

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460

DEC -5 2017

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

- Biological and Economic Analysis Division (BEAD) Response to Public SUBJECT: Comments Submitted in Response to BEAD's Assessment entitled "Benefits of Neonicotinoid Seed Treatments to Soybean Production" Dated October 15, 2014, OPP Docket: EPA-HQ-OPP-2014-0737
- Clayton Myers, Ph.D., Senior Biologist FROM: Nikhil Mallampalli, Ph.D., Entomologist **Biological Analysis Branch**

TJ Wyatt, Economist Economic Analysis Branch

h 7 Wjatt Mousha Kaul Monisha Kaul, Chief **THRU: Biological Analysis Branch**

> Tim Kiely, Chief Economic Analysis Branch

Neil Anderson, Chief TO: Risk Management and Implementation Branch I (RMIB 1) Pesticide Re-evaluation Division (7508P)

Product Review Panel: December 21, 2015

INTRODUCTION

In October, 2014, the Biological and Economic Analysis Division's (BEAD) of the Office of Pesticide Programs (OPP) published an assessment of the value soybean growers obtained from the use of nitroguanidine neonicotinoids, imidacloprid, thiamethoxam, and clothianidin, as seed treatments, "Benefits of Neonicotinoid Seed Treatments to Soybean Production" (Myers and Hill, 2014). BEAD concluded in that assessment that these seed treatments provided negligible benefits on average to soybean producers in most situations. In comparison to the next best alternative pest control measures, BEAD estimated that, on average across the U.S., growers were likely to obtain \$0 to \$6 per acre in benefits by using one of these neonicotinoid seed treatment products on soybeans. This represents an impact of 0% to 1.7% to net operating revenue. Given the distribution of benefits across the treated acreage, BEAD estimated the total benefit to the soybean industry to be at most \$52 million per year. BEAD also noted potential insurance benefits of neonicotinoid seed treatments against sporadic and unpredictable pests. However, BEAD did not find publically available information on the magnitude or significance of these potential benefits. BEAD found that these benefits may be particularly relevant for the southeastern United States, but characterized them as uncertainties.

OPP received numerous public comments in response to the assessment. Of the more than 40,000 public comments submitted to the EPA docket in response to this assessment, BEAD has identified approximately 150 comments that contained substantive information and/or cited additional data that was directly relevant to BEAD's analysis. A large number of comments consisted of letter-writing campaigns by multiple stakeholders, mainly in opposition to neonicotinoids. There were also numerous comments in support of neonicotinoid seed treatment, some of which included anecdotal claims of yield benefits or lack thereof.

This memo provides responses to the approximately 150 substantive comments submitted, generally grouped according to similar content and is organized as follows.

- I. Responses to broad and generalized topics that were raised in numerous comments related to
 - A. the registration review process and timing of assessments, p. 4;
 - B. the purpose and scope of the benefit assessments, p. 6
 - C. various advantages and disadvantages of neonicotinoid seed treatments, p. 6; and
 - D. other benefits or costs that commenters thought should be considered, p. 9.
- II. Responses to extensive comments from specific stakeholders. Stakeholders include A. registrants, p. 10;
 - B. non-governmental organizations, p. 23;
 - C. government stakeholders, p. 31; and
 - D. university extension programs, p. 35.

Based on the information in these comments, Section III (p. 43) provides a revised assessment of the benefits of neonicotinoid seed treatments. The revised assessment accounts for regional differences in production practices and pest pressure and is summarized below.

SUMMARY OF NEW CONCLUSIONS

Numerous commenters stated that the original analysis on the benefits of seed treatments on soybeans did not adequately address differences in pest control needs by region. BEAD acknowledges this limitation and, given data and information provided through the public comment period, modifies the estimated impacts for two areas of the country where usage of neonicotinoid seed treatments is likely to have higher benefits than the national average as presented in BEAD's initial analysis.

- In the mid-South, including the states of LA, MS, AR, TN, and MO, climatic, biological, and agronomic practices combine to cause a high level of pest pressure from soil-dwelling insects, many of which are not well-identified. BEAD estimates that, in the absence of neonicotinoid seed treatments, reductions in yield could reduce net revenue by about \$23 per acre, about 8%, for areas in the mid-South with known high pressure from soil pests. This result assumes that permethrin seed treatments, although similar in cost and efficacy for soil pests, remain unmarketed in the United States. If permethrin seed treatments become available for widespread use, then estimated impacts would be negligible.
- For the Midwestern U.S., comprised of IA, NE, SD, ND, MN, IL, and WI, commenters pointed out that bean pod mottle virus (BPMV) vectored by bean leaf beetle (BLB) is a significant concern. Neonicotinoid seed treatments would likely be replaced by a foliar insecticide application at an increased cost of \$5 per acre, or 1% of net operating revenue. In rare cases, a second application might be required within the early-season window of typical seed treatment bioactivity; BEAD estimates the total additional insecticide cost to be about \$17 per acre (4% of net operating revenue). BEAD's estimate for this cost differential may underestimate the impacts somewhat since there is a risk that ground applications cannot be made in the early season due to wet conditions, however BLB could still be adequately controlled with a later application.

Numerous comments from the Agricultural Research Service of the Department of Agriculture (USDA-ARS) and university extension experts, support BEAD's original conclusions that, outside of these two areas, the benefits of neonicotinoid seed treatments are generally low for most soybean growers in the United States.

BEAD estimates the total benefits of neonicotinoid seed treatments nationally to be up to \$215 million per year.

I. GENERAL TOPICS

Numerous submitted public comments cited identical information, identified common concerns, or shared common elements. This section addresses these common topics, without attribution to specific comments. Appendix I provides a list of the comments, by docket reference number, addressed by each of BEAD's responses.

A. Issues of Process

1. The release of a benefit assessment prior to release of a risk assessment is unusual, improper, invalid, and politically motivated.

RESPONSE: The timing of release was somewhat unusual, but not improper. In general, during Registration Review, EPA conducts both human health and ecological risk assessments and issues them at the same time. Assessments of pesticide benefits or of impacts of potential risk management actions are conducted to inform the registration review decision but are typically issued at the same time as the proposed decision. Due to the role the neonicotinoid insecticides have occupied in the dialogue around pollinator health, EPA initiated specific pollinator risk assessments for clothianidin, dinotefuran, imidacloprid, and thiamethoxam, following the harmonized pollinator assessment framework developed by the Agency in collaboration with other regulatory entities (EPA, PMRA, CDPR, 2014). Seed treatments were particularly contentious. See, for example, the Center for Food Safety Report, "Pollinators and Pesticides" (CFS, 2013). Moreover, some published research review material at the time (Stevens and Jenkins, 2014) found limited benefits to the use of neonicotinoid seed treatments. OPP, therefore, decided to review the available information, inform the public of its findings, and solicit comments. While unusual in timing, the assessment was not a violation of any review process.

BEAD also notes that the publication of its assessment has elicited numerous comments and brought about valuable input from additional stakeholders that has helped BEAD to refine its estimates. BEAD has incorporated additional data submitted by registrants, university researchers, and other stakeholders and has revised impact estimates accordingly. This is precisely the point of a public comment process and BEAD appreciates the input it has received.

2. EPA should not wait for the registration review process to proceed before conducting benefit analyses for neonicotinoid use on other crops and EPA should not wait to take regulatory action on the neonicotinoids, based upon established risks.

RESPONSE: BEAD will conduct additional benefits assessments when OPP determines it is necessary to conduct such assessments to evaluate whether the use of a pesticide is consistent with the FIFRA standard.

3. BEAD did not follow, or did not have in place, appropriate processes for collecting information to conduct the assessment.

RESPONSE: BEAD followed the usual process for conducting a benefit assessment. The benefits of a pesticide for the user are evaluated in comparison to the available alternatives for the same use. Briefly, the Division relies on pesticide labels, market research data, and extension publications to identify the pests targeted by a pesticide application and to identify possible alternatives that could be used. Likely alternatives are chosen based on economic theory and biological considerations. The benefits of a pesticide's use are measured in comparison to the next best available pest control option in terms of increased pest control costs per acre or, if appropriate, losses in yield or quality of product. Market research data and extension publications inform the estimates of cost differentials and comparative product performance. The Division frequently solicits input from research personnel through contacts with USDA's Office of Pest Management Policy (USDA OPMP). These procedures were followed to gather information to conduct the assessment of benefits of neonicotinoid soybean seed treatments.

