and the District of Columbia. The 1994-96 and 1998 data are based on the reported food consumption of more than 20,000 individuals. The CSFII is designed to be representative of the United States population including major identifiable population subgroups. The dietary modeling software uses the demographic and residues in food commodities to derive estimates of dietary exposure for various population subgroups. For more information on the CSFII program, see <http://www.barc.usda.gov/ghnrc/foodsurvey/>

Issues Not Appearing to Meet the Substantive Requirements for a Hearing Request

The following issues in the FAN objections do not appear to meet the requirements for an administrative hearing. We have explained below the reason for this conclusion as to each of the issues. Unless you can explain why these issues are proper for resolution in a hearing, EPA intends to deny a hearing with regard to them. EPA's identification in this letter of various issues that do not appear to meet the requirements for a hearing does not preclude EPA from determining that other issues in FAN's objections have similar flaws. Nor does the identification of particular flaws below preclude EPA from determining that the issues listed below have additional flaws not identified here.

Issue 1. EPA has failed to consider reasonable alternatives to Dow's use of sulfuryl fluoride. (FAN Objection No. 7).

FAN argues that there are other safer alternatives to methyl bromide than sulfuryl fluoride. FAN asserts that other countries have ended use of methyl bromide and adopted use of safer fumigants such as steam and carbon dioxide rather than sulfuryl fluoride. FAN notes that EPA's website identifies alternatives to methyl bromide other than sulfuryl fluoride.

EPA Response: As EPA's regulations make clear, "an evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested." 40 C.F.R. § 178.32(b)(3). Whether or not there are safer fumigants than sulfuryl fluoride is not a relevant issue in determining whether it was proper for EPA to establish the sulfuryl tolerances that are subject of FAN's objections. Subject only to a narrow exception not applicable to sulfuryl fluoride, section 408 establishes a risk-only standard for the approval of tolerances. To establish a tolerance EPA must determine that the tolerance poses a reasonable certainty of no harm. 21 U.S.C. § 346a(b)(2)(A). Section 408 does not allow EPA to deny tolerances to pesticides that meet this safety standard if other, even-safer pesticides are available. Accordingly, **even if FAN could prove that there are safer fumigants than sulfuryl fluoride that are equally efficacious, that showing would not be determinative of FAN's request for a revocation of the sulfuryl fluoride tolerances.**

Issue 2. Sulfuryl fluoride poses an unacceptable risk to workers. (FAN Objection No. 7).

FAN asserts that the acute toxicity of sulfuryl fluoride poses an unacceptable risk to workers. FAN claims that sulfuryl fluoride can damage workers' brains. FAN states that EPA has no regulatory function to assess the risk to workers but urges EPA to work with other agencies to regulate sulfuryl fluoride.

Response: This issue is not appropriate for a hearing because it also is not determinative of the action requested. Section 408 specifically dictates that occupational exposures to pesticides are not a proper consideration in making a decision on the safety of a tolerance. 21 U.S.C. § 346a(b)(2)(D)(vi). FAN, however, is incorrect to claim that EPA has no regulatory authority with regard to workers exposed to pesticides. Under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq., EPA is charged with taking into account "the economic, social, and environmental costs" of

pesticides. One of the potential costs of pesticides is harm to pesticide handlers and applicators from occupational exposure to pesticides. Risks to pesticide handlers and applicators are routinely considered during the pesticide registration process under FIFRA and were considered in approving the sulfuranyl fluoride registration. [See Enclosure 4, pp. 38-40]

Issue 3. It is confusing to have pistachio in a separate category from "nut, tree, group." (FAN Objection No. 8.)

Response: This issue is not proper for a hearing because it is not an appropriate objection to the sulfuranyl fluoride tolerance rulemaking. The exclusion of pistachio from the Crop Group 14 - Tree Nuts is based on a long-existing regulation. See 40 C.F.R. § 180.41. The existing crop group regulation may not be challenged through a procedure allowing an administrative review of a separate current action (i.e. the establishment of the sulfuranyl fluoride tolerances). In any event, EPA does not believe its crop group regulations are confusing. Crop groups have been established by EPA to facilitate the establishment of tolerances for related crops that have similar proposed or registered pesticide application patterns. The regulation defining Crop Group 14 - Tree Nuts clearly does not list pistachio as one of the included crops. 40 C.F.R. § 180.41(b)(14). A pesticide tolerance established for the Tree Nuts Crop Group plainly only authorizes pesticide residues on the tree nuts listed in 40 C.F.R. § 180.41(b)(14). A pesticide tolerance established for the Tree Nuts Crop Group plainly only authorizes pesticide residues on the tree nuts listed in 40 C.F.R. § 180.41(b)(14). EPA is reviewing the commodities included in the various crop groups in section 180.41 and may, in the future, amend Crop Group 14 to include pistachio. Until such amendment is made, however, the regulation is clear as to whether pistachio is covered.

Issue 4. EPA must withdraw tolerances for commodities not addressed in Dow's petition. (FAN Objection No. 10).

