

August 24, 2009

FROM:  
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TO:  
Office of Pesticide Programs  
Environmental Protection Agency  
Special Review and Reregistration Division (7508P)  
1200 Pennsylvania Ave., NW.  
Washington, DC 20460-0001

**RE: SULFURYL FLUORIDE**

Docket ID. EPA-HQ-OPP-2009-0136  
Registration Review; Pesticide Dockets Opened for Review and Comment; Closure of  
the Terpeneols Registration Review Case

Federal Register at  
<http://www.epa.gov/fedrgstr/EPA-PEST/2009/June/Day-24/p14735.htm>

Hitherto we have been very comprehensive in our Objections, and having repeated our case three times, without any response from the Office of Pesticide Programs (OPP), we are not going in to ALL the issues as they have been presented in our submissions that are listed below. However, we will recap a central argument that simply cannot be denied, or obfuscated by the OPP: their manipulation of the reference dose for fluoride to give a totally unacceptable level for infants.

It is extremely enigmatic, and a further cause for concern, that the OPP has opened a Registration Review of Sulfuryl fluoride when it has yet to respond to multiple Objections (submitted in 2004, 2005); a Petition to revoke all sulfuryl fluoride tolerances submitted in 2006; two submissions of Consolidated Objections, both requested by EPA, submitted in 2005 and 2006; in 2009 a submission of 23 published papers reporting an association of decreased IQ in children and exposure to fluoride. The specifics are as follows:

- **2002: The first Objection submitted by Fluoride Action Network** on Dow AgroSciences request for tolerances for an Experimental Use Permit  
--Objection online at  
<http://www.fluoridealert.org/pesticides/sulfuryl.f.objections.apr02.htm>

EPA responded to this Objection at the same time it issued the first-time tolerances for sulfuryl fluoride, which were the highest residue tolerances for fluoride in the history of the EPA, by stating

Because the tolerances that were objected to have now been revoked,  
the objections are moot and are denied on that ground.

Ref: *Federal Register*, January 23, 2004, Sulfuryl Fluoride; Pesticide Tolerance. <http://www.epa.gov/fedrgstr/EPA-PEST/2004/January/Day-23/p1540.htm>

EPA then stated,

EPA fully considered, however, all of the Fluoride Action Network's objections as a part of today's action and has responded to each significant objection lodged by the Fluoride Action Network.

Ref: *Federal Register*, January 23, 2004, Sulfuryl Fluoride; Pesticide Tolerance. <http://www.epa.gov/fedrgstr/EPA-PEST/2004/January/Day-23/p1540.htm>

EPA's responses to our 2002 Objections were seriously scientifically flawed. EPA's response was a waste of their time, and FAN's, because they did not allow a resolution of FAN's Objections before the first-time tolerances were approved. More importantly, the tolerances pose a threat to the public.

• **2004: Objections to first-time tolerances** for the use of sulfuryl fluoride as a post-harvest fumigant submitted by the Fluoride Action Network and Beyond Pesticides. ([Attachment 2005.objections.pdf](#))

*APPENDIXES (included separately as Attachments to 2004 Objections)*

A. [Summation of Data on Fluoride & Bone Damage \(at Exposure Levels Relevant to EPA's Current MCL\)](#).

([Attachment 2004.appendix-a.pdf](#))

B. [Fluoride & Bone Damage: Published Data](#).

(Attachment: [2004.appendix-b.pdf](#))

C. [Translation of Chinese Fetal Bone Study](#).

(Attachment: [2004.appendix-c.pdf](#))

D. [FAN's response to EPA's criticisms of submitted health studies](#).

(Attachment: [2004.appendix-d.pdf](#))

E. [Translation of Bachinskii Paper](#).

(Attachment: [2004.appendix-e.pdf](#))

F. [A comparison of a review of animal studies on fluoride's reproductive effects by Stan Freni \(1994\) and the DHHS \(1991\)](#).

(Attachment: [2004.appendix-f.pdf](#))

G. [Adverse Effects on Male Reproductive System](#)

(Available at:

<http://www.fluoridealert.org/pesticides/sf.comments.male.repro.htm>)

H. [Adverse Effects on Brain](#).

(Available at:

<http://www.fluoridealert.org/pesticides/sf.appendix.brain.htm>

J. [Fluoride Ingestion from Toothpaste](#).

(Attachment: 2004.appendix-j.pdf)

K. [Objections based on OPP failure to adhere to statutes and guidelines](#).

(Attachment: 2004.appendix-k.pdf)

1-L. [Comparisons of Residue Tolerances: Final vs. Proposed](#).

(Available at: <http://www.fluoridealert.org/pesticides/sf.comparisons.htm>)

- **2005: Objections to an expansion of sulfuryl fluoride tolerances.** These Objections were submitted by the Fluoride Action Network (FAN), Beyond Pesticides, and the Environmental Working Group. (Attachment: 2005.objections.pdf)

TABLES (included separately as Attachments to 2005 Submission)

1. [Sulfuryl Fluoride: Brain effects from animal studies](#).

(Attachment: 2005.table.1.brain.pdf)

2. [Sulfuryl Fluoride: Thyroid, Adrenal Cortex, Heart, Kidney, Lung effects from animal studies](#).

(Attachment: 2005.table.2.sf.non-brain.pdf)

3. [Fluoride Studies on Brain effects](#).

(Attachment: 2005.table.3.brain.studies.pdf)

4. [Fluoride Studies on IQ and Behavioral effects](#).

(Attachment: 2005.table.4.iq.behav.pdf)

5. [Fluoride Studies on G-Proteins](#).

(Attachment: 2005.table.5.g-proteins.pdf)

6. [Fluoride Studies on Male Reproductive System effects](#)

(Attachment: 2005.table.6.male.repro.pdf)

- **2005: Supplementary Objection and Request for Hearing submitted in September** by Chris Neurath of Fluoride Action Network. (Attachment: 2005.supplemental.obj.neurath.pdf)

- **2005: Consolidated Objections, submitted at EPA's request**, by Paul Connett, Director, Fluoride Action Network; Richard Wiles, Sr. Vice President, Environmental Working Group; and Jay Feldman, Executive Director, Beyond Pesticides. (Attachment: 2005.1st.consolidated.pdf)

- **2006: Petition to revoke all sulfuryl tolerances** submitted by Perry Wallace, Esq., on behalf of the Environmental Working Group, FAN, and Beyond Pesticides.  
(Attachment: [2006.petition.revoke.pdf](#))

- **2006: Second Consolidated Objections**, submitted, at EPA's request, by Perry Wallace, Esq., on behalf of the Environmental Working Group, FAN, and Beyond Pesticides.  
(Attachment: [2006.2nd.consolidated.pdf](#))

- **2007: Memorandum. Legal Standard for Grant of Hearings on Objections under Federal Food, Drug, and Cosmetic Act Section 408**, submitted at EPA's request, by Perry Wallace, Esq., on behalf of the Environmental Working Group, FAN, and Beyond Pesticides. January.  
(Attachment: [2007.memorandum.pdf](#))

- **2009: Submission of 23 published papers that found an association of decreased IQ in children with exposure to fluoride.** Perry Wallace, Esq., submitted these papers to EPA's Office of Pesticides on behalf of FAN, EWG, and Beyond Pesticides.  
(See <http://fluoridealert.org/iq.studies.html> for access to pdf copies of these studies.)

FAN has not received any serious response from the OPP to all these submissions - which have now occupied us for over 7 years - while the use of sulfuryl fluoride -despite our scientifically valid objections- continues to be used and continues to add to the over-exposure to fluoride of the American people, especially infants and young children. Incredibly, despite the failure of the OPP in this respect, they now seek to expand the use of sulfuryl fluoride still further. In addition to the use of hundreds of foodstuffs in warehouses and processing plants (to which we have objected), Dow AgroSciences requests to use it for pre-plant soil fumigant use.

We will make some comments here but we do so with little confidence that they will be treated with a scientific response - or any response at all. One wonders why on earth the EPA puts the public through these time-consuming and expensive exercises if it does not seem to make a scrap of difference to their regulatory behavior. Can we be excused for suspecting that the EPA's OPP is more interested in protecting the interest of Dow AgroSciences than it is in protecting either the public health or its reputation?

- **2009: Fluoride Action Network comment to US EPA on Dow AgroSciences request for pre-plant soil fumigant use.**  
(Attachment: [2009.fan.comment.pdf](#))

We will begin our comments by summarizing some of our key concerns about the way the OPP manipulated its three health risk assessments in its effort to defend the safety of the fluoride residues (tolerances) it proposed for Dow's use of sulfuryl fluoride. Needless to say, expanding the use of sulfuryl fluoride to include pre-plant soil fumigant use, can only ADD to the fluoride exposure of the American people, for which there is clear evidence of over-exposure already (CDC, 2005). Thus, this additional use can only strengthen our arguments that no more fluoride exposure should be sanctioned.

**A brief history of the OPP's three risk assessments for fluoride residues and**

**FAN's interventions.**

Since Dow AgroSciences first sought a temporary use permit for two foods (walnuts and raisins) in 2001, the Fluoride Action Network (FAN) along with the Environmental Working group (EWG) and Beyond Pesticides (BP) have argued that the use of this fumigant for this purpose should be denied because people, especially infants, are already exceeding the reference dose (0.114 mg/kg/day) for its major breakdown product (the fluoride ion) which it has previously used for fluoride in the case of cryolite.

Rather than concede this point, the OPP responded by changing the reference dose after the FAN, EWG and BP interventions. It has done this twice.

First, the OPP raised the reference dose for infants by a factor of 5, to 0.571 mg/kg/day (making it five times the reference dose for an adult).

Second, after another FAN, EWG and BP intervention, it raised the reference dose for infants still higher - to 1.14 mg/kg/day - which made it ten times higher than the reference dose for adults. (i.e. the original reference dose used by OPP for fluoride residues from cryolite use).

There is no other example in EPA's regulation of pesticides or pesticide residues, where a reference dose has been set HIGHER for an infant than an adult. Not only is it blatantly absurd from a toxicological point of view (infants are considered to be more sensitive than adults to toxics, not less so), but it is also a clear violation of the Food Quality and Protection Act (FQPA), which requires that an extra margin of safety be applied to protect infants.

With the latest application by Dow AgroSciences to extend the use of sulfuryl fluoride as a soil fumigant (Federal Register, June 10, 2009, Docket ID EPA-HQ-OPP-2009-0298. Available at <http://www.epa.gov/fedrgstr/EPA-PEST/2009/June/Day-10/p13475.htm> ) time to growing food (not just to post harvest food in warehouses and processing plants), the OPP continues to nurture the fiction that infants are ten times more tolerant of fluoride than adults. They didn't spend much time on this, merely mentioning in passing that 8 mg/day of fluoride was safe for everyone. They add that the Water Division is reviewing the MCLG for fluoride (4 ppm), which was the starting point for all three of their health risk assessments for fluoride. The major focus of their latest health risk assessment was on the sulfuryl fluoride itself.

However, claiming to wait for the EPA Water Division to come up with a new MCLG, is completely disingenuous, since this cannot rescue their bogus manipulations of the reference dose, but instead make their starting point, and hence final reference dose even lower, which ever of the three manipulations they choose to use. In turn this will put even more people over the reference dose, making further exposure to fluoride for the use of sulfuryl fluoride unacceptable.

The OPP knows that the 2006 National Research Council of the National Academies report, Fluoride in Drinking Water: A Scientific Review of EPA's Standards (requested by the EPA Office of Drinking Water to review the MCLG for fluoride) concluded that the MCLG of 4 ppm was unprotective of health and recommended that the water division perform a new risk assessment to determine a new value. The new value for the MCLG can only be lower than 4 ppm, since the NRC showed that the end point on which it is

based - namely crippling skeletal fluorosis - was not the most sensitive end point of concern when considering fluoride's damage to bone. The NRC concluded that earlier symptoms, when fluoride accumulates in the bone and joints, which are similar to arthritis, should be considered an end point of concern. The NRC also stated that the EPA's Office of Drinking Water MCLG of 4 ppm fluoride was not protective of bone fractures.

**Re-examination of the OPP's fiction on the reference dose for the fluoride ion for infants.**

In its third health risk assessment the OPP used the following reasoning. As with the previous two risk assessments, the OPP started with the derivation of the MCLG of 4 ppm. This has several key steps.

Step 1. The assumption that the only health end point of concern was crippling skeletal fluorosis.

Step 2. The assumption that the LOAEL at which this occurs is 20 mg per day

Step 3. The assumption that a safety factor of 2.5 would be protective for all adults from this end point. Thus 20 mg/day divided by 2.5 gives a safe daily dose for adults of 8 mg/day.

At this point the normal and traditional way of determining what a safe dose would be for any other age range (and thereby range of bodyweight) is to divide this safe daily dose for adults by an adult's body weight (70 kg) to derive a safe REFERENCE DOSE of 0.114 mg/kg/day. This reference dose can then be used to back-calculate the safe daily dose for any other age range, by multiplying by the average weight for the age range in question. For an infant the weight is taken as 7 kg, thus a safe dose would compute for them:  $0.114 \text{ mg/kg/day} \times 7 \text{ kg} = 0.8 \text{ mg/day}$ .

That's the traditional way – taking into account the difference in bodyweight for each age range. In the OPP's third assessment, the results which we have challenged but appear to have been carried over in this current risk assessment for sulfuryl fluoride BY DEFAULT, the OPP abandoned this traditional way – and toxicologically defensible way – and instead said that if 8 mg/day was safe for adults then it was safe for everyone regardless of age or bodyweight! This is clearly a preposterous suggestion and makes as much sense as saying that, if 2000 mg of aspirin is safe for an adult, it would also be safe for 7 kg infant!

By assuming that 8 mg per day was safe for everyone regardless of age or bodyweight, it allowed the OPP to produce an outrageously high reference dose for a 7 kg infant of 1.14 mg/kg/day:  $8 \text{ mg/day} \text{ divided by } 7 \text{ kg bodyweight} = 1.14 \text{ mg/kg bodyweight/day}$ .

There is no rational scientific defense for such a manipulation. The only conclusion is that OPP was working backwards from what was needed to produce a risk assessment that would allow them to approve Dow AgroSciences agenda for using sulfuryl fluoride as an alternative to methyl bromide. In other words, OPP is violating scientific integrity and betraying the public's trust.

The OPP has failed to address the FAN, EWG and BP's challenge on these

manipulations in their latest attempt to expand the use of Dow AgroScience's use of sulfur dioxide and simply continued as if we had not intervened at all. This clearly demonstrates a lack of good faith on their part. Why on earth should the OPP go through the exercise of asking for public comment, not just once – but now FOUR TIMES - if they are merely going to ignore well-argued and well-documented interventions by those members of the public like ourselves who take the trouble to respond. Such behavior, in our view, simply underlines the OPP's desire to follow Dow AgroScience's agenda at all costs. The costs being in this case: the public's health, the public's trust, scientific integrity and the mandates of the Food Quality and Protection Act.

### **Use of the Food and Nutrition Board's UL**

There is one other tame argument that the OPP has used to justify its use of a 8 mg/day as being safe for everyone and that is their claim that the Food and Nutrition Board of the Institute of Medicine (IOM) 1997 report, Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride (online at <http://www.nap.edu/openbook.php?isbn=0309063507> ) used an upper tolerance level (UL) value of 10 mg per day for a wide age range. However, this hurts their case rather than helping it. The IOM did indeed come up with a UL of 10 mg/day but did so only for adults and children of 8 years and above. The value they used for children younger than eight years, especially for infants, was much lower than this.

**UL for Infants, 0 through 6 months - 0.7 mg/day**

**UL for Infants, 7 through 12 months - 0.9 mg/day**

**UL for Children, 1 through 3 years - 1.3 mg/day**

**UL for Children, 4 through 8 years - 2.2 mg/day**

**UL for Children and Adults > 8 years - 10 mg/day**

**If we consider just the UL for infants 0 through 6 months, and take the average bodyweight for this age range of 7 kg, this translates to a reference dose of 0.1 mg/kg/day (0.7 mg /day divided by 7 kg bodyweight)**

**This is ELEVEN TIMES lower than the 1.14 mg/kg/day used by the OPP's third and latest health risk assessment.**

\*The IOM applied a totally unjustifiable safety factor of 1 (in their language an uncertainty factor of 1) to the revised LOAEL for skeletal fluorosis of 10 mg/day

### **Evidence that children are being over-exposed to fluoride**

Empirical evidence that many people – especially infants and children - are already being over-exposed to fluoride comes in the form of the dental fluorosis rates in the US. According to the Centers for Disease and Prevention (CDC) 32% of American children have a condition called dental fluorosis (Surveillance for dental caries, dental sealant, tooth retention, edentulism and enamel fluorosis --- United States 1988-1994 and 1992-2002. MMWR. August 26, 2005 / 54(03);1-44.) Online at

<http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5403a1.htm> This percentage has increased by at least 9% since 1987. Dental fluorosis is well-accepted evidence that a child has been over-exposed to fluoride before its permanent teeth have erupted. According to the NRC (2006) review, several other tissues are impacted by ingested fluoride.

It is simply inexcusable for the OPP to sanction a further increase in fluoride exposure to the US population, and their notion that somehow infants are far more tolerant of fluoride than adults, by using a bogus reference dose TEN times higher than adults, is a dishonest attempt to obscure this truth.

Thus the OPP's current health risk assessment for sulfuryl fluoride, is completely moot, unless and until the OPP is able to demonstrate that the consumption of fluoride residues that this fumigant leaves on food (and permitted by the OPP as tolerances), when combined with existing exposures, will not exceed a genuine scientific reference dose. This is something that they have failed to do, in three separate attempts, since Dow AgroSciences first applied for the use of this fumigant on food in 2001. For how long will the OPP continue to waste taxpayers' money on prolonging this exercise?

Not only does the failure of the OPP to justify its use of a reference dose for fluoride at a level ten times higher for infants than adults, violate the clear mandates of the FQPA, and violate that need of government agencies to exercise scientific integrity in their regulatory behavior as urged by President Obama, but it also continues to threaten the health of millions of Americans every day this fumigant is used on the food supply.

We again request responses to all our arguments that have been submitted to EPA by FAN, EWG, and Beyond Pesticides.

Sincerely,

Paul Connett, Director  
Fluoride Action Network