4. BEAD was too selective and narrowly focused in their data analyses and did not take into account data on benefits from registrants and the contracted analysis done by AgInfomatics (2014).

RESPONSE: BEAD worked with the USDA's Office of Pest Management Policy (OPMP) and the North Central IPM Center to collect information, including unpublished data. Because registrants are not required to submit efficacy data for agricultural pesticides unless specifically requested by the Agency and except as provided under FIFRA Section 6(a)(2), BEAD did not have immediate access to data held by registrants and did not require submission of such data. It is unclear how much of the available data measures efficacy in terms of crop yield, which is the type of data most useful for an impact analysis. The 2014 AgInfomatics analysis was not submitted until after BEAD had completed and released its draft analysis. BEAD has received numerous sets of additional data from multiple registrants, reviewed the submission from AgInfomatics (which included an analysis of a larger data set and included registrant data), and considered this information in the revised benefits assessment. It is notable that BEAD's original impact estimates of 0-\$6 per acre for soybeans was comparable to the impact projected by AgInfomatics (\$3.30 per acre for soybeans).

Finally, all comments and additional data received will be considered before any risk management proposal is made. BEAD re-iterates that seed treatment efficacy against target pests is well-established and not at all in question with regard to this analysis. BEAD recognizes that these products are effective. The question of benefits is a separate issue.

B. Scope of the Assessment

1. BEAD's scope of inquiry was too narrow and BEAD should have discussed the costs and benefits of alternatives.

RESPONSE: The assessment, and this response document, both evaluate whether alternatives provided more/less/similar control of pests (benefits) and considers the comparative costs.

2. EPA should release reviews for other crops, especially corn and canola.

RESPONSE: As part of OPP's ongoing registration review process, analysis of benefits for any pesticide and/or chemical use pattern may include additional evaluations of seed treatments and/or foliar applications on additional crops. If forthcoming risk assessments or other information indicate that seed treatment usage on additional crops could drive unacceptable levels of risk, BEAD will consider the benefits of seed treatments on those additional crops to inform the Agency's registration review decisions. OPP will provide an opportunity for public comment on any registration review decision.

C. Advantages and Disadvantages of Seed Treatments

1. Neonicotinoid seed treatments are the only viable option in soybeans for controlling soil pests, which are very difficult to scout and are often sporadic in occurrence/economic importance. This was particularly emphasized for soybeans in the mid-South U.S., due to various agronomic factors occurring in that growing region.

RESPONSE: Commenters from land grant universities expanded on this comment (see Section II.D). While BEAD agrees that soil pests are problematic with regard to scouting and predicting outbreaks, permethrin seed treatments are an effective, registered method for controlling soil pests, such as seedcorn maggot (Hammond, 2002). BEAD confirmed with the registrant that the permethrin seed treatment products are being produced and marketed. However, discussions with numerous extension experts, particularly in the mid-South indicated that these products may not be widely marketed. BEAD understands that given the apparent limited availability of permethrin treated seed (possibly due to low production that is driven by the current availability of neonicotinoids) and the lack of any systemic activity (i.e., protection of the plant after germination), this may not necessarily be an ideal alternative to seed treated with neonicotinoids. Numerous commenters have underscored the potential difficulty in controlling problematic soil pests if neonicotinoid treated seed was not available.

2. Seed treatments allow for early planting into cool and/or wet soils.

RESPONSE: BEAD has received numerous comments and additional information regarding the importance of early planting of soybeans, particularly in the mid-South United States, and a more detailed specific response to those issues presented by land grant universities in Section II.D. BEAD did not originally take planting date into account when estimating benefits of treated soybean seed, and now has incorporated this agronomic benefit into its analysis of the mid-South production region. Because early planting often coincides with cool and damp soils that are conducive to higher populations of some soil-borne insect pests, the use of insecticide-treated seed can provide a useful insurance-based protection against attack from these pests. BEAD notes that a permethrin seed treatment product is registered for use on soybeans and available (although not widely used at this time), and that this product has been demonstrated to be efficacious against seedcorn maggots (Hammond, 2002). However, other commenters have noted that they are uncertain about the actual availability of this product. BEAD understands that given the apparent limited availability of permethrin treated seed, and the lack of any systemic activity (i.e., no protection of the plant after germination) this may not necessarily be an ideal alternative to seed treated with neonicotinoids.

3. Seed treatments preclude the need for foliar spraying on soybeans.

RESPONSE: BEAD disagrees with this comment and has determined that seed treatment adoption has not resulted in a reduction in foliar insecticide usage on soybeans. BEAD analyzed data on pesticide use from 1998-2013 for soybeans and notes that usage of foliar insecticides has increased appreciably over the same time period as the observed increased usage of neonicotinoid seed treatments, 2004-present (MRD, 1998-2013). While it is true that significant soybean acreage in the U.S. that is treated with insecticide receives only a seed treatment, it remains notable that prior to 2004, almost no insecticide usage was observed on soybeans at all. Also, given the lack of an identified target pest for much of this usage, and based on a number of other submitted comments, BEAD is confident in concluding that much of this existing seed treatment usage on soybeans is preventative, and that in the hypothetical absence of neonicotinoid seed treatments, much of this acreage would remain untreated with any insecticide. Furthermore, given that neonicotinoid seed treatments are known to only confer 3-4 weeks of protection to the emerging plant after planting, that later season outbreaks of bean leaf beetles, soybean aphids, or other foliar feeding pests that exceed threshold would still necessitate a foliar insecticide application. This is particularly true for areas of the U.S. that have seen heavy infestation pressure from soybean aphid, which is most often observed later in the growing season, long after any protective efficacy would be observed from neonicotinoid residues remaining in plants from treatment of the seeds. BEAD agrees that there are conceivable examples of situations where a seed treatment could preclude an early season foliar insecticide application (particularly for control of bean leaf beetles in areas where the bean pod mottle virus is present, which is discussed later). BEAD does not agree with the implication that seed treatments always, or even often, preclude the need for a subsequent foliar spray, particularly in situations where late-arriving pests become established and exceed treatment thresholds.

- 4. Comments presented two views on preventative/prophylactic pesticide usage:
 - a. Prophylactic applications are not a favorable approach for integrated pest management.
 - b. Prophylactic pest control tactics can be a legitimate and useful tactic within a larger IPM framework, and just because target pest populations aren't always known at the

time of planting, does not mean that seed treatments are unnecessary or without benefits.

RESPONSE: A cornerstone of integrated pest management (IPM) is the concept that any pest control tactics must effectively target pests that are expected to cause economic damage. The decision to deploy any tactic is therefore based upon an understanding of the expected benefits of the tactic in terms of protected value from yield and/or quality. Some pest problems occur in agriculture with such frequency and predictable regularity that preventative or prophylactic approaches are very often warranted. Any such decision requires background information about the site history, soil and climatic conditions, agronomic practices, and past pest incidence. For sites with a known history of infestation from problematic pests, a pre-planting decision to make use of a prophylactic control tactic such as insecticidal seed treatment may well be the most biologically and economically preferred option. On the whole, there is nothing in any widely accepted definition of IPM that automatically precludes the judicious use of preventative tactics. However, if there is reason to believe that pest pressure will not exceed established economic thresholds or if there is no history of problematic pest occurrence at a given site, the benefits of preventative tactics may be low, or at the least, much less certain. BEAD concludes that for instances where pest pressure is known to be low or where there is little to no history of past pest problems, and given the availability of effective alternatives to control even a large emergence of those pests later, the benefits of preventative treatments are likely to be negligible.

5. Seed treatments preclude the need for soybean re-planting and allow for reduced tillage systems to be effective.

RESPONSE: BEAD agrees that in instances where soil pest pressure necessitates control, that neonicotinoid seed treatments are very effective at protecting the seed from damage and thus precluding the need for replant. BEAD notes that seed treatments containing permethrin remain registered, are effective against soil pests such as seedcorn maggot (Hammond, 2002) and are available for use on soybeans in the United States, although these products are apparently not widely used or marketed, according to MRD (2004-2013) as well as input from other commenters. The lack of usage may be due to the widespread existing usage of neonicotinoid seed treatments. However, BEAD also understands that given the possible limited availability of permethrin treated seed, and the lack of any systemic activity (i.e., protection of the plant after germination) this may not necessarily be an ideal alternative to seed treated with neonicotinoids. As discussed below (Section III), BEAD acknowledges that in some areas of the United States, the benefits of preventative seed treatment usage in soybeans are likely to be higher than what was estimated in BEAD's original assessment.

