Memorandum

Legal Standard for Grant of Hearings on Objections under Federal Food, Drug, and Cosmetic Act Section 408

Introduction

This memorandum addresses certain arguments advanced by counsel to Dow AgroSciences, LLC, (Dow and Dow Paper) concerning Objectors' Oppositions and Requests for Hearing with respect to certain pesticide chemical residue tolerances for Sulfuryl Fluoride and Fluoride Anion issued by EPA. Specifically, the memorandum addresses Dow's assertion that Objectors should not be granted an oral evidentiary hearing as provided for under Section 408 of the Federal Food, Drug and Cosmetic Act, (FFDCA) as amended by the Food Quality Protection Act of 1996. 21 U.S.C. §346a(g)(2)(B)

This matter is unlike the typical cases for which "administrative summary judgment" (agency decisions made without oral evidentiary hearing) and the customary broad deference to agency discretion and interpretation may be appropriate. See, *Puerto Rico Aqueduct & Sewer Authority v. EPA*, 35 F.3d 600 (1st Cir. 1994) (PRASA) Moreover, this case is different from the ordinary ones in which "an agency deserves an extra measure of deference with regard to factual questions involving scientific matters in its area of expertise." PRASA, 35 F. 3d 604; *Baltimore Gas &Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). Such deference and discretion have limits. And the present case abundantly illustrates those limits. Indeed, "the suggestion that …[agency] determinations are entitled to deference and do not require *complete* factual support does not mean that agencies are free to engage in unreasoned decisionmaking." *International Ladies' Garment Workers' Union, et al. v. Donovan*, 722 F2d 795 (D.C. Cir. 1983).

The agency's failures here are unprecedented in their scope, nature and implications for public health. Without the benefit of the requested hearing to resolve crucial, underlying factual issues, these substantive and procedural failures will ultimately provide a basis for invalidating the tolerance decisions. This is because, first and foremost, EPA has not proceeded properly in determining under FFDCA Sec. 408(b)(2)(A)(ii) that "there is a reasonable certainty that no harm will result from aggregate exposure" to the fluoride chemical pesticide residues. Additionally, under the Administrative Procedure Act, (APA) the decisions will have been made in a manner that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A)(1988). See, e.g., *Sierra Club v. Marsh*, 976 F2d 763, 769 (1st Cir. 1992).

Unlike the more typical cases, here, a hearing is vital in order to cure the failures of analysis and the omissions that could ultimately render EPA's decisions invalid. Without a hearing to adduce evidence as to the "genuine and substantial " factual issues whose resolution is a condition precedent to valid decisionmaking , EPA's tolerance decisions will be flawed for want of a proper and complete administrative record.

I. This Matter is Appropriate for an Oral Evidentiary Hearing. Congress Provided Expressly and Extensively for Such a Hearing in the FFDCA and Many Questions Raised in this Matter Come Squarely within the Hearing Requirements of the FFDCA and Relevant Regulations.

A. The Express and Extensive Language of the FFDCA Reflects Congress's Intent that an Oral Evidentiary Hearing be a True Possibility and Not an Insignificant Rarity or Afterthought

Notwithstanding Dow's observations, the question whether or not EPA has ever held an oral evidentiary hearing under FFDCA Section 408(g)(2)(B) is irrelevant to the present decision about whether to hold one. What is relevant are Congress's expressions of intent regarding the place and importance of such a hearing. In this regard, the language of the subsection reflects Congress's determination that some objections to chemical pesticide residue tolerance decisions may require an oral evidentiary hearing. Far from being a minor, unimportant provision, this one is substantive and detailed and it is meant to be taken seriously. Section 408(g)(2)(B) provides, in pertinent part, as follows:

> An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall … hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. (Emphasis added)

Further, the subsection creates significant powers and authorities to aid the hearing process. These features only underscore Congress's intent that an oral evidentiary hearing be a prominent feature of agency decisionmaking:

- The subsection provides for a "presiding officer" at the hearing;
- The presiding officer may "authorize a party to obtain discovery";
- The presiding officer may "issue a subpoena to compel testimony or production of documents from any person." Such a subpoena, where contested, "may be enforced by a Federal District Court"; and
- The subsection contemplates a formal hearing process. For example, the presiding officer "shall be governed by the Federal

Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced."

