Before the

ENVIRONMENTAL PROTECTION AGENCY

In Re Final Rules on Sulfuryl Fluoride Pesticide Residue Tolerances	)	Docket Nos. OPP-2005-0174; OPP-2003-0373

To:

Office of the Hearing Clerk (1900L)
Environmental Protection Agency
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MOTION OF OBJECTORS FOR STAY OF FINAL RULES ESTABLISHING TOLERANCES FOR RESIDUES OF SULFURYL FLUORIDE AND FLUORIDE ANION

Objectors Environmental Working Group,(EWG) Fluoride Action Network (FAN) and Beyond Pesticides/National Coalition Against the Misuse of Pesticides (BP) (Objectors) hereby move that the Administrator of the Environmental Protection Agency (Administrator or EPA) stay the effectiveness of certain regulations establishing

tolerances for residues of sulfuryl fluoride and of fluoride anion (fluoride) in or on all raw and processed food commodities. (Regulations) Section 408(g)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes the Administrator to order such a stay.

Objectors urge the issuance of a stay order based on (1) the likelihood that the legal positions asserted by Objectors will prevail on the merits, (2) the imminent, substantial and irreparable harm posed by the tolerances set in the Regulation to the populations and interests represented by Objectors, (3) the fact that no other parties interested in the proceedings will be substantially harmed in a manner protected by the FFDCA by the issuance of a stay, and (4) that the public interest lies overwhelmingly in favor of the issuance of a stay. Further, and as to all these considerations, while the threat posed by these tolerances extends to members of the general population, Objectors urge that the need for a stay is particularly urgent because of the potential harm posed to certain highly vulnerable subgroups, notably infants and children. Indeed, the FFDCA expressly requires that EPA pay special attention to these subgroups's health interests in the establishment of tolerances.

In July 2005, EPA issued one of the Regulations (2005 Regulation) as a final rule, with an effective date of July 15, 2005. Fed. Reg., Vol. 70, No. 135, July 15, 2005. In January 2004, EPA issued the other Regulation (2004 Regulation) as a final rule, with an effective date of January 23, 2004. Fed. Reg., Vol. 69, No. 15, January 23, 2004. The process leading to issuance of the Regulations had been initiated by a petition for rulemaking by Dow AgroSciences, LLC (Dow) requesting that EPA amend 40 CFR Part 180 to set the tolerances at issue. Objectors timely filed their Objections and Requests for Hearing with respect to both Regulations. (Objections 2004, 2005a,b) Objectors

incorporate by reference all of their previous submissions as to the Regulations. These submissions will therefore be cited and referred to throughout this Motion. (Objections 2002, 2004, 2005a,b,c; Comments 2001, 2002, 2005)

INTRODUCTION AND SUMMARY OF ARGUMENT

Objectors assert that the subject Regulations are flawed because EPA proceeded superficially, inadequately, and thus in violation of the FFDCA and the Administrative Procedure Act (APA), when the agency failed to evaluate, in the thorough and detailed manner required by law, the exposures and risks associated with the establishment of tolerances for pesticide chemical residues of sulfuryl fluoride and fluoride anion.

In July 2005, EPA approved even higher fluoride tolerances, including 900 parts per million (ppm) in or on dried eggs, 125 in or on wheat flour, and 70 ppm in or on all "processed foods" (excepting those with specific tolerances). As a result of these broad-reaching, staggeringly high fluoride tolerances, EPA's own data shows that sulfuryl fluoride will become the second largest daily source of fluoride in the US. According to EPA, the sulfuryl fluoride tolerances will contribute more fluoride to an average American's intake than all current food products combined. The tolerances, therefore, represent a major new source of fluoride exposure in the US and will--in conjunction with all other sources of fluoride to which Americans are exposed—contribute to millions of Americans exceeding EPA's purported safe dose.

Objectors base their arguments in part on the express requirement in the FFDCA that the Administrator may only establish tolerances that are "safe," meaning that before any such tolerances are set, the Administrator must have determined that "there is a reasonable certainty that no harm will result" thereby. Further, as regards the general

population and particularly with respect to vulnerable groups, the FFDCA requires that the Administrator evaluate "aggregate" exposures to pesticide chemical residues, "including all anticipated dietary exposures and all other exposures for which there is reliable information."[1] Important in this regard is a March 2006 report by the National Research Council of the National Academies entitled *Fluoride in Drinking Water: A Scientific Review of EPA's Standards* (NRC Report). EPA itself requested the study leading to this report "[b]ecause new research on fluoride is now available and because the Safe Drinking Water Act requires periodic reassessment of regulations for drinking-water contaminants." NRC Report at 1. The NRC Report confirms emphatically, soundly and in great detail the positions taken by the Objectors in the Objections filed previously in this matter, while at the same time undercutting and in some instances directly refuting EPA's rationales and positions.

The NRC specifically examined the standard which EPA used in its risk assessment for the tolerances (Maximum Contaminant Level Goal, MCLG)[2] and concluded it was unsafe and should be lowered. According to NRC:

> In light of the collective evidence on various health end points and total exposure to fluoride, the committee concludes that EPA's MCLG of 4 mg/L should be lowered. Lowering the MCLG will prevent children from developing severe enamel fluorosis and will reduce the lifetime accumulation of fluoride into bone that the majority of the committee concluded is likely to put individuals at increased risk of bone fracture and

[1] See FFDCA Section 408(b)(2)(A)(ii) requiring that in setting tolerances, the Administrator must adhere to the strict standard of "reasonable certainty that no harm will result" from "aggregate exposure" to pesticide chemical residues, including anticipated dietary and other exposures for which there is reliable information.

[2] See, Safe Drinking Water Act Section 1412(b)(4)(A), 42 U.S.C. §300g-1(b)(4)(A):

> Each maximum contaminant level goal established under this subsection shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.

See also, 40 C.F.R. §141.2 (2002).

> possibly skeletal fluorosis, which are particular concerns for subpopulations that are prone to accumulating fluoride in their bone. NRC Report at 299.

The report further recommends that in order to develop levels that protect against these harms, "EPA should update the risk assessment of fluoride to include new data on health risks and better estimates of total exposure .. for individuals." NRC Report at 8.

Although EPA specifically requested the in-depth study performed by the Committee, the agency proceeded with the promulgation of the Regulations rather than await the obviously pertinent and important conclusions of the NRC Report. Further, although one Regulation was issued in July, 2005, the final risk assessment supporting it was not issued until January, 2006 and received by Objectors in February, 2006. In addition, many of the key supporting documents that EPA relied upon for its risk assessment were never placed in the public docket and were not available as of March 8, 2006. And, with respect to the 2004 Regulation, EPA has simply not responded to Objectors's substantive Objections.

In sum, EPA has repeatedly ignored the extensive and sound evidence and commentary on this subject submitted by Objectors. (Objections 2002, 2004, 205a,b,c Comments 2001, 2002, 2005) By so doing, the agency has rendered its assessment of risks and exposures relative to the requested tolerances flawed, untrustworthy, and violative of both substantive and procedural legal requirements. EPA's actions were thus in violation of applicable law.