6. Seed treatments confer increased convenience.

RESPONSE: While BEAD's original assessment assumed that applications of alternative foliar insecticides could be done via tank-mixing with other pesticides already being applied to fields, BEAD acknowledges that a number of technical and timing issues can preclude the ability of growers to tank mix an alternative insecticide with an herbicide or fungicide

application. BEAD discusses this in more detail below and revises the impact estimate to include the cost for additional pass(es) over fields. Beyond the cost of the additional pass over the field, BEAD has not been able to quantify the value of 'convenience' for growers, since the use of seed treatments alone does not necessarily preclude the subsequent need for scouting and potentially additional pesticide applications to a field, beyond the typical period of bioactivity for seed treatments (i.e., 3-4 weeks after planting).

7. The high adoption rates of seed treatments are themselves indicative of benefits; i.e., if growers didn't see real benefits from use of seed treatments, they wouldn't use them on such a large scale.

RESPONSE: BEAD agrees that widespread use of a pesticide can be indicative of benefits to the use of the pesticide (or application method). However, widespread use is not necessarily correlated with the magnitude of benefits on a per-acre or per-farm basis. Moreover, in the case of seed treatments, farmers may not have complete choice. Seed treatments are often subject to seed company marketing agreements and are often packaged according to pre-selected regional criteria. USDA-ARS (see comment EPA-HQ-OPP-0737-0943), and other commenters, including soybean entomologists and Extension experts that responded to the USDA IPM Center's questionnaire (Myers and Hill, 2014) have indicated that it can often be very difficult for soybean growers to obtain the specific varieties of soybeans they want without getting a seed treatment package that may include fungicides, neonicotinoid insecticides, or both. Other commenters, particularly registrants, indicate that choice of seed treatments is not an issue. While it is true that many soybean seed treatments are applied downstream from the original seed packager (in contrast to corn, for example), BEAD has been made aware of situations where the difficulty in de-coupling seed treatment options has made it onerous for some growers to obtain seed without a neonicotinoid insecticide seed treatment applied. Data on pesticide use (MRD, 2004-2014) indicate that approximately 59% of soybean seed treatment insecticides (by weight, nearly all of which is neonicotinoids) is applied commercially. Another 39% is applied downstream by retailers who may be responsive to the requests of individual customers (growers). Only 2% of products are applied 'on-farm.' If widespread issues indeed exist with growers being able to obtain untreated seed, this situation would belie the notion that growers are making independent, site-specific pest management choices and would thus contradict any correlations between the actual need/demand for seed treatments with their observed rates of adoption.

D. Other Benefits or Costs of Neonicotinoid Seed Treatments

1. Seed treatments provide jobs in the seed treatment sector.

RESPONSE: BEAD does not usually evaluate these types of input supply or 'upstream' effects in an analysis of the benefits of the use of a pesticide. BEAD evaluates grower impacts as a means of assessing impacts on the agricultural economy. Often, constraints on one pesticide lead users to shift to another pesticide (or application method) implying that upstream impacts are generally off-setting.

- 2. BEAD underestimated or didn't account for numerous effects of seed treatments, including non-monetary benefits or costs, as follows:
 - a. Seed treatments pose lesser/fewer risks to pollinators and workers than foliar alternatives.
 - b. Seed treatments have minimal off-site drift in comparison to foliar alternatives.
 - c. Risks of neonicotinoid seed treatments and their alternatives.
 - d. Environmental costs associated with the use of neonicotinoid seed treatments (i.e., reduced value of ecosystem services, tri-trophic disruptions) and, specifically, yield benefits of bee pollination into account with our benefit assessment.

BEAD RESPONSE: FIFRA mandates that EPA consider both the risks and the benefits of the use of the pesticide in determining whether the pesticide causes 'unreasonable' adverse effects. BEAD's memo was an analysis of the benefits to the user, not a risk-benefit analysis or regulatory decision document. The purpose of this assessment is to describe and, if possible, quantify the benefits neonicotinoid seed treatments offer to soybean growers in comparison to likely alternatives. It will be used to inform decisions in the review of the registrations for these active ingredients in conjunction with human health and ecological risk assessments. The environmental effects of the pesticide are addressed in the risk assessments. This analysis, other benefit analyses, and information gathered through the public comment periods will be used in the course of registration review to balance risks and benefits of neonicotinoid insecticides. Information on the comparative risks to human health and the environment of any alternatives will be considered in any future risk management or risk mitigation decisions.

II. COMMENTS FROM SPECIFIC STAKEHOLDERS

Extensive comments were submitted by some stakeholders. Not all comments raised by these stakeholders are specifically cited in the responses below. Some were covered in the general topics of Section I, as they were raised by many other commenters as well. Some of these stakeholders each raised similar issues and BEAD summarizes many comments to address these themes. Appendix I provides a list of the comments, by docket reference number, addressed by each of BEAD's responses.

A. Registrant Comments

Six registrants of neonicotinoids provided comments and they are addressed in alphabetical order: Bayer, DuPont, Loveland Products, Monsanto, Syngenta, and Valent. There is considerable overlap in some of the issues raised; in the interest of space, issues addressed elsewhere in this document are noted. Most of the registrants raised issues of process, addressed in Section I.A.

1. Bayer CropScience (Bayer). Bayer is a registrant and distributor of pesticides. Bayer submitted a large set of comments and included both a summary and an external review their own meta-analysis approach. Bayer's full comment is available at regulations.gov, docket EPA-HQ-OPP-2014-0737, document 0905.

- a. "EPA has already determined that soybean seed treatment provides benefits in Soybean." Based upon a Section 18 exemption granted in 2003 for Iowa and Wisconsin for imidacloprid seed treatment for control of bean leaf beetle to help limit the spread of bean pod mottle virus. "It is not clear from EPA's opinion document what information differs from 2003 when EPA either concurred with, or at the very least was convinced by the market, that such a need was fulfilled by imidacloprid."
- b. Bayer discusses extensive technical objections to the preliminary conclusions of BEAD's memo:
 - i. Bayer characterizes EPA's analysis as a 'vote count' approach and suggests that meta-analysis of the same data shows a significant yield benefit for soybeans.
 - ii. They note that fungicidal and nematicidal seed treatments might have confounded EPA's analysis.
 - iii. The length of activity of neonicotinoid seed treatments is higher than what is stated by BEAD. Bayer claims 6-7 weeks after planting rather than 3-4, with citations indicating that aphid mortality is observed at 6-7 weeks after planting.
 - iv. The ability of farmers to tank-mix insecticides with current herbicide and fungicide applications is challenged.
 - "Farmers often cannot effectively apply a tank mix of an insecticide and another pesticide. Herbicide applications are often applied at different times than insecticides and require different spray nozzles." (for droplet size control, for example).
 - "... only about 20% of soybean acres receive a foliar fungicide. In addition fungicide applications are most frequently made at the third reproductive stage of soybean, which often occurs before the optimal timing for insecticide applications targeting soybean aphids or late season bean leaf beetles."
- c. A meta-analysis conducted by Bayer found "yield responses in 82% of the observations, with a statistically significant benefit of 2.6 bushels per acre on average." Based on current soybean market prices, the average yield increase delivers more than a three to one return on investment to the grower. Furthermore, this finding is in agreement with an independent study conducted by mid-South entomologists on their own dataset which found a positive yield increase of 2.5 bushels/acre from neonicotinoid seed treatment use.
 - i. "Our meta-analysis approach also allows us to separate out the data by different factors and analyze the benefit of insecticidal seed treatments."
 - ii. "Seed applied insecticides when used with a foliar insecticide brought a statistically significant yield benefit of 3.3 bushels per acre, compared to a foliar insecticide alone."
 - iii. Yield benefits of 2.6 bushels represents approximately \$26 per acre given 2013 prices. Neonicotinoid seed treatments cost the farmer approximately \$7.50 per acre, therefore generating around \$18.50 in profit for soybean farmers on each acre or greater than a 3 to 1 return on investment."
 - iv. A third-party review from RTI International agrees with Bayer's findings.