B. The Standard for Granting a Hearing.

EPA clearly understood Congress's plain and express intent that the FFDCA contemplates an oral evidentiary hearing in appropriate circumstances. Indeed, this understanding is best reflected in the agency's promulgation of specific regulations implementing Section 408(g)(2)(b). Essentially, the regulations set forth the requirements for a determination as to when such a hearing should be held.

To call the regulations "intentionally rigorous" is misleading; they merely identify the commonly-known, logically narrow objectives of trial-type adjudicatory hearings: (1) such hearings should be reserved for genuine and material factual questions (as opposed to legal or policy ones); and (2) those questions must be ones as to which relevant, probative and (ultimately) determinative evidence can be adduced. See, Richard J. Pierce, Jr., Administrative Law Treatise 542-43, Vol. 1, 2002. Importantly, that this objective is logically narrow does not diminish its fundamental nature, because it relates to nothing less than due process under law. Therefore, the regulations require the following:

1. There must be placed in dispute "genuine and substantial issue[s] of fact for resolution at a hearing" and not "issues of policy or law." (Thus, the issues must be factual, genuine and material)

2. There must be a "reasonable possibility that available evidence identified by the requestor [of the hearing] would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary." Mere allegations, denials, or general descriptions of positions and contentions are not acceptable as a basis for a hearing. Further, even accurate data and information would not justify a hearing "if the Administrator concludes …[they] would be insufficient to justify the factual determination urged." (Thus, the evidence must be relevant and probative)

3. Resolution of the factual issues in the manner sought by the requestor must be "adequate to justify the action requested." (Thus, factual issues and their resolution as proposed by the requestor must be "determinative" with respect to the action requested)

40 C.F.R. § 178.32(b)(1-3)

Objectors will discuss below the issues that justify an oral evidentiary hearing. Because of the unprecedented nature and implications of the defects in EPA's decisions as to these tolerances, issues have been presented that qualify for such a hearing. These defects resulted, among other things, in a failure to identify (in some instances) or

analyze properly (in other instances) the data and information that are logically a part of the relevant decisionmaking process. As will be made clear from the following discussion, Objectors have presented numerous factual issues worthy of a hearing. The discussion will make it clear that the issues are "material," in that they "may affect the outcome of the case." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986) Further, the issues are "genuine," in that they are "worthy of being adjudicated." See, *United States v. One Parcel of Real Property*, 960 F.2d 200, 204 (1st Cir. 1992).

II. Contrary to Dow's Assertions, Objectors Have Raised Material Issues of Fact.

Dow has isolated a small number of Objectors' numerous issues and claimed that Objectors have not raised any "material issues of fact" that would justify a hearing. Yet, as carefully documented in Objectors' November 2006 Consolidated Objections, Objectors have presented many material issues of fact that can clearly be resolved based on "ascertainable data" in Objectors' favor. This resolution would provide substantial evidence that would overturn the tolerances. The following issues are prime examples of some of the fundamental and pivotal questions pertinent to the tolerance decisions that Objectors have raised:

1. Are Americans exceeding the reference dose (RfD) from aggregate exposures to fluoride ion? (See Section IV of the Consolidated Objections)

2. Can the tolerances produce doses of fluoride ion that exceed the doses documented to produce acute toxicity in humans? (See Section V of the Consolidated Objections)

3. Is EPA's use of the same mg/day RfD for infants as adults an unprecedented action that violates the basic principle of toxicology that bodyweight affects a person's response to a chemical? (See Section II of the Consolidated Objections)

III. EPA Has Ignored Relevant Evidence in the Record. Thus, The Agency Has Left Major Underlying Issues of Fact Open and Unresolved

Although Dow argues that the courts would allow EPA "a wide degree of latitude in its decision to reject an objector's hearing request," this deference should not be accorded where, as here, EPA has not given "adequate consideration to all relevant evidence on the record." See, Dow Paper at 5-6. Objectors' November 2006 Consolidated Objections set forth this failure. The most egregious example is the agency's decision to adopt the same mg/day RfD for children as adults. Indeed, as detailed by Objectors, it is now a matter of public record that, in adopting this RfD, EPA failed to consider a wide body of relevant evidence, including:

