

APPENDIX K:

Objections based on OPP failure to adhere to statutes and guidelines

The EPA OPP (Office of Pesticide Programs) has failed to adhere to FQPA statutory mandates and failed to follow OPP Science Policy documents, OPP Standard Operating Procedures, and OPP guidance documents in their tolerance determination for sulfurlyl fluoride. FAN demonstrates how multiple failures lead to improper decisions at many points in the decision making process. FAN requests a hearing on these process and factual errors.

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OPP has not followed statutes or internal guidance when they accept an RfD from an outside department.

The EPA Office of Pesticide Programs (OPP) has not adhered to statutes, nor followed their own standards and guidance in performing their health risk assessment (HRA) for the sulfurlyl fluoride (SF) residue fluoride (F).

The OPP abrogates their responsibility to determine a reference dose (RfD) using their own methodology in an open and transparent manner when they rely on an RfD taken from another division of EPA. The OPP acknowledges taking the maximum contaminant level (MCL) for water, set by the EPA Office of Water Quality, for use in the OPP's HRA for F residue. The OPP adapts the MCL of 4 ppm and converts that into equivalent dosage of mg/kg bw/day by simply multiplying this concentration by the average water consumption and dividing by the average weight of Americans. These are the sole inputs to determining the OPP's RfD for F.

The OPP has no statutory authority or internal guidance allowing it to take RfDs from other agencies or divisions of the EPA.

Different departments apply different standards and methods.

OPP guidance states, "... the Agency's other regulatory programs or risk assessment processes ... are carried out under different statutory authorities [than FQPA]" (EPA OPP 2002). An RfD developed under those different conditions could very well be different. Other methodologies are likely to apply different assumptions, different standards of cost/benefit weighting, different degrees of confidence, different levels of data completeness, different cumulative methods, different aggregation methods, different childhood risk methods, different standards of transparency and openness, etc.

OPP's only justification for accepting outside department RfD is endorsement by Surgeon General of the Public Health Service.

OPP's claim that the Surgeon General of the US Public Health Service endorsement of the 4 ppm MCL is in any way pertinent to setting an RfD by OPP is also unfounded in any statute or guidance. The Surgeon General is the administrative head of a totally different agency of the US government. The Surgeon General, even in his own agency, has no statutory authority to determine an enforceable toxic exposure standard. If the OPP believes otherwise, they must clearly state under which statute the Surgeon General may set or endorse a toxic exposure standard.

We also note that even if the OPP is only citing the SG's endorsement of 4 ppm MCL, their OPP's choice of endorser runs counter to the most basic principle of impartiality. The SG is the administrative head of an agency (The Public Health Service), which has been the foremost promoter of fluoridation since the concept of public fluoridation was first launched in the early 1950s. The PHS continues to promote fluoridation vigorously. Accepting a SG endorsement on the F MCL is essentially no different than if the OPP accepted an RfD for sulfuric fluoride endorsed by the president of Dow. The entire point of an OPP health risk assessment is to make an independent, scientifically backed, transparently produced, unbiased, regulatory decision.

If the OPP believes otherwise, they must cite the statute or OPP policy document that allows any weight to be given an RfD from a party with a substantial conflict of interest regarding the RfD.

Finally, it should be emphasized that the OPP is statutorily required to determine the RfD and make a HRA without regard to any cost/benefit balancing. They can not balance a benefit such as a possible reduction in dental caries against the adverse health effects of F in determining their RfD.

FAN requests hearing on OPP's short-circuiting of their risk assessment process.

In essence, the OPP's entire HRA and tolerance setting process for sulfuric fluoride (SF) is invalid as they have relied on a RfD from a different branch of the EPA. FAN is requesting a hearing to correct this fundamental flaw in the OPP's regulatory decision making. OPP's statutory obligations for HRA's are clearly defined by the FQPA and FIFRA. They are further clarified and specified in the OPP's own voluminous Science Policy documents, Standard Operating Procedures, and many specific guidance documents.

The only way the OPP could conceivably justify borrowing a RfD from a different department would be if they can show that the RfD was established using essentially the same statutes, methods, standards, and guidance as the OPP follows. If the OPP feels, under FQPA statutes, they may accept an RfD established by a different department and based on different methods, then they must cite the explicit statute language permitting

such action. They must also explicitly give complete evidence that the other department's methods and standards are essentially the same as OPP would have to use if establishing the RfD themselves.

