Message

**From**: Janet Collins [jcollins@croplifeamerica.org]
**Sent**: 6/16/2017 12:15:43 AM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**CC**: Jay Vroom [JVroom@croplifeamerica.org]; Mary Jo Tomalewski [mjtomalewski@croplifeamerica.org]; Beau Greenwood [BGreenwood@croplifeamerica.org]; Cindy Baker-Smith (csmith@gowanco.com) [csmith@gowanco.com]
**Subject**: Follow up materials
**Attachments**: f CLA Petition for rulemaking_epidemiological criteria 122810.pdf; EPA response to epi petition.pdf; FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf; EPA Literature Review Neuro Dev of OPs Sept 15 2015.pdf; 2016 Literature ReviewEPA-HQ-OPP-2008-0316-0073.pdf; 2016 Framework EPA-HQ-OPP-2008-0316-0072.pdf

**Flag**: Flag for follow up

Nancy- thanks very much for taking an appointment yesterday with CropLife America (CLA) CEO and President, Jay Vroom; CLA member, Cindy Baker Smith from Gowan Company; Executive Vice President, Government Relations, Beau Greenwood; and me to discuss concerns our members have regarding EPA/HED use of epidemiological data and a literature review supporting the EPA position, in spite of the fact that the Administrator has questioned the use of epidemiologic study outcomes in human risk assessment. We are concerned that the continual posting of such documents on open dockets, as supporting documents in those dockets, creates a record as to where EPA is acting and regulating with respect to its approach to integration of data sources and weight of evidence in human risk assessment.

Attached please find documents that provide some perspective as to the approach EPA is taking, and CLA objections to such approach:

- CLA 2010 petition to EPA, requesting guidance from EPA on use of epi studies prior to any regulatory use of such studies in human risk assessment;
- EPA response letter, denying the petition, but stating that EPA would put out guidance on the topic for notice and comment which has not occurred;
- CLA 2016 petition requesting EPA not use such epidemiologic studies until EPA developed criteria for use and design of the studies- November 2016, no response to date;
- 2015 EPA literature review to support EPA/HED use of epi studies in organophosphate [OP (and by association, other OPs)] human risk assessment;
- 2016 EPA literature review updated from 2015, posted to dockets in late May, 2017; and,
- EPA's 2016 Framework (updated from 2010) for integration of epidemiological studies- posted on the EPA website on December 28 2016, with no notice or comment.

After your review of these documents, should you wish to discuss them or ask specific questions, please let me know and we will arrange a time to meet as quickly as convenient for you.

Once again, thanks for the time you spent with us on this important issue.

My best,

Janet E Collins, Ph.D., R.D.
Executive Vice President, Science and Regulatory Affairs
CropLife America
1156 15th Street, NW; Suite 400
Washington DC 20001

**Ex. 6**