- published studies showing skeletal damage at the mg/kg/day dosages that EPA now allows for children;

- published studies showing that children's bones accumulate significantly more fluoride than adults;

- published studies showing that children can develop skeletal fluorosis in less than 10 years;

EPA's failure to consider all evidence relevant to the purported safety of the new RfD for children is illustrated by the fact that EPA never issued a scientific justification for altering the RfD from 4 mg/day to 8 mg/day. Instead, EPA defended the 8 mg/day RfD for children (issued in July 2005) by using the same two-sentence explanation it had previously used to defend the prior 4 mg/day RfD for children (issued in January 2004). This brief explanation provided no reference, or response, to the long line of scientific evidence casting serious doubt on EPA's unprecedented assumption that children can safely tolerate much higher mg/kg/day exposures than the EPA considers safe for adults.

Such an approach fails abysmally in the face of FFDCA Section 408(2)(C), which specifically addresses "Exposure of infants and children." That subsection provides, in pertinent part, as follows:

> In establishing …a tolerance…the Administrator --
> (i) shall assess the risk of the pesticide chemical residue based on—(I) available information about consumption patterns among infants and children…(II) available information concerning the special susceptibility of infants and children…(III) available information concerning the cumulative effects on infants and children…
> (ii) 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…. 21 U.S.C. §346a(b)(2)(C).

What adds further to the arbitrary and capricious nature of this RfD is the history of its derivation. As noted above, the 8 mg/day RfD is not the first RfD used by the EPA in its risk assessment of sulfuryl fluoride, but the third. The RfD initially used by EPA, when assessing Dow's request for temporary tolerances, was the same RfD the agency had traditionally used for risk assessments of fluoride-based pesticides (0.114 mg/kg/day). This initial RfD was applied to all age groups, as had been done in the past. However, after Objectors intervened and showed that some infants were exceeding the RfD from aggregate exposures, the EPA derived a new RfD which – in contrast to the initial RfD - varied by bodyweight. For example, whereas the initial RfD considered an exposure of 0.114 mg/kg/day to be the maximum safe dosage for an infant, the new RfD considered the maximum safe dosage for an infant to be 5 times higher at 0.571 mg/kg/day. After Objectors again showed, however, that some older children would exceed this altered RfD, the EPA promulgated yet another RfD, this time increasing the maximum allowable dosage for infants to 1.14 mg/kg/day.

What makes EPA's decision to increase the RfD (from less than 1 mg/day for infants to 8 mg/day for infants) so arbitrary and capricious is that it was derived from the same starting point (the MCLG of 4 ppm in water) and no new scientific research was offered to justify the increase. The end result of these alterations is that EPA has promulgated an RfD for infants that is ten times higher than the initial RfD, and ten times higher than the RfD currently allowed for adults. As Objectors detailed in their November 2006 objections, EPA's current RfD for children is based on the unprecedented assumption – not backed up by any factual record – that 8 mg/day of fluoride is as safe for infants as it is for adults, irrespective of the approximate ten-fold difference in bodyweight. In making this assumption, EPA violated the standard toxicological and regulatory principle that bodyweight affects an individual's response to a chemical.

The express and extensive language of the FFDCA makes Congress's intent clear that EPA may only issue tolerances that are protective of infant and childhood health. Correspondingly, EPA's efforts in behalf of protection of infants and children are wholly inadequate. Thus, whatever deference a court would ordinarily accord EPA, the agency has placed such an entitlement in doubt by having rendered itself vulnerable to claims that it violated both the APA and the FFDCA. "[T]here is no indication in the cases that agencies can ignore important factors …or can reach judgments that are irrational given the evidence." *International Ladies' Garment Workers' Union* 722 F.2d at 822. *And* at the base of these violations is the failure to probe fully and fairly a crucial threshold issue: Whether, and to what extent, children are more vulnerable to fluoride than adults.

IV. The NRC Report is Highly Relevant to the Tolerance Decisions. EPA's Failure to Wait for and Consider that Report Left Its Own Evaluation of the Material Facts and Its Decisions Flawed.