FAN requests a hearing to establish whether OPP has followed their statutory obligations in accepting an RfD from an outside department with almost no critical examination. Endorsement by the Surgeon General is no substitute for critical examination.

If contrary to our contentions, it is established that OPP does have the discretion to accept the 4 ppm MCL, then FAN requests a hearing on the question of whether that MCL established by the EPA Division of Water Quality was performed using essentially identical methods, standards, data inputs, and decision making policies as would have been required by the OPP if they had determined the RfD. One important requirement for OPP decision-making is transparency. That is, each step and decision in the process must be explained clearly and in detail sufficient for the public to understand and verify the basis for each step and decision. They must cite specific scientific findings and explain the reasoning used in making all decisions.

OPP was not transparent and open in developing RfD.

If it is decided that OPP was allowed to skip certain procedures and standards by accepting another division's RfD, then we request the opportunity to question the RfD, on the same basis as if it had been prepared by OPP. In other words, the requirement that OPP's methods and decision be transparent cannot be waived just because the OPP used the work of a different department.

The OPP must cite specific scientific studies and explain the reasoning for each step in determining the 4 ppm MCL just as if they had performed it themselves. Failing this, the OPP must "start from scratch" and determine the RfD themselves.

FAN reserves right for further objections when OPP has transparently described their RfD determination process.

Determination of an RfD is one of the most important parts of a HRA. This is not some minor point of dispute. It lies at the core of the OPP tolerance decision. It is hardly possible for FAN to raise questions of fact about the individual components used to determine an RfD until the OPP has transparently followed the statutorily required methods.

Detailed examination of OPP's Health Risk Assessment shows factual errors and flawed reasoning.

Not only does FAN believe the OPP broke the rules by accepting the Water Quality Division's RfD, we also believe they made mistakes in several other steps of their HRA and tolerance decision process.

We believe OPP's tolerance decision contains factual errors and uses flawed reasoning. For clarity we have divided our arguments into two "tracks". In Track 2, we do what we believe OPP was required to do: we determine an RfD based on FQPA, FIFRA, and OPP methods and standards. OPP, mostly as background, provides some information that allows us to see dimly (not transparently) into their rationale for adopting the 4 ppm MCL. We will give special attention to these hints as we determine an RfD using OPP's own published guidance.

Track 1 accepts for the sake of argument that OPP can adopt 4 ppm MCL for their RfD with no verification or use of OPP methods. We examine the OPP's HRA and tolerance decision from that point onward and show where mistakes were made.

Track 1: OPP's HRA flawed and not transparent.

What percentile of a subpopulation should OPP protect?

The OPP Science Policy and guidance documents state that for acute exposures, they will regulate to protect 99.9% of a population from exceeding the RfD. That implies that 1 in 1000 people may receive more than the RfD and may be risk for developing adverse health effects. While this does not seem fully protective of all Americans, for the sake of argument we accept this risk management decision level. We could not find where the OPP makes a similar policy or guidance for chronic exposure leading to chronic health effects. If in fact, there is a lower standard for protecting people from chronic health effects, then OPP must state this explicitly in their HRA and tolerance decision. If they so state, then we object on the grounds that chronic health effects can be just as serious as acute health effects. A cynic might say that the reason the OPP is more protective for acute health effects is because an acute event could be traced back to the chemical at fault and potentially to a legally liable party. However, a chronic health effect is almost impossible to trace to a specific chemical, let alone an exposure event. So it is virtually impossible to determine legal liability.

On a health basis, this is flagrantly wrong. Chronic health effects are likely to be more debilitating and expensive than acute health effects. Acute effects are by definition reversible (other than death), whereas chronic are frequently not reversible and get progressively worse. There is no defensible health argument for a lower standard for protecting against chronic than acute effects.

The OPP must explicitly state the percentile of a population they have decided to protect from chronic health effects by keeping their exposures below the RfD.

If it is not at least 99.9% then they must clearly justify why they have departed from their Science Policy guidance.

How large must a subpopulation be for OPP to decide to protect 99.9% of its members?