ARGUMENT

I. Authority of the Administrator to Issue a Stay and Standard of Review

The Administrator is authorized to issue a stay in this matter by FFDCA Section 408(g)(1), 7 U.S.C. §346a(g)(1), which provides as follows:

> The Administrator may stay the effectiveness of the regulation … if, after issuance of such regulation …objections are filed with respect to such regulation.

Objectors contend that the applicable standard of review for a stay consists of the criteria enunciated in *Virginia Petroleum Jobbers Ass'n v. FPC,* 259 F.2d 921 (D.C.Cir. 1958):

1. Has the petitioner made a strong showing that it is likely to prevail on the merits;
2. Has the petitioner shown that without such relief it will be irreparably harmed;
3. Would the issuance of the stay substantially harm other parties interested in the proceedings;
4. Where lies the public interest.

See also, *Cuomo v. United States Nuclear Regulatory Comm'n*, 772 F.2d972, 974 (D.C. Cir 1985); *Hilton v. Braunskill,* 481 U.S. 770, 776 (1987).

II. Legal Framework

In prohibiting the shipment in interstate commerce of "any food …that is adulterated," FFDCA, Section 402(a)2)(B), 7 U.S.C. §342(a)(2)(B), deems food to be adulterated "if it bears or contains a pesticide chemical residue that is unsafe." A pesticide is not "unsafe" if EPA has either (1) established a tolerance for the pesticide on a particular commodity or in a particular food and the quantity of the residue is within the tolerance limit or (2) exempted the pesticide from the tolerance requirement. 7 U.S.C. § 346a(a)(1) A "tolerance" is the maximum permissible level of residue for the pesticide, and it applies to "pesticide chemical residues," which are residues in or on raw

agricultural commodities or processed food of a pesticide chemical (or an acceptable substance that is the result of metabolism or other degradation of a pesticide chemical). 7 U.S.C. §§ 346a, 321 (q)(2).

The establishment of a tolerance for a pesticide chemical residue is meant to be a thorough and considered process, one grounded in extensive review of relevant data and studies and directed almost exclusively toward public health and safety. Thus, FFDCA Section 408(b)(2) and (3) list more than 20 risk-related factors that must be considered by the Administrator in determining whether to approve a tolerance. The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue either in response to a petition properly filed or on the Administrator's own initiative, so long as the final tolerance is "safe." The Administrator may modify or revoke a tolerance if the Administrator determines the tolerance is not "safe." 7 U.S.C. §346a(b)(2(A)(i) Significantly, the determination of safety was raised to an appropriately demanding standard by the Food Quality Protection Act (FQPA), which modified FFDCA:

> [T]he term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

7 U.S.C. § 346a(b)(2)(A)(ii)

The stringency of the process for the establishment of tolerances is particularly well reflected in the requirements of FFDCA Section 408((b)(2)(C) that the Administrator assess the risk of a subject pesticide chemical residue based on available information on infants and children regarding the following:

> (1) consumption patterns likely to result in disproportionately high consumption of foods containing or bearing pesticide chemical residues in comparison to the general population;
>
> (2) special susceptibility to pesticide chemical residues, including neurological differences between infants and children and adults and effects of in utero exposure to those residues, and
>
> (3) the cumulative effects on this group of such residues and other substances having a common mechanism of toxicity.

7 U.S.C. § 346a(b)(2)(C)

Additionally, that section requires that the Administrator "shall ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue," publish a "specific determination" regarding the safety of the residue for infants and children, and, in consultation with the Secretaries of Health and Human Services and Agriculture, conduct surveys to document dietary exposure to pesticides among this group. In cases of pesticide chemical residues demonstrating "threshold effects," the standard determination of a "safe" tolerance requires an "additional ten-fold margin of safety for the pesticide chemical residue and other sources of exposure …to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure."

Section 408(b)(2)(D) sets forth the nine factors that the Administrator shall consider, among other relevant factors, in establishing, modifying, leaving in effect, or revoking a tolerance. These include the available information, with respect to the subject pesticide chemical residue, (1) concerning the validity, completeness, and reliability of the available data, (2) the toxic effect, (3) the relationship of the results of studies to human risk, (4) the dietary consumption patterns of consumers (and major consumer groups), (5) the cumulative effects of such residues and other substances having a

common mechanism of toxicity, (6) the aggregate exposure levels of consumers (and major identifiable subgroups), (7) the variability of the sensitivities of major identifiable subgroups, (8) information the Administrator may require as to the potential effect on humans of a pesticide chemical residue similar to that produced by endocrine effects, and (9) safety factors that qualified experts on the safety of food additives recognize as appropriate for the use of animal experimentation data. 7 U.S.C. § 346a(b)(2)(D)

Finally, "any person" may file "objections" to a regulation establishing a tolerance and request a hearing. FFDCA Section 408((g)(2)(A), (B) In such an instance, the Administrator "may stay the effectiveness of the regulation." FFDCA Section 408(g)(1) Findings of fact made pursuant to a hearing must be "based only on substantial evidence of record." FFDCA Section 408(g)(2)(C) Judicial review of regulations and related orders may be sought by "adversely affected" parties in certain United States Courts of Appeals. See FFDCA Section 408(h)

III. Objectors are Likely to Prevail on the Merits.

As described in the previous section, the FFDCA requires a stringent, careful and methodical evaluation of relevant data in the establishment of tolerances for pesticides, especially for vulnerable subgroups. Notwithstanding this basic statutory intent, the fluoride residue tolerances approved for sulfuryl fluoride were established under improper, unreliable procedures that yielded the highest tolerances ever allowed in the history of the agency. As Objectors demonstrate herein, the tolerances set by EPA will contribute, in conjunction with many other sources of fluoride to which the general public is exposed, to the exceeding of the current reference dose of 0.114 mg per kg of bodyweight per day (8 mg/ day for a 70 kg adult) for millions of Americans. Further, the

safety standard (MCLG) underpinning the current reference dose is not based in sound science and has now been rejected by the National Research Council of the National Academies. Thus, people exposed to fluoride levels below the current reference dose will be adversely affected.

When EPA's approach to setting the tolerances in the Regulation is judged against the central and fundamental requirements of the FFDCA that there be "a reasonable certainty that no harm will result" and that vulnerable subgroups receive special consideration, it becomes clear that the agency has acted in violation of law. Further, these flaws in the manner in which EPA proceeded has made it impossible that the agency could have based its decisions establishing the tolerances on "substantial evidence" from a fair and complete record as required by the APA.[3]

Additionally, from the perspective of procedural fairness, EPA's handling of the overall process has impaired its compliance with the requirement in applicable law that in informal rulemaking proceedings "the agency … shall give interested persons an opportunity to participate."[4] Here, (1) the failure to prepare and produce the Final Health Risk Assessment, as well as the failure to wait for the conclusions of the NRC Report, before issuing the 2004 and 2005 Regulations, (2) the failure to include supporting documents to the risk assessment in the public docket, and (3) the failure even

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[3] See, FFDCA Section 408(g)((2)(c), providing that where a hearing is held pursuant to a request by persons filing objections, the Administrator's final decision and order shall , "with respect to questions of fact at issue … be based only on substantial evidence of record at such hearing."
See APA Section 706(2)(E), 5 U.S.C. § 706(E). See also, JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 347 (3rd ed. ABA 1998) (use of the more demanding "substantial "evidence" standard in "hybrid" informal rulemaking instead of the usual "arbitrary and capricious" standard reflects Congress's view that "the more stringent test afforded the courts more leeway to monitor agency actions in implementing …new regulatory programs."