A. Dow Claims the NRC Report Pertains Only to "Fluoride in Drinking Water" and is Thus Immaterial to a Sulfuryl Fluoride Risk Assessment. But Fluoride in Water is Still Fluoride, and the FFCA Requires an Assessment of "Aggregate Exposures" to Fluoride

Dow attempts to dismiss the NRC report by arguing that because the NRC report does not make any conclusions specific to sulfuryl fluoride it is irrelevant to EPA's risk assessment of sulfuryl fluoride.[1] See, Dow Paper at 13. But such an argument fails to take account of the mandate at the heart of the FFDCA: "aggregate" exposures are to be the basis of EPA's risk assessment in determining whether a chemical pesticide residue tolerance is "safe":

[1] The NRC did not review EPA's latest risk assessment on Sulfuryl fluoride. (January 2006) The NRC's review of sulfuryl fluoride was limited instead to EPA's January 2004 risk assessment. This is significant because the January 2004 risk assessment did not take into account the hundreds of additional sulfuryl fluoride tolerances that EPA later approved in 2005. As a result of the new tolerances approved in 2005, as well as major changes that have occurred in the labeling requirements, EPA now estimates that the tolerances will contribute 10 times more fluoride than it had estimated in 2004. By not having access to this revised data, the NRC's review on sulfuryl fluoride was inherently limited.

> [T]he term "safe" … 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. FFDCA Section 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii)((Emphasis added)

The NRC decisively concluded that the MCLG is unsafe and should be lowered. This conclusion is directly relevant to the sulfuryl fluoride risk assessment because the MCLG is the health standard that the Office of Pesticide Programs (OPP) used to assess the safety of the tolerances and aggregate exposures to fluoride ion. The fact that a prestigious body such as the NRC concluded that the MCLG is unsafe, placed beside OPP's conclusion that it is safe, at a minimum creates material issues: Is the existing MCLG for fluoride safe? If so, what facts serve to justify a conclusion contrary to that of the NRC? If not, what is an appropriate MCLG for the tolerances?

Objectors note in this regard that it was EPA itself that requested the NRC review of the effects of fluoride on human health, obviously because of the NRC's superior expertise—and unquestioned independence. Such a highly regarded source should not be readily dismissed.

B. Dow's Attempt to Dismiss the NRC's Principal Conclusions on Hard Tissues (Bone & Teeth) Lacks Merit

1. Severe Dental Fluorosis

In its January 2006 risk assessment, the EPA acknowledged that some children in the US are exceeding the dose (2 mg/day) that will put them at risk for severe dental fluorosis. Meanwhile, according to the NRC, severe dental fluorosis is a condition that can adversely affect a child's health. Thus, on the basis of EPA's data showing that current aggregate exposures can cause severe dental fluorosis, and the NRC's conclusion that this condition is an adverse health effect, Objectors have argued that there is no safe room for the additional fluoride exposures that will result from tolerances.

In response, Dow now claims that the NRC has provided insufficient basis to determine whether severe dental fluorosis is an "adverse health effect" according to EPA criteria. Here, not only has Dow found itself contradicting one of the most prestigious scientific bodies in the world, but, ironically, in doing so it has helped to articulate material issues of fact: How serious is the impact on human health is severe dental fluorosis caused by fluoride exposure? Do the underlying facts lead to a conclusion that this condition is an adverse health effect?

According to Dow:

> The NRC Report does not define "adverse health effect." Nor does it identify the sources of the "prevailing risk assessment definitions" upon which the conclusion of adverse health effect is based. Thus, there is no basis to judge whether the NRC Committee's belief as to what constitutes an "adverse health effect" is at all relevant to the Office of Water's analysis of adverse effect on health under the Safe Drinking Water Act." See, Dow Paper at 20-23.

In contrast to Dow's contention, however, there is ample basis to determine whether the NRC's conclusions on severe fluorosis fit the criteria set forth by EPA as to what constitutes an "adverse health effect." The NRC concluded that severe fluorosis is an adverse health effect because it damages the "health-protective function" of the teeth.

