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Dow AgroSciences

October 31, 2006

Roger R. Martella, Jr.
Acting General Counsel
U.S. Environmental Protection Agency
Ariel Rios Federal Building – Mail code 2310A
1200 Pennsylvania Avenue, NW
Washington DC 20460

November 3 Meeting Between EPA Office of General Counsel and Dow AgroSciences

Dear Mr. Martella,

Again thank you for agreeing to meet with us this Friday. Representing our company at the meeting will be Charles Kirk, Regulatory Affairs Counsel, Stanley Abramson from Arent Fox, and me.

At the meeting we would like a brief overview of Dow AgroScience and then turn to the substantive legal issues around certain objections, motion for stay and request for hearing made in connection with the tolerances EPA has established in support f the FIFRA registration for ProFume™ gas fumigant.

In advance of our meeting, we would like to provide for your consideration the enclosed memorandum from Mr. Abramson discussion in detail our legal interpretation of EPA's discretion to deny an administrative law hearing. Our attorneys believe that EPA has broad discretion to deny this hearing and that granting a hearing on the establishment of pesticide tolerances would be unprecedented and represent a significant shift in EPA policy and practice.

If you or your staff has any questions or wish to discuss this prior to our meeting, please do not hesitate to contact me. Otherwise, we look forward to the meeting this Friday.

Sincerely

Bradley A. Shurdut
Global Director, Government and Public Affairs
202-429-3434 (Office)
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Enclosure

Cc: Jonathan Fleuchaus, Esq.
Stanley H. Abramson, Esq.

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Memorandum

Standard for Granting a Hearing under the Federal Food, Drug, and Cosmetic Act Concerning Objections to Tolerances Established by EPA for Pro-Fume™ Gas Fumigant

1. INTRODUCTION

This memorandum addresses an issue of critical importance with respect to the interpretation and implementation of Section 408 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"),[1] as amended by the Food Quality Protection Act of 1996 ("FQPA"),[2] by the U.S. Environmental Protection Agency ("EPA" or "Agency").

By way of introduction, on August 4, 2006, we submitted a response on behalf of our client, Dow AgroSciences LLC ("DAS"), to the most recent request for public comments announced by the EPA. Sulfuryl Fluoride: Request for Stay of Tolerances. 71 Fed. Reg. 38.125 (July 5, 2006). The public comment period was associated with a June 1, 2006, Motion of Objectors for Stay of Final Rules Establishing Tolerances for Residues of Sulfuryl Fluoride and Fluoride Anion ("Motion"), in which certain public interest groups ("Objectors") requested EPA to stay pesticide tolerances previously established by the Agency in 2004 and 2005 in conjunction with the registration of the pesticide product ProFume™ Gas Fumigant ("ProFume"). DAS is the registrant and producer of ProFume. The active ingredient in ProFume is sulfuryl fluoride. In its comments DAS discussed numerous legal, procedural and policy arguments in support of a denial of the Objectors' Motion by the Agency.[3]

Also pending before the Agency is Objectors' request for a formal evidentiary hearing under FFDCA Section 408, with respect to objections that have been raised as to the tolerances issued by the Agency for residues that might result from the labeled uses of ProFume. Given the

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1. 21 U.S.C. §346a.
2. Pub. L. No. [illegible]-170, 110 Stat. 1489 (1996).
3. As set forth in DAS's response to the Agency's request for public comments, the Objectors' Motion is flawed in a number of respects and should be denied by EPA. *See* Response of Dow AgroSciences LLC to Request for Public Comments, Sulfuryl Fluoride: Request for Stay of Tolerances, Docket Identification Numbers; EPA-HQ-OPP-2005-0174 and EPA-HQ-OPP-2003-0373 (Aug. 4, 2006) ("DAS Response to Request for Public Comments"). For example, the Motion relies in significant part on the recommendations contained in a report issued by the National Academy of Sciences National Research Council's Committee on Fluoride in Drinking Water, released in March 2006 ("NRC Report"). The NRC Report had been commissioned by EPA under the Safe Drinking Water Act as part of a six-year review of the existing fluoride maximum contaminant level goal ("MCLG") and secondary maximum contaminant level ("SMCL"). However, the EPA has already established, in the conditional registration for ProFume, a procedure for (i) review of the NRC Report under SDWA, (ii) re-assessment of the current MCLG and SMCL for fluoride under SWDA and (iii) possible re-evaluation of the tolerances issued with respect to sulfuryl fluoride under FFDCA. That process, which should proceed, does not contemplate a stay of tolerances, which would be arbitrary, unfair, and unwarranted. *See* DAS Response to Request for Public Comments at 5-7.

significant precedent that would be established should EPA decide to exercise its discretion to hold the first ever hearing under Section 408,[4] this memorandum provides information regarding the threshold standard for holding such a hearing and how the Food and Drug Administration ("FDA") and the courts have applied a very similar standard under the FDA's companion authority in Section 409 of the FFDCA.

As set forth herein, we respectfully submit that a careful application of the Section 408 hearing standard reveals two conclusions: (i) the objections raised with respect to the tolerances for both sulfuryl fluoride (the parent active ingredient of ProFume) and the fluoride anion (the primary residue of interest), do not meet the requisite hearing standard; and (ii) to the extent the Agency believes that a hearing might be appropriate, that decision should be deferred until the NRC Report has been reviewed by the EPA's Office of Ground Water and Drinking Water ("Office of Water") under the Safe Drinking Water Act. Further EPA administrative analyses - *i.e.*, additional risk assessment, rulemaking, etc. – would then be used to determine the impact, if any, of that review on the tolerances that have been issued.

II. HISTORY OF ESTABLISHMENT OF SULFURYL FLUORIDE TOLERANCES AND OBJECTIONS TO THOSE TOLERANCES

Among the extensive and diverse mix of products registered and produced by DAS for agriculture are two fumigant products containing the active ingredient sulfuryl fluoride. Sulfuryl fluoride has been registered in the United States since 1959 as a structural fumigant ("Vikane") and remains the most effective tool for the control and eradication of drywood (above ground) termites. In 2004, EPA granted a registration for sulfuryl fluoride (ProFume®) for the control and eradication of a wide range of post-harvest pests in mills, commodity storage structures and food handling facilities. Fumigation is a preferred method of control in both these contexts because of the ability of a gas fumigant to penetrate wherever pests are located.

ProFume was developed specifically to serve as a direct replacement in the food processing industry for methyl bromide ("MeBr'), an ozone depleting substance which was scheduled for complete phaseout by December 31, 2004.[5] In fact, in 2002, EPA recognized DAS with the Stratospheric Ozone Protection Award for its development of ProFume and the contributions which ProFume was expected to make to protection of the Earth's stratospheric ozone layer. The safety, economics, and performance of sulfuryl fluoride have permitted many MeBr users in this industry to adopt this alternative fumigant.

In 2002, pursuant to Section 408(d) of the FFDCA, DAS first petitioned the EPA to establish tolerances to cover potential residues of sulfuryl fluoride and the fluoride anion (F-), collectively "ProFume tolerances," in or on more than forty raw and processed food commodities. As required by FFDCA Section 408(d)(3) the EPA noticed DAS's petition by publishing in the Federal Register a "Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food" and solicited public comments on the DAS petition. 67 Fed.

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4. Section 408 was added to the FFDCA in 1954.
5. The phaseout schedule was established under the Montreal Protocol by the United States and 182 other countries.

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Reg. 7156 (Feb. 15, 2002).[6] In that Notice, the EPA printed DAS's summary of the pesticide petition. *Id.* at 7157

In response to the EPA notice, Objectors, including FAN, submitted comments on DAS's petition on March 18, 2002. In total, more than sixty studies and reports on fluoride's alleged effect on various aspects of human health were cited in the comments submitted to the Agency. On January 16, 2004, the EPA responded, in detail, to all comments, which, in general addressed either (a) the process utilized by EPA to establish the tolerances or (b) the scientific issues concerning human health. *See* Response to Public Comments Concerning the Use of Sulfuryl Fluoride as a Post Harvest Fumigant (EPA Jan 16, 2004) (hereinafter "2004 Comment Responses"). In response to concerns that it was relying on outdated data in the process of establishing the requested tolerances, EPA explicitly stated that it has "carefully considered all of the recent data that was referenced in the comments to determine whether there are any new data that substantially change the weight of the evidence that supports the conclusions reported in the 1993 NRC review" regarding the effects of fluoride on human health. *Id* at 3.[7]

Furthermore, the Health Effects Division ("HED") in the Office of Pesticide Programs c concluded a thorough risk assessment, which "reviewed the toxicology and residue chemistry data submitted to support the petition [by DAS] . . . examined the potential for exposures [of both sulfuryl fluoride and F-] via dietary (food and drinking water), non-dietary oral, inhalation, and dermal routes." *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 at 1 (EPA Jan. 20, 2004) (hereinafter "2004 EPA Risk Assessment"). EPA Risk Assessment at 1 (Jan. 20, 2004). Cited as support for this risk assessment were more than twenty studies and reports, including the comprehensive 2002 World Health Organization report. Based on the recommendations contained in the HED risk assessment, EPA issued final tolerances on January 23, 2004. On March 23, 2004, FAN and Beyond Pesticides ("BP") submitted objections to the tolerances issued by EPA and requested a formal evidentiary hearing.

