November 6, 2015 [filed via email]

Dr. Kristina Thayer
Director, Office of Health Assessment and Translation
DNTP, NIEHS
111 T.W. Alexander Drive
Research Triangle Park, NC 27709

RE: Nominations to the Report on Carcinogens and Office of Health Assessment and Translation; Request for Information (80 FR 60692; October 7, 2015)

Dear Dr. Thayer:

CropLife America (CLA) appreciates the opportunity to comment on the nomination of "neonicotinoid pesticides" for evaluation of non-cancer health outcomes by the Office of Health Assessment and Translation (OHAT), in the subject Request for Information (RFI). The neonicotinoid class of pesticides includes several substances, which are not specifically listed in the RFI. From contacts with your office, we understand the following substances are under consideration: clothianidin, dinotefuran, imidacloprid, acetamiprid, thiamethoxam, nitenpyram, and thiacloprid.

CLA is the national trade association that represents the manufacturers, formulators and distributors of crop protection products. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by farmers, ranchers and landowners in the United States. CLA comments publicly on issues of general importance and concern to our member companies.

CLA sees no reason or rational scientific motivation for OHAT to pursue this evaluation. Since the nomination process is shrouded in mystery, we are unable to respond to specific rationale or justification offered for conducting such an evaluation. The FIFRA registrations for all products containing thiacloprid have been cancelled, and they are no longer used in the United States. Nitenpyram has never been registered under FIFRA in the U.S.

The remaining substances are all in advanced stages of Registration Review by EPA, in close collaboration with pesticide regulatory authorities in California's Department of Pesticide Regulation (CalDPR) and Canada's Pesticide Management Regulatory Authority (PMRA), to be completed in large part by December 2017. Registration Review is required under FIFRA §3(g) and implementing regulations. It involves a comprehensive reevaluation by EPA's cadre of toxicologists of –

(a) all the studies submitted to EPA by registrants in support of the original registration of each active ingredient, in accordance with requirements detailed in 40 CFR Part 158 and associated study protocols;

(b) all studies conducted and submitted to EPA, subsequent to that initial registration, to support expanded uses of the products and revision of product use instructions;
(c) all studies and research conducted on the compounds by anyone, anywhere, identifying health effects that are new or different or observed at-lower doses or in different species (required by FIFRA §6(a)(2) and implementing regulations);
(d) all reports of observed adverse health effects potentially resulting from exposure to the substances (required by FIFRA §6(a)(2) and implementing regulations);
(e) all new studies required of the registrants by EPA during initial stages of Registration Review, in the course of comparing data on hand to current data requirements for registration support, or additional toxicological concerns that may have arisen; and
(f) a current, comprehensive review of the peer reviewed literature, including "gray" literature.

EPA's assessment routinely involves a deep dive by competent toxicologists into the raw data from the various studies, not just a superficial dependence on the peer review process that would be conducted for publication in a scientific journal. All studies conducted under (a), (b), and (c) above must comply with strict and robust Good Laboratory Practice Standards (40 CFR Part 160) to assure data quality and integrity, under penalty of civil and criminal sanctions.

OHAT's review cannot expect to accomplish more than unnecessary duplication of a small fraction of this process at a relatively shallow level, which would be wasteful of government resources. Conclusions and recommendations that the OHAT review process might reach would omit consideration of the bulk of the scientific information available.

From contacts with your office, we understand that commenting on the nominations is an open process, not bound by a hard deadline. We anticipate submitting additional information to OHAT by December 15.

Sincerely,
[Redacted]

Ray S. McAllister
Senior Director, Regulatory Policy

Cc: Jack Housenger, Rick Keigwin, Dana Vogel (EPA/OPP)
Sheryl Kunickis (USDA/OSec/OPMP)