- d. Neonicotinoid seed treatments provide important control of soybean aphid.
 - i. For soybean aphid, this extended period of activity is significant. "Soybean plants do not experience yield loss in response to soybean aphid feeding after the middle of the fifth reproductive stage (R5.5), vulnerable to soybean aphid in the midwest [*sic*]. Therefore, neonicotinoid seed treatments are capable of protecting soybean plants for half of the season from soybean aphid."
 - ii. "University research currently undergoing the peer-review publication process found that the adoption of neonicotinoid seed treatments has led to a regionwide decrease in both the severity and frequency of soybean aphid outbreaks (Bahlai et al. 2014) . . . "by delaying the establishment and growth of soybean aphid populations to the extent that they either reach the economic threshold later in the season or outright fail to reach threshold. The decrease in soybean aphid outbreaks provides region wide economic and environmental benefits through decreased need for foliar insecticide applications."
- e. The comparable cost of applications of neonicotinoid seed treatments and foliar insecticides is discussed.
 - i. "... a true comparison of the economic benefits of neonicotinoid seed treatments must account for the application cost savings."
 - "Capturing the true cost of pesticide applications is often difficult given variable fuel costs and spray equipment and maintenance costs for farmers. Therefore, the rates charged by private pesticide applicators are often used to most accurately measure the cost of pesticide applications for farmers."
 - iii. A table is provided that summarizes costs of application as \$7-\$17 per acre for ground applications (the extra \$10 accounts for a bushel yield loss for late season applications due to field damage from ground equipment) and \$10 for aerial applications.
- f. Other points:
 - Cites Gaspar (2015) to point out that seed treatments allow for high yield at lower seeding rates than untreated seed. "At higher seeding rates (which are less profitable) the advantage of neonicotinoid seed treatments decreases . . . The cost of soybean seed continues to increase each year, causing farmers to switch to lower planting populations. This trend will continue into the future and could potentially accelerate as multiple herbicide tolerance traits are pyramided into soybean cultivars to combat weed resistance issues."
 - ii. Bayer claims that "current pest management thresholds do not accurately predict the value of insecticidal seed treatments due to the nature of the benefits from neonicotinoids which results in yield gains when multiple soil and foliar pests are present below their individual threshold level."
 - "The Mid-South entomologists' results (75% positive response, 2.5 bushel average) are very similar to our meta-analysis of the EPA's cited studies. Therefore the magnitude of benefits observed by Mid-South entomologists are not unique to their region, but instead demonstrate that the use of appropriate and thorough analyses consistently demonstrate the significant yield benefits provided by neonicotinoid seed treatments."

RESPONSE: BEAD appreciates Bayer's submission.

BEAD agrees that an emergency exemption may indicate benefits to the use of a pesticide. However, conditions may change drastically over the course of a decade.

With regard to BEAD's use of a 'vote count' (a term used by Bayer) approach in its analysis of publicly available efficacy data that measured yield, BEAD is concerned that an oversimplification can occur when multiple studies are aggregated to determine an overall mean. Without careful statistical treatment of various confounding sources of variability, some of the proposed meta-analytical approaches appear to attempt to draw meaning from small numerical differences in spite of statistical insignificance for many of those comparisons. Therefore, BEAD would note that a meta-analysis approach has its limitations and pitfalls as well. However, BEAD does appreciate that a regionally balanced and standardized approach for meta-analysis approach would be very useful for estimating impacts from neonicotinoid seed treatments on soybeans. For the purposes of refined regional benefit estimates for the mid-South, a 2.5 bushel per acre yield estimate was used, which corresponds well to the results obtained by Bayer, mid-South researchers, and other commenters.

With regard to meta-analysis, without access to raw data or a more detailed discussion of site selection criteria and statistical methodology, BEAD cannot come to any specific conclusion regarding this data sets that were mentioned by multiple commenters. It is unclear from several of these analyses, for example, how much the final yield benefit estimates are weighted by sampling from areas with high insect pressure. As has been stated in response to other meta-analysis submissions, given that BEAD's original benefits analysis was criticized for lacking adequate characterization of regional variability, it stands to reason that the same criticism likely applies to the other meta-analysis approaches discussed here, which seek to define an overall national average for soybean benefits.

BEAD appreciates the additional information regarding the relative duration of bioactivity in soybean plants for seed treatments applied to soybeans. BEAD does agree that for soybean aphid in particular, there might be instances where early season controls exerted on low-level populations may delay or preclude the need for a foliar insecticide targeting aphids. BEAD agrees that this could provide benefits to soybean growers in limited situations. However, as has been noted by other commenters, soybean aphids are not usually the primary target pest for seed treatment usage on soybeans.

BEAD has revised its estimates to include the additional costs associated with a foliar application. See Section III. BEAD notes that its estimate for ground applications, derived from enterprise budgets for soybean production in Iowa, is the same as the estimate provided by Bayer in the preceding comments. BEAD did not include any cost factor for the loss of plants due to the use of ground application equipment, as BEAD's assessment is focused on early season ground applications where these effects would be expected to be very small.

Bayer's other points are addressed separately as they are raised by extension specialists at land grant universities.

- 2. Comments from Keri Carstens, Ph.D., from DuPont, who purchases neonicotinoid seed treatments for application to its Pioneer brand corn and soybean seeds. DuPont is also a pesticide registrant and manufacturer of a number of insecticides and other crop protection products. Dr. Carstens also met with OPP in person to discuss DuPont's proprietary meta-analysis of seed treatment benefits for corn and soybeans, which is discussed below. DuPont's full comment is available at regulations.gov, docket EPA-HQ-OPP-2014-0737, document 0862.
 - a. "DuPont has generated more than ten years of data directly evaluating neonicotinoid seed treatment product performance across critical corn and soybean growing regions in the U.S... designed to assess yield impact, as well as other important agronomic characteristics." These studies show:
 - i. "that neonicotinoid seed treatments provide a yield advantage 80% of the time, with an average increase of 1.6 bu/acre across average soybean growing conditions" based upon analysis of 59 replicated research locations.
 - ii. "In conditions with heavier insect pest pressure, DuPont data show neonicotinoid seed treatments deliver a yield advantage 83% of the time, with a mean of 2.7 bu/acre yield advantage." This subset appears to focus on areas of high bean leaf beetle pressure, based on analysis of 12 replicated research locations.
 - iii. "USDA yield trend data show that yield increases of 0.5 bu/acre can be significant for soybean production." DuPont's studies were prospectively analyzed for adequate sample size, statistical rigor, etc. and designed to detect differences at this level.
 - b. In particular, early season defoliation by bean leaf beetle (BLB) is problematic and this insect vectors detrimental diseases.
 - c. While raw data were not provided, a summary appendix presented the various yield and agronomic trait differences by treatment under the 2 study scenarios, along with a basic description of methodology. Of note, the threshold for statistical significance was set at P < 0.1, rather than P < 0.05.

RESPONSE: BEAD appreciates this data submission, as it provides information that helps inform uncertainties identified in BEAD's original benefits assessment with regard to the 'insurance' benefit of preventative seed treatment usage on soybeans. DuPont's probabilistic approach appears to utilize similar comments and methodology to the work cited by Gaspar et al., and attempts to quantify both the magnitude of expected benefits and the likelihood of growers to see these benefits. BEAD also acknowledges that there is a large amount of uncontrolled variability in play when any meta-analysis seeks to merge data from different parts of the country with different soybean varieties, different soil conditions, different agronomic practices, etc.

Without access to raw data or a more detailed discussion of site selection criteria and statistical methodology, BEAD cannot come to any specific conclusion regarding this

data set. However, BEAD would note that DuPont's conclusions do provide a counterpoint to BEAD's original assertion that much of the existing neonicotinoid seed treatment provides 'no benefit' in terms of yield, particularly for areas of the country where the extent of actual pest pressure is unknown. It is unclear from this analysis how much the final yield benefit estimates are weighted by sampling from areas with high insect pressure. BEAD notes that this variability might be masked somewhat by the choice of setting p < 0.1 as a threshold for statistical significance rather than the more commonly accepted threshold of p < 0.05.