Then, in 2005, DAS petitioned EPA to establish ProFume tolerances for an additional 600 food commodities. As it had previously, EPA noticed DAS's petition by publishing in the Federal Register a "Notice of Filing a Pesticide Petition to Establish Tolerances for a Certain Pesticide Chemical in or on Food" and solicited public comments on the DAS petition. 70 Fed. Reg.10,621 (Mar. 4, 2005). Again FAN submitted comments on the DAS petition. These comments are dated April 19, 2005. As it had with the public comments submitted for the first set of

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6. Prior to the submission of its request for permanent tolerances, DAS, in 2001, petitioned EPA to grant it an Experimental Use Permit (EUP) for sulfuryl fluoride and to establish temporary tolerances and tolerance exemptions for certain food commodities. 66 Fed. Reg.32.618 (June 15, 2001). In response to the Agency's establishment of the temporary tolerances, Fluoride Action Network ("FAN") submitted objections and requested a hearing on April 8, 20002. Those objections subsequently became moot upon DAS's withdrawal of its EUP in early 2004. As such, these objections and hearing request submitted by FAN to the temporary tolerances are not addressed herein.

7. In the early 1990s, NRC was asked "to review current toxicological and exposure data on fluoride and determine whether EPA's existing drinking water standards are adequate for protecting the public from adverse health effects of fluoride." See 58 Fed. Reg. 68.826, 68.827 (Dec. 29, 1993) (to be codified at 40 C.F.R. [unreadable] NRC's findings were released in a 1993 report, which concluded that EPA's MCL of 4mg/L was an appropriate standard.

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Tolerances. EPA responded, in detail, to the public comments submitted in response to DAS second request for tolerances. See Response to Public Comments Concerning the Use of Sulfuryl Fluoride in Food Handling Facilities (EPA July 14, 2005) (hereinafter "2005 Comment Responses"). On July 15, 2005, EPA granted the DAS petition for additional ProFume tolerances. On September 11, 2005, FAN, BP, and the Environmental Working Group submitted objections to the second set of tolerances issued by the EPA. In response to a communication from the Office of General Counsel, Objectors consolidated their March 2004 objections and their September 2005 objections into one comprehensive set of objections (collectively "Consolidated Objections"), which was submitted to the Agency on December 20, 2005.

Notably, on January 18, 2006, the EPA released a revised risk assessment to clarify issues with "the assumptions made in the [original] risk assessment and the uses that were being allowed on the product label." *Human Health Risk Assessment for Sulfuryl Fluoride and Fluoride Anion Addressing the Section 3 Registration of Sulfuryl Fluoride as a Fumigant for Foods and Food Processing Facilities,* PP# 3F6573, at 24 (EPA Jan. 18, 2006) (hereafter "2006 EPA Risk Assessment"). While the amended risk assessment resolved those issues, the HED reaffirmed the conclusions and regulatory recommendations it had reached in the first risk assessment notably that it supported the "establishment of permanent tolerances for residues of sulfuryl fluoride and fluoride anion." *Id.*

Notwithstanding the multiple comprehensive reviews undertaken by EPA in establishing the ProFume tolerances, FAN, the Environmental Working Group, and BP – the Objectors – have continued to pursue their objections. In addition, Objectors have requested that EPA grant a formal evidentiary hearing to review what Objectors assert to be material issues of fact warranting a revocation of the ProFume tolerances. Furthermore, Objectors have submitted a Motion to Stay the tolerances (filed with EPA June 1, 2006) purportedly based upon the findings and recommendations contained in the recently released NRC Report dealing with fluoride in drinking water. The Motion essentially renews and reiterates most of the Consolidated Objections.

Perhaps the most significant statement in the NRC Report was the conclusion reached by a majority of the members of the NRC committee that EPA's maximum contaminant level goal of 4 mg/L established under the Safe Drinking Water Act for fluoride in drinking water should be lowered because lifetime exposure at the 4 mg/L level and higher is likely to increase the risk of bone fracture. The NRC Report did not recommend a new MCLG. It did not make any recommendations with respect to ProFume or any other sulfuryl fluoride or fluoride product. Most importantly, the report did not recommend or even suggest that the ProFume tolerances established by EPA should be re-evaluated, stayed, or modified in any way.

In the comprehensive review of the Consolidated Objections that follows, it will become clear that the piecemeal objections raised over the last four years of this administrative rulemaking process hardly raise material issues of fact which would require the EPA to convene a Section 408 hearing. In light of the standards governing such hearing requests. Objectors' request for a hearing is unfounded and should be denied.

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8. *See* discussion in note 4 *supra* – *[do not know where reference 8 appears on this page due to poor legibility]*

III. STANDARD FOR GRANTING A HEARING UNDER FFDCA SECTION 408

As a general matter the Supreme Court has held than an applicant seeking an administrative hearing must "meet a threshold burden of tendering evidence suggesting the need for a hearing." *Castle v. Pac. Legal Found.*, 445 U.S. 198.214 (1980) (Clean Water Act hearing). Such is the case under Section 40-8(g) of FFDCA, which permits a person to file an objection to a pesticide tolerance issued by EPA and request a formal evidentiary hearing on that objection, which shall be granted "if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the object ions." 21 U.S.C. § 346a(g)(2)(B).

Part 178 of EPA's regulations implements Section 408(g) and established an intentionally rigorous, three-part test to be used by the Administrator to determine whether a hearing is necessary. See 40 C.F.R. § 178.32(b)(1-3). Under that test, EPA must determine that materials submitted in support of the objections show all of the following:

1. There is a 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 of 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 determination 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 issue were resolved in the manner sought.

40 C.F.R. § 178 .32(b)(1-3). Put simply, this three-part test is designed to "establish whether a formal evidentiary public hearing will advance the administrative process by resolving factual issues that are material to [a] . . . decision on an order or regulation." 41 Fed. Reg. 51,706, 51,708 (Nov. 23, 1976) (commenting on the FDA's need for its procedural rules for formal evidentiary hearings under FFDCA Section 409 and other FDA statutory provisions).

A. EPA Has Enormous Discretion in Its Determination of Whether to Hold a Hearing

EPA has never before held an evidentiary hearing under Section 408 of the FFDCA, See e.g., 53 Fed. Reg. 41,126, 41,127 (Oct. 19, 1988). Short of the hearing rules themselves, there is little EPA guidance as to the type of "genuine and substantial issue [ ] of fact" that would merit a formal evidentiary hearing. *Id* at 41,129. In promulgating these rules, however the EPA made

it quite clear that Part 178 was "to a very large extent . . . based on the FDA regulations that [govern formal evidentiary hearings under Section 409(f) of FFDA and other FDA statutory provisions]." *Id.* Indeed, the EPA regulations governing objections and hearing requests are nearly identical to their FDA counterparts. 21 C.F.R. 12.24(b)(1-6). 9 "To the extent that the language in [Part 178] is the same as or substantively similar to the FDA regulations, EPA relies on FDA's explanations in support of [those regulations] and refers readers to them." 10 53 Fed. Reg. at 41,129.

Accordingly, FDA guidance and court precedents addressing the scope, meaning, and application of the FDA hearing requests under Section 409(f) are instructive in understanding the parallel EPA regulations and predicting how the EWPA would most appropriately treat such a request. Therefore, FDA precedent and guidance, as well as EPA guidance (where available), are persuasive in determining the proper circumstances in which an objector's hearing request would be granted.

The EPA enjoys a wide degree of latitude in its decision to reject an objector's hearing request. The Agency need only give "adequate consideration to all relevant evidence on the record" in making such a determination. *Cmty. Nutrition Inst. V. Young*, 773 F.2d 1356, 1362 (D.C. Cir, 1985) (FDA food additive hearing) (hereinafter "CNI"). In addition, a court will be slow to overturn the Agency's denial of a hearing request because of its reluctance to "substitute its judgment on highly technical and factual matters for that of the agency charged with the supervision of the industry." *Id*. at 1363. Indeed, a court's "scope of review, the exactitude of the fit that [it] require[s] between the agency's conclusions and the germane facts it investigated, is necessarily deferential*." Id.; see also Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 851 (Fed. Cir. 1970) (judicial review of agency's denial of hearing request need only "assure that the agency has given reasoned consideration to all the material facts and issues").

