CENTER FOR REGULATORY EFFECTIVENESS ("CRE")
COMMENTS OPPOSING
OFFICE OF HEALTH ASSESSMENT AND TRANSLATION ("OHAT") REVIEW OF NEONICOTINOID PESTICIDES:
http://www.gpo.gov/fdsys/pkg/FR-2015-10-07/pdf/2015-25434.pdf.

COMMENTS FILED NOVEMBER 6, 2015 AT
http://ntp.niehs.nih.gov/go/763346 **AND AT** thayer@niehs.nih.gov

OHAT is considering review of the non-cancer human health effects of seven neonicotinoid pesticides ("neonics"):

> CASRN 135410-20-7 or 160430-64-8 (acetamiprid), CASRN 210880-92-5 (clothianidin), CASRN 165252-70-0 (dinotefuran), CASRN 138261-41-3 OR 105827-78-9 (imidacloprid), CASRN 150824-47-8 (nitenpyram), CASRN 111988-49-9 (thiacloprid), and CASRN 153719-23-4 (thiamethoxam). [1]

OHAT should not review these neonics for the following reasons.

- First, OHAT's reviewing thiacloprid would be a waste of time and money because thiacloprid's FIFRA registration has been cancelled. [2]

- Second, OHAT's reviewing nitenpyram would be a waste of time and money because we have been unable to find any FIFRA-registered U.S. products containing nitenpyram.[3] Moreover, the FDA has extensively reviewed the safety of nitenpyram, and OHAT review would add little if anything.[4]

- Third, OHAT's reviewing imidacloprid, thiamethoxam, clothianidin, acetamiprid, or dinotefuran would be a waste of time and money because EPA is already reviewing them with more available resources, power and expertise than OHAT could ever have. As part of its review, EPA will prepare and publish for comment human health risk assessments for both cancer and non-cancer effects. OHAT could comment on

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[1] http://ntp.niehs.nih.gov/pubhealth/hat/noms/index-1.html#neon .
[2] http://www2.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides .
[3] *See, e.g.,* http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC43609
[4] *See, e.g.,* http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm117258.pdf ; http://www.accessdata.fda.gov/spl/data/63b9d7f5-ca5e-4b45-978f-22031dac526e/63b9d7f5-ca5e-4b45-978f-22031dac526e.xml ; and http://www.fda.gov/ohrms/dockets/98fr/nada141-205-fois0828703.pdf.pdf .

EPA's draft risk assessments if OHAT believes it has anything to add to EPA's extensive work.[5]

EPA is statutorily required to assess and regulate these neonics under FIFRA. EPA has already reviewed them once during their FIFRA registration and imposed those use restrictions that EPA deems necessary to protect human health. During EPA's review, the Agency developed an extensive expertise in neonics.

EPA is again reviewing the five active neonics under FIFRA.[6] EPA has authority to require additional studies if necessary and appropriate, and EPA has authority to impose use restrictions necessary and appropriate to prevent any human health risks they may present.

By contrast, OHAT has no experience regulating these neonics, and OHAT is not statutorily required to assess and regulate them. OHAT would be engaging in the same activities and providing the same services to the same beneficiaries as EPA if OHAT reviews these neonics. Consequently, OHAT review of these neonics would be a duplicative and an unproductive waste of time and taxpayer money.

OHAT is not transparent about the neonic review nominations. There is no publicly available record as to who nominated them, or why they were nominated.

We assume that the nomination may have something to do with the recent European Food Safety Authority's ("EFSA") *Scientific Opinion on the Developmental Neurotoxicity Potential of Acetamiprid and Imidacloprid*.[7] For the following reasons, this article does not support OHAT's review of the seven nominated neonics.

- First, the EFSA article only discusses acetamiprid and imidacloprid. It could not support review of the five other nominated neonics.