Given that BEAD's original benefits analysis was criticized for lacking adequate characterization of regional variability, it stands to reason that the same criticism likely applies to DuPont's meta-analysis approach which seeks to define an overall national average for soybean benefits. Given likely variability in numerous factors affecting yield, it may have been preferable to conduct smaller, region-specific meta-analyses for soybeans to distinguish which regions most significantly benefit from seed treatment usage (presumably the areas of the country with highest early-season pest pressure, for example).

BEAD is appreciative of the specific mention of the vectoring of bean pod mottle virus (BPMV) by the bean leaf beetle. This comment falls in line with similar comments received from extension experts regarding the importance of this disease and the importance of controlling the early-season overwintering generation of BLB that both vectors this disease, and also causes early season defoliation damage to newly emerged soybean seedlings. BEAD concurs that this particular benefit was underestimated in the original benefit assessment. BEAD also concurs with the general implication that the likelihood (and magnitude) of benefits for neonicotinoid seed treatment is probably more clear for sites with higher BLB pressure, as DuPont's data showed when a subset of 'high pressure' BLB fields were analyzed. It stands to reason that the probability of a specific measureable yield benefit from seed treatment usage will be higher for sites with a known history of pest pressure from pests that would be controlled with neonicotinoid seed treatments during the early part of the growing season. Despite uncertainty regarding the results of this and other cited meta-analyses that have been mentioned by other commenters, BEAD considered how projected yield impacts would affect revenue for soybean growers. This will be discussed in more detail in Section IV.

- 3. Comments from Lisa Nichols, Loveland Products, who is a registrant and manufacturer of fertilizers, adjuvants, seed treatments, and other crop protection products. Loveland Products' full comment is available at regulations.gov, docket EPA-HQ-OPP-2014-0737, document 0777.
 - a. Key elements were missing from BEAD's analysis:
 - i. "Use and review of additional registrant and seed company data, along with data and input from farmers, agronomists, plant pathologists, agricultural economists, and food value chain experts."

- ii. "Examination of the benefits of seed treatments as a mode of application;" including early planting, disease prevention and reduction, compatibility with notill practices, less exposure to non-targets, and Ag handler safety.
- iii. A more "inclusive assessment of insect pressure on soybeans" with specific regard to early season pests and disease.
- iv. Potential for resistance "resulting from the loss of neonicotinoid seed treatments as a tool."
- b. "Growers believe in seed treatments, they have for a long time. A grower would simply not pay the up-charge on seed treatments if they did not see the value in doing so . . . If growers who utilize, and rely on the use neonicotinoids, could vote on this issue, there would be no question that they would vote to continue to have access to this important technology."
- c. "Neonicotinoid seed treatments have generated a new equipment sector." This has created jobs in seed treatment manufacturing, infrastructure, maintenance, and these "technologies (were) derived from the use of neonicotinoids."
- d. "Internal" trials indicate that "Insecticides year over year show on average an 87% increase in yield over a fungicide only treated seed. . . . Data and statistics support the yield, and other benefits of neonicotinoid use on soybeans."
- e. Losing neonicotinoids "will undoubtedly promote, require, and motivate the use of foliar and in-furrow application of insecticides—at a much higher application rate."
- f. "The (EU) ban has already proven what many agronomists warned against. Farmers in Europe have seen a decline in metric tons per hectare and an increase in insect pressure."
- g. Resistance issues were highlighted.

RESPONSE: With regard to data sources, BEAD reiterates that in evaluating yield protection/effectiveness, BEAD relies upon studies that are deemed suitable for publication in either the peer-reviewed public literature, or in the Entomological Society of America's technically reviewed journal Arthropod Management Tests. Because BEAD has not seen the commenter's "internal" data from research trials on neonicotinoid seed treatments, we have no way to evaluate the specific claims of 87% yield impact, for example. Further, because a myriad of uncontrolled variables can affect pest densities and product performance on a farm by farm or trial by trial basis, BEAD realizes that there are cases where any specific pest control measure can out-perform or under-perform compared to results observed in controlled and replicated studies. Realizing that the available published data (which measures efficacy all the way to soybean yield) was relatively limited, BEAD worked with the North Central IPM Center (with assistance from USDA) to collect additional information that was not published in available literature from the leading national experts in soybean entomology.

BEAD's analysis was centered upon neonicotinoid insecticide seed treatments, and thus discussions of other seed treatment active ingredients (such as fungicides, for example) and associated claims regarding disease prevention are not germane to this particular analysis. Additionally, to reiterate, BEAD's memo was strictly an analysis of the benefits for growers and not a risk assessment or regulatory decision document. See Section I.D. BEAD's benefit analysis, and the additional information considered in this response to

comments memorandum will be used in the course of registration review to balance risks and benefits of neonicotinoid seed treatments if/when any future risk management or risk mitigation decisions are made.

With specific regard to early planting and compatibility with no-till practices, BEAD agrees that some additional consideration of these benefits is warranted, as pointed out specifically by the commenters representing soybean production areas in the mid-South United States. BEAD concurs that there are instances, particularly in this region, where cropping practices (including use of no-till and cover-cropping, for example) can lead to high levels of soil insect infestation and thus increase the relative benefits of soybean seed treatments applied preventatively.

With regard to grower adoption of seed treatments, BEAD refers to Section I.C.4. While it is true that many soybean seed treatments are applied downstream from the original seed packager (in contrast to corn, for example), EPA has been made aware of situations where the difficulty in de-coupling seed treatment options has made it onerous for some growers to obtain untreated seed. If widespread issues indeed exist with being able to obtain untreated seed, this situation would belie the notion that growers are making independent, site-specific pest management choices and would thus contradict any correlations between the actual need/demand for seed treatments with their actual rates of adoption.

BEAD also reiterates that this benefit assessment makes no recommendation for any regulatory action regarding neonicotinoid seed treatments. BEAD agrees that whenever possible, it is preferable for growers to have as many varied pest control options available as possible. With specific regard to resistance, BEAD concurs that the ability to rotate chemistry and have multiple insecticide modes of action available for use is key in the ability to manage insecticide resistance, but would also note that widespread, prophylactic usage of one mode-of-action (i.e., neonicotinoid seed treatments) also causes concern for development of resistance.

BEAD appreciates the information regarding the outcome of neonicotinoid bans in the E.U. Impacts in the E.U. could provide valuable information for U.S. regulators regarding the importance of neonicotinoid seed treatments on a variety of crops and also provide some measure of the importance of these chemicals and the potential impact to growers when neonicotinoids are not available. However, cropping systems and pest pressure can be quite different in different parts of the world. OPP plans to continue to closely monitor the situation in the E.U.

4. Comments from Phillip Miller, Ph.D., Monsanto, commercial seed producer and seller of Acceleron® seed treatment products for soybeans, which include neonicotinoid insecticides and other crop protection products. Monsanto's full comment is available at regulations.gov, docket EPA-HQ-OPP-2014-0737, document 0348.

- a. Neonicotinoid seed treatments allow flexibility in planting dates and reducing planting rates, and a 1-3 bushel/acre yield advantage, particularly for early planted soybeans. Gaspar et al. (2014) was cited in support of this point.
- b. "it would be helpful for EPA to provide more in depth analysis of the regional differences in soybean pests, with pailicular attention paid to the mid-south region (Alabama, Arkansas, Louisiana, Mississippi, North Carolina, Tennessee and Virginia)."
- c. Monsanto claims neonicotinoid seed treatment use has been increasing in this region in recent years.
- d. A meta-analysis of data derived from all research publications referenced in the Agency's assessment was also suggested, to provide a "more reliable understanding" of the benefits these seed treatments deliver to growers.
- e. Monsanto asked to review the data cited in the assessment as coming from the North Central IPM Center and Douglas et al. (2014).

RESPONSE: BEAD appreciates Monsanto's comments and strongly agrees that a regional analysis would provide a fuller understanding of the benefits of soybean neonicotinoid seed treatments; see Section IV. BEAD acknowledges that some of the specific regional issues identified in the above comment were not adequately understood or addressed in BEAD's assessment. Based upon earlier comments and expert input from researchers in the mid-South as well as other regions of the country, BEAD has a better understanding of the unique pest control challenges faced by growers in the mid-South, and a more nuanced understanding of the relative likelihood of benefits on a region-by-region basis, particularly for soil-dwelling pests. BEAD also concurs with the comment that neonicotinoid seed treatment usage on soybeans has been increasing in this region in recent years, as indicated by pesticide use data (MRD, 2003-2013).