B. There Must be A Genuine and Substantial Issue of Material Fact

Prong one of the EPA test consists of two distinct elements, both of which must be satisfied to obtain a hearing. The party seeking a hearing must show that (1) there exist factual issues and (2) the resolution of those issues is material to the outcome of the proceeding. 41 Fed. Reg. at 51.708.

The issue on which a hearing request is based must be one of fact – not law or policy. 53 Fed. Reg. at 41.129. While attempting to draw bright lines as to what constitutes an issue of fact versus an issue of policy or law is not always an easy task, in many instances, "it is clear from the fact of a comment or objection that it expresses solely a disagreement over policy or legal interpretation." 41 Fed. Reg. 51.709.

Notwithstanding the sometimes muddled nature of the inquiry, however, issues asserted by an

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9 The FDA's test actually consists of six parts but establishes, essentially, the same threshold standards that exist under EPA's three-part test.

10 While the language in FFDCA regarding hearings is slightly different under Section 408 (EPA food tolerances) and 409 (FDA food additive regulations), the two address companion statutory provisions and appear to allow for hearings under the same circumstances.

objector that are clearly policy based do not form the basis of a material issue of fact worthy of a hearing. Determinations as to the application of new science policies or the relevancy of new scientific procedures, for example, are matters of policy within the sole province for the Agency to determine. *See CNI*, 773 F2d at 1365. Similar policy issues include agency estimates of consumption levels or exposure rates, *see id*. At 1366 (holding that "FDA could properly exercise its discretion in deciding [the importance of patterns of aspartame ingestion]"), agency decisions regarding the necessity of extra testing, *see id*. at 1365 (holding that "FDA could as a matter of policy decide against requiring additional testing without holding a hearing on the issue"), and Agency determinations as to what constitutes an adverse health effect. *See NRDC v. EPA*, 812 F.2d 721, 724 (D.C. Cir. 1987) (refusing to substitute the court's judgment for that of EPA on determination as to whether dental fluorosis was an adverse health effect).

Even is ascertainable issues of fact exist, FDA has indicated that "it serves no useful purpose to convene a formal evidentiary public haring to resolve an issue of fact that is immaterial to the [agency's] decision." 41 Fed. Reg. at 51.708. As such, the first prong also requires that a hearing be granted only if "petitioners raise a **material** issue in their objections." *CNI.* 7731 2d at 1363 (emphasis added). In other words, a request to hold a hearing "in order to 'sharpen the issues' and 'fully develop the facts' does not meet the test." *Georgia-Pacific Corp. v. EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982) (Clean Water Act hearing).

C. There Must be Available Evidence that Resolves Issues in Favor of Objectors

Prong two of the EPA test requires the material issues of fact asserted by objectors be, with reasonable possibility, capable of resolution in favor of the objector with available, identifiable evidence. Short of the "reasonable possibility" guideline set forth in the rule, the exact quantum of evidence necessary to meet this burden is unclear, and the dearth of EPA guidance offers little help in hypothesizing the proper amount needed to support a hearing request. The corollary FDA rule, which requires that a factual issue be capable of resolution by "available and specifically identified reliable evidence," 21. C.F.R. § 12.24(b)(2), and related case law, offer some assistance in interpreting the EPA requirement.

A hearing should be denied by EPA if the evidence proffered is insufficient to justify the material fact urged by the objector, 40 C.F.R. § 178 32(b)(2). Moreover, and as the EPA's rule explicitly states, "[a]n evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions . . ." *Id.* Similarly, "[m]ere differences in the weight or credence given to particular scientific studies . . . are insufficient" to compel the Agency to grant a request for a hearing. *CNI*, 773 F.2d at 1363 (discussing the reasons why the court refused to overturn FDA's decision to deny a hearing request on the allowance of food additives). As FDA noted in establishing its hearing procedures:

The [threshold] requirements … are intended to establish where a formal evidentiary public hearing will advance the administrative process by resolving factual issues that are material to the Commissioner's decision on an order or regulation. Thus, if the state of scientific, medical, or technical knowledge is such that there is no reasonable likelihood that the grounds for an objection can be established, then it is pointless and wasteful of public resources to conduct a formal evidentiary public hearing on the off chance that the requisite information

41 Fed. Reg. 51.708.

In short, this prong protects the Agency from having to hold a hearing on what is little more than a sweeping, baseless assertion of fact, a scientifically-reasoned but empirically unsupported hypothesis or a scientific study about which EPA and the objector differ with respect to significance or credibility.

For example, following its allowance of the we use of aspartame, the FDA denied a hearing request because the objections asserted in support of the request were little more than "interesting, but untested, hypotheses." 49 Fed. Reg. 6672, 6674 (Feb. 22, 1984). The Agency reasoned that that "no purpose would be served by holding a hearing, because no issue material fact is raised by the hypotheses" and that "a hypothesis, standing alone, does not justify a hearing in the absence of data on which to base a resolution of the issue raised. *Id*.

D. Resolution of the Factual Issue Must Justify the Relief Requested

Prong three of the EPA standard for holding an evidentiary hearing evaluates the relevance of an asserted issue of material fact. Even assuming an objector is able to assert and identify evidence in support of a material issue of fact, "[r]esolution of the factual issue in the way sought by the person must be adequate to justify the relief requested in the objections and requests for hearing." 40 Fed. Reg. 22.950, 22.968

For example, in *Dyestuffs & Chemicals, Inc. v. Flemming*, 271 F.2d 281 (8th Cir. 1959), the court addressed whether the FDA erred in denying petitioners' request for a hearing on the FDA's decision to remove certain harmful coal-tar colors from its unrestricted use list. Notwithstanding a then-recent Supreme Court decision that prevented the FDA from establishing tolerances for certain uses of harmful coal-tar colors, petitioners objected to the FDA's order on the grounds that the FDA should instead take action to reduce exposure to excessive concentrations of the coal-tar. *Id*. at 185. The court affirmed the FDA's action, holding that where, as here, objections are "frivolous or inconsequential" and "legally insufficient, their effect is a nullity and no objections have been stated." *Id.* at 286.

IV. THE CONSOLIDATED OBJECTIONS FAIL TO MEET THE THRESHOLD FOR THE GRANTING OF A SECTION 408 HEARING

As noted above, Objectors submitted two sets of objections and two requests for hearing in response to the two different sets of tolerances issued by EPA. Those two sets of objections were, at the EPA's suggestion, combined by Objectors in late 2005 (referred to here as the Consolidated Objections). In addition, in June 2006, Objectors requested EPA to stay the tolerances in light of the then-recently released NRC study on fluoride in drinking water.[11]

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11. Objectors' Motion for Stay of Tolerances did not raise any new objections but rather uses the findings of the NRC Report to bolster the objections which were previously submitted to the Agency. In discussing the flaws with Objectors' original objections, the sections that follow will address the findings of the NRC to the extent they were cited by Objectors.

Objectors have raised many issues in an attempt to force EPA to revoke the ProFume tolerances. A critical examination of the issues raised, however, show that these issues suffer from one or more fatal flaws and certainly do not warrant a formal hearing.

As set forth below, in many cases Objectors have simply rehashed disagreements over the merits of particular studies and the conclusions one might draw from them by relying on studies that the Agency has either previously reviewed or had available to it when it first issued the ProFume tolerances. Similarly, some of Objectors' issues are little more than baseless assertions, unsupported by empirical data, which they would have the Agency believe justify a reexamination of the tolerance setting process. In other cases, Objectors raise issues of policy and law – not fact – in clear violation of the standard governing the instances in which EPA can grant the type of hearing requested by Objectors. In a few instances, the issues raised by Objector are completely unintelligible and cannot even be addressed within the appropriate analytical framework established by Section 408.

For the foregoing reasons, as applied below, neither the Consolidated Objections - framed as "issues" by Objectors – nor the motion for stay submitted by Objectors meet the threshold standard that governs EPA grants of formal evidentiary hearings. As such, Objectors' request for a hearing should be denied.

A. Many "Issues" Advanced By Objectors Fail to State a Material Issue of Fact upon Which a Hearing Could Be Granted

As set forth above, the most basic element EPA must look for in a hearing request is whether the objector has successfully raised a material issue of fact. A majority of the issues asserted by Objectors fail to meet even this most basic threshold. While the issues advanced certainly demonstrate Objectors' general discontent with the ProFume tolerances established by EPA, many fail to identify any material factual discrepancy befitting a hearing under Section 408(g).

