January 23, 2015

SUBMITTED TO THE ELECTRONIC DOCKET

OPP Docket
Environmental Protection Agency Docket Center
1200 Pennsylvania Ave, N.W
Washington, DC 20460-0001
Via Regulations.gov

RE: ***Benefits of Neonicotinoid Seed Treatments to Soybean Production;*** **79 FR 63118; October 22, 2014; Docket No. EPA-HQ-OPP-2014-0737.**

Ladies & Gentlemen:

The American Seed Trade Association (ASTA) and CropLife America (CLA) appreciate the opportunity to provide comments to docket EPA-HQ-OPP-2014-0737 regarding EPA's assessment of the benefits of neonicotinoid seed treatments on soybeans.

ASTA's mission is to enhance the development and movement of quality seed worldwide. ASTA's diverse membership consists of over 700 companies involved in seed production, distribution, plant breeding and related industries in North America. ASTA represents all varieties of seeds, including grasses, forages, flowers, vegetables, row crops and cereals. Many ASTA members are research-intensive companies engaged in the discovery, development and marketing of seed varieties with enhanced agronomic and end-use quality characteristics.

CLA is the national trade association representing the manufacturers, formulators, and distributors of crop protection products in the US. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers. CLA represents its member companies' interests by, among other things, monitoring legislation, federal agency regulations and agency actions and related litigation to identify issues of concern to the crop protection and pest control industry, and participating in such actions when appropriate.

We challenge the conclusion of EPA's preliminary report stating neonicotinoid insecticide seed treatments provide "limited to no benefit." Our comments document that neonicotinoid insecticide seed treatments are valuable tools for soybean production because of the demonstrated benefits they provide. While it is understood that EPA is conducting a re-evaluation of clothianidin, imidacloprid, and thiamethoxam under the registration review program, we respectfully submit that a benefits assessment for a single use *before* the Agency

has completed its final risk assessment for imidacloprid, thiamethoxam and clothianidin compromises registration review. Inviting public comment on a portion of the review on a single crop is highly unusual and appears to be motivated by external pressure regarding neonicotinoid insecticides.

Summary:

- **Neonicotinoid insecticide seed treatments have been available commercially for over 10 years; numerous data sets exist that show the value of the technology to soybean production.**
- **Yield benefits are best assessed from replicated trials or through meta-analysis approaches.**
- **While yield is an important factor for an economic benefits analysis, other factors are also important to consider including agronomic benefits, risk management needs, environmental benefits and disadvantages associated with alternatives.**
- **The process used by EPA to date is inconsistent with law and basic principles of fairness.**
- **We feel the publication of this report has needlessly cast uncertainty over products with demonstrated benefits, which our comments and those of many others describe.**

1. Yield and economic impact of neonicotinoid insecticide seed treatments on soybeans

The EPA BEAD preliminary report underestimated yield benefits of neonicotinoids to soybean production. Before finalizing their analysis, EPA should seek input from soybean farmers, seed industry experts and academics, in particular extension agronomists, plant pathologists, and entomologists to better understand the value of the technology as it relates to different crop management practices and regions. Extension papers, journal articles, and other public documents are likely sources of accurate information on benefits of neonicotinoid seed treatments, including yield. A few examples are below.

- The consulting firm AgInfomatics (Mitchell, 2014c) conducted a meta-analysis of soybean yield data from 23 states from 2001-2013 from trials conducted by university faculty and academic staff and third-party private researchers (not including data used in the BEAD report). AgInfomatics found an average **yield advantage of 2.8% for soybeans**, using neonicotinoid seed treatments relative to untreated seed.
- USDA ERS (2014) reported that US soybean yields averaged 42.5 bushels per acre from 2004 to 2014, with typical season-to-season average increases of 1% or less. An increase of 2.8% would represent a significant improvement to a soybean grower, and an input that could economically deliver a 2.8% increase would be a worthwhile investment. With average yields below 50 bushels per acre, and 5-year soybean prices received by U.S. farmers ranging from $9.59 per bushel to $14.40 per bushel (USDA ERS, 2015), it is critical that soybean farmers have access to every crop protection tool to protect the value of their harvest.
- Gaspar et al. (2014a) reported a **4% and 12% yield increase** for soybeans planted at 140,000 and 40,000 seeds per acre, respectively, in Wisconsin field trials, when using a

combined fungicide and neonic seed treatment versus fungicide only or the untreated control.