For a discussion of the Gaspar et al. (2014) submission, see Section II.D.

With regard to data sharing, the Douglas et al. data are now publically available in a peerreviewed publication (Douglas et al., 2015). The North Central IPM center gathered information from regional experts but did not provide BEAD with raw data, just a summary of responses.

- 5. Comments were submitted by Carrol Moseley, Ph.D., from Syngenta. Syngenta is a pesticide registrant and is producer of numerous insecticide products, including thiamethoxam. Syngenta's full comment is available at regulations.gov, docket EPA-HQ-OPP-2014-0737, document 0901.
 - a. Syngenta cited the pest protection from early season insect damage, particularly for early soybean plantings, that can be obtained from neonicotinoid seed treatments, as a compelling benefit. This comment also cited a 1-3 bushel/acre yield benefit, and also cited the importance of seed treatments in crops grown in southern states.
 - b. Regarding pests, the comment highlighted the effectiveness of seed treatments against soil dwelling insects (seedcorn maggots, wireworms, etc.), the bean leaf beetle, and the soybean aphid. In discussing the soybean aphid, Syngenta disputed the Agency's

conclusion that seed treatments are unnecessary for control. They cited selected extension and research publications that suggest neonicotinoid seed treatments be used for late-planted or double-cropped soybeans in the North Central region, and that at least one aphid predator, the multi-colored Asian ladybeetle, is better able to keep aphid populations in check when seed treatments are used.

- c. They also cited results (summarized) of their own field trials that showed that in some tests, neonicotinoid seed treatments delayed aphid populations from reaching economic threshold by 1-3 weeks and that in many trials foliar insecticide applications for aphid control were unnecessary when seed treatments were used.
- d. They also cited the work done by AgInformatics on the economic benefits of neonicotinoid seed treatments in soybeans.
- e. Finally, Syngenta also mentioned that insect resistance management is more feasible with such treatments because repeated use of products with the same mode of action is unnecessary.

RESPONSE: BEAD appreciates Syngenta's comments. With regard to the discussions on soybean aphid, BEAD notes that bioactivity in soybeans may not align well with typical population dynamics in the field. However, there are instances where control of an early season infestation via seed treatment might help to prevent or delay the needs for a subsequent foliar insecticide treatment targeting aphids, if the population remains below threshold levels.

With regard to meta-analysis, without access to raw data or a more detailed discussion of site selection criteria and statistical methodology, BEAD cannot come to any specific conclusion regarding this data set that was mentioned in the comments. It is unclear from this analysis, for example, how much the final yield benefit estimates are weighted by sampling from areas with high insect pressure. As has been stated in response to other meta-analysis submissions, given that BEAD's original benefits analysis was criticized for lacking adequate characterization of regional variability, it stands to reason that the same criticism likely applies to Syngenta's meta-analysis approach, which seeks to define an overall national average for soybean benefits. However, BEAD does appreciate that a regionally balanced and standardized approach for meta-analysis approach would be very useful for estimating impacts from neonicotinoid seed treatments on soybeans. BEAD is not in a position to either concur or object to the results of Syngenta's approach at this time and is interested in getting more information about how such analytical approaches might better inform BEAD's benefit analyses.

With regard to resistance, BEAD concurs that having an adequate number of available modes of action for rotation is important for the goals of resistance management. However, BEAD does not agree with any implication that continuous, widespread preventative use of any one particular mode of action has direct benefits for resistance management. It is likely that such widespread selection is adding selection pressure for pesticide resistance rather than mitigating it.

- 6. Valent U.S.A. Corporation (Valent). Valent is a registrant and distributor of pesticides. The full comment is available at regulations.gov, docket EPA-HQ-OPP-2014-0737, document 0917.
 - a. "While registration review is in progress for imidacloprid, clothianidin, and thiamethoxam, Valent is not aware of EPA being near the point of having to make a risk-benefit assessment or regulatory decision for any of these chemicals. . . In this context, we believe it is inappropriate to reach a conclusion at this stage of the process that 'seed treatments provide negligible overall benefits to soybean production,' based on a relatively limited data set. . . it is inappropriate not to request data from Valent, in its capacity as the registrant of technical clothianidin. Valent also questions EPA's decision not to consult the community of soybean growers directly when assessing the benefits of these products. . . Valent requests clarification from EPA on the purpose and intent of releasing the soybean benefits assessment for public comment at this time . . . Valent would also like to understand if EPA intends to address the benefits of neonicotinoids for other crops in a similar manner, and if so, whether EPA will publish assessments for those crop/use scenarios having both positive as well as negative benefit conclusions."
 - b. Cites the AgInfomatics report and notes Valent's co-sponsorship of said analysis.
 "While BEAD based its preliminary yield benefits conclusions on 34 field efficacy studies for thiamethoxam and 26 for imidacloprid in nine states, the AgInfomatics (2014) analysis was based on 642 observations of neonicotinoid soybean seed treatment versus untreated controls generated from 289 site-years of data from small plot studies conducted in 23 states from 2001 to 2013. These observations included all those cited by BEAD."
 - c. Cites Esker and Conley (2012) discussing a probabilistic approach to seed treatment benefits for soybean growers and the benefits of prophylactic usage.
 - d. Valent disagrees with EPA's assumption of tank-mixing in the original benefits estimate, and states that "... target pest scouting for treatment thresholds" would dictate insecticide timing "rather than timing of another pesticide application. In addition, practical considerations such as nozzle/sprayer setup and tank-mix chemical compatibility must be considered before adding an insecticide to an existing foliar spray..."
 - e. Valent objects to BEAD's characterization of the 'no pest response' associated with most seed treatment usage in the U.S. "When farmers buy treated seed, they are buying a package which includes specific soybean genetic material protected with several active ingredients intended to ensure a strong crop stand. The acceptance of an insecticide in this package is a conscious choice made by farmers because they believe, or have historically observed, a benefit from its use. It is unreasonable to assume that simply because farmers cannot identify each specific pest that this package is protecting against, that they would pay for something they did not expect to derive value from."
 - f. "Furthermore . . . (citing AgInfomatics) . . . attributes that farmers value are not solely economic, but include the reduced environmental and health risk presented by neonicotinoid seed treatment as compared to foliar application of older broad spectrum chemistries."

g. "We believe that, in their totality, the AgInfomatics reports represent a much more complete and objective analysis of the socio-economic value that neonicotinoid insecticides bring than any other studies published to date. In this spirit, we urge EPA reviewers to give all of these reports their full and serious consideration as registration review of the neonicotinoid insecticides proceeds to completion."

RESPONSE: With regard to risk-management procedures under Registration Review, BEAD reiterates that its benefit analysis is not a risk management document; it provides one part of the risk and benefit information that is required under FIFRA. OPP will respond separately to comments that relate to OPP's processes, procedures, and scientific quality standards.

With regard to the AgInfomatics 2014 analysis, BEAD received the final AgInfomatics analysis after completing the draft benefits assessment for soybeans. Additionally, after several in-person discussions with the primary authors, BEAD is generally familiar with their analytical approach, which even for soybeans, was broader in scope than BEAD's own approach, which was solely focused on seed treatments. Generally speaking, BEAD notes that AgInfomatics utilized data that was not immediately available to BEAD at the time of the original analysis, and that typically, BEAD benefit assessments are based upon publicly available efficacy literature including peer-reviewed sources, and ESA's Arthropod Management Tests database. BEAD notes that publication of both its original assessment and the AgInfomatics assessment has been very helpful in bringing additional data to light for OPP's consideration. BEAD also had differences of opinion with the way AgInfomatics arrived at benefit estimates, particularly with their assumptions regarding the costs of scouting in current scenarios vs. neonicotinoid-free scenarios, as well as the way acreage was allocated to alternatives, even for usage where no target pest was identified. However, BEAD notes that final impact estimates (\$0-\$6 an acre by BEAD vs. \$3.30 per acre by AgInfomatics) were comparable.

With regard to the tank-mixing assumption, BEAD acknowledges that the original assumption that foliar insecticides would simply be tank-mixed with existing pesticide applications to soybeans is not valid in all cases. BEAD concurs that an impact estimate should include the costs of an additional pass over the field to make such a foliar application, and the revised impact tables that are presented later reflect this change.