At best, Objectors' submission of these issues amounts to a request that EPA prolong the administrative process with respect to ProFume in order to "sharpen the issues" and "fully develop the facts." As discussed earlier, such objections do not properly form the basis for a hearing. In other cases, the Consolidated Objections are unintelligible and barely make sense in the context of this ongoing administrative proceeding, much less raise a material issue for particularized agency review. Indeed, in a number of places Objectors' issues are premised not upon factual issues but presumptions ("It is possible that…," "It is not clear whether…," "It may be relevant to note that…"). Of course, such requests are inappropriate and do not meet Section 408's threshold standard.

The bullets below provide examples from the Consolidated objections that fail to state some material issue of fact and should, therefore, be rejected by EPA.

• In Issue 34, Objectors predict that EPA's incremental approval of food tolerances may ultimately affect overall fluoride exposure. Objectors fail far short of asserting an actual issue of fact, though asserting instead that current EPA exposure assessments "may fail to account for the exposures that will result if Dow receives tolerances for the Raw Agricultural Commodities (RAC) that are pending. Clearly, the type of contingent issue does not meet the threshold for obtaining a hearing request.

• In Issue 35, Objectors state that "[i]t is not clear whether EPA's underestimates has [sic] used the most current pesticide label requirements on which to base . . . exposure assumptions." Whether EPA's tolerance review is understood by the Objectors is not the basis for a hearing. No issue of fact is asserted and, indeed, it is unclear as to what, if anything, Objectors are objecting.

• In Issue 36, Objectors point out that EPA "seems to have" changed a label restriction at the request of a public commenter, and in so doing may have underestimated the possible levels of sulfuryl fluoride and amounts of food affected. It is entirely unclear as to why Objectors raise this issue, whether the label restriction was in fact changed, or what factual dispute lies behind their thinly-veiled criticism of the EPA's actions. Ironically, though, even Objectors seem uncertain as to the reason the raise this issue, stating only that the objection "may be relevant."

• In Issue 38, Objectors conclude that because the United Kingdom allegedly restricts the use of ProFume in the fumigation of flour. EPA committed error by not similarly requiring such a restriction. This objection is, of course, nothing more than a complaint about purported policy distinctions between EPA and the United Kingdom, and does not raise an issue of material fact suitable for hearing.

• Issues 33 and 39 reference the different (2004 and 2005) labeling requirements for ProFume. Far from asserting a material issue of fact, Objectors appear confused as to what labeling requirements presently exist and about the methods which were used to determine the labeling requirements. As a result, Objectors end up arguing with themselves in the alternative and certainly do not state any factual issue upon which a hearing could be based.

• In Issue 47, Objectors assail EPA's alleged failure to "properly validate the analytical chemistry methods for measuring levels of [SF] and [F-] in cereal grain commodities." But they give no indication as to why this alleged failure is material. The objection is built upon speculation and assumption and falls woefully short of the materiality requirement that has been established by the regulations.

• In Issue 48, Objectors lament EPA's alleged failure to order DAS to conduct an Oral DNT test for sulfuryl fluoride. It is unclear what Objectors would expect to learn from such a test and even more unclear as to why the refusal to order such a test should result in a revocation of the ProFume tolerances. Objectors are advocating for the equivalent of a scientific fishing expedition rather than asserting an intelligible, factually based objection on which a hearing could be granted.

B. Many of the Consolidated Objections Raise Issues of Policy and Law, Not Fact as Required by Agency Regulation

1. Objections Regarding Characterization of Health Effects and Analysis of Exposure Levels Address Issues of Policy

Inherent in prong one's mandate than an objector must raise a material issue of fact is the requirement that objections not be about issues of policy, which are for the Agency alone to decide, or law, which are for the courts to decide. See 40 C.F.R. § 178.32(b)(1). Such questions are inappropriate for the type of formal hearing contemplated under the EPA's rules and hearing requests driven by differences in opinion on policy matters should be denied. Objectors

nevertheless have raised a number of policy-based issues in their Consolidated Objections.

Numerous objections question science policy judgments made by the Agency in conducting its risk assessment for the ProFume tolerances. Objectors repeatedly question so-called "non-conservative assumptions" in EPA's exposure analyses and the extent to which those exposure analyses adequately consider "significant subpopulations" of consumers. Perhaps the most obvious policy issue is Objectors; reliance on the NRC Report's characterization of severe dental fluorosis as "a toxic effect that is consistent with prevailing risk assessment definitions of adverse health effects.[12] NRC Report at 3; *see also* p. 104. Despite this opinion offered by the majority of the 2006 NRC committee members, the regulatory determination as to what constitutes an adverse health effect for purposes of the SDWA FFDCA or any other EPA statute is a policy issue entirely within the province of the Agency. See *NRDC v. EPA*. 812 F.2d 721, 7624 (D.C. Cir. 12987) ("Experts can describe what dental fluorosis does to the body; whether that constitutes an adverse effect on health under the SDWA, however, is a question of statutory interpretation. . . The pivotal question, therefore, is whether EPA reasonably concluded that dental fluorosis does not significantly impair the functioning of body or mind.") The United States Court of Appeals for the District of Columbia Circuit held, on a record very similar to the one now facing EPA, that the Agency had rationally concluded that dental fluorosis was not an adverse health effect under the SDWA. *Id*. at 725.

The Supreme Court has held that "while the Agency must support its finding that a certain level of risk exists by substantial evidence, we recognize that its determination that a particular level of risk is "significant" will be based largely on policy considerations. *Indus. Union Dept. AFL-CIO v. America Petroleum Inst*. 448 U.S. 607, 655 n.62 (1980) (discussing OSHA's obligation to find the presence of significant risk before declaring a place of employment as "unsafe*"), see also Public Citizen v. Young*, 831 F.2d 1108, 1112 (D.C. Cir. 1987) (stating that "the agency must decide 'what risks are acceptable in the world in which we live' and set limits accordingly*"); Florida Coalition for Peace and Justice v. Bush*, 1990 WL 157934 (D.D.C. 1990) on reviewing whether EPA's risk assessments were flawed, "the Court is only required to determine whether or not the agency has adequately considered the environmental risks of a particular project . . . [and] not required to second guess the judgments of the agency's experts").

2. Objectors' Procedural Objections Do Not Justify a Formal Agency Hearing.

In Issue 37, Objectors complain that EPA did not make its full health risk assessment and supporting documents available to the public until after the final tolerances were announced in the Federal Register. According to Objectors, this not only fails to inspire confidence in the Agency process but also calls into question whether EPA I proceeding with a reasonable certainty that no harm will result from its actions. Notwithstanding their lack of faith in the EPA to carry out its regulatory mandate, Objectors do not raise an issue of material fact as required by 40 C.F.R. §178.32(b)(1). At best, Objectors raise a legal issue, specifically a procedural question, which fails to fulfill prong one of the threshold standard that governs EPA grants of formal evidentiary hearings.

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12. A similar opinion is expressed in the NRC Report regarding stage II skeletal fluorosis. NRC Report at 295.

Similarly, in Issue 29, Objectors assert that EPA has no provision for enforcing a restriction on the number of times a processing facility will be fumigated each year. This is clearly an issue of law or, in the minds of Objectors, lack thereof. Regardless, the issue fails to fulfill prong one of the threshold standard.

C. Many Issues Raised by Objectors Consist of General Contentions and Denials That Do Not Meet the Test for an Evidentiary Hearing

As noted earlier, explicit in the regulations governing EPA's response to a hearing request is 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). Objections must be based on available and reliable evidence. Id. Neither untested hypotheses nor conclusions lacking sufficiently reliable empirical support can compel EPA to hold a hearing and will not fulfill prong two of the threshold standard that governs EPA grants of formal evidentiary hearings. The examples below detail several instances in which Objectors have made unsupported allegations and general denials in hopes of obtaining a hearing in support of factual claims.

• Issues 30, 31, and 32 regarding the possibility of acute fluoride exposure from consumption of dried egg are entirely lacking in empirical support. For example, in Issue 31 Objectors make a general contention that "[a]n acute poisoning scenario could occur in as many as 1% of meals prepared from dried eggs even if EPA is correct in assuming only 1% of all dried eggs will be fumigated." Objectors did not, however, offer any data in support of this claim. Similarly, without any support whatsoever, Objectors claim that there will be "400 to 4000 very likely cases of acute fluoride poisoning per year" from fumigated dried eggs.