[4] See, APA Section 553, 5 U.S.C. § 553(c):

> [T]he agency [in informal rulemaking] shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments …

to respond to the substantive Objections to the 2004 Regulation, made a farce of this legal requirement. Finally, EPA's failure to respond to Objectors's substantive Objections to the 2004 Regulation not only substantially restricted Objectors's effort to "participate" in the rulemaking process, but it also constituted "agency action unlawfully withheld or unreasonably delayed" in violation of APA Section 706(1).[5]

A. The NRC Report Undercuts Basic Assumptions Offered By EPA in Support of its Risk Assessment;

EPA's decision not to wait for the NRC Report is best criticized by the contents of that report itself. In the report, the NRC soundly rejects many of the fundamental assumptions underlying EPA's current reference dose. For example:

- **The NRC concluded that severe dental fluorosis <u>is</u> an adverse health effect**. EPA's health risk assessment wrongly assumed that severe dental fluorosis is not an adverse health effect. See Objections 2005c, Issue 3.
- **The NRC concluded that fluoride can cause adverse effects to the skeletal system (e.g. bone fracture & arthritic pain) <u>before</u> it causes crippling skeletal fluorosis**. EPA's health risk assessment wrongly assumed that crippling skeletal fluorosis is the first, and <u>only</u>, adverse effect that can result from chronic exposure to fluoride. See Objections 2005c, Issue 11.
- **The NRC concluded that fluoride "is an endocrine disrupter."** Dow's petition, as well as EPA's health risk assessment, was wrongly based on the assumption that fluoride is not an endocrine disrupter. See Objections 2002, 2004, 2005a, 2005c at Issue 15; Comments 2001, 2004, 2005.

Based on these findings, the NRC has concluded that the 4 ppm MCLG is an unsafe standard and "should be lowered", due to the risk it presents for severe dental fluorosis, bone fracture, and stage II skeletal fluorosis. Such a conclusion by the NRC – the highest scientific authority in the country – invalidates EPA's risk assessment for sulfuryl fluoride, since the 4 ppm MCLG was the sole basis for EPA's reference dose. Thus, EPA's tolerances would not be "safe," because they are not based on a determination of

[5] 5 U.S.C. § 706(1). See also, APA Section 555(b) , 5 U.S.C. §555(b), providing that "within a reasonable time, each agency shall proceed to conclude a matter presented to it."

"reasonable certainty that no harm will result" from "aggregate exposure" to fluoride as required by the FFDCA.

When tolerances were first issued in January 2004, Objectors stated in their submission of March 2004 that it "was unwise and undefendable" to do so before the NRC Report was released. In two submissions to EPA in 2005, Objectors again stressed this issue. See Objections 2004, 2005a,c. Also, in five of Objectors' submissions to EPA, detailed argumentation was presented on the inappropriateness of using the Office of Water Maximum Contaminant Level Goal (MCLG) of 4 ppm fluoride in drinking water as the basis of its risk assessment for sulfuryl fluoride. Objections 2002, 2004, 2005a,c; Comments 2002. Hence, EPA was fully informed of these issues frequently and continually over past years.

B. The NRC has Identified Numerous Potential Risks and Uncertainties that Undermine EPA's Assertion of "Reasonable Certainty"

Under the FQPA, EPA needs to have "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." As the Objectors have pointed out, EPA has failed to meet this burden with respect to the potential harm that may result from aggregate exposures to fluoride. The Objectors' contention on this matter has been strongly reinforced by the NRC. The NRC Report has described in detail many areas where studies indicate there is legitimate basis for concern about fluoride toxicity, but where there is uncertainty about a precise safe dose for human exposure. For pesticide residues, where adverse effects are identified and confirmed in repeated studies, it is standard practice for the EPA to employ safety factors to account for any remaining uncertainties regarding the human health risks that will arise from the actual exposures

that people encounter. Notably, the EPA has not applied a single safety margin for even one of the following endpoints identified by the NRC:

-Fluoride's Interactive and Synergistic Effects with Other Chemicals

> Fluoride's toxicity can be greatly enhanced by interactions with other chemicals, such as aluminum and iodine. NRC Report at 218, 222. See Objections 2005c at Issue 19, p. 33.

-Fluoride and the Brain

> Fluoride can interfere with the functions of the brain and may, in turn, affect IQ and learning, create other deficits, and contribute to dementia, although more research is needed to clarify the effects and the doses that may cause them. NRC Report at 6, 186-87. See also, Objections 2002, 2004 at Appendix H, 2005a, and 2005c at Issue 12; Comments 2001, 2002.

-Fluoride and Diabetes

> The weight of current scientific evidence indicates that fluoride can worsen diabetic conditions. NRC Report at 217. See Objections 2005c at Issue 14.

-Fluoride and Endocrine Effects

> Fluoride is an endocrine disrupter, and may cause effects on the endocrine system at levels below 4 ppm. This contradicts the position taken by Dow. The EPA stated that it would wait until the NRC made a determination on whether fluoride was an endocrine disruptor. EPA 2004 HRA, p 18; EPA HRA, 2006. P 20. See also, Objections 2005a,c; Comments at 2001, 2002, 2005.

-Fluoride and the Thyroid Gland

> Fluoride can affect thyroid function, and these effects can occur at notably low levels (0.01-0.03 mg/kg/day) among people with iodine deficiency. Twelve percent of Americans (about 36 million people) are believed to suffer iodine deficiency. NRC Report at 197, 218, 222. See Objections 2005c, Issue 19.

-Fluoride and the Pineal Gland

> Studies on animals and humans suggest that fluoride may interfere with the functioning of the pineal gland, altering melatonin production and the

timing of sexual maturity. These effects are biologically plausible due to the high concentrations of fluoride that can accumulate in the pineal. NRC Report at 221-22. See also, Objections 2002, 2004, 2005a,c; Comments 2001, 2002, 2005.

-Fluoride and the Immune System

High fluoride concentrations in drinking water can accumulate in and around bone marrow, where immune cells develop, and could adversely affect the immune system. But more research needs to be conducted. NRC Report at 249-50.

-Fluoride and Cancer

Fluoride appears to have the potential to initiate or promote cancers, particularly of the bone, but the evidence to date is tentative and mixed. NRC Report at 275, 286, 288. See also, Objections 2004 in Appendix D at Issue 10, 2005a at Issue 9.7, and 2005c at Issue 20, Comments 2001, 2002. Subsequent to the NRC review, a new study has been published which adds additional support to a link between fluoride and cancer during specific ages of exposure. (Bassin 2006)

-Fluoride and Gastrointestinal Effects

Fluoride may cause adverse gastrointestinal effects in 1% of people consuming 4 ppm fluoride, but additional research needs to be conducted. NRC Report at 230-1, 250, 258.

- Fluoride and Kidney –

"On the basis of studies carried out on people living in regions where there is endemic fluorosis, ingestion of fluoride at 12 mg per day would increase the risk for some people to develop adverse renal effects…" NRC Report at 247. See Objections 2005c at Issue 13.

