

# Comments on the EPA-IRIS IAP for Methylmercury

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# Need

- The RfD (finalized in 2001) is severely out of date
- Many epidemiological studies published since 2001 have documented both adverse effects of MeHg on cognitive development and beneficial effects of fish consumption
- A majority of those studies have associated adverse effects with MeHg doses close to or even below the RfD
- Current federal (EPA/FDA) fish consumption advice is based on preventing exposure above the RfD
- Thus current guidance has no basis in current science
- That is unacceptable. An update is urgently needed

# Scope

- Restricting the focus to developmental neurotoxicity may be necessary for “module 1,” but other possible hazards, such as cardiovascular toxicity, must also be addressed ASAP.
- To sort out mutual confounding, many studies have examined benefits of fish consumption along with adverse effects of MeHg exposure; other studies looked at one or the other.
- Sound policy decisions require that both benefits and risks be estimated as objectively and precisely as the data permit.
- IRIS’s expertise is risk assessment, not benefits assessment. Nevertheless, the opportunity must not be passed up to give the benefits data the same level of rigorous, critical review and analysis the hazard data will receive.

# Key Issues, I

- **Biomarkers:** I agree with colleagues at Harvard that the question of imprecision of biomarkers requires careful assessment.
- **Confounding:** The beneficial effects of nutrients in fish on cognitive development can obscure adverse effects of MeHg exposure, and vice-versa. IRIS should give greater weight to studies in which both beneficial and adverse effects are well quantified and statistical analyses adjusted the magnitude of effects in each direction to account for the opposing effects.
- Studies that simply show “net effects,” positive or negative, without adjusting for confounding, should get less weight.

# Key Issues, II

- **Outcome Measures:** The available studies have used a wide variety of measurement tools to assess cognitive development in subjects ranging from two days old to late adolescence.
- An important issue is whether and to what extent those many different outcome measures detect effects (beneficial and adverse) of greatest significance. Some indices (such as IQ) may in fact fail to “see” important developmental effects.
- **“Critical” Effect:** Developmental neurotoxicity is actually a broad catch-all category that encompasses many different effects. One goal of IRIS’s assessment should be to determine whether any one aspect (such as visual memory, for instance) stands out as the most sensitive indicator of adverse effect.

# Key Issues, III

- The IRIS review of evidence should attempt to specify and quantify, AMAP, both **beneficial effects** of fish intake by pregnant women **and adverse effects** of prenatal MeHg exposure.
- Both types of effects must be assessed for policymaking and the best approach is to estimate both in the same rigorous, transparent, comprehensive manner.
- Risks and benefits should be quantified **separately**.
- **The concept of “net effects” should be avoided.**
- IRIS should also **avoid risk-benefit modeling**. Models have their uses but they are arbitrary and can mislead.

# Final Thoughts

- IRIS must focus on determining what the evidence shows about the nature and magnitude of risks and benefits, and set aside any consideration of the ultimate policy implications
- Revising (i.e., lowering) the RfD may not be the ultimate policy outcome, but it is an essential step.
- A new, scientifically defensible definition of the “maximum tolerable daily intake” of MeHg is urgently needed, while managing risks of MeHg exposure without simultaneously considering benefits of fish consumption seems likely to be counterproductive for public health.
- Thus IRIS must simply tell us, as closely as the evidence can, what the benefits and risks are, and let others decide how to use that information in policy formulations.