- Second, the EFSA article concludes that additional testing is necessary to reliably characterize the neurotoxic potential of acetamiprid and imidacloprid . The article concludes that the current literature base is inadequate for this task, and the article criticizes the available studies.[8]

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[5] On November 6, 2015, and after public notice and comment, EPA revised existing tolerances with regional restrictions for residues of acetamiprid in or on clover, forage and clover, and hay. http://www.gpo.gov/fdsys/pkg/FR-2015-11-06/pdf/2015-28356.pdf .OHAT could have commented on this EPA action but didn't.

[6] http://www2.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides . This link provides links to EPA's FIFRA dockets for the OHAT nominated neonics .

[7] http://www.efsa.europa.eu/en/efsajournal/pub/3471 .

[8] *E.g.*, EFSA Article, Abstract and pages 3-4, http://www.efsa.europa.eu/en/efsajournal/pub/3471 .

OHAT would only review the current literature. It would not conduct or order additional testing.[9] Consequently, if the EFSA article is correct about the need for additional testing, then it would be a waste of time and taxpayer money for OHAT to review the nominated neonics.

By contrast, EPA'S FIFRA review is not limited to the current literature base. EPA can order additional testing if necessary and appropriate.

Any OHAT review of neonics would have to meet the NIH/HHS Information Quality Act ("IQA") Guidelines.[10] Based on the EFSA article, none of the studies suggesting that neonics cause neurotox effects could comply with the IQA Guidelines. If the EFSA article is correct, then OHAT would also be unable to meet reproducibility requirements for any current studies indicating neurotoxicity from neonics.[11] The EFSA article itself states:

> "The *in vitro* system used in the study of Kimura-Kuroda et al. (2012) covers only very limited aspects of brain functions and its limitations currently prevent its use as a tool for screening developmental neurotoxicants in the regulatory arena. In particular, the *in vitro*system as proposed by this study requires considerable further characterisation and should be investigated to assess its relevance to the *in vivo* situation. ***To extend confidence in findings, provision of positive and negative controls and scrutiny of data for reliability and reproducibility are required***. Only then should a test based on this system be considered as a possible screening tool for neurotoxicity potential."[12]

It should be noted that the Department of Justice in *Harknonen v. DOJ and OMB* informed the court that OMB has the final decision authority when requests ate filed under the IQA.[13] Petitioners can also seek judicial review in the courts as CRE did in *Tozzi v. HHS*.[14]

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[9] See, *e.g.,* http://www.gpo.gov/fdsys/pkg/FR-2015-10-07/pdf/2015-25434.pdf ("On behalf of NTP, OHAT conducts literature-based evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures… cause adverse non-cancer health outcomes").

[10] These IQA guidelines are available at http://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public/i-national-institutes-health .

[11] See, *e.g.*, Intersection of Systematic Review Methodology with the NIH Reproducibility Initiative, at http://ehp.niehs.nih.gov/wp-content/uploads/122/7/ehp.1408671.pdf and NIH's Reproducibility Initiative website at http://www.nih.gov/science/reproducibility/ .

[12] Summary, at http://www.efsa.europa.eu/en/efsajournal/pub/3471 (emphasis added) .

[13] http://thecre.com/pdf/20130609_Harkonen_Armicus.pdf .

[14] http://www.thecre.com/pdf/20020425-tozzi.pdf .

Any DQA litigation over OHAT neonic review would be enhanced by The National Academy of Sciences' recent report entitled *Reproducibility Issues in Research with Animals and Animal Models: Workshop in Brief (2015).* This NAS Report cited estimates "that 85% of research investment/resources is ultimately 'wasted'" because they are not reproducible and have other quality problems.[15]

For the reasons stated above, OHAT review of the neonics would be wasted and duplicative and should not occur. OHAT has no standard regulatory structure, no means or experience to provide an open review, has not been transparent about the review nominations, and has no authority under FIFRA to regulate neonics. Based on this, the US Taxpayer should not fund two review organizations, one of which has no regulatory authority.

We thank you for the opportunity to submit these comments.

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[15] http://www.nap.edu/read/21835/chapter/1 .