FAN argues that because Dow's petition to establish sulfuranyl fluoride and fluoride tolerances on various commodities did not specifically request tolerances on barley (bran), barley (flour), barley (pearled), corn (aspirated grain fractions), oat (flour), and oat (rolled), EPA was not permitted to establish tolerances on these commodities.

EPA Response: Evidentiary hearings are for the purpose of resolving genuine and substantial issues of fact. Evidentiary hearings are not granted on legal issues such as whether EPA's action on a petition may vary from the action requested by the petitioner. See 40 C.F.R. § 178.32(b)(1). There are no disputed facts here. Dow's petition did not request tolerances on the six commodities listed above. Dow did, however, request tolerances on the main raw agricultural commodities associated with each of the six commodities - barley (grain), corn (grain), and oat (grain). Under FFDCA section 408(d)(4)(A)(i), EPA is authorized in issuing a tolerance regulation in response to a petition to "vary [the regulation] from that sought by the petition." Setting tolerances on subsidiary or processed forms of a commodity when the petition has only sought a tolerance on the underlying commodity falls well within EPA's authority to vary from a petition in acting upon it.

Issue 5. EPA must withdraw tolerances for commodities where EPA excessively increased the value of the tolerance requested in Dow's petition (FAN Objection No. 10).

In acting on Dow's petition, EPA set fluoride tolerances for wheat (flour) and wheat (milled byproducts) at 125 ppm and 130 ppm, respectively. Dow had petitioned for tolerances of 10 ppm on wheat (flour) and 35 ppm on wheat (milled byproducts). FAN contends these increases are excessive but provides no explanation as to why that is the case.

EPA Response: EPA's regulations make clear that "[a]n evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and

contentions" 40 C.F.R. § 178.32(b)(2). FAN's hearing request regarding this issue is unsupported by any factual allegations. As such, EPA does not believe a hearing is appropriate. By way of explanation, EPA would note that it varied the level of the tolerances for these two commodities from the level requested by Dow based on residue data showing that the higher values were needed to legalize levels that could result from intended use. [See Enclosures 5 and 7].

Issue 6. EPA has no statutory authority or guidance to accept RfDs from other agencies or divisions in EPA. (FAN Objections, Appendix G, p. 1).

FAN contends EPA's Office of Pesticide Programs abrogated its responsibility to determine a RfD for fluoride using its "own methodology" and instead relied on an RfD from another division in EPA. FAN claims the Office of Pesticide Programs has no "statutory authority or internal guidance allowing it to take RfDs from other agencies or divisions of the EPA."

Response: Evidentiary hearings are for the purpose of resolving genuine and substantial issues of fact. Evidentiary hearings are not granted on legal issues such as the scope of EPA's statutory authority. See 40 C.F.R. § 178.32(b)(1).

Issue 7. EPA has short-circuited the risk assessment process and FAN is requesting a hearing to correct this error. (FAN Objections, Appendix G, p. 2).

FAN claims that the Office of Pesticide Programs ("OPP") short-circuited the risk assessment process by relying on the Maximum Contaminant Limit (MCL) for fluoride promulgated by EPA's Office of Water. FAN asserts that even if OPP can legally rely on the MCL, a hearing is necessary to give FAN "the opportunity to question the RfD, on the same basis as if it had been prepared by OPP." FAN states that "the requirement that OPP's methods and decision be transparent cannot be waived just because the OPP used the work of a different department."

Response: This hearing request is faulty because it seeks a hearing on legal issues (e.g., Can EPA waive steps in the risk assessment process?) and as a means of gaining information on the basis of EPA's decision. As noted above, hearings are not granted on legal issues. Further, hearings are granted for the purpose of resolving genuine, disputed issues of fact; not for the purpose of investigating whether disputed issues of fact exist.

Issue 8. EPA should protect 99.9 percent of the public from chronic risks. (FAN Objections, Appendix G, pp. 4-6).

FAN claims that the FFDCA requires that EPA protect at least 99.9 percent of the population from chronic risks of pesticides.

Response: This is a legal issue and as such, is not appropriate for an evidentiary hearing. Further, EPA would note that FAN appears to have misunderstood the purpose in using population percentiles of exposure in estimating risk. EPA does not use such percentiles as a means of defining the percentage of the population that deserves protection but rather as a way of estimating exposure for the overall population and major identifiable subgroups taking into account the degree of conservatism present in various exposure values and risk assessment methodologies. [See Enclosure 13].

Issue 9. EPA has failed to protect the following subpopulations: (a) People with kidney disease such as diabetes who drink lots of water; (b) People over 50 who excrete less fluoride; (c) People who live in areas with water with naturally high fluoride levels; (d) Nursing age infants; (e) Formula fed infants; (f) People exposed occupationally; (g) Children who swallow most of their toothpaste; (h) People who are given fluoride dental products such as mouthwashes; (i) Athletes, and others, who exercise more and consume more water; (j) People whose diets include many

high fluoride foods; (k) People living near active volcanic areas; and (l) People who stockpile food. (FAN Objections, Appendix G. pp 6-8).

FAN argues that each of these subgroups is likely to have higher exposures. Except with regard to children swallowing most of their toothpaste, FAN cites no data or reports to support these allegations. As to children's exposure to toothpaste, elsewhere in its hearing request, FAN does reference studies bearing on fluoride exposure from toothpaste. It is not clear as to whether these cited data address the amount of toothpaste swallowed by children.