• In Issue 41, Objectors attack EPA's risk assessment based on their "**belief**" that the processing factor used by the EPA is "**not likely** to be protective of significant portion of the American population." Outside of reference to studies showing that Americans may be eating more whole grains in the future, Objectors offer no empirical data demonstrating the processing factor utilized by EPA was insufficient.

• In Issue 44, Objectors take issue with the number of residue tests actually conducted on foods failing under the "processed foods" category, reasoning that "[i]f dried eggs absorb massive quantities of fluoride from fumigation . . . it is reasonable to expect other processed foods to similarly exhibit very high residue levels." No data were offered in support of this presumption.

• In Issue 45, Objectors attack the residue data used in EPA's 2004 risk assessment as being "not even marginally sufficient" to accurately reflect real world fumigation processes and assert that "[t]o base tolerances on data from only a single site is highly presumptuous." Objectors, however, offer no studies or data supporting their claim.

• In Issue 46, Objectors hypothesize, without citing to any empirical data, that the public will face increased exposure to sulfuryl fluoride and fluoride anion by virtue of ingesting deboned meat since livestock eat grains and people eat meat. No study in support of this theory was offered, rather objectors simply assert that there is a "strong probability that [exposure from deboned meat] will be significant."

D. Many Issues Raised by Objectors Reflect a Mere Disagreement with EPA and Are Not Supported by the NRC Report

A close reading of the Consolidated Objections makes it readily apparent that the majority of "issues" raised by Objectors amount to no more than mere disagreements with Agency

Note: this is a hand-typed copy due to the poor legibility of this document sent to us by EPA,

Determinations made in earlier stages of the rulemaking process. In many instances, Objectors support their issues by citing to studies that have already been reviewed by the EPA and have either expressly or effectively, been found scientifically inadequate, procedurally flawed or lacking in the requisite amount of empirical support. Objectors cite to these studies in spite of the clear edict that "[m]ere differences in the weight or credence given to particular scientific studies . . . are insufficient" to prompt EPA to hold a hearing. CNI. 773 F.2d at 1363. Clearly, Objectors disagree with EPA's interpretations of these studies, but such disagreement is irrelevant in the Agency's decision to grant a hearing on the objections submitted.

Perhaps most importantly, in their motion for a stay of the tolerances, Objectors have touted the release of the NRC Report on fluoride in drinking water as an endorsement of t heir objections to the ProFume tolerances. *See Fluoride in Drinking Water: A Scientific Review of EPA's Standards*, National Research Council of the National Academies, The National Academies Press (Mar. 22, 2006) (hereinafter "NRC Report" or "2006 NRC Report"). As a threshold matter, it must be noted that the NRC Report made no findings or recommendations whatsoever with respect to the ProFume tolerances established by EPA, nor would such statements have been appropriate. The NRC Report is a Safe Drinking Water Act 9"SWDA") report – it was not commissioned under the provisions of federal pesticide law. To the extent Objectors seek action from EPA to address the recommendations in the NRC Report, they must do so under the SDWA, not in a tolerance hearing under the FFDCA.

As regards the ProFume tolerances, the NRC, in the course of completing its drinking water study, addressed many of the same public health issues raised by Objectors, as evidenced by NRC's refusal to reach the conclusion snow advocated by Objectors. This, of course, is essentially a tacit endorsement of the EPA's previous disposition of those same issues in the context of the ProFume risk assessments. While the NRC Report does discuss many of the same studies cited by Objectors, the Report's refusal to make the same drastic and conclusory leaps advocated by Objectors is further support of EPA's ProFume determinations made between 2003 and 2006. The NRC Report also provides further proof that Objectors' insistence on revisiting many of the same issues already considered by EPA is not indicative of a lack of careful, contemplative consideration by EPA. Rather Objectors' requests are indicative of disagreements between EPA and Objectors on interpretations of scientific data and science policy issues and therefore insufficient for a hearing.

As the table below illustrates, the above-described flaws permeate the Consolidated Objections. Moreover, the table shows that, with respect to the issues discussed below, the NRC Report does not reach any conclusions materially different that the conclusions reached by EPA during the rulemaking process.

TABLE ON PAGES 14-16

Issue Raised In Consolidated Objections	Previous Disposition of Same Issue by EPA	Statements in NRC Report
Issue 16 Fluoride's impact on the male reproductive system	In the 2004 Comment Responses, EPA addressed Objectors' claim that "exposure to fluoride results in many fertility and reproductive effects in humans and animals, including lowered fertility, lowered testosterone levels, lowered sperm quality, early puberty, and decreased birth weight," 2004 Comment Resp. at 21. EPA found "the evidence to be insufficient to establish a causal link between fluoride exposure and effects on reproductive function in humans." *Id.* at 22. Further, upon reviewing the open literature (e.g.*, Health Effects of Ingested Fluoride*, National Research Council of the national Academies, The National Academies Press (1993) (hereinafter "1993 NRC Report") *and Environmental Health Criteria for Fluorides* (WHO 2002) (hereinafter "2002 WHO report"), EPA found that "the use of skeletal fluorosis as the toxicological endpoint in conducting the human health risk assessment for fluoride is the most protective for the U.S. population" making any assessment of fluoride's effects on reproduction irrelevant, 2005 Comment Resp. at 8-9.	In its review of the reproductive effects of fluoride, the NRC determined that the available studies were "few and have significant shortcomings to design and power, limiting inferences," 2006 NRC Report at 164.
Issue 17 Biological plausibility of a fluoride/ endocrine effect	Objectors assert that EPA cannot state with a reasonable certainty that harm will not occur via a G-protein mechanism. However, EPA addressed this very issue in 2004, stating that it had "considered the new information on fluoride, and [was] not convinced that the data support the statement that fluoride is an endocrine disruptor," 2004 Comment Resp at 18.	The NRC noted that "[t]he available studies on the effects of fluoride exposure on endocrine function have several limitations," including failure to report nutritional status of subjects, having too few exposure groups, poorly characterizing the human exposure, etc. 2006 NRC Report at 222. Far from Objectors' claims, the NRC found that fluoride was not an endocrine disruptor "in the sense of mimicking a normal hormone." Id. at 223. The NRC concluded that more research was needed to fully explore this area.
Issue 19 Fluoride's impact on the thyroid	Objectors state that "[c]onsidering the significant problem of hypothyroidism in the United States, and the widespread and increasing exposure to fluoride, this issue needs urgent attention" Consolidated Objections, Issue 19 at 33. Leaving aside the obvious absence of evidence in support of this objection, by raising the issue	With respect to fluoride's effect on parafollicular cell function, the NRC Report concluded that it was not clear "what the clinical significance of elevated calcitonin concentrations

	of fluoride exposure and thyroid function, Objectors simply ignore EPA's previous disposition of this matter. In 2004 the EPA dismissed Objectors' concerns over fluoride's effect on the thyroid, finding that "[t]he papers submitted by FAN do not convince EPA that fluoride produces significant effects on the thyroid because of study design and **PAGE 15** report deficiencies.' 2004 Comment Resp. at 17.	might be in individuals," 2006 NRC Report at 221. Similarly, with parathyroid function the NRC concluded that "it is not clear **PAGE 15** whether altered parathyroid function is a direct or indirect result of fluoride exposure. " *Id.*
Issue 18 Fluoride's impact on the pineal gland	Objectors assert that fluoride concentrations could interfere with G-proteins and enzymes in the pineal gland and that there is a "scientific plausibility that fluoride's ability to concentrate in the pineal has the potential to cause adverse effects." In support of their claim they cite to the Luke study. EPA has already addressed fluoride and the pineal gland on two occasions. First, EP found in 2004 that available data were too limited support any conclusions and that more laboratory studies were needed. 2004 Comment Resp. at 19. Moreover, EPA commented in 2005 that the Luke study, which formed the basis of Objectors' argument, was "too limited in scope for EPA to use the information to serve as the basis of any regulatory decision(s)." 2005 Comment Resp. at 8.	The NRC Report simply found that "[w]hether fluoride affects pineal function in humans remains to be demonstrated." *Id.*
Issue 12 Fluoride's impact on children's intelligence	Objector's point to a number of Chinese studies (Xiang 2003), Lin Fa-Fu (1991), Zhao (1998) that suggest a lowering of IQ in children associated with exposure to fluoride. EPA has already reviewed many of the studies relied on by Objectors and found them to be inconclusive, flawed, or both. In its 2003 review of the studies submitted by FAN, EPA commented that the Xiang study was "severely deficient in its discussion of potential biases and confounders." Karl Baetchke et al., A Preliminary Evaluation of Articles Related to Fluoride Cited by the Fluoride Action Network (FAN) as Objections to the Sulfuryl Fluoride Pesticide Tolerance Rule,24 (EPA Nov. 18, 2003) (hereinafter "2003 Review"). The Lin Fa-Fu study, which was only available in Chinese, was found to contain "insufficient details of study method and result." Vicki L. Dellarco, Ph.D. Senior Scientist, memorandum to Dennis McNeilly re:	The NRC Report reviewed three studies to assess the effect of fluoride between 2-4 mg/l on human cognitive abilities nd found that "the studies lacked sufficient detail for the committee to fully assess their quality and their relevance to U.S populations . . ." 2006 NRC Report at 185.