-Fluoride and the Liver

Lifetime ingestion of certain quantities of fluoride from drinking water might have long-terms effects on the liver, but more research is necessary. NRC Report at 248.

-Fluoride and Reproduction

A few human studies suggest that high concentrations of fluoride exposure might be associated with alterations in reproductive hormones, effects on

> fertility and developmental outcomes, but design limitations made those studies insufficient for risk evaluation. NRC Report at 6, 161. See also, Objections at 2004 at Appendix G, 2005a at Issue 9.3.1, and 2005c at Issue 16.

In light of these many serious uncertainties identified by NRC, uncertainties based not on frivolous speculation but on actual research that fairly and reliably documents the uncertainty, it is presumptuous and without merit for EPA to claim it has "reasonable certainty" that no harm will occur from aggregate exposures to fluoride. Moreover, because of the seriousness of the risks identified by NRC (e.g. aggravation of diabetic conditions, neurotoxicity, and thyroid toxicity; bone fracture, endocrine disruption, cancer, etc), it is imperative that EPA employ safety/uncertainty factors to ensure that the risk of the respective effects will not be increased due to exposure to fluoride in-utero, during infancy or childhood and that these effects will not occur disproportionately in infants, children, other vulnerable subgroups or in the general population. Until such time as EPA does this, its risk assessment and tolerances can not be accepted as either valid or safe.

EPA wisely sought the views of one of the most respected and authoritative bodies of scientific experts in the world but then unwisely proceeded without the benefit of those views by acting before publication of the NRC Report. Clearly, any single one of the NRC's views identified in this discussion, standing alone, is sufficient to undermine the validity of EPA's risk analysis for fluoride and thus of the tolerances. Accordingly, any review of the agency's risk analysis would find serious fault with the failure to consider the NRC Report, and, correspondingly, any such review would likely rely heavily on that same report in assessing EPA's compliance with the FFDCA. For

this reason, EPA has failed to adhere to the "reasonable certainty" standard of the FFDCA and therefore Objectors are likely to succeed on the merits of their Objections. A stay of the tolerances's effectiveness is thus required because the requirements of applicable law have not been met.

C. People are Already Exceeding EPA's Current Reference Dose; There is No Safe Room for Additional Exposures

As the Objectors have previously detailed, and as the NRC Report makes clear, many Americans (including diabetics and others who drink a lot of water) are already exceeding EPA's current reference dose (0.114 mg/kg/day), even without the addition of sulfuryl fluoride to food. See Objections 2005c at Issue 2a. EPA obscured this fact, in its various risk assessments, by (1) using an incorrect estimate of the average fluoride content in U.S. water supplies, by (2) failing to consider people who drink more than the average amount of water, and by (3) failing to consider the nearly 2 million Americans (EPA 2003b; Table C.33.m) living in areas with greater than 2ppm fluoride in water.

Consistent with Objectors's arguments, the NRC Report shows that high-end water consumers (e.g. diabetics) can exceed EPA's current reference dose by drinking water with as little as 1 ppm fluoride. NRC Report, tables 2-14 & 2-13. Because EPA is required to protect sensitive subgroups of consumers, and because the NRC report has clearly shown that sensitive subgroups (e.g. diabetics) are already exceeding the reference dose, it is readily apparent that there is no safe room for additional fluoride exposures in food as would result from approval of these tolerances. Thus, EPA's actions were in violation of law.

The NRC Report's important conclusions and recommendations vindicate positions long held by Objectors, positions Objectors have repeatedly urged EPA to take

seriously. In submissions to the EPA on sulfuryl fluoride in September 2001 and in March and April 2002, Objectors provided EPA extensive documentation that certain subsets of the population were already receiving too much fluoride and that no more fluoride exposures could be safely tolerated. This has now been substantiated by the NRC Report. See Objections at 2002, 2004 at Issue 1.3, 2005a, 2005b, 2005c at Issue 3; Comments 2001, 2002. Accordingly, Objectors are confident that when EPA is compelled to consider the NRC Report in the context of an adjudicatory hearing, the agency will arrive at the same conclusions as did Objectors.

D. The Challenged Tolerances Violate the Food Quality Protection Act by Not Protecting Children and Infants from Adverse Health Effects.

In setting its reference dose for children, EPA has violated the basic tenets of the FFDCA, as amended by the Food Quality Protection Act (FQPA). Rather than issue a more protective reference dose for infants and children, the EPA has set a reference dose for children that is up to 10 times higher than the respective dose for adults. Notably, many of the important potential risks identified by the NRC particularly concern children (e.g., IQ deficits, dental fluorosis, altered pineal function, and cancer during developmental periods). A recently published study from Harvard University further underscores this point. (Bassin et al. 2006)[6]

By making several non-conservative, non-protective, assumptions[7], EPA has issued a reference dose that it readily acknowledges can cause severe dental fluorosis in

[6] Even skeletal fluorosis has been shown to occur in children and can be made more likely in adults from excessive exposure as a child. See Objections 2005c at Issues 4-6.

[7] In setting its reference dose, EPA used an adult consumption and body weight to determine a safety standard for children (in contradiction of EPA's own SMCL drinking water standard). The EPA then used an adult intake as opposed to a childhood intake (2 L/day versus 1 L/day, respectively) to derive a safe dose, 8 mg/day for a 70 kg adult. The EPA then used this 8 mg/day for children even though the average infant is 10 times smaller than an adult.

children. EPA 1985; EPA 2006, p.4. As noted previously by the Objectors, EPA failed to show with reasonable certainty that severe dental fluorosis is not an adverse health effect. See Objections 2005c at Issue 3. According to the National Research Council, severe dental fluorosis is indeed an adverse health effect – as Objectors have always contended. It is imperative, therefore, that EPA revise its reference dose for children in order to prevent this condition from occurring.

Based on EPA's own data (EPA, 2006, Appendix 2), it is apparent that the establishment of a reference dose that protects children from getting severe dental fluorosis would, in turn, undermine EPA's approval of the tolerances. According to EPA's Final Health Risk Assessment (EPA, 2006, Appendix 2), the introduction of sulfuryl fluoride into the US food supply will result in 6-12 year old children exceeding EPA's reference dose (2 mg/day) for severe dental fluorosis. Moreover, if EPA were to correct its current underestimation of childhood fluoride exposure from toothpaste ingestion, it would become clear that many 2-5 year old children will also exceed the 2mg/day reference dose following the introduction of the tolerances. See Objections 2005c at Issue 2b. Thus, EPA's essential duty to protect the public's health – in this case, preventing the adverse health effect of severe dental fluorosis –necessitates the immediate termination of the tolerances. In failing to take into account the special vulnerabilities of infants and children, as expressly required in FFDCA Section 408(b)(2)(C), EPA has acted in violation of law and thus there is a substantial likelihood that Objectors will succeed on the merits of this matter.