OPP does not seem to have any policy or guidance for choosing the number of people exposed above its RfD at which point their exposure is deemed excessive. It's also not clear whether OPP considers it more imperative to regulate when a large fraction of small group exceeds the RfD or when a small fraction of a large group exceeds the RfD. Furthermore, it's not clear whether the degree of exceedence of the RfD should play a strong role in final HRA decision. That is, if it were predicted that only a "small" number of people would exceed the RfD, but they exceeded it greatly, would that point to a more stringent standard of regulation?

The OPP must explicitly state how they base their decisions in regard to the numbers of people allowed to exceed an RfD. As will be described later, for fluoride, just with current exposures through drinking water, there is a significant fraction of the US population (probably exceeding 0.1%) who already exceed the RfD. Figure 4.2.1 in the EPA OPP's HRA on SF shows that they acknowledge that the top 0.1% of all Americans are exposed to more than 3.94 ppm in drinking water. That, combined with food exposures, will put all of these people over the RfD. That alone should be grounds to deny any use of sulfuric fluoride. Below, we will also describe many subpopulations who for myriad reasons are already likely to be exposed to high levels that will put some of their members over the RfD.

Lacking OPP response, we infer what percentile of any subgroup should be protected

Lacking policy or guidance or response from the OPP on what numbers of people may exceed the chronic RfD exposure we will use other methods to infer what would be appropriate.

A general guideline for risk policy is to try to keep individual risk of any serious endpoint lower than 1 in a million or at most 1 in 100,000. This is particularly the case when there are little or no counterbalancing benefits for the individual. In the case of SF use, there are at best miniscule economic benefits to the consumer, compared to alternative pest control measures.

The 1 in a million guide is most often used for a specific point source risk. For example, if a chemical factory were planned, then an HRA which showed a 20 in a million cancer risk from benzene emissions to the few people living downwind at the point of maximum impact typically would be found unacceptable to risk managers. They are protecting perhaps only a few hundred people by regulating to keep individual risks below 1 in a million.

Contrast the protecting of these few hundred people with the exposed population for fluoride which is the entire US population of 280 million.

Clearly, the responsibility is much greater when setting regulations affecting the entire US population, rather than just a few hundred people. If the OPP has any rationale for making decisions less protective, then they must fully and clearly explain their reasoning. They should explicitly state their policy for choosing how many people affected is too many.

Another way to infer the number of people exposed above the RfD that would be too great, is to examine the size of subpopulations the OPP is directed by FQPA to protect. The FQPA says “children”. In the US children age 0-20 may make up, say, 20% of the population. This suggests that at a bare minimum, the FQPA directs OPP to protect 99.9% or about 50 million people, leaving 0.1% or 50,000 unprotected.

The OPP has not considered many subpopulations likely to be highly exposed or especially sensitive to fluoride.

If, instead of regulating to protect an absolute number, the OPP policy is to protect a fraction of a subpopulation, then the OPP must determine what are those most exposed subpopulations, and what fraction of them they wish to protect. The FQPA statute directs the OPP to protect any subpopulation which might be highly exposed or sensitive, not just children.

For F exposure, the OPP has not identified some key at-risk subpopulations. FAN pointed out some of these subpopulations before, yet OPP appears to have ignored them.

Here is a detailed list of those subpopulations who are likely to have increased exposure or whose members are likely to be unusually sensitive to F health effects.

1. Those people with kidney disease such as diabetes. They drink much more water than average and excrete F less efficiently. This group of people may be exposed to several times more F through drinking water, and internally may be exposed to significantly higher levels because of lowered excretion. This is a very large group in the US.
2. F excretion also decreases with age. People over 50 excrete less, which makes their internal serum, and bone levels increase faster. This is also a very large subpopulation.
3. Those people who, through no fault of their own, live in areas with naturally high F levels. As mentioned earlier, the OPP themselves document that as much as 0.1% of the US population may live in areas where they receive the RfD from drinking water alone.