- Catchot et al. (2014) at Mississippi State University investigated the impact of planting date, soybean maturity group, and insecticide seed treatment on soybean yield and economics over multiple years, in work funded by the Mississippi Soybean Promotion Board. At all locations, the insecticide seed treatment resulted in yields significantly higher than the fungicide only treatment. The average yield advantage was **2.5 bushels/acre** across planting dates, maturity groups, and locations.
- In University of Tennessee Extension's 2013 Insect Control Recommendations for Field Crops, Stewart and McClure (2013) report an average **soybean yield increases of 1 to 3 bushels/acre**, attributable to insecticide seed treatments, with higher responses occurring in early planted soybeans.
- A meta-analysis of yield data referenced in the BEAD report reveals a **2.6 bushels/acre benefit** of neonicotinoid seed treatments (Bayer 2015). Using the EPA's grower cost estimate for a neonicotinoid seed treatment ($7.50 per acre), and 5-year soybean prices received by U.S. farmers ranging from $9.59 per bushel to $14.40 per bushel (USDA ERS, 2015), an average yield increase of 2.6 bushels/acre delivers $25/acre to $37/acre, or more than a three to one return on investment to the grower.

2. Assessing yield benefits

EPA expressed certainty regarding its conclusions in the report despite the fact that it is based on a limited data set of 26 insect efficacy studies from university publications, nine articles, and responses of 21 academic entomologists to an unpublished questionnaire.

Most concerning is that EPA evaluated each of the studies independently, rather than using a common scientific approach of a meta-analysis. By summarizing the results of multiple studies, a meta-analysis increases the sample size and thus the power to discern the effects of interest, in this case yield effects. The main objectives of a meta-analysis are to summarize and integrate results from a number of individual studies, analyze differences in the results among studies, overcome small sample sizes of individual studies to detect effects of interest, analyze end points that require larger sample sizes, and increase precision in estimating effects.

The individual studies cited by EPA were small plot studies to assess insect damage, often limited to a single location and with seeding rates that greatly exceed what is common practice for commercial soybean production. This is not appropriate for a yield benefits study. Insect damage studies can also be challenging due to the migration of above ground insects such as bean leaf beetles and soybean aphids. A more effective method to assess yield would be a study of larger plots or a larger number of small plots specifically designed to assess the yield effect of insecticide-treated seed. Such studies would consider timing of planting, standard seeding rates, varietal differences, and replications in multiple locations. Despite the limitations of these studies, we note that a meta-analysis of the EPA-cited data reveals consistent yield benefits.

We are concerned that EPA did not contact our member companies to better understand available benefits data on soybeans. If EPA had reviewed data from the registrants and seed companies or

had performed their own analysis differently they would have had a more robust and accurate data set showing clear benefits.

3. Assessing benefits to farmers – a holistic perspective

The BEAD report focuses solely on efficacy of neonicotinoid seed treatment to soybean aphid. Such an important assessment should not singularly focus on entomology, which is a narrow lens to extrapolate yield, which in itself is also an incomplete measure of benefit. A benefits assessment for an insecticide seed treatment should include a robust understanding of yield benefits, but should not be limited to only yield, instead it should consider the full production cycle. The assessment should include data from and consultation with seed companies, farmers, agronomists, entomologists, plant pathologists, agricultural economists and food value chain experts.

We support EPA taking a broader approach in performing any economic benefits analysis for seed treatments and recommend that EPA consult with the US Department of Agriculture to gain a better understanding on how to devise an appropriate assessment.