	Review of Five Recent Papers on Fluoride Submitted by the Fluoride Action Network, 1 (EPA Jan. 8, 2004) (hereinafter "EPA Five Papers Review"). With respect to the Zhao study, EPA found parts to be "not clear." 2003 EPA Review at 18. As a general matter, the Agency also commented on fluoride's purported effects on child intelligence, concluding very simply that "conclusions regarding fluoride exposure and reduction in IQ can not be drawn." 2004 Comment Resp. at 29.	
Issue 12. Fluoride crossing the blood brain barrier.	Objectors assert that it is "abundantly clear" that fluoride circulating the bloodstream will enter the brain; however, in its Comment Responses at EPA characterized that assertion as "speculative and conjectural at this time." 2004 Comment Resp. at 19,21. Objectors cited to the Isaacson (1997) study, which was previously reviewed by the NRC in its 1993 report that EPA used to conduct its health risk assessment for the sulfuryl fluoride and F- tolerances, and to the Guan (1998) study, which the EPA in 2004 found to be "insufficient to support a **PAGE 16** Convincing association of fluoride exposure and impaired mental functioning." 2004 Comment Resp. at 21. Objectors also cited to Long (2002) and Varner (1998) on the blood brain barrier issue. EPA found the Long study to "not provide a compelling basis to depart from the EPA's current MCLs." EPA Five Papers Review at 1, and found the Varner study suffered from "major limitations" and needed to be repeated. 2003 EPA Review at 45. Moreover, in its 2004 Comment Responses, EPA pointed out that one of the authors of the Varner study admitted that the results "do not support a conclusion that aluminum or fluoride selectively damage the brain . . . ." (2004 Comment Resp. at 21. The Mullenix (1995) study was discredited by EPA "due to a number of problems with [the] study." 2004 Comment Resp. at 29.	The NRC report stated that "[t]he blood-brain barrier is thought to reduce fluoride transfer" but did not specifically review this issue. 2006 NRC Report at 74. In general, the NRC Report concluded that "[m]ore research is needed to clarify fluoride's biochemical effects on the brain." *Id*. at 186. **PAGE 16** Specifically, with respect to the Mullinex study, the NRC Report, said that it suffered from "analytical error," that it was "idiosyncratic," and that there were "difficulties with interpreting the results of the study." *Id.* at 181.
Issue 12. Fluoride's prenatal effects	Objectors discuss the passage of fluoride through the placenta to assert the possibility of fluoride's negative pre-natal effects. Notwithstanding the fact that Objectors cite to the WHO report in support of this issue, which was used by EPA in formulating their risk assessment, Objectors ignore the fact that EPA has previously addressed fluoride's pre-	Studies reviewed by the NRC "indicate that adverse reproductive and developmental outcomes occur only at very high concentrations [of fluoride]." 2006 NRC Report at 171.

	natal effects, finding that "[t]o date, the Agency is not convinced that fluoride is a developmental toxicant." 2004 Comment Resp. at 35.	
Issue 12. Fluoride's effects on G-proteins	Objectors object to the sulfuryl fluoride and F-tolerances on the grounds that fluoride ions are well-known activators of G-proteins. EPA, however, addressed and dismissed fluoride/G-protein link in 2004, stating that "[t]he effects of Aluminum-fluoride complexes on G-protein and the enzymes associated with G-protein activation have only been demonstrated in vitro or when injected directly into the brain of laboratory animals. Thus, many significant questions still need to be addressed regarding biological availability and relative affinity for cellular and subcellular sites following human exposure." 2004 Comment Resp. at 18.	In discussing the potential link between fluoride and activation of G-proteins, the NRC Report concluded that "[m]ore research is needed to clarify fluoride's biochemical effects on the brain." 2006 NRC Report at 186.
Issue 2b EPA's toothpaste analysis.	Objectors devote a significant amount of attention to the exposure analysis undertaken by EPA with respect to toothpaste. Specifically, Objectors assail the EPA's reliance on warning labels on dental products, like toothpaste, to limit dietary exposure to fluoride-containing dental products. However, EPA noted in its 2004 Comment Responses that its "exposure assessment included exposures from fluoridated tooth paste based on data on actual exposures measured **before** the warning labels were instituted in 1997." 2004 Comment Resp. at 11 (emphasis added). Indeed, the Agency's reference to warning labels was only to point out that "the exposure assessment may **overestimate** the exposures resulting from the use of fluoridated tooth paste." *Id.* (emphasis added)	The NRC Report does not specifically address toothpaste labeling and its effect on preventing excessive dietary exposure to fluoride. The report does, however, estimate typical daily fluoride intake from toothpaste. See 2006 NRC Report at 35, Tabl 2-7. Interestingly, NRC's exposure estimates appear to comport with EPA's conclusion that "maximum exposures to fluoride observed in those studies appear to converge to approximately 0.3 mg/day . . . ." 2004 EPA Risk Assessment at 34. *See* 2006 NRC Report at 35.

EPA has a responsibility to "give [ ] adequate consideration to all relevant evidence on the record." CNI. 773 F.2d at 1362. Upon fulfilling this responsibility, however, it is not required to re-investigate or re-review the same issues. To place such a requirement on the Agency would be to invite misuse of the administrative process and waste of valuable EPA resources. Objectors were afforded a fair opportunity to voice their concerns during the rulemaking process. Indeed, even the most cursory review of the administrative record reveals that EPA has given more than adequate consideration to Objectors' issues and addressed in detail, the reasons why it did not find compelling Objectors' comments and concerns, and nothing in the recent NRC review casts doubt on EPA's previous disposition. Accordingly, a hearing based on these issues is neither required nor appropriate and EPA should deny Objectors' hearing request.

E. Statements Found in the NRC Report Differing from EPA Positions Do Not Support Objector's Hearing Request

The foregoing has detailed the instances in which the 2006 NRC Report has either expressly or tacitly endorsed EPA's interpretations of numerous studies propounded by Objectors as well as EPA's conclusions regarding a majority of the issues advanced by Objectors. The NRC Report does, however, take positions different from those of EPA with respect to three issues: (1) fluoride in drinking water and the increased risk of bone fracture; (2) fluoride in drinking water and skeletal fluorosis; and (3) severe dental fluorosis as an adverse health effect. Based on at least one of these positions (bone fracture), the NRC Report concludes that the current MCLG for fluoride in drinking water is not sufficiently protective of human health. Objectors point to these positions as providing support for their contention that EPA erred in issuing the ProFume tolerances and that those tolerances should be immediately revoked. *See* Motion of Objectors for Stay of Final Rules Establishing Tolerances for Residues of Sulfuryl Fluoride and Fluoride Anion (June 1, 2006).

However, as set forth below and in DAS's Response to Request for Public Comments, the NRC Report was not a report on sulfuryl fluoride, nor was it a free standing study that provided new data on skeletal fluorosis, increased risk of bone fracture or severe dental fluorosis. Instead, it was a review under the SDWA of the existing literature on fluoride, which, almost without exception, was available to EPA during the tolerance rulemaking process. As set forth in its report, NRC's Committee on Fluoride in Drinking Water was convened, at EPA's request, "because the Safe Drinking Water Act requires periodic reassessment of regulations for drinking water contaminants . . . ." NRC Report at xi. The NRC Committee's task was to review research on fluoride, "focusing primarily on studies generated since the early 1990's "in order to evaluate the adequacy of EPA's MCLG and SMCL for fluoride to protect public health. NRC Report at xi and 2.

The NRC Committee did not generate any new data. Specifically, the NRC Report was released on March 22, 2006. EPA completed risk assessments evaluating the appropriateness of ProFume tolerances on January 20, 2004, and January 18, 2006. In these risk assessments, EPA relied on several of the studies that were also reviewed by NRC. *Compare* 2004 EPA Risk Assessment, 2006 EPA Risk Assessment *with* 2006 NRC Report. Indeed, many of the studies reviewed by the NRC Committee were critically reviewed by EPA in the preparation of its risk assessments in

2004 and 2006. In other words, little of the data reviewed by the NRC Committee was "new" since EPA issued its risk assessment, and, by extension, the positions taken by NRC were, by definition, based on essentially the same body of data as were those of EPA.