According to the NRC:

> One of the functions of tooth enamel is to protect the dentin and, ultimately, the pulp from decay and infection. Severe enamel fluorosis compromises that health-protective function by causing structural damage to the tooth. The damage to teeth caused by severe enamel fluorosis is a toxic effect that is consistent with prevailing risk assessment definitions of adverse health effects. NRC Report at 4**.**

The criteria used by the NRC clearly match the criteria set forth by EPA as to what constitutes an adverse health effect under the Safe Drinking Water Act. (SDWA) According to EPA: "In the case of regulating fluoride under the SDWA, the EPA agrees with the Surgeon General that adverse health effects are considered to be death, gastrointestinal hemorrhage or irritation, arthralgias, and crippling fluorosis, or any other effect which results in functional impairment." (Fed Reg, Nov 14, 1985, p. 47143).

In contrast to Dow's claims, therefore, the NRC has provided sufficient information to conclude that severe dental fluorosis is, in fact, an adverse health effect using EPA's own criteria. Thus, unless EPA can scientifically demonstrate that severe fluorosis does not result in "functional impairment" of teeth, then Dow's argument is without merit. Again, at a minimum, material issues have been squarely posed in this matter, and only an oral evidentiary hearing can provide the opportunity for resolution of those issues. Objectors believe that these issues would be resolved in their favor, leading to a determination that the tolerances were invalidly and illegally established.

2. Bone Fracture

Dow also takes on the NRC with respect to the role of fluoride in bone fracture. As it did in its August 2006 submission, Dow goes to great lengths to cast doubt on the NRC's conclusion regarding fluoride and bone fracture. Dow's case is comprised of three main arguments. See, Dow Paper at 18-20.

First, Dow claims that most of the data that formed the basis of the NRC's conclusions on fracture risk had already been reviewed by EPA. Dow points out, for instance, that EPA had reviewed the clinical trials on fluoride and fracture and found them to be irrelevant. But Dow's claim misses the point that the EPA dismissed the clinical trials based on a demonstrably false claim grounded in a demonstrably erroneous calculation. Unlike the NRC, the EPA failed to convert the dose of sodium fluoride into the respective dose of fluoride ion. As a result, EPA falsely claimed that the clinical trials used 60 mg/day of fluoride ion, whereas in reality the trials had used between 20 and 34 mg/day. It is clearly erroneous, therefore, for Dow to claim that EPA's review of the clinical trials negates the more thorough review of this data from the NRC .[2] See, NRC Report at 158-165**.**

Second, Dow attempts to undermine the NRC's findings on fluoride and fracture by observing that "25%" of the NRC committee did not agree with the panel's conclusion that the MCLG increases fracture risk. But there is a considerably more important percentage in the NRC report: 75% of the NRC panel concluded that the present MCLG for fluoride will increase the risk of fracture. So Dow's argument is of no moment. Indeed, even the 25% who disagreed with the majority did not conclude that the MCLG poses no fracture risk. Rather, they concluded that the MCLG "might" increase fracture risk, but that more research was needed to fully resolve the issue. Thus, even the minority opinion of the NRC panel does not support Dow's and EPA's conclusion that there is "reasonable certainty" of no harm from EPA's RfD. At most, the NRC majority provides a conclusion contrary to those of Dow and EPA. And at least, the majority and minority, together with EPA's and Dow's views, have posed a valid "material issue" that should be addressed in an oral evidentiary hearing. See, NRC Report at 7.

Third, Dow seeks to undermine the NRC's conclusions on fracture risk by claiming that the most recent study on the issue (Sowers 2005) did not find an increased risk of fracture at the current MCLG. What Dow fails to acknowledge, however, is that the NRC committee looked very closely at this study and discussed it at length in their review. First and foremost, the NRC notes that the risk for osteoporotic fractures was, in fact, elevated in the high-fluoride area, with the risk being relatively similar to the authors' previous studies in the same area (Sowers 1986, 1991). While the authors of the study dismissed this finding due to the lack of association between fracture risk and blood fluoride level, the NRC notes that the blood fluoride data was hampered by a major methodological limitation which could have easily biased the results towards a "no effect" showing.