The consulting firm AgInfomatics analyzed a more robust set of factors in a study of neonicotinoid benefits. They surveyed 500 U.S. soybean farmers about the value they derive from neonicotinoid seed treatments. The AgInfomatics analysis shows that neonicotinoid-treated seeds have an average value of $11.93 per acre for soybean growers relative to their next best alternative. For all soybean acres using neonicotinoids, this adds up to more than $400 million in 2013. This value estimate captures the pest control and yield benefit of neonicotinoid-seed treatments to farmers, along with **time saving, improved risk management, improved resistance management, and enhanced human safety** (Mitchell, 2014a).

Additional factors (direct and indirect) that should be quantified and included in an EPA benefits analysis of seed treatments include, but are not limited to:

- Seed treatment enables early planting, more even plant emergence and more uniform stand establishment;
- Early season pest management;
- Early disease prevention and disease incidence reduction via suppression or control of insect vectors;
- Improved risk management for farmers;
- Environmental benefits including the enablement of environmentally beneficial no-till practices;
- An understanding of alternative pest control options for early season pests, considering
    a) Practicality of implementation on broad acres;
    b) Safety profile of those alternatives, including to beneficial insects; and
    c) Cost of those alternatives to farmers and to the agriculture economy.

A further analysis of the benefits of neonicotinoid seed treatments in soybeans would reveal the benefits they provide regarding earlier planting. Early planting increases yield potential for the crop, but has associated risks for increased disease and early-season insect pest pressure. Earlier planting results in the growth of more vegetative nodes - where flowers and pods are produced –

a major yield factor. Furthermore, early planting maximizes the growing season and allows for timely harvest, which can enable harvest of higher quality grain and better grower returns. However seedlings must be protected by seed treatments at their earliest stages to manage insects and seedling diseases. Gaspar et al. (2014b) found that soybeans treated with neonicotinoid seed treatments had an average increase of 20% in initial plant stands, compared to untreated controls.

The EPA recognized that the adoption rate for neonicotinoid seed treatment on soybeans is fairly low compared to other crops due to reduced insect pest risk factors in soybean production. As noted in the BEAD report, on average, from 2008-2012, neonicotinoid-treated seeds were applied on 30% of soybean acres. Therefore, according to EPA's own report, soybean growers can and do make a determination closer to planting to use neonicotinoid pesticides. Soybean seed treatment typically occurs at the retail level to accommodate this real-time decision making. It is clear, based on the adoption rate noted in the BEAD paper, that non-treated soybean seed is readily available.

Farmers rely on historical data and data provided by university extension staff when making their decisions on how to protect their harvests and their seed investments. While the BEAD report focuses on efficacy of neonicotinoid seed treatment to soybean aphid, the impact of seed treatment on early season pests warrants further analysis. Foliar alternatives exist to help U.S. farmers manage several soybean pests, but foliar insecticides will not provide protection from soil dwelling pests, such as seed maggots, wireworms and white grubs.

Wireworms, seed maggots, bean leaf beetle, grubs or other early season insect pests may be of equal significance as aphids to soybean production and managing risk on the farm. These early season soil dwelling pests are important and understudied targets for insecticide seed treatments, but it is assumed that control of these early season pests plays a role in the consistent increase of yield for neonicotinoid treated seed versus untreated. Currently scouting tools for these pests are either not available or not practical for farmers to implement across the broad acreage most soybean farmers manage. Although there are soil insecticides registered for use in U.S. soybeans, farmers are not using these alternatives because of additional equipment needs that do not fit their standard farming practices. Therefore, insecticide seed treatments have become the most practical and economical method to manage soil-dwelling pests.

- Due to the variability of soil-borne insect pests, and the costs associated with their broad-scale study, there is a paucity of data in the peer-reviewed literature on their occurrence and significance. However AgInfomatics analysis of GfK Kynetec data, based on annual surveys of approximately 4,300 U.S. soybean growers, shows that about one-third of neonicotinoid seed treatments are specifically targeted at soil-dwelling pests (14% at seed maggots, 13% at wireworm and 6% at white grubs) (Mitchell, 2014b).