In effect, the three positions taken in the NRC Report which differ from EPA's decisions reflect nothing more than a series of differences in opinion between EPA and the NRC. With respect to the issue of increased risk of bone fracture, the NRC's position is actually contrary to the latest scientific evidence. Certainly, the opinions of NRC are entitled to their fair share of respect, but for the purposes of the procedural inquiry as to whether Objectors should be granted a formal evidentiary hearing, the NRC's positions do not outweigh the contradictory conclusions of the Agency.[13] To the contrary, NRC's differences in opinion on the three issues detailed below are just that – mere differences of opinion – and should be evaluated as such.

1. NRC Position # 1: Bone Fracture

A majority of the NRC Committee reviewing literature on fluoride in drinking water concluded that "lifetime exposure to fluoride at drinking water concentrations of 4 mg/L or higher is likely to increase fracture rates in the population . . . ." 2006 NRC Report at 296. This conclusion was far from unanimous. Indeed, 25 percent of the Committee disagreed with this conclusion, finding that "more evidence is needed that bone fractures occur at an appreciable frequency in human populations exposed to fluoride at 4 mg/L before drawing a conclusion that the [current] MCLG is *likely* to be not protective. *Id.* (emphasis in original). Moreover, the majority's conclusion was also based on the findings of studies which EPA had previously reviewed. *Id.* By definition, then, the conclusion of the NRC's majority simply reflects a disagreement with those of EPA and, therefore, does not support Objectors' hearing request.

For example, the NRC Report relied heavily on the Li *et al*. and Alarcon-Herrera *et al*. studies in concluding that "lifetime exposure to fluoride at drinking water concentrations of 4 mg/L or higher ti likely to increase fracture rates in the population . . . ." 2006 NRC Report at 146. However, EPA, in its 2004 Comment Responses addressed the claim that fluoride exposure at 4 mg/L presented an increased risk of bone fracture, and specifically reviewed the Li *et al.* (2001)[14] and Alarcon-Herrera *et al*. (2001)[15] studies. 2004 Comment Resp. at 23-25. EPA found both studies to be <u>inconclusive</u> on the issue of increased risk of bone fractures:

> The Agency found the results of Li et al. (2001) study cited by the Fluoride Action Network to be inconclusive due to inadequate exposure assessment,[16] potential biases associated with misclassification of exposure,

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13. *See. Supra*. Section II.A discussing the enormous discretion afforded to EPA by the courts on highly technical and factual questions.

14. Li Y, C. Liang, C.W. Slemenda, R Ji, S. Sun, J. Cao, C.I. Emsley, F. Ma, Y. Wu, P. Ying, Y. Zhang, S. Gao, W. Zhang, B.P. Katz, S. Niu, S. Cao and C.C. Johnston Jr*., Effects of Long-Term Exposure to Fluoride in Drinking Water on Risks of Bone Fractures*, 2001, J. Bone Miner. Res. 16(5):932-939.

15. Alarcon-Herrera, M.T., I.R. Martin-Dominguez, R. Trejo-Vazquez, and S. Rodriguez-Dozal, *Well Water Fluoride, Dental Fluorosis, and Bone Fractures in the Guadiana Valley of Mexico*, 1001, Fluoride 34(2):139-149.

16. The NRC Report even conceded that the *Li et al*. study "did not directly assess fluoride at 4 mg/L," thus begging the question of how this study supported a review of the 4 mg/L stndrd when the study did not even address drinking water exposures at that level. NRC Report at 128 (emphasis added).

> the failure to examine fractures, other than hip separately, and limited statistical analysis found in this report. The Alarcon-Herrera et al. (2001) paper was also found to be inconclusive . . . . [I]t is not possible to determine, from this study, what contribution of fluoride in drinking water is to increasing risk for non-traumatic fractures.

2004 Comment Resp. at 24-25.

Moreover, the 2006 NRC Report cites to Turner (1995), Sowers (1986), Sowers (1991), and Waterhouse (1980) in support of its findings on fluoride and bone fracture; however, all of these studies were included in the 2002 WHO Report which EPA expressly relied on in conducting its health risk assessment prior to setting the ProFume tolerances. Similarly, the NRC report cites to Riggs (1990), which "[did] not convince EPA that there is a need to depart from OPP's use of the current Agency MCLG/MCL in pesticide risk assessments at this time." 2004 Comment Resp. at 25. Gutteridge (2002), which EPA dismissed for its use of "high does [sic] of fluoride (60 mg/day) which are above current EPA MCL," 2003 EPA Study Review at 34, and Bayley (1990), which also "[did] not convince EPA that there is a need to depart from OPP's use of the current Agency MCLG/MCL in pesticide risk assessments at this time," 2004 Comment Resp. at 25. Interestingly, the 2006 NRC Report did not review the Hedlund (1989) study cited by Objectors, which the EPA criticized for its examination of subjects exposed to doses of fluoride higher than current allowable levels. 2003 EPA Review at 34.

Aside from the studies that were available to EPA in the course of its rulemaking, NRC reviewed one recent study, conducted in 2005 by the University of Michigan Department of Epidemiology and funded by the National Institutes of Health, not available to EPA prior to establishing the ProFume tolerances. Ironically, this study, done by M.F. Sowers et al. actually supports **the Agency's** findings.[17] The study looked at 1,300 residents of three small communities in order to determine if there was an association between serum fluoride concentrations, which reflect individual fluoride exposures, and bone mineral density and bone fractures. The results of the study were unequivocal:

> [T]his study with individual measures of long-term exposure to fluoride did not demonstrate an association with [bone mineral density] or the risk of bone fracture. . . . We conclude that. . . . the risk of deleterious bone-related outcomes was not related to fluoride exposure. The U.S. Environmental Protection Agency has set its primary drinking-water standard (enforceable) at [4 mg/L] to protect against the risk of crippling skeletal fluorosis. The present findings agree that at this level, there is little evidence of a bone demineralization defect associated with low [bone mineral density] or fracture.

Sowers, et al. at 2251. There is simply no question that this University of Michigan study, the most recent scientific analysis of the relationship between fluoride in drinking water and

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17. M.F. Sowers, G.M. Whitford, M.K. Clark, M.L. Jannausch, *Elevated Serum Fluoride Concentrations in Women Are Not Related to Fractures and Bone Mineral Density*, J. Nutr 135(9):2247-2252.

increased risk of bone fracture, not only supports the current EPA standard but is also directly at odds with the NRC Committee's less-than-unanimous view on this issue. EPA should be mindful of this dichotomy in reviewing the findings of the NRC Report with an eye towards Objectors' request for hearing.

Based on the foregoing, it is clear that NRC's position with respect to fluoride and bone fractures (i) amounts to little more than a difference in opinion with EPA findings regarding the same studies and (ii) is actually inconsistent with the latest available study on the issue. As such, NRC's position does not bolster Objectors' hearing request.

2. NRC Position # 2: Skeletal Fluorosis

The NRC Report expresses the opinion that "stage II skeletal fluorosis (the stage before mobility is significantly affected) should also be considered an adverse health effect." 2006 NRC Report at 295. Based on that statement, Objectors now contend that the current 4 mg/L standard for fluoride is unsafe because of the risk, according to the NRC Report, such exposure presents for stage II skeletal fluorosis. Objectors' Mot. at 11.

However, a close reading of the NRC Report's analysis of this issue belies Objectors' contention. The NRC Report in fact stated that *"the existing epidemiologic evidence is insufficient for determining whether stage II skeletal fluorosis is occurring in U.S. residents. Thus, before any conclusions can be drawn, more research is needed to clarify the relationship between fluoride ingestion, fluoride concentrations in bone, and stage of skeletal fluorosis."* 2006 NRC Report at 295 (emphasis added).

As was set forth earlier, explicit in the regulations governing EPA's decision to grant a hearing request is 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). Neither untested hypotheses nor opinions lacking sufficiently reliable empirical support can compel EPA to hold a hearing and will not fulfill prong two of the threshold standard that governs EPA grants of formal evidentiary hearings. The NRC's call for more research is far from a conclusion of increased risk at 4 mg/L and more akin to an allegation in need for further support. Moreover, as established earlier and in the discussion that follows, an evidentiary hearing "will not be granted on issues of policy . . . ." 40 C.F.R. §178.32(b)(1). Accordingly Objectors' claims with respect to the NRC opinions on skeletal fluorosis do not create a material issue of fact upon which Objectors' hearing request should be granted.