[2] Dow's repetition of EPA's mistake on the doses used in clinical trials highlights another problem with Dow's analysis. Dow refers to EPA's critique of the studies submitted by Objectors *without* mentioning Objectors' rebuttal. Had Dow reviewed Objectors' response, it would have seen that Objectors had already corrected EPA on this error. Dow would also have found that EPA's analysis suffered from other serious deficiencies, including a failure to adequately assess all relevant evidence. For example, EPA dismissed a critically important human study on Fluoride's effect on the thyroid gland (Bachinskii 1985) on the sole basis that it was written in Russian. This is clearly arbitrary and capricious. On the other hand, the NRC translated the Bachinskii paper into English and carefully reviewed the study's findings.

According to personal correspondence with the lead author of the study (Sowers), the NRC learned that the blood fluoride levels were not uniformly taken during fasting, but were instead taken "whenever possible." Because non-fasting blood fluoride levels do not reliably reflect chronic exposure to fluoride, the NRC concluded that the inclusion of both fasting and non-fasting blood fluoride data significantly limited the ability of this study to find a relationship between blood fluoride and fracture risk. Indeed, as the NRC points out, the study was not even able to find a relationship between an individual's blood fluoride level and their duration of exposure to fluoride. Thus, blood fluoride levels of people living for five decades in the high fluoride community were no different than the blood fluoride levels of people living for less than one decade! This is a highly unusual finding that contradicts most other research on the subject. Because of these and other problems, Dow's contention that the Sowers study is the most definitive study on the subject is directly contradicted by NRC's review. Again, at a minimum, a "material question" is presented whose resolution could significantly influence a rational decision in setting tolerances. See, NRC Report at 155-156**.**

3. Skeletal Fluorosis

In its discussion of the NRC's findings on stage II skeletal fluorosis, Dow acknowledges NRC's conclusion that stage II skeletal fluorosis is an adverse health effect. But it attempts to dismiss this conclusion by emphasizing the absence of epidemiological studies investigating the prevalence of stage II fluorosis in the US. Here, Dow misses the key point. See, Dow Paper at 20.

The fact that stage II fluorosis has not been systematically investigated in the US does not excuse the fact that EPA's RfD – by its own admission – does not provide for prevention of this effect. As Objectors' have previously pointed out, EPA's RfD is based on the premise that the only stage of skeletal fluorosis which is harmful to health is the end-stage crippling phase. Based on this premise, EPA's RfD was only designed to protect against the crippling phase of skeletal fluorosis.

By only protecting against crippling skeletal fluorosis, EPA's RfD cannot be considered protective against the earlier stages of fluorosis, including Stage II. As a result, the risk assessments supporting the tolerances were not conducted so as to support decisions protective of health, as required in the FFDCA. It is not a mere hypothetical assertion to say that stage II fluorosis is a health threat. It is a matter of scientific fact that can be resolved by ascertainable data at an oral evidentiary hearing.

C. Dow's Argument that the NRC's Findings on Soft Tissue Effects are not "Materially Different" from EPA's Findings is Blatantly Incorrect

In addition to trying to dismiss the NRC's principal conclusion on hard tissue effects, Dow also attempts to dismiss that body's findings on soft tissue effects. In the table on pages 14-16 of its submission, Dow argues that the NRC report agrees with EPA on a range of soft tissue effects associated with fluoride exposure. According to Dow: "the table shows that, with respect to the issues discussed below, the NRC Report does

not reach any conclusions materially different than the conclusions reached by EPA during the rulemaking process."

A close inspection of this table, however, reveals that Dow has severely misrepresented the findings of the NRC review on these effects.

1. Endocrine Disruption

Dow summarizes the NRC's findings on endocrine disruption in the following manner: "Far from Objectors' claims, the NRC found that fluoride was not an endocrine disruptor 'in the sense of mimicking a normal hormone.'"