- Soybean aphids are generally considered later season pests, so it is not expected that an insecticide seed treatment would be likely to provide full control of such a late season pest. A more likely possibility could be suppression of soybean aphid populations. A different study design would be required to measure population suppression than what was used in the trials analyzed in the BEAD report. Although soybean aphids are perhaps the most-studied

of the soybean insect pests, focusing on soybean aphid provides only a narrow view of insect pests in soybean production.

- Another early season pest of significance for soybeans, the bean leaf beetle, can defoliate plants and spread crop diseases, such as bean pod mottle virus, which can greatly impact yield and grain quality. AgInfomatics estimated the impact of neonicotinoid insecticides on pest management practices, estimated that bean leaf beetle was the targeted pest for 10.77 million acres of soybean production (Mitchell 2014b). Controlling insect vectors of disease via insecticide seed treatments provides the added benefit of decreasing risk of crop diseases (*e.g.*, Bradshaw et al. 2008).

Farmers make many decisions about their crop, inputs, and crop management practices to ensure they can produce a high quality crop at harvest, while maintaining economic viability. Accordingly, many of those decisions are based on managing risks to their crop and their livelihood. For many pests, there are no rescue treatments available if a damaging infestation occurs. A farmer cannot protect plants that have already been killed by pests, so he may be forced to replant the crop. Reducing the probability and thereby the financial consequences of replanting are important considerations for most growers. Replanting results in automatic loss of yield (and income) due to the shortened growing season, as well as additional costs for inputs, labor, and machinery depreciation. Additional trips over the field contribute to detrimental soil compaction (Lauer 2002).

Seed treatments are important tools for farmers, as they allow for the right amount of product to be applied in the right place, at the right time for the right pest, decreasing the number of spray applications of agrichemical products and reducing exposure to humans and non-target species, including pollinators. Potential soil surface exposure is reduced by up to 90 percent compared to other application methods such as in-furrow applications or broadcast sprays.

Neonicotinoids also have improved toxicological and ecotoxicological profiles when compared to some of the older chemistries. By limiting access to effective seed treatments, EPA could be removing tools and thereby encouraging insecticide resistance to a more limited group of insecticides.

According to GfK Kynetec data analyzed by the consulting firm AgInfomatics, if neonicotinoid pesticides were not available, 77% of neonicotinoid treated acres would switch to other insecticides - likely organophosphates and synthetic pyrethroids (Mitchel 2014b). 4.0 million pounds of neonicotinoid seed treatments would be replaced with 19.1 million pounds of foliarly applied alternatives (or each pound of neonicotinoid would be replaced with nearly 5 pounds).

Seed treatments have helped encourage the broad adoption of conservation tillage practices by assisting in management of damaging pests that can survive and thrive in cooler, moister soils and crop residues common in early planting, no-tillage systems. According to USDA data, soybeans have the highest adoption rate of no-tillage practices of major crops in the U.S. Soybean farmers used no-tillage at a rate of 45.3 percent in 2006; and almost 50 percent in 2009 (Horowitz 2010).

Lastly, the BEAD report is incorrect to assume that a foliar insecticide spray could automatically be included with an herbicide spray without additional cost. Differential timing of insect pressure and weed pressure may necessitate a separate spray, thus adding expense and additional fuel cost as well as potential environmental impacts. Additional costs may also be required for equipment modification.

4. The Process Used By EPA To Date Is Inconsistent With Law And Basic Principles Of Fairness

FIFRA §3(g) and EPA's regulations at 40 C.F.R. Part 155, Subpart C, provide for a systematic registration review process. That process includes authority for EPA to request relevant data to inform its risk assessments, providing sufficient time for registrants and other stakeholders to generate and supply the data, for EPA to review the data, and for EPA to incorporate the data into its risk assessments. In keeping with its procedures and standard practice, EPA has routinely identified other data – unrelated to benefits – as necessary for registration review. Consistent with FIFRA §3(g), the Agency requests the data and identifies timelines to facilitate registrants and other stakeholders generating and providing relevant data in time to be considered by EPA in completing its risk assessments and reaching its registration review decisions.