3. NRC Position # 3: Severe Dental Fluorosis

In its report, NRC expressed its opinion that (1) severe dental fluorosis "is a toxic effect that is consistent with prevailing risk assessment definitions of adverse health effect" and as such, (2) the current drinking water standard for fluoride is unsafe because it does not protect against severe dental fluorosis.[18] Again, however, the NRC Report's statements runs directly counter to the EPA's recent decisions on the same issues.

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18. See NRC Report at 3; see also p. 104. The NRC Report does not define "adverse health effect." Nor does it identify the sources of the "prevailing risk assessment definitions" upon which the conclusion of adverse health effect is based. Thus, there is no basis to judge whether he NRC Committee's belief as to what constitutes an "adverse health effect" is at all relevant to the Office of Water's analysis of adverse effect on health under the Safe Drinking Water Act.

By its own admission, the NRC Report recognizes that that "[w]hether to consider enamel fluorosis, particularly the moderate to severe forms, an adverse cosmetic effect or an adverse health effect has been the subject of debate for decades." 2006 NRC Report at 87. Indeed, two members of the NRC Committee did not even agree that severe dental fluorosis should now be considered an adverse health effect. 2006 NRC Report at 294. Consistent with this debate and as late as 2005, the American Dental Association stated that severe dental fluorosis is "a cosmetic condition with no known adverse health effect." *Fluoridation Facts*, American Dental Association at 40 (2005) (citation omitted).

Of course, EPA has weighed in on the debate, stating in 2004, that:

> it does not consider moderate to severe dental fluorosis (also known as objectionally dental fluorosis) to be an adverse health effect. The Agency believes that the current evidence indicating that dental fluorosis is more than a cosmetic effect is not sufficiently persuasive to warrant regulation as an adverse health effect under the Federal Food, Drug, and Cosmetic Act. Therefore, at this time, based on the information available to the Agency, EPA is not concluding that the dental fluorosis associated with fluoride exposure is an adverse health effect under the FFDCA.

2004 Comment Resp. at 16. More recently, the EPA affirmed this belief in its 2006 ProFrume risk assessment. 2006 Risk Assessment at 4.

Given the long-standing debate on this issue in the scientific and public health communities, it is not entirely surprising that NRC and EPA differ with respect to the characterization of severe dental fluorosis. Importantly, though, the view of the majority of the NRC Committee that severe dental fluorosis is an adverse health effect is not based on any novel data to which EPA was not privy. In fact, the NRC majority's finding that severe dental fluorosis is an adverse health effect is based on the same studies that EPA reviewed in drawing its conclusions in 2004 and 2006. The difference stems from a subjective interpretation of the same set of data. While the Agency may want to examine this "mere disagreement," in no way does it create a material issue of fact upon which Objectors' hearing request should be granted.

Even more important, and perhaps curious, is NRC's decision to even attempt to address the question of what constitutes an adverse health effect. In December 1991, as part of EPA's then fluoride risk assessment, EPA instructed the NRC Committee "to review current toxicological and exposure data on fluoride and determine whether EPA's existing drinking water standards are adequate for protecting the public from *adverse health effects* of fluoride." See 58 Fed. Reg. 68,826 (Dec. 29, 1993) (to be codified at 40 C.F.R. pt. 141) (emphasis added): *Health Effects of Ingested Fluoride*, National Research Council of the National Academies, The National Academies Press (1993) (hereinafter 1993 NRC Report). Armed with that charge from the EPA, the NRC was quite explicit that "the question of whether to consider dental fluorosis a cosmetic effect or an adverse health effect and the balancing of the health risks and health benefits of

Fluoride are matter to be determined by regulatory agencies and are beyond the charge or expertise of this committee." 58 Fed. Reg. 68,827 (Dec. 29, 1993). Given that EPA's charge to the NRC in commissioning this most recent report was nearly identical to the 1991 instructions, it does not appear that an opinion as to whether severe dental fluorosis is an adverse health effect was within the scope of NRC's task. See 2006 NRC Report at 2 (stating the NRC Committee's charge was to "evaluate independently the scientific basis of EPA's MCLG of 4 mg/L and SMCL of 2 mg/L in drinking water and the adequacy of those guidelines to protect children and others from *adverse health effects*" (emphasis added).

Regardless of the 2006 NRC committee's rationale behind stepping outside the apparent scope of its authority, what is important to keep in mind is that, despite the opinion offered b the NRC, the regulatory determination as to what constitutes an adverse health effect for purposes of the SDWA, FFDCA or any other EPA statute is a policy issue entirely within the province of the Agency.[19] Moreover, as a result of a challenge to a prior EPA proceeding under SDWA, the United States Court of Appeals for the District of Columbia Circuit held, on a record very similar to the one now facing the Agency, that EPA had rationally concluded that dental fluorosis was not an adverse health effect. See *NRDC v. EPA*, 812 F.2d at 725.

IV. If EPA Determines that Any of Objectors' Issues Might Meet the Threshold for a Formal Hearing, that Decision Should be Deferred Until the NRC Report Has Been Reviewed Under the SWDA

The foregoing has set forth myriad reasons why the issues advanced by Objectors in support of a hearing are substantively flawed. Objectors have adopted a "kitchen sink" strategy yet failed to assert one issue that successfully fulfills the threshold standard governing EPA grants of formal evidentiary hearings. Notwithstanding the shortcomings of the Consolidated Objections, however, we recognize that the recent release of the NRC Report, which was commissioned by the EPA's Office of Water, and certain opinions expressed therein may give the Agency reason for pause prior to dismissing, our of hand, all of Objectors' arguments. To the extent that the Agency is uncomfortable with a summary rejection of Objectors' claims, it should defer any final decision on the grant of a formal evidentiary hearing under the FFDCA until the issues raised by the NRC Report have been properly reviewed under the provisions of the SWDA.

Objectors have based the majority of their objections to the ProFume tolerances on the theory that the 4 mg/L MCLG for fluoride in drinking water is not sufficiently protective of the population and therefore all other sources of fluoride exposure, specifically the ProFume tolerances, must be eliminated. It seems, then, that the issue most properly addressed by EPA is not whether the ProFume tolerances are appropriate under the FFDCA but whether, in fact, the 4 mg/L MCLG is appropriate under the SDWA in light of the opinions expressed in the NRC Report.

Evident from the conditions of registration for ProFume is that EPA was fully prepared for the eventual receipt of the NRC Report and, indeed, established an explicit two-step process within which it planned to review the NRC Report. The first step in this process is that "[s]ubsequent to [NRC's] review, the Office of Water will undertake an analysis to assess the adequacy of the

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19. *See* discussion in text in note 12.

current maximum contaminant level goal (MCLG) and secondary maximum contaminant level (SMCL) for fluoride."[20] Now that the NRC Report has been completed, it is up to the Office of Water to conduct its analysis.

In the event that the Office of Water finds flaws with the reasoning and opinions found in the NRC Report and sustains the current drinking water exposure levels, then most, if not all, of the objections to the ProFume tolerances will become moot. Should EPA determine that the MCLG does, indeed, need to be lowered, appropriate administrative and procedural steps will be required to first determine the new MCLG. Then, and only then, will it be appropriate to reassess the proper ProFume tolerance levels based on a fresh risk assessment that accounts for the changed MCLG.

October 30, 2006

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20. The registration issued by EPA for ProFume Gas Fumigant under the Federal Insecticide, Fungicide, and Rodenticide Act contained numerous conditions, including the following express reference to the NRC's review of data associated with national drinking water standards for fluoride:

> Subsequent to [the NRC Review of fluoride in drinking water], the Office of Water will undertake an analysis to assess the adequacy of the current maximum contaminant level goal (MCLG) and secondary maximum contaminant level (SMCL) for fluoride. If the Office of Water determines that revisions to either the MCLG or the SMCL are required or if the Agency subsequently determines that dental fluorosis is an adverse health effect under the Federal Food, Drug, and Cosmetic Act, the Agency may undertake a re-evaluation of the adequacy of the tolerances established for sulfuryl fluoride and fluoride as a result of this or subsequent registration actions for this product.

See Notice of Conditional Pesticide Registration for ProFume Gas Fumigant at 6 (EPA Jan. 26, 2004).

Clearly then, EPA has a process in place for determining what actions should be taken in light of the NRC Report. That process, conveniently not addressed by Objectors, requires EPA consideration under the SDWA of the NRC findings and recommendations, followed by the possible re-evaluation of ProFume tolerances by the Agency's Office of Pesticide Programs under the FFDCA. Abandoning now a process established by the Agency and relied upon by sulfuryl fluoride registrants and the scientific community would be arbitrary, unfair and unwarranted.