By narrowly focusing on NRC's conclusion that fluoride does not mimic a natural hormone, Dow failed to mention the far more relevant conclusion from NRC that fluoride is an endocrine disrupter. The NRC's summary of its findings on endocrine function is as follows:

> In summary, evidence of several types indicates that fluoride affects normal endocrine function or response; the effects of the fluoride-induced changes vary in degree and kind in different individuals. Fluoride is therefore an endocrine disruptor in the broad sense of altering normal endocrine function or response, although probably not in the sense of mimicking a normal hormone. The mechanisms of action remain to be worked out and appear to include both direct and indirect mechanisms, for example, direct stimulation or inhibition of hormone secretion by interference with second messenger function, indirect stimulation or inhibition of hormone secretion by effects on things such as calcium balance, and inhibition of peripheral enzymes that are necessary for activation of the normal hormone. NRC Report at 266**.** (Emphasis added)

Notably, Dow cites EPA's position – prior to the release of the NRC report – that it was "not convinced that the data support the statement that fluoride is an endocrine disruptor." But, given the express language of the NRC report, Dow's argument that NRC's views on this matter are not "materially different" from EPA's views is patently untrue.

2. Thyroid Effects

Dow makes a similarly flawed attempt to demonstrate that the NRC's conclusions regarding fluoride's thyroid effects are not materially different than EPA's conclusions. Most curious about Dow's argument on this matter is that it never actually cites any statement from the NRC on fluoride and the thyroid gland. Instead, it cites irrelevant statements from the NRC regarding fluoride's effect on the parathyroid gland and parafollicular cells.

The fact of the matter is that the NRC – in sharp contrast to the EPA – concluded that fluoride does affect the thyroid gland, in both animals and humans. As noted by the NRC, "several lines of information indicate an effect of fluoride exposure on thyroid function.... Fluoride exposure in humans is associated with elevated TSH concentrations, increased goiter prevalence, and altered T4 and T3 concentrations; similar effects on T4 and T3 are reported in experimental animals.." NRC Report at 234, 262**.** (Emphasis added)

3. Brain Effects

In its discussion about fluoride's effect on the brain, Dow simply fails to acknowledge that the NRC agrees with Objectors on their key contention: that fluoride affects the brain. According to the 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 Report at 222**.** (Emphasis added)

Rather than admit that the NRC agrees with Objectors on their central claim that fluoride can damage the brain, Dow attempts to obscure matters by focusing on a few sub-issues which are ultimately peripheral to the key question whether fluoride affects the brain.

4. Insulin Secretion

In its table, Dow omits any reference to Objectors' concerns about fluoride's impact on the insulin secretion. This is particularly curious because NRC's concerns on this issue are almost identical to Objector's concerns. See, NRC Report at 260**.** On the other hand, there are numerous "material differences" in the views of EPA and NRC, and these, in turn, underscore the existence of material issues that deserve to be explored in an oral evidentiary hearing.

V. EPA Should Not Defer a Decision on the Tolerances Without Imposing a Stay. The Public Health is at Stake and If EPA Deferred a Decision Without a Stay It Will Have Issued Tolerances Without a Proper Determination "That There Is a Reasonable Certainty That No Harm Will Result from Aggregate Exposure" to Fluoride.

Dow urges that should EPA be "uncomfortable with a summary rejection of Objectors'claims, it should defer any final decision on the grant of a formal evidentiary hearing under FFDCA until the issues raised by the NRC Report have been properly reviewed under the provisions of the [Safe Drinking Water Act]."

Dow does not mention that a deferral of a final decision would leave the tolerances in place, allowing exposures to the public in amounts that abundant and

credible evidence has shown is dangerous. In fact, what is strikingly absent from Dow's discussion is any consideration of the public health. And there is certainly no reference to the clear and substantial requirements of the FFDCA requiring that EPA proceed in a manner that is protective of the public health. Instead, Dow draws upon EPA's prior articulation of a "two-step process within which [EPA] planned to review the NRC Report."

The FFDCA does not permit the option that Dow suggests. Further, the existence of another statute (the SDWA) and another office (the Office of Water) may call for some degree of cooperation but not a wholesale refusal to comply with the mandate of a major federal statute. Further, Dow does not—and indeed cannot—cite a single legal authority for such a sweeping preemption. Therefore, Objectors contend that EPA must either proceed with its decision on the hearing or, in the alternative, impose the stay previously requested by Objectors should the agency decide to proceed with an extensive process based on the NRC report.

Perry E. Wallace January 17, 2007