E. EPA Has Failed to Protect the Health of Susceptible Populations

As discussed above, EPA did not take into account the unique susceptibilities of certain subgroups of the population– including children and high-end water consumers - when issuing its tolerances. Other identifiable at-risk populations that EPA has failed to protect include: people with kidney disease (See Objections 2005c at Issue 8); people with nutritional deficiencies (See Objections 2005c at Issues 10 & 19); people exposed to sources of fluoride not identified by EPA (e.g. fluorinated pharmaceuticals that metabolize into fluoride anion (See Objections 2005c at Issue 24) and people who regularly consume above-average amounts of foods that will now be fumigated with sulfuryl fluoride (See Section H below). By failing to account for the special vulnerabilities of these consumers, EPA has abandoned its responsibility to protect susceptible subpopulations of the general population. For example:

- The NRC has identified children as a major susceptible subpopulation at increased risk from fluoride (NRC Report at 298), however EPA's reference dose for children is less protective than it is for adults.
- The EPA has conceded that 4 ppm fluoride in water may not adequately protect people with advanced kidney disease from suffering adverse effects (EPA 1985, p. 47152), a concession that is supported by substantial scientific evidence but was ignored by the agency in the final decision to issue tolerances for sulfuryl fluoride. See Objections 2005c at Issue 8.
- The NRC identified iodine deficiency as a major risk factor for fluoride toxicity and observed that the increasing population of iodine deficient individuals in the US (approximately 12% of the population) could be harmed

by fluoride levels lower than those that may harm a healthy individual. EPA has yet to even consider this possibility.

The foregoing demonstrates that EPA failed to conform its evaluation and decisions with the requirements of FFDCA Section 408(b)(2)(C), requiring that particular care be paid to infants and children in the establishment of tolerances and the requirement that tolerances ensure a reasonable certainty of no harm to exposed individuals. Therefore, the agency has acted in violation of law and thus Objectors are likely to succeed on the merits in an adjudicatory hearing on this matter.

F. EPA Failed to Make a Meaningful Evaluation of Adverse Acute Effects Other than Death in Its Risk Assessment

EPA lists sub-lethal acute health effects from fluoride such as vomiting in its risk assessment, citing first those dosages associated with death and then extrapolating back to a so-called "safely tolerated dose" of 8 to 16 mg/kg. But as the Objectors have pointed out, these doses are greater than the doses documented to cause symptoms of acute fluoride toxicity (e.g. gastrointestinal pain, vomiting, etc) and even *death* in some people. See Objections 2005c at Issue 26. Failure by EPA to evaluate fully and carefully the available studies and data in this area constitutes a failure to observe the standards set by the FFDCA and hence a violation of law.

Furthermore, objectors have pointed out that dried eggs fumigated at EPA's allowed tolerance level of 900 ppm, could easily result in doses exceeding 0.1-0.3 mg/kg and could thereby produce acute fluoride toxicity in both children and adults. See Objections 2005c at Issue 26.

It remains unclear whether EPA has actually implemented any action that will legally prohibit either the use of sulfuryl fluoride on eggs or the contamination of eggs

with residues of sulfuryl fluoride. Nothing short of cancellation or deletion of the use from all of the registrations and the revocation of the tolerance will be adequate to legally bar use and residues in food. Until these steps are taken, it impossible to exclude these risks from the assessment of risk and consideration in connection with this Motion. Thus, the population remains at risk of acute fluoride toxicity from consumption of dried eggs fumigated with sulfuryl fluoride. The fact that this risk remains renders EPA's risk assessment inadequate and contrary to law.

The high tolerances for dried eggs are not the only tolerances which could lead to acute toxic exposures. Wheat is a staple of most diets and EPA has granted wheat flour the second highest tolerance of any food item of 125 ppm. For example, roughly four slices of bread (about 100 g wheat) would contain 12 mg of fluoride if fumigated at the allowable tolerance. For a 25 kg child this would be 0.5 mg/kg-bodyweight, which exceeds the minimum acute dosage. Adults could also exceed an acute toxic dose when eating large servings of wheat-based foods which have been fumigated at the legal limit.

Based on the foregoing discussion, EPA has acted in violation of the FFDCA and thus Objectors are likely to succeed on the merits in this matter at an adjudicatory hearing.

G. EPA's Waiver of the Developmental Neurotoxicity (DNT) Studies Compromised the Integrity of the Tolerances

EPA acted in a confusing and inconsistent manner by stating a need for a DNT study in the July 2005 final rule, when, in fact, it had waived the DNT study condition in April 2004 (Dellarco et al.). This is what EPA stated in the final rule 15 months after it waived the condition for a DNT study:

> [T]he 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… It is considered possible that the results of the DNT study could impact the endpoint selection for risk assessments…" (EPA, 2005) (Emphasis added)

It was not until February 2006 that the Objectors received confirmation from Jonathan Fleuchaus, EPA's Legal Counsel, that the DNT study condition was waived on April 22, 2004. In January 2006, Dan Kenny, EPA's team leader on sulfuryl fluoride, told one of the Objectors (Ellen Connett) that EPA had not waived the DNT study, when in fact it had been waived in 2004. EPA stated the need for a DNT study on at least seven occasions. (US EPA 2001, 2002, 2003a, 2004, 2004a, 2005a,b).

In justifying its approval of Dow's request for the waiver, EPA stated:

> Dow indicated in their waiver justification that they recently conducted a rat metabolism study that showed sulfuryl fluoride is rapidly released to fluoride. Thus, given the known toxicology of fluoride coupled with the minimal inhalation exposure to humans, neurotoxicity to the adult or developmental neurotoxicity would be highly unlikely. (Dellarco et al.)

However, a rat metabolism study published by Dow scientists in 2005 (Mendrala et al.). does not definitively identify fluoride as the source of sulfuryl fluoride's toxic effects.[8] Acccording to Dow, "toxicity elicited by SO2F2 may be due to the release of fluoride ions, rather than a direct toxic action of SO2F2." The Dow authors stated their

[8] The blood fluoride data presented in Dow's metabolism study is almost certainly incorrect. Objectors note that the blood fluoride anion levels in the control rats of Dow's metabolism study (0.44-1.33 ppm) are up to 150 times greater than the blood fluoride levels in the control rats (0.009-0.013 ppm) of well controlled animal studies on fluoride toxicity (Dunipace 1995; Turner 1996), and up to 8.5 times greater than the blood fluoride levels (0.156 ppm) of the high-dose (79 ppm) rates in NTP"s 1990 cancer bioassay (NTP 1990, table i5). Earlier rat studies by Dow (see Cal EPA, table 5) are similarly flawed, with average blood fluoride levels as high as 0.607 in the control females and 0.996 ppm in the control males. (Curiously, the exposed rats in the mid-dose groups had lower blood fluoride levels than the controls. (See: Cal EPA, table 5.) There are other anomalies in Dow's animal studies, including elevated urinary and kidney fluoride levels in the control rats of the metabolism study. Taken together these unexplained anomalies raise serious questions about the methods used, and results obtained, in Dow's animal research.

latest finding supports Nitschke et al. (1986) that "the likely cause of SO2F2 toxicity is the metabolic release of fluoride ions." (Emphasis added)

The serious issue of what exactly causes sulfuryl fluoride's toxic effects is not resolved. Moreover, the fact that sulfuryl fluoride may rapidly metabolize into fluoride anion does not diminish the need for a DNT study. Indeed, as detailed by the NRC, the weight of scientific evidence supports the conclusion that fluoride – in and of itself - is a neurotoxin. According to NRC:

> On the basis of information largely derived from histological, chemical, and molecular studies, it is apparent that fluorides have the ability to interfere with the functions of the brain and the body by direct and indirect means. (NRC, p. 187)

Because of the evidence linking fluoride to neurotoxic effects, the NRC specifically has recommended more animal and human studies "to clarify fluoride's biochemical effects on the brain." NRC Report at 186. EPA's claim, therefore, that sulfuryl fluoride's quick release into fluoride ion relieves the need of having a proper DNT study is directly contradicted by the findings and recommendations of the NRC.

