Reviewer's report

Title: Application of the Food Quality Protection Act Children’s Health Safety Factor in the U.S. EPA Pesticide Risk Assessments

Version: 1 Date: 14 Jan 2020

Reviewer: Rebecca Dzubow

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The manuscript is much improved. Thank you for the extensive revisions.

p. 5, lines 14-16. Please be clear that "other sources of uncertainties" existed prior to FQPA and these were folded into the definition of the FQPA SF. Therefore, the general understanding that the FQPA SF always represents a protection for children's health is a misnomer.

p. 8-9, Table 3 for OPs. Although presumably the FQPA SF is not included as is for Tables 1 and 2 because the FQPA will likely be equivalent for all of them, it would be helpful to include this column.

p. 9, line 1,2 - Please rephrase "The FQPA regulations require the EPA to review each registered pesticide at least every 15 years" by deleting "at least".

p. 10, lines 3-5. There are updated human health risk assessments for 5 pyrethroids from November 2019 that could be cited:


p. 10, lines 5-6: For metalaxyl, it is not quite right to say that "EPA did not publish an FQPA determination for the chronic dietary exposures". Rather, "No chronic dietary endpoint was
identified for mefenoxam or metalaxyl; therefore, no chronic dietary assessment was conducted in this assessment.” [51]

p. 10, line 8: when referring to acute exposure, please clarify this is acute dietary exposure.

p. 10, lines 17-19. Please provide a justification for not including the consideration of the FQPA SF for the acute dietary exposures in your assessment; there may be children's health concerns based on adverse effects observed after an acute dietary exposure. Also, provide a citation for stating that chronic dietary exposure "is most relevant for daily exposure to pesticide residues for the general public."

p. 12, lines 14-15. For tebuconazole, please clarify that while EPA first used an FQPA SF of 3X in 2008, it was retained in 2018 [56]. Please also include a discussion as to why the 10X was reduced to 3X in 2008.

P. 12, lines 21-22. For thiophanate methyl, please include a discussion as to why a 3X was selected over a 10X for lack of a developmental thyroid study.


p. 14, line 17. The citation [90] does not seem to match with the text. This reference is the 2011 chlorpyrifos human health risk assessment, and the text refers to a non-published study.

p. 14-16. When referring to the FQPA SF for exposures other than chronic dietary, it would be helpful to discuss briefly that the selection of an endpoint may be from a different study most relevant to that exposure route, necessitating the use of a different FQPA SF.


p. 15, line 15. Please consider revising "an additional 10X factor was applied" to "a 10X factor was also applied".

p. 16, lines 6-7. Please confirm that for all of the other pesticides reviewed in the document, only the two listed had FQPA SF above 1X for acute dietary exposures.
p. 17, lines 13-17. To explain the "baffling decision" to change the endpoint in the metalochlor assessment, please note that the metalochlor tolerance cited dated 3/21/18 used a 1-year chronic dog study with a LOAEL of 33 mg/kg/day based decreased body weight gain in female. EPA has, as required for Registration Review, reassessed all endpoint selections. In the 9/12/19 risk assessment EPA determined that decreased body weight gain in absence of a decrease in body weight ≥10% is not an adverse effect. The endpoint for chronic dietary exposure was replaced by the 2-generation reproduction study in rats with a LOAEL is 86 mg/kg/day based on decreased pup body weight.

p. 18, lines 13-16. In Table 2, it would be helpful to add a footnote or other indication for which pesticides are pyrethroids and neonic.


Replace citation 29 for Ametoctradin scoping doc with the 2017 risk assessment which finds there are no adverse effects, and therefore the FQPA SF is not needed. https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0518-0005

Consider deleting citation 94, as citation 95 as the primary reference should be sufficient.

Consider citing the publication "Toxic Hangover" by the Center For Biological Diversity that was published on January 7, 2020: https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/Toxic-Hangover.pdf

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