Compliance with the Requirement to Submit All Written Material Relied Upon

EPA regulations make clear that for a hearing request to be considered by the Agency, the request must "include a copy of any report, article, survey, or other written document (or the pertinent pages thereof) upon which the objector relies to justify an evidentiary hearing, unless the document is an EPA document that is routinely available to any member of the public." 40 C.F.R. § 178.27(c). This requirement is mandatory and failure to comply is grounds for denial of the hearing request. Although FAN has attached copies of a few of the reports on which it relies to justify its hearing request, it cites to hundreds of other reports and documents that have not been submitted. Until FAN submits copies of all these documents EPA cannot proceed other than to deny the hearing request.

Conclusion

At the present time, EPA is still considering whether to grant your hearing request. This letter, among other things, describes various flaws in your hearing request which may result in a denial of a hearing as to some or all of the issues you have raised. If you wish to respond to this letter, we request that that response be made 90 days from receipt. Such response should be sent to EPA at:

Public Information and Records Integrity Branch,
Information Resources and Services Division (7502C)
Docket ID No. OPP-2003-0373
Office of Pesticide Programs
U.S. EPA
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

A copy should be sent to:

Jonathan Fleuchaus (2333A)
Office of General Counsel
U.S. EPA
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

If you have questions concerning this letter or need additional time to prepare a response please contact Jonathan Fleuchaus in EPA's Office of General Counsel. He can be reached by telephone at (202) 564-5628 or by email at fleuchaus.jonathan@epa.gov

Sincerely

James J. Jones
Director, Office of Pesticide Programs

Enclosures:

1. U.S. EPA, Reregistration Eligibility Decision, Cryolite (August 1996)
[Note: EPA sent FAN a hard copy. It is also [available online](http://www.epa.gov/opsrrd1/REDS/0087.pdf) at <http://www.epa.gov/opsrrd1/REDS/0087.pdf>]
2. U.S. EPA, Memorandum from David Soderberg to Deborah McCall, Cryolite (List A). Summary of Issues on Tolerance Reassessment, Including Reassessment of Tolerances on Stone Fruits and Reassessment of the Time-Limited Tolerances for Potato and Potato Waste, with a Revised Dietary Exposure Assessment (December 18, 2001).
3. U.S. EPA, Memorandum from Michael Doherty and David Soderberg to Michael Doherty, Chronic Dietary Exposure Assessments for Sulfuryl Fluoride and Fluoride Anion, Addressing the Section 3 Registration of Sulfuryl Fluoride on Stored Cereal Grains, Grain Processing Facilities, Dried Fruits, and Tree Nuts (January 13, 2004).
4. U.S. EPA, Memorandum from Michael Doherty to Dennis McNeilly/Richard Keigwin, Human Health Risk Assessment for Sulfuryl Fluoride and Fluoride Anion Addressing the Section 3 Registration of Sulfuryl Fluoride Post-Harvest Fumigation of Stored Cereal Grains, Dried Fruits and Tree Nuts and Pest Control in Grain Processing Facilities. PP#1F6312 (January 20, 2004).
[Note: This was attached to the Docket of the January 23, 2004, Final Rule. [Available online](http://www.fluorideaction.org/pesticides/sf.jan.20.2004.epa.docket.pdf) at <http://www.fluorideaction.org/pesticides/sf.jan.20.2004.epa.docket.pdf>]
5. U.S. EPA, Memorandum from Michael Doherty to Dan Keny/Meredith Laws. PP#1F06312 - Sulfuryl Fluoride. Section 3 Registration for the Post-harvest Fumigation of Stored Cereal Grains, Dried Fruits, and Tree Nuts, and Fumigation of Grain Milling Establishments. Corrected Summary of Analytical Chemistry and Residue Data (October 12, 2004).
6. U.S. EPA, Data Evaluation Report, Sulfuryl Fluoride/078003 (October 14, 2004).
7. U.S. EPA, Memorandum from Michael Doherty to Dennis McNeilly/Kerry Leifer. PP#1F06312 - Sulfuryl Fluoride. Section 3 Registration for the Post-harvest Fumigation of Stored Cereal Grains, Dried Fruits, and Tree Nuts, and Fumigation of Grain Milling Establishments. Summary of Analytical Chemistry and Residue Data (January 13, 2004).
8. EPA, Residue Chemistry Guidelines: OPPTS 860.1000 Background (August 1996).
9. EPA, Notice of Pesticide Registration, Profume Gas Fumigant (Reg. No. 62719-376) (January 26, 2004).
10. Label, Kryocide (May 15, 2003).
[Note: EPA sent FAN a hard copy. What EPA sent differs from the following label. Both have the same Registration No. (4581-116). FAN is including the following for information purposes only.
EPA Specimen Label at <http://www.fluorideaction.org/pesticides/msds/cryolite.label.kryocide.epa.pdf>
Material Safety Data Sheet at <http://www.fluorideaction.org/pesticides/msds/cryolite.kryocide.pdf>
]
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