With regard to the Esker and Conley (2012) paper, BEAD agrees that this research provides an interesting insight into probabilistic approaches to estimation of seed treatment benefits. BEAD has provided specific responses to this work in an earlier response to the comments submitted by Adam Gaspar. Generally speaking, the probabilistic approach presented by Esker and Conley reveals a good deal of variability in the yield response for soybeans grown in Wisconsin. Further, the work projects that the probability of benefits is highly correlated with both the baseline yield for a given site, and also with the soybean commodity price, whereby the likelihood of a seed treatment investment providing a break-even return are much more likely under conditions of high soybean prices and high baseline yields, and the likelihood of returns decreases as these variables decrease. However, for sites with known pest pressure, BEAD concurs with the general conclusion that soybean seed treatments are very effective at protecting seeds from soil-dwelling pests and that yield is protected under conditions of high pest pressure.

With regard to target pest designation, BEAD understands that there can be instances where growers decline or are unable to respond with a target pest on the surveys used to collect data. However, it is notable how a much higher proportion of seed treatment usage, particularly on soybeans, is not associated with any pest, indicating that much of the use is likely to be prophylactic. In comparison to neonicotinoid seed treatments, BEAD notes that the proportion of users reporting no target pest is about an order of magnitude (10 times) lower for all other non-seed treatment insecticide applications made from 2004-2014 (MRD, 2000-2014). Table 1 shows the total treated acreage by crop for insecticidal seed treatments (and the relative proportion of that acreage that lists no target pest) in comparison with the total insecticide treated acreage for all crops and all application types, except seed treatment acres (MRD, 2004-2014). Among crops treated with insecticidal seed treatments, soybean has the highest proportion of treated acreage for which no target pest is assigned, indicating that a great deal of seed treatment usage on soybeans may be prophylactic in nature. For all other crops, the proportion insecticide treated acreage (excluding seed treatments) not listing a target pest ranged from 0% to 8%, with an average of 4.6%.

Сгор	Total	Total Acreage	% of Treatments
	Insecticide	Treated, "No	Associated with "No
	Treatment	Answer" for Target	Answer" for Target
	(1,000 acres	Pest	Insect Pest
	treated)	(1,000 acres)	
Seed Treatments			
Soybeans	162,091	83,067	51%
Corn	636,557	291,546	46%
Wheat, Spring	19,503	6,007	31%
Wheat, Winter	36,750	10,781	29%
Sorghum (Milo)	13,538	3,377	25%
Cotton	53,881	12,810	24%
Sugar Beets	2,674	414	15%
Potatoes	1,633	207	12%
Sum Total:			
All Seed Treatment Crops	926,628	408,205	44%
All Other Insecticide			
Applications, Excluding			
Seed Treatments, All	1,016,651	46,626	5%
Crops			

 Table 1. Insecticide Treated Acreage, 'No Answer' Response for Target Pest, Seed

 Treatments and Other Applications, 2004-2014.

Source: MRD, 2004-2014.

While BEAD agrees that growers would typically be expected to make pest management decisions in accordance with their own site-specific needs, BEAD remains concerned about the potential availability of untreated seeds to growers.

Finally, BEAD reiterates that its analysis is not a risk assessment or risk management document. As such, the stated considerations about non-monetary benefits such as reduced risk to workers and the environment, while important for future risk management consideration under registration review, is not immediately germane to BEAD's analysis.

B. Comments from Non-Governmental Organizations

This section addresses comments from AgInfomatics, a consulting firm employed by registrants to assess the benefits of neonicotinoids; the Center for Food Safety, a non-profit that has published several reports questioning the benefits of neonicotinoid seed treatments; the American Seed Trade Association and CropLife, which are industry representatives; and the Center for Regulatory Effectiveness, a non-profit concerned with environmental regulation.

- AgInfomatics (EPA-HQ-OPP-2014-0737-0350): AgInfomatics, a collaborative group of entomologists, agronomists, and economists, authored a report on the value of neonicotinoid insecticides to American agriculture on behalf of a number of pesticide registrant sponsors. In addition to the submitted comments below, AgInfomatics submitted their complete 2014 study. AgInfomatics researchers also met in person with BEAD staff on two occasions to discuss methodology, results, and contrasts with BEAD's effort, which focused solely on neonicotinoid seed treatments on soybeans.
 - a. "BEAD based its preliminary conclusions on a limited number of efficacy studies (34 for thiamethoxam and 26 for imidacloprid). AgInfomatics completed its own yield benefits analysis using 642 observations of neonicotinoid seed treatments vs. untreated controls generated from 289 site-years of data from small-plot studies conducted in 23 states from 2001 to 2013. These studies included yield data for small plots treated with clothianidin, imidacloprid, and thiamethoxam, plus a few treated with dinotefuran and mixtures of more than one of these neonicotinoids. In addition, 216 observations of neonicotinoid seed treatments came from a variety of public sources . . . and included all the studies used in the BEAD analysis.
 - b. We found significant variability in the yield benefits of soybean seeds treated with neonicotinoids compared to untreated control plots or when compared to other insecticides . . ." averaging 2.8% relative to the untreated control. AgInfomatics' analysis indicates that a farmer would recoup the cost of a seed treatment approximately 59% of the time. "This \$8.26/acre average net gain and 59% breakeven probability are simple national averages across all soybean acres. Many growers using neonicotinoid seed treatments have higher average yields and face greater insect pressure, and so would earn greater net returns to neonicotinoid seed treatments and, at a minimum, have a larger break-even probability."
 - i. "Neonicotinoid seed treatments have relatively large yield benefits in some states, particularly in some northern locations and southern states. These data show that sweeping geographic generalizations regarding the yield impacts of

neonicotinoid seed treatments are probably erroneous. To state, as the EPA did, that there are 'no significant benefits' confounds the meaning of a minor statistical significance test with the production realities of thousands of North American soybean farmers.

- ii. Using survey data to capture non-monetary benefits (as estimated by growers), AgInfomatics estimates an "average value of \$11.93/acre for soybean growers relative to their next best alternative." This estimate includes grower estimates accounting for "effectiveness of insect control, improved risk management, protecting the yield, time-saving, resistance, and reduced worker exposure concerns."
- c. "Foliar insecticides will not provide protection from soil dwelling pests, such as seed maggots, wireworms, and white grubs. . . No soil insecticides are registered for use in U.S. soybeans, so farmers have no insecticide alternatives available to manage these and similar soil-dwelling pests except neonicotinoid seed treatments."
- d. "...the cost of alternative foliar insecticides is comparable to neonicotinoid seed treatments. However, once the additional cost of scouting and foliar applications are included, we estimate the net cost increase for farmers currently using neonicotinoid seed treatments is \$3.30 per acre to switch to a foliar system. This increase occurs, even when assuming about one-third of the acres currently treated with neonicotinoid seed treatments would remain untreated ..."

RESPONSE: BEAD appreciates the comments submitted by AgInfomatics and notes here that beyond the above submitted public comments, BEAD has also evaluated the entire analysis for neonicotinoids and has met in person with the main authors of the analysis to discuss the methodologies and conclusions. BEAD acknowledges that AgInfomatics used a larger number of studies, including data from registrants that was not immediately available to BEAD at the time of its analysis. BEAD agrees with the conclusion reached by AgInfomatics that yield impacts from seed treatments on soybeans are variable. This is underscored by the conclusion that break-even costs are only expected to be recouped approximately 60% of the time. BEAD notes that in contrast to other analyses, such as Esker and Conley (2012), this probability is not discussed in terms of variable commodity prices and baseline yields. BEAD agrees that the likelihood of benefits would likely be higher for growers with high insect pressure and would state that this particular effect might be most notable for the mid-South, as has been discussed in previous comment responses. BEAD agrees that the regional nuances to benefits are important and that some particular regions are likely to see benefits that are higher than average for neonicotinoid seed treatments.