EPA made it clear during its rulemaking for registration review that it would assess a pesticide's benefits during registration review *after* the Agency identifies risks of concern. 71 Fed. Reg. 45720, 45725 (August 9, 2006). We respectfully submit that a benefits assessment for a single use *before* the Agency has completed its final risk assessment for imidacloprid, thiamethoxam and clothianidin compromises registration review. EPA should prepare a benefits assessment for all of the uses of an active ingredient after it has completed its risk assessment and after it has established a risk of concern. A benefit assessment must be conducted in the context of a completed risk assessment. Moreover, EPA should first use its authority under FIFRA § 3(c)(2)(B) to call-in benefits data from registrants and engage stakeholders in order to assure that it is has a complete benefits data base.

By contrast, in this case, EPA has published an incomplete benefits analysis for public comment; out of sequence for appropriate risk assessment; without first requesting, receiving, or reviewing all available relevant data; and without incorporating those data into its analysis.

Each registrant must ensure through testing that its product is efficacious and EPA reserves the right to require submission of product performance data. 40 CFR §158.400(e). While EPA does not routinely call in and review the efficacy data for agricultural uses of products, it reserves the right to do so. Such efficacy data would be highly relevant to the conduct of a benefits assessment. Yet to our knowledge, the agency has not called in the efficacy data for these uses of the specific neonicotinoid insecticides. Before EPA completes its consideration of the benefits here, it should follow established procedures, including ensuring that data rights are protected under FIFRA §3 and §10.

It is also important that EPA considers that products undergoing registration reviews, which have been commercialized for a period of time, are likely to have additional or perhaps more robust

benefits data sets compared to pre-commercial products, due to acreage restrictions on field trials of unregistered products.

Moreover, EPA took the highly unusual step of recommending alternatives based on an incomplete subset of information on benefits, before it had the relevant data and conducted its risk assessments, and before conducting a complete alternatives analysis taking into account the human health and environmental risks and benefits of the alternatives. The Agency did so, despite its usual practice of conserving resources by conducting a benefits evaluation only when necessary, for instance, if a completed risk assessment identifies a risk of concern that cannot be sufficiently mitigated through re-formulation of the product or revisions to its label. The Agency did so, despite being in the midst of registration reviews for each of the three neonicotinoid active ingredients discussed in the benefits memo, and despite having announced associated timelines and procedures previously under FIFRA §3(g) and EPA's implementing regulations at 40 CFR Part 155, Subpart C.

EPA's action is not only inconsistent with its own established procedures and practices, it singles out three active ingredients for handling different than the other active ingredients registered for use on soybeans, contrary to core principles embodied in FIFRA. *See, e.g.*, FIFRA §3(c)(5) ("*Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other.*")

5. Requests In Light Of Comments

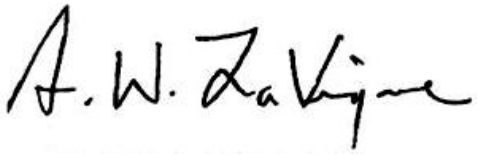
Based on the information included here and in comments submitted by companies, university scientists, and farmers with intimate knowledge of seed treatment yield impacts, we find the announcement by EPA that "U.S. soybean farmers see little or no benefit from neonicotinoid seed treatments" to be incorrect and damaging.

CLA and ASTA respectfully request that:

- EPA not take action or rely on the broad conclusions set forth in the BEAD memorandum, which is based on partial information and an incomplete analysis;
- EPA request, and provide sufficient time for the generation and submission of, relevant benefits data;
- after submission of the registrant data, EPA review and incorporate those data into its analysis; and
- if it becomes appropriate to consider alternatives in the future after completing its risk assessments, EPA conduct a complete alternatives analysis, taking into account the full health and environmental risks and benefits of the alternatives, with a meaningful opportunity for public comment.

For any questions regarding these comments, please feel free to contact Jane DeMarchi (703-837-8140; jdemarchi@amseed.org) and Ray McAllister (202-872-3874; rmcallister@croplifeamerica.org).

Sincerely,



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