Other justifications cited by EPA for granting the waiver are similarly flawed. According to EPA (Dellarco et al.) the waiver was justified because the tolerances would result in "essentially no chronic dietary exposure." Objectors note, however, that since this waiver was granted, EPA has approved a new set of broad-reaching tolerances that have greatly increased the expected exposure to fluoride anion. When EPA issued the waiver, it estimated that the tolerances would result in an average fluoride exposure of 0.028 mg/day. (EPA 2004b) EPA now estimates, however, that the tolerances will result in a daily exposure of 0.667 mg, a 24-fold increase since the waiver and enough fluoride

to make sulfuryl fluoride the second largest source of fluoride anion in the U.S. (EPA 2006) Thus, it is not valid for EPA to say that the tolerances will result in "essentially no chronic dietary exposure."

Another reason that Dow requested EPA to waive the DNT study, was the "potentially confounded scientific and technical aspects of conducting an inhalation DNT." (Dellarco et al.) This concern is not applicable, however, to an oral DNT study with fluoride anion. An oral DNT study is critical because the tolerances are expected to become the second largest source of fluoride exposure in the US and because the majority of these residues will be ingested, not inhaled.

Thus, the need for an oral DNT study for fluoride is further underscored by the following facts:

1) sulfuryl fluoride breaks down to the fluoride anion in foods and the human body;

2) the vast majority of the fluoride residues will be ingested, not inhaled;

3) the NRC has concluded that fluoride can damage the brain and that more research is necessary to clarify its effects;

4) fluoride has been found to damage the brain of rats at levels as low as 1 ppm (Varner 1998);

5) the brain has been a target organ for rare and severe toxic effects in Dow's sulfuryl fluoride animal inhalation studies, but "the long-term and functional consequence of such damage has not been studied …" See Cal EPA at 54-55.

6) an oral DNT study on fluoride has never been conducted; and

7) only adult brains were examined in the critical rat and rabbit developmental toxicity studies and the 2-generation rat reproductive

toxicity study. Fetal and pup brains were not examined histologically in these studies. See CA EPA at 95.

In summary, the exact mechanisms causing toxic effects from sulfuryl fluoride are unknown, and it is also unknown why severe and rare liquefactive necrosis (dissolution of brain tissue and cells into an unstructured, mushy substance) and vacuolation (formation of holes within or between brain cells) occurs in the brains of experiment animals. Since the NRC has concluded that fluoride can damage the brain, and since sulfuryl fluoride appears to rapidly metabolize into fluoride ion, it is imperative that an oral DNT study be conducted on fluoride before the tolerances are approved. EPA's action in waiving the DNT study was based on faulty reasoning and flawed science. As a result it was not protective of the public's health. See Objections 2005a,b,c & California EPA 2005. For these reasons, EPA has acted in violation of the FFDCA and Objectors are likely to succeed on the merits in this matter at an adjudicatory hearing.

H. Significant Uncertainties/Limitations Remain with EPA' Estimate of Fluoride Exposure from Tolerances

As identified by the Objectors (See Objections 2005c at Issues 34-48), EPA's estimates of the fluoride exposure that will result from the tolerances is significantly hampered by a multitude of uncertainties and limitations in the data. For example:

- In estimating the fluoride exposure that will result from the tolerances, EPA only considered the average consumption of food for fumigated commodities. By only considering average consumption patterns for a food item, EPA's exposure estimates have failed to take into account, and protect, individuals who consume larger amounts of particular food items. According to the FDA, there is usually a four-fold difference in consumption between the average consumer (50th percentile) and the 95th percentile consumer for any given food

product. This difference is likely to be considerably greater if the 99th and 99.9th percentile consumers are considered. See Objections 2005c at Issues 40 & 43.

- EPA has granted tolerances for an indefinitely large number of food items under the catch-all heading "processed foods." Only a small fraction of current "processed foods", however, have had any actual residue tests conducted on them. Considering that the composition of each food item (e.g.its protein and fat content) is a major determining factor for how much fluoride it will retain, the absence of any test data on most processed foods raises the distinct possibility that – as with dried eggs - some processed foods may concentrate fluoride to higher than expected levels. Also, the DEEM computer model used by EPA to assess exposure from food does not allow for estimation of exposure from "processed foods." Only residues in raw agricultural commodities may be used in DEEM. EPA has still not supplied Objectors with the full supporting documentation for the Final Health Risk Assessment, so it is impossible to determine whether EPA even included "processed foods" in their exposure assessment. Failure to include this wide range of foods or improper methods of estimation could lead to significant underestimation of exposures. See Objections 2005c at 43.
- While EPA is no longer permitting the direct fumigation of either dried eggs or edible oils, it still allows both items to be "incidentally" fumigated. EPA's use of the term "incidental" raises more questions, however, than it answers. Most notably, EPA has failed to quantifiably define how often such food items can or will be fumigated, and what, if any, monitoring structure will be in place to ensure compliance with EPA's vague "incidental use" policy.
- While permitting the "incidental" treatment of both dried eggs and edible oils, EPA has excluded both products from its most recent dietary exposure and risk estimates. EPA defended this decision on

the basis that it expects neither product to be fumigated regularly. Such a decision, however, was non-protective in light of the agency's failure to define its use of the term "incidental", and its failure to describe the mechanisms in place to ensure that only "incidental" treatment occurs. EPA hasn't informed the public of the alternative fumigation chemicals that will be used to fumigate dried eggs.

- EPA has repeatedly stated (EPA 2004b, 2005b, 2006) that the testing methods used by Dow to measure the fluoride residues on fumigated foods may underestimate the level of total fluoride compounds present. The fact that all residue data has been collected using methods that may have underestimated the true fluoride content undermines EPA's ability to predict the true extent of fluoride exposure from the tolerances. See Objections 2005c at Issue 47.
- In its January 2006 Health Risk Assessment, EPA "appears" to have approved a new tolerance for "Animal Feed," that was not included in the July 2005 final rule. EPA states that the "Animal Feed" tolerance will be covered under "All processed food commodities not otherwise listed." EPA approved the "Animal Feed" tolerance without any discussion or clarification on the extent to which this will increase human exposure to fluoride. Because animals readily accumulate fluoride in their bone, and because particles from animal bone readily enter certain meat products (e.g. mechanically deboned meat), it can be expected that the new feed tolerances will result in increased fluoride exposure among humans. EPA's failure to take this secondary route of exposure into account has impaired EPA's ability to fully assess the impact of the tolerances. See Objections 2005c at Issue 46.
- When the actual data upon which EPA's tolerances were determined is examined, it can be seen that it is insufficient to assure that the limited data will adequately reflect real world fumigation practices and residues. For example, for the critical commodity wheat flour, the range of fluoride residues found was 15 ppm to 82 ppm and most of

this data was not from fumigation at the approved application rate. All of this data, meanwhile, was from a single flour mill facility, so there is no way to know how residues will vary under the unique fumigation conditions found at each facility. Fumigation is a complicated process involving many variables of temperature, ventilation rates, building leakage rates, fumigant injection sites, outside wind, shielding foods from exposure, etc. To base tolerances on data from only a single site is presumptuous. Indeed, even within this single facility the HRA reports there was "a fairly high degree of variability across treatment replicates" [EPA HRA Oct. 2004 p 13]. The HRA goes on to state there was even more variability due to the properties of the food commodities themselves. See Objections 2005c at Issue 45.