Evolution-based approach to toxicity

But these high levels of F exposure from water are far greater than the levels in which Homo sapiens evolved. They are caused by the use of wells. If one takes an evolution-based approach to toxicity, it is important to note that humans evolved over millions of years at significantly lower exposures to F than are now prevalent in the US. The range of F in surface water in the US is only 0.01 – 0.03 ppm. That’s

almost 100 times lower than water people now drink. If F does have subtle effects on survival and reproduction, there would not have been any selective pressure to adapt biologically protective countermeasures. This brings us to the next subpopulation at high risk to overexposure because they may be unusually sensitive.

4. Nursing age infants. Human breast milk is up to 100X lower in F than today's typical drinking water. This suggests the possibility that infants are more sensitive than older people to health effects of F. Lacking any studies to the contrary, the OPP should have considered this fact during their Hazard Characterization. They should have requested studies be done to address this question. Without such studies, the OPP is certainly not justified in reducing the default 10X FQPA safety factor for infants through age 1-2 years.
5. Formula fed infants. Formula is typically made from tap water so it will have the same or greater level of F as found in that tap water. Therefore, formula fed infants will receive about 100X more F than breast fed infants. This is an important and large subpopulation to protect.

Finally, there is an entire class of subpopulations, most of them smaller than those already described. However, since the OPP has never specified the minimum relevant size for a subpopulation these groups should have been considered. The OPP must state where the cut-off point is in size or other measure at which they will not try to protect these groups:

6. Occupationally, and residentially exposed people to high airborne F. Aluminum plant workers, steel works, glass, phosphate fertilizer, etc. All these industries have some workers with high exposures to airborne F. People living near any of these industrial facilities may also receive high airborne exposures. Cryolite workers obviously had huge occupational exposures. The OPP must address this potentially large group of people.
7. Those children who swallow most of their toothpaste or even eat toothpaste because of its sweetness and food-like added flavors. OPP does not address how large a group this may be, but it is very real and there should be heightened concern because these children may be exceeding their RfD many times over.
8. Similarly, those people who take or are given dental products like mouthwash, F tablets, F rinses, etc. which can, even if carefully used, lead in some cases to very high exposures. Again, the OPP presents little data on how large this group may be. But considering the size of the overdoses, they must either gather more data or explicitly give their rationale for why this group is not large enough to protect.
9. Athletes, people who exercise, manual laborers, all those occupations that are done in hot environments or involve strenuous activity. Also all those who live in hot climates. All of these people would typically drink several times more liquids than the average. OPP fails to address this large subpopulation at all. They simply use average water consumption.
10. People with diets that include many high F foods. This could be anyone from a child whose favorite drink is grape juice (high F residues from cryolite) or an ethnic group that has specialty items with high F. An example might be people

who eat lots of canned sardines, where high F levels result from the bones dissolved into the fish by cooking. Another example is those who drink lots of tea, which naturally accumulates high F levels.

11. People living near active volcanic areas. The Island of Hawaii is a prime example. Many thousands of people are affected by the emissions from volcanoes locally known as “vog”. Volcanic emissions have been shown to have high HF levels.
12. Finally, is the OPP willing to protect those very small numbers who purely through chance are highly exposed to F? An example will illustrate this point. Some people stockpile their favorite non-perishable foods. This could be cereal, crackers, or even someone who buys a 100 lb sack of flour and makes all their own baked goods from it. If that particular batch of wheat flour happened to come from the part of a mill’s production that had been fumigated, it could contain up to 125 ppm F residue. Dow and OPP provided an estimate for how much flour is likely to be exposed to SF and it is more than 1%. If the consumer eats lots of goods from this batch of highly contaminated flour for the next year, that person might get exposed to as much F as in a lifetime of normal exposure. Average levels of F in food are less than 1 ppm. There won’t be a lot of people in this situation, but out of 280 million Americans, there will be a few. Is OPP saying that these cases of over-exposure are not worth protecting against?

Some people will belong to more than one subpopulation whose risk is additive. OPP has not addressed this issue.

Some of these groups are small, but others are quite large and certainly deserve to be addressed in OPP’s HRA. Furthermore, there is likely to be overlap for some people who are members of two or more of these groups. For example, an aluminum worker who lives in a community with 2 ppm F in the water who has a strenuous physical job so that he drinks 2X the average amount of liquid, and who chooses iced tea as his favorite drink. On top of that, all the sugar in the iced tea puts him over the edge for diabetes which forces him to drink even more and his kidneys become less efficient at excreting F. Add to all these the simple fact that he continues working from age 50 until 65 before retiring. One could almost make a joke out of this. But the fundamental point is serious. There will be many people who are members of two or more subgroups whose exposure will be additive.