With regard to the non-monetary benefits estimated by AgInfomatics, BEAD notes that this estimate appears to be based on an aggregation of growers' opinions from listening sessions and survey instruments. BEAD has not attempted to put monetary value on attributes such as convenience, ease of use, etc. BEAD also reiterates that its benefits analysis is not a risk assessment or risk management proposal. As such, the stated considerations about non-monetary benefits such as reduced risk to workers and the environment, while important for future risk management consideration under registration review, is not immediately germane to BEAD's analysis. Regarding soil insecticides, BEAD understands that control options for soil insects are limited for soybeans. BEAD was able to confirm that seed treatments containing permethrin are marketed available for use on soybeans in the United States, although these products are not widely utilized given the availability of neonicotinoid seed treatments. However, BEAD also understands that given the apparent limited current availability of permethrin treated seed, and the lack of any systemic activity (i.e., protection of the plant after germination) this may not necessarily be an ideal alternative to seed treated with neonicotinoids. Several commenters have also underscored the potential difficulty in controlling problematic soil pests if neonicotinoid treated seed was not available.

Finally, with regard to costs of foliar applications, BEAD acknowledges that there are costs to applying foliar insecticides beyond the cost of the product itself and in a revised impact analysis presented later, does incorporate the costs of additional trips across the field for insecticide application(s). BEAD notes that AgInfomatics' analysis seems to fundamentally double-count impact by counting the yield-loss associated with comparisons to untreated soybeans, but also counting the costs of foliar insecticides, which should be expected to be equally effective as seed treatments, and thus eliminate yield losses. With regard to scouting, BEAD disagrees with the implication that seed treatments significantly reduce scouting costs for soybeans. While the need for scouting might be somewhat reduced during the time immediately after planting (i.e., the time of highest bioactivity in emerging soybean seedlings), scouting is still necessary in soybeans for weeds, foliar diseases, nutrient management, and insect pests that fall outside the activity spectrum of neonicotinoid seed treatments. Therefore, BEAD would not project that scouting costs would decline very much for soybeans with treated seeds vs. untreated seeds.

 The Center for Food Safety (CFS) submitted a coordinated response with other stakeholders and other non-governmental organizations (NGOs). CFS claims that BEAD overstated the benefits of soybean seed treatments, that submitted registrant data are flawed, and that EPA should warn growers that seed treatments can negatively impact yield, citing, for example, Douglas et al. (2015).

RESPONSE: BEAD reviewed CFS's analysis 'Heavy Costs' (Stevens and Jenkins, 2014). Beyond the studies cited in CFS's analysis, BEAD also sought out additional data on yield protection from both the peer-reviewed and non-peer reviewed literature, including the Entomological Society of America's online repository of efficacy trials, Arthropod Management Tests (AMT). Based on analysis of numerous sources, BEAD disagrees with the assertion that the assessment overstated the benefits. BEAD did conclude that, when viewed broadly and on a national scale, pest management benefits of neonicotinoid seed treatments are low to negligible in most cases. When compared to available alternatives, there are scenarios where insurance benefits of seed treatments might have important benefits, particularly in areas with high pressure from soil-borne pests, for example. BEAD sought additional information on the significance of such

benefits and agrees with numerous other commenters that neonicotinoid seed treatments on soybeans can provide important benefits in certain pest scenarios.

- 3. Combined comments from Andrew LaVigne from the American Seed Trade Association (ASTA) and Jay Vroom, from CropLife America (CLA). ASTA represents over 700 companies involved in seed production, distribution, plant breeding, and related industries in North America. CLA is the national trade association representing the manufacturers, formulators, and distributors of crop protection products in the U.S. The full comment is available at regulations.gov, docket EPA-HQ-OPP-2014-0737, document 0928.
 - a. "... 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."
 - b. "Numerous data sets exist that show the value of (neonicotinoid insecticide) technology to soybean production."
 - i. "The BEAD preliminary report underestimated yield benefits of neonicotinoids to soybean production . . . 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."
 - ii. AgInfomatics report is cited, which "found an average yield advantage of 2.8% for soybeans . . . relative to untreated seed."
 - Gaspar et al. (2014), Cachot et al. (2014), and Stewart and McClure (2013) are cited for yield impacts of soybean seed treatments, along with a meta-analysis from Bayer (2015).
 - c. "Yield benefits are best assessed from replicated trials or through meta-analysis approaches."
 - i. "EPA evaluated each of the studies independently, rather than using a common scientific approach of 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 interests, 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 . . . Despite the limitations of these studies, we note that a meta-analysis of the EPA-cited data reveals consistent yield benefits."
 - ii. "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."

- d. "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."
 - i. "The BEAD report focuses solely on efficacy of neonicotinoid seed treatment to soybean aphid."
 - ii. "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."
 - iii. "Additional factors (direct and indirect) that should be quantified and included in an EPA benefits analysis of seed treatments include:
 - "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 practicality of implementation on broad acres, safety profile of those alternatives, including to beneficial insects, and cost of those alternatives to farmers and the agriculture economy."
 - iv. "The EPA recognized that the adoption rate for neonicotinoid seed treatment on soybeans is fairly low compared to other crops . . . 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 . . . non-treated soybean seed is readily available."
 - v. A comment emphasizes the importance of soil dwelling pests, and notes that seed treatment options are preferable to application of soil insecticides.
 - vi. "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."
 - vii. The importance of bean leaf beetle (BLB) and its vectoring of the bean pod mottle virus (BPMV) is emphasized.
- e. "The process used by EPA to date is inconsistent with law and basic principles of fairness."
 - i. "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."
 - "EPA should first use its authority under FIFRA Section 3(c)(2)(B) to call-in benefits data from registrants and engage stakeholders in order to assure that it has a complete benefits data base" including efficacy/product performance data.
 "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 Sections 3 and 10.

iii. "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 the core principles embodied in FIFRA. See e.g., FIFRA Section 3(c)5 ('Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other.')."

RESPONSE: BEAD appreciates CLA's and ASTA's submission of comments. Regarding the comments on OPP's processes, procedures, and scientific quality standards, please refer to Section I.1, page 3 of this document.

BEAD notes that the publication of its assessment has elicited numerous comments and brought about valuable input from additional stakeholders that has helped BEAD to refine its estimates. BEAD has incorporated additional data submitted by registrants, university researchers, and other stakeholders and has revised impact estimates accordingly. This is precisely the point of a public comment process and BEAD appreciates the input it has received. Further, OPP met with USDA-OPMP on numerous occasions and got input prior to publishing this analysis: including a coordinated effort with USDA's North Central IPM Center that was used in the analysis. USDA-OPMP also offered comments on our draft on multiple occasions.

With regard to meta-analysis, without access to raw data or a more detailed discussion of site selection criteria and statistical methodology, BEAD cannot come to any specific conclusion regarding the data sets that were mentioned by multiple commenters. It is unclear from several of these analyses, for example, how much the final yield benefit estimates are weighted by sampling from areas with high insect pressure. As has been stated in response to other meta-analysis submissions, given that BEAD's original benefits analysis was criticized for lacking adequate characterization of regional variability, it stands to reason that the same criticism likely applies to the other meta-analysis approaches discussed here, which seek to define an overall national average for soybean benefits. However, BEAD does appreciate that a regionally balanced and standardized approach for meta-analysis approach would be very useful for estimating impacts from neonicotinoid seed treatments on soybeans. BEAD is neither in a position to concur with, nor object to the results of the various meta-analyses discussed at this time and is interested in getting more information about how such analytical approaches might better inform BEAD's benefit analyses.

BEAD reiterates that its analysis is not a risk assessment or risk management document. As such, the stated considerations about non-monetary benefits such as reduced risk to workers and the environment, while important for future risk management consideration under registration review, are not immediately germane to BEAD's analysis. While BEAD agrees that growers would typically be expected to make pest management decisions in accordance with their own site-specific needs, BEAD remains concerned about the potential availability of untreated seeds to growers, which has been discussed elsewhere in this document. BEAD agrees that soybean aphids are not intended to be the primary target pest of neonicotinoid seed treatments applied to soybeans. BEAD further agrees that early-season control of BLB is important to mitigate the risks of BPMV on soybeans, as has been pointed out by other commenters. BEAD has modified its benefit estimates accordingly.

- 4. Center for Regulatory Effectiveness. The Center for Regulatory Effectiveness is a private regulatory watchdog organization. A primary interest of the Center is agency compliance with "good government' statutes such as the Data Quality Act. The Center raised several points relevant to the substance of the Soybean Assessment, listed below. Center comments regarding EPA processes and procedures are addressed in Section I. The full comments are available at regulation.gov, docket EPA-HQ-OPP-2014-0737, document 0785.
 - a. The 'baseline' and methodology of the economic analysis was unclear.
 - b. Average soybean yields used in the economic analysis were not consistent with the underlