

Fluoride Action Network Pesticide Project

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January 4, 2006

Maureen P. Serafini
Director
Bureau of Pesticides Management
625 Broadway
Albany NY 12233-7254

Re: NYS Registration of ProFume® (EPA Reg. No. 62719-376)
Your letter of November 28, 2005, to Mr. Jim Baxter of Dow AgroSciences

Dear Director Serafini,

Yesterday was the first time that we read your November 28, 2005, letter to Mr. Jim Baxter of Dow AgroSciences, stating your approval of ProFume® as a "Restricted Use Pesticide" product in New York State.

Fluoride Action Network (FAN) is a non-profit group that has been actively engaged with the US EPA since September 2001 on the dangers inherent in the use of sulfuryl fluoride as a food fumigant.

As of this date we have submitted three Objections and Requests for an Evidentiary Hearing on EPA's issuance of tolerances for fluoride and sulfuryl fluoride. In brief, our Objections were submitted:

April 8, 2002 (1): on EPA's issuance of temporary tolerances for an Experimental Use Permit (EUP) (2). In a January 23, 2004, Final Rule, EPA stated that our Objections were moot because Dow AgroSciences withdrew its EUP (3).

March 23, 2004 (4): on EPA's first-time issuance of permanent tolerances for post-harvest food commodities (3). Beyond Pesticides joined in this submission.

September 13, 2005 (5): on EPA's issuance of permanent tolerances for ALL processed food (6). The Environmental Working Group and Beyond Pesticides joined with us in this submission.

At this time, US EPA is considering combining our 2004 and 2005 Objections and Requests for an Evidentiary Hearing. I enclose our latest submission of December 16, 2005, to EPA, which clarifies the issues for a combined hearing (7).

On behalf of the FAN Pesticide Project, I ask that you revoke New York State's approval of the use of ProFume® for the following reasons:

1. Three public advocacy groups (FAN, Environmental Working Group, and Beyond Pesticides) have presented serious concerns on the use of sulfuryl fluoride on food commodities to EPA. These issues have not been resolved and are summarized in the attached submission sent to EPA on December 16, 2005 (7). We anticipate that a resolution of these issues will occur via an EPA evidentiary hearing. Until these issues are resolved, we ask that you revoke your approval of sulfuryl fluoride on food commodities in New York State.

2. In your November 28, 2005, letter to Mr. Jim Baxter, you state:

On November 15, 2005, Dow Agro provided the Department with confirmation that USEPA had waived the inhalation rat developmental neurotoxicity study.

This was clearly a surprise to us. As you must know, EPA stated in its Final Rule of July 15, 2005:

Based on the available evidence, the Agency is requiring an inhalation DNT study in rats (OPPTS Harmonized Guideline 870.6300) as a condition of registration in order to more clearly and fully characterize the potential for neurotoxic effects in young animals (6).

Due to the findings of serious brain effects in all animal species exposed to sulfuryl fluoride via inhalation and to the findings of subclinical effects on the central nervous system of Vikane® occupational workers (8), we believe that it was imperative for the following DNT studies to have been conducted prior to the issuance of any tolerances:

- An ORAL DNT study for fluoride. None has been conducted.
- An ORAL DNT study for sulfuryl fluoride. None has been conducted.
- An ORAL DNT study for simultaneous exposure to fluoride + sulfuryl fluoride. None has been conducted.

3. The risk assessment that EPA utilized for tolerances in its Final Rule of July 15, 2005 (6), has not been released to the public:

... Exposure estimates for the subgroups addressed by the model will be included in EPA's forthcoming human health risk assessment for Petition 3F6573 ... (9)

4. EPA used the 1985 Office of Water's 4 ppm fluoride Maximum Contaminant Level (MCL) in drinking water for its risk assessment of sulfuryl fluoride as a food fumigant. However, this MCL has been under review, at the request of the Office of Water, since 2003, by the National Research Council (NRC). Their report (*Toxicologic Risk of Fluoride in Drinking Water*) is expected to be released early this year. EPA's decision to approve the use of sulfuryl fluoride on food before the NRC report was published was rushed and unwise.