Fluoride is unique in OPP risk assessment because it is ubiquitous. OPP must therefore conduct an extra thorough HRA.

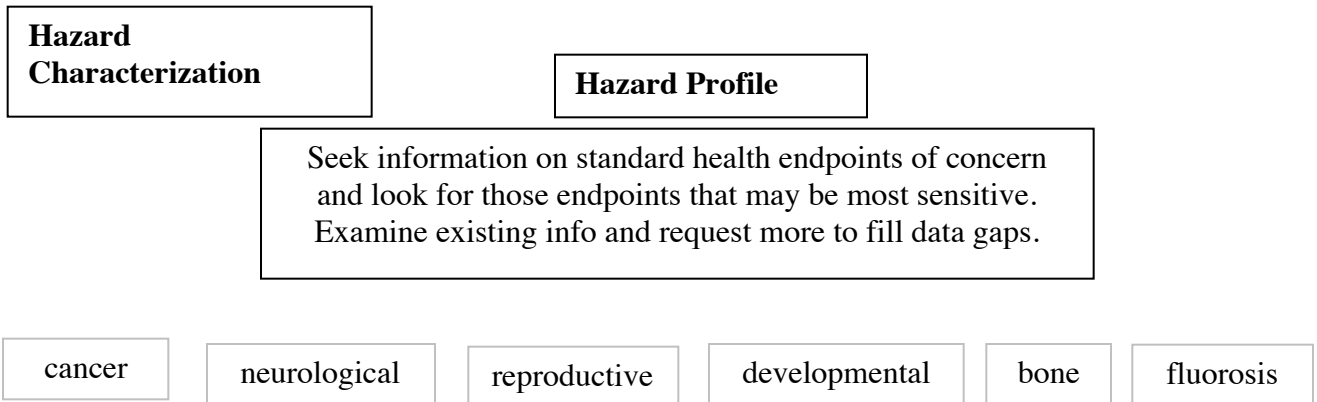
All these significant issues of exposure and are likely unique to F among pesticide residues assessed by OPP. NO other toxic pesticide residues are intentionally added to public water supplies, are used in so many dental products, are emitted by so many major industrial sources, are even naturally occurring in water, and some air and foods. A HRA by OPP of F needs to have a very complete Hazard Characterization. It needs a much broader Exposure Assessment, and a much more critical Risk Management process than for other pesticides whose source is typically only as a carefully regulated pesticide.

Even accepting OPP's flawed RfD for adults, a proper exposure assessment demonstrates that more than 0.1% of the population exceeds the RfD already. OPP even acknowledges this high exposure group from drinking water, but refuses to protect these 280,000 people.

Before even the first pound of SF is used to fumigate food crops, everyone in the US is already being exposed to its toxic breakdown product: fluoride. And the entire US population is being exposed at significant levels. Many in the US are already exposed to levels to which, if the OPP followed FQPA, would clearly necessitate the rejection of Dow's request for additional F residues from SF use.

The OPP uses a metaphor to describe how it manages risks with the RfD. They say that it is like a cup. Once that cup is full no more exposures are allowed. The cup is already full for many people in the US. No additional exposures can be allowed.

Track 2. Following FQPA and OPP policy for determining RfD instead of adopting MCL



According to FQPA statute and OPP policy, the HRA must include a Hazard Characterization. During the Hazard Profile stage possible adverse health effects must be examined with special attention to those for which the chemical may be especially toxic. The OPP failed to carefully examine several adverse health endpoints submitted by FAN in earlier comments. These are addressed elsewhere.

The next step of a Hazard Characterization is to seek a dose-response assessment. Since OPP never looked closely at all the special adverse health effects, they never requested

more data from the applicant to see whether these adverse health effects could occur at relatively low exposures.

We have shown elsewhere, that the dose-response assessments for several endpoints are flawed.

Bibliography

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EPA OPP (1998) Health Effects Test Guidelines OPPTS 870.4100 Chronic Toxicity