- There is a serious lack of understanding of the transfer of sulfuryl fluoride to the contents of fumigated packaged food products. In its 2006 Health Risk Assessment, EPA stated:

> "For a number of finished products; the residues of sulfuryl fluoride in the packaged configuration were greater than in the open configuration. In all such cases, the packaging contained a polymer film, either as a bag liner or as lined paper. The phenomena were not mirrored in the fluoride residue levels. HED does not have a satisfactory theory to explain these observations at this time. Method performance leaves a high degree of uncertainty surrounding residues of sulfuryl fluoride in Oreo ® cookies, powdered eggs, and baking soda; and for residues of fluoride in white cake mix, pet foods, parsley, and baking powder" (page 22)

- EPA has offered no clarification or discussion on how the consumer will be exposed to "sufuryl fluoride" tolerances, as compared to the "fluoride" tolerances. For example, no

> information has been provided on whether any of the fumigated foods will result in inhalation exposure to sulfuryl fluoride.

The totality of the above-mentioned uncertainties and limitations have handicapped EPA's ability to estimate the full range of fluoride exposures that will result from the tolerances. These substantial uncertainties and limitations, therefore, rendered EPA incapable of determining that there was a "reasonable certainty that no harm will result" from aggregate exposures in setting the tolerances, as mandated by the FFDCA. Therefore, EPA acted illegally and thus Objectors are likely to succeed on the merits in an adjudicatory hearing in this matter.

I. EPA's Procedural Errors Have Rendered the Entire Process Flawed And in Flagrant Violation of the Requirements of the Administrative Procedure Act

FFDCA Section 408(g)(2)(c) provides that in a hearing on objections to tolerances, the final decision should be based on "substantial evidence of record." Administrative Procedure Act (APA) Section 706(2)(E), 5 U.S.C. § 706(2)(E), provides guidance as to this strict standard and the statute provides in general for the fair conduct of federal administrative agency proceedings. EPA's conduct throughout the entire process of establishing the tolerances at issue has been in flagrant violation of the requirements of the APA.

In reviewing agency informal rulemaking under the substantial evidence test:

> [A court's] paramount objective is to see whether the agency, given an essentially legislative task to perform, has carried it out in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future.

Industrial Union Department v. Hodgson, 499 F.2d 467, 475 (D.C. Cir. 1974), *citing Automotive Parts & Accessories Ass'n v. Boyd,* 407 F.2d 330.336 (1968). In this matter, rather than "negate the dangers of arbitrariness and irrationality" in the rulemaking process, EPA, to the contrary, has effectively courted those very dangers. Further, the agency's actions become particularly acute given the demanding standard of the substantial evidence test and the dangers to public health posed. See, JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 347 (3rd ed. ABA 1998) (use of the more demanding "substantial "evidence" standard in "hybrid" informal rulemaking instead of the usual "arbitrary and capricious" standard reflects Congress's "view that the more stringent test afforded the courts more leeway to monitor agency actions in implementing …new regulatory programs.") Thus, in this case, EPA has clearly acted in violation of the substantial evidence test, as required in both the FFDCA and the APA.

An additional and pertinent APA requirement is the one in Section 553 (c) that in informal agency rulemaking agencies "shall give interested persons an opportunity to participate in the rulemaking." 5 U.S.C. § 553(c) As described throughout this Motion, and as particularly set forth in this section, EPA's actions failed to afford this opportunity to Objectors in a meaningful way. Courts have found that such participation can be particularly important in their review of "pre-enforcement, complex, scientifically based agency rules." LUBBERS, supra, at 197. In *Portland Cement Ass'n v. Ruckelshaus,* 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974), the D.C. Circuit reviewed EPA rulemaking under the Clear Air Act wherein EPA relied on test results that had not been made available for public comment. The court held as follows:

> [There was a] critical defect in the decision-making process in arriving at the standard … in the initial inability of petitioners to obtain—in timely fashion—the test results and procedures used …[in determining the standard]. … It is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data or on data that, [in] critical degree, is known only to the agency.

Id. at 393. See also, *United States v. Nova Scotia Food Products Corp.,* 568 F.2d 240, 252 (2d Cir. 1977) (emphasizing the importance of full disclosure by the Food and Drug Administration of scientific research being relied on in order to generate meaningful public comment). Thus, the case law supports Objectors's contention that EPA has failed to provide a meaningful opportunity for participation as required by the APA.

Closely related to the citizen participation requirement is the requirement that there be a proper and complete "record" in rulemaking proceedings. See, APA Section 553(c), 5 U.S.C. § 553(c). An adequate record in the proceedings promotes not only public participation but also effectiveness in the rulemaking process and proper judicial review. See, LUBBERS, supra, at 214-24. The caselaw strongly supports the need for such a record even where a court may have ruled against some petitioners on the narrow facts of the particular case. See, *National Coalition Against the Misuse of Pesticides v. Thomas,* 809 F.2d 875, 884 n.10 (D.C. Cir. 1987) (petitioners were found to have had adequate opportunity to comment, but the court observed that "clearly supplied information [is] critical to informed comment on EPA's proposal to reestablish the 30 [ppb] tolerance, and, for that matter, to review by the court").

In this matter, as described throughout this Motion and in this section in particular, EPA has repeatedly failed to include complete, timely information. This has greatly harmed the prospects for a fair and informed proceeding leading to tolerances that

comport with the requirements of the FFDCA and the APA. See Objections 2005c (Letter to James J. Jones), and 2005b.

Under APA Section 706(1), a reviewing court may "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1) In this matter, Objectors first submitted their Objections and Request for a Hearing in April 2002 on EPA's tolerances. These objections were deemed "moot" by EPA in its final rule of January 2004. EPA's explanation for this was "[b]ecause the tolerances that were objected to have now been revoked, the objections are moot and are denied on that ground." EPA offered this rationale at the exact time it issued its first-time tolerances for fluoride and sulfuryl fluoride on January 23, 2004. Thus, at the most critical juncture in setting tolerances, Objectors were locked out. EPA has since failed to respond to the substantive Objections to the January 23, 2004 Final Rule. Here, even given the reasonable discretion accorded to agencies in this area, such a failure to act cannot be deemed acceptable under the APA. In *Public Citizen Health Research Group v. Food and Drug Administration,* 740 F.2d 21, 34 (D.C. Cir. 1984), the D.C. Circuit remanded the case to the district for a determination whether FDA had "unreasonably delayed" resolution of a challenge to health warnings on aspirin bottles. Noting particularly the underlying statute's concern for health and safety, the court observed that "[i] f the district court finds unreasonable delay, it must fashion an appropriate remedy." *Id.* at 35 The court stated further:

> In deciding whether the pace of decision is unreasonably delayed, the court should consider the nature and extent of the interests prejudiced by delay, the agency justification for the pace of decision, and the context of the statutory scheme out of which the dispute arises. *Id.*

Based on the egregious nature of EPA's refusal, and considering the factors set out by the D.C. Circuit, EPA is in violation of APA Section 706(1).