We request copies of the following documents cited in your November 28, 2005, letter to Mr. Baxter:

- November 15, 2005, confirmation from Dow AgroSciences that USEPA had waived the inhalation rat developmental neurotoxicity study.
- The summary studies of occupational and residential data (ten studies) that Dow provided to your department.

Lastly, in your November 28, 2005, letter to Mr. Baxter, you state

There is a New York State drinking water standard for fluoride, which is 2.2 milligrams per liter (10 NYCRR Part 5, Public Water Systems).

Is the 2.2 ppm fluoride in drinking water the highest level that certain New Yorkers are exposed to? Are there other communities in the state who are exposed to higher fluoride levels in their drinking water? We request a list of those communities in New York state that are exposed to fluoride levels greater than 1 ppm in their drinking water.

Sincerely,

Ellen Connett,
Director,
Fluoride Action Network Pesticide Project

Attachment:

December 16, 2005, submission to US EPA from FAN, Environmental Working Group, Beyond Pesticides. Also available online at

<http://www.fluorideaction.org/pesticides/sf.submission.12-16-05.pdf>

CC:

Richard Wiles, Sr. Vice President
Environmental Working Group
1436 U Street NW, Suite 100 Washington, DC 20009

Jay Feldman, Executive Director
Beyond Pesticides/National Coalition Against the Misuse of Pesticides
701 E Street, SE Washington DC 20003

References:

1. Written Objections and Request for Hearing in the matter of: Sulfuryl fluoride; Temporary Pesticide Tolerances. Final Rule. April 8, 2002. Submitted by Paul and Ellen Connett. Federal Register Docket OPP-301166A. Available online at <http://www.fluoridealert.org/pesticides/sulfuryl.f.objections.apr02.htm>
2. Sulfuryl Fluoride; Temporary Pesticide Tolerances. Final Rule. Federal Register. February 7, 2002. Available online at <http://www.epa.gov/fedrgstr/EPA-PEST/2002/February/Day-07/p2983.htm>
3. Sulfuryl Fluoride; Pesticide Tolerance. Final Rule. Federal Register. January 23, 2004. Available online at <http://www.epa.gov/fedrgstr/EPA-PEST/2004/January/Day-23/p1540.htm>
4. Written Objections and Request for Hearing in the matter of: Sulfuryl Fluoride; Pesticide Tolerance. Final Rule. Docket control number OPP-2003-0373. Submitted to US EPA by Fluoride Action Network and Beyond Pesticides. March 23, 2004. Available online at <http://www.fluorideaction.org/epa-sf.htm>
5. Objections and Request for Hearing. Sulfuryl fluoride; Pesticide Tolerance. Final Rule. Docket No. OPP-2005-0174. Submitted to US EPA by FAN, the Environmental Working Group, and Beyond Pesticides. September 13, 2005. Available online at <http://www.fluorideaction.org/pesticides/epa-sf/epa-sf2.pdf>

6. Sulfuryl fluoride; Pesticide Tolerance. Final Rule. Federal Register. July 15, 2005. Available online at

<http://www.epa.gov/fedrgstr/EPA-PEST/2005/July/Day-15/p13982.htm>

7. Issues for an evidentiary hearing concerning sulfuryl fluoride tolerances. Submitted to US EPA by Fluoride Action Network, Environmental Working Group, and Beyond Pesticides. December 15, 2005. Available online at

<http://www.fluorideaction.org/pesticides/sf.submission.12-16-05.pdf>

8. Calvert GM et al. (1998). Health effects associated with sulfuryl fluoride and methyl bromide exposure among structural fumigation workers. American Journal of Public Health 88(12): 1774-1780.

9. Response to public comments concerning the use of sulfuryl fluoride in food handling facilities. US EPA Office of Prevention, Pesticides and Toxic Substances. July 14, 2005. Docket No. OPP-2005-0067-0020. Available online at

<http://www.fluorideaction.org/pesticides/sf.epa.response.july.14.2005.pdf>