The following discussion sets forth EPA's failure to accord procedural fairness to Objectors in this matter.

First, EPA erred in attempting to unlawfully supplement the admittedly inadequate record of the tolerances after the tolerances had been promulgated. Both the June 2005 and January 2006 Health Risk Assessments (HRA) were not available to the public and were sent to the Objectors in February 2006, long after the tolerances were promulgated on July 15, 2005. As set forth above, the APA requires that the full record of any rulemaking be made available to the public prior to promulgation of the rule. The courts have repeatedly struck down rules which violate this requirement. This procedural error had the effect of impairing the ability of the general public and petitioners in particular to meaningfully comment on the rule. In addition, it also greatly delayed the process of challenging the rule by means of objections. The delay of the objections process caused by the failure of the Agency to timely docket support for the tolerances has subjected the public to an unnecessary additional period of risk that can only be redressed by means of a stay of the tolerances.

Second, the EPA committed a fatal procedural error when it promulgated the rule without waiting to finalize the HRA and to await the report of the NRC. In both instances it was well aware when it issued the rules that it had not completed the HRA, and that, despite having requested the NRC review, it had not received the report. It knew that both reports were essential to a complete understanding of the risks of the

proposed tolerances. Yet, it provides no explanation for its failure to await both of these crucial documents.

The Agency's behavior is particularly difficult to fathom in light of the fact that it requested the NRC report because it recognized that important new research was available. Indeed, at the first public meeting of the NRC in August 2003, an EPA official told the Objectors (Ellen and Paul Connett) that the EPA would not issue tolerances until the NRC issued its report. When tolerances were first issued in January 2004, the Objectors stated in their submission of March 2004 that it "was unwise and undefendable" to do so before the NRC Report. See Objections 2004. Accordingly, the Agency failed to act based on "substantial evidence on the record" when it decided not to await crucial information and analyses before promulgating the tolerances and provided no justification in the record or the tolerance documents for its haste.

Third, EPA did not put the overwhelming majority of documents that it relied on and cited in its decision making process, into the docket for the public to access. For example, the April 2004 waiver of the DNT study, all animal studies, as well as many other documents pertaining to sulfuryl fluoride fumigation issues, were not placed into the docket as of March 8, 2006. On March 13, 2006, the Objectors requested from EPA numerous documents, which, aside from a few, it has yet to receive. FFDCA Section 408(d)(2)(A)(iv) requires applicants to provide "full reports of tests and investigations made with respect to the safety of the pesticide chemical..." with their petition for a tolerance. Subsection (v) imposes the same requirement for residues in food. The agency is then compelled to consider these documents by 408(d)(4)(A): "The Administrator shall, after giving due consideration to a petition... and any other information available to

the administrator...". Since these documents are mandatory components of the basis for the rule, they must in accordance with the APA, be included in the docket for comment.

Objectors assert that these failures by EPA are fundamental to procedural fairness and therefore constitute a gross violation of the APA. Thus, for the reasons discussed in this section, Objectors are likely to succeed on the merits of this matter.

IV. Without a Stay of its Effectiveness, the Regulation Poses a Threat of Irreparable Harm to the Populations and Interests Represented by Objectors,

Objectors assert that without a stay of its effectiveness, the Regulations pose a threat of irreparable harm to the general public, particularly certain subpopulations. In the previous section of this motion, Objectors laid out in considerable detail why they would be likely to prevail on the merits. At the heart of the discussion were the grave health effects posed by the approval of fluoride pesticide residue tolerances by EPA in a manner that failed to ascertain that the tolerances carried a "reasonable certainty that no harm will result" from their issuance and that particular attention is paid to infants and children and certain other subpopulations.

To allow the Regulations to be effective would be to intensify the threat of high levels of fluoride from pesticides that in many instances were already a threat at previous tolerance levels. The previous section also emphasized the importance of a thorough, in-depth risk assessment performed by EPA relying upon the new findings and recommendations of the authoritative studies such as the NRC Report. Indeed, the failure of EPA to comply with the strict standard of the FFDCA, a law dedicated to the protection of public health, is precisely the reason that there is a threat of irreparable harm to the public's health.

V. No Other Parties Interested in the Proceedings will be Substantially Harmed in a Manner Protected Under the FFDCA by the Issuance of a Stay.

Granting a stay would not substantially harm any interested parties in a manner protected by the FFDCA. Even the petitioner for rulemaking Dow AgroSciences and other industry would not be substantially harmed in view of the overwhelming concern for public health at the heart of the statute.

Given the flawed manner, contrary to law, in which EPA conducted its risk assessment, there is a high likelihood of Objectors's success on the merits and thus the effectiveness of the Regulation would cease. In the meantime, affected industry actors would have expended the considerable sums necessary to restructure their production processes for the new tolerances, only to have to suffer the embarrassment and losses related to food recalls and food scares and ultimately resort to different methods when the Regulation is declared invalid. Indeed, having been aware of Objectors's well-founded concerns, alternatives to sulfuryl fluoride should have been considered.

Finally, the FFDCA recognizes public health as paramount, and economic and benefit-related interests cannot begin to compete with the primary concern of that law. This crucial feature of the FFDCA is the result of the Food Quality Protection Act (FQPA) amendments. The benefit-related provisions in effect before the FQPA were deleted and replaced with a new regime in which "EPA may now consider the benefits of a pesticide only in a narrow set of circumstances." ELIZABETH C. BROWN, ANN CLASSEN, CAROLYNE R. HATHAWAY, JEFFREY HOLMSTEAD, THOMAS POWELL, WILLIAM WEHRUM & KENNETH WEINSTEIN, PESTICIDE REGULATION DESKBOOK (2001). See, FFDCA Section 408(b)(2)(B).

For these reasons, no other parties interested in the proceedings will be substantially harmed by the issuance of a stay.

VI. The Public Interest Lies in the Assurance that Public Health is Being Protected in the Process Leading to the Establishment of Pesticide Risk Tolerances

In these proceedings, Objectors's interest is in promoting the public interest itself. In seeking to have EPA be required to conduct a proper risk assessment as a prelude to establishing tolerances, the sole objective is to provide for the protection of public health. For this reason, the public interest lies in the issuance of a stay of the Regulation.

CONCLUSION

Objectors move for a stay of the Regulation in the interest of protection of public health. This Motion has set forth considerable facts and observations that speak to the failure of EPA to carry out a full and fair process for the establishment of tolerances for sulfuryl fluoride and fluoride anion. EPA's risk assessment itself was not made final until *after* the issuance of the final rule, which not only casts doubt on its credibility but also hampered the opportunity for Objectors to make their case in opposition to the Regulation.

Given these significant substantive and procedural faults, Objectors request that the Administrator stay the effectiveness of the Regulation in the interest of protection of the public health and in order that Objectors may have a fair opportunity to contribute to this process in the manner envisioned by the FFDCA.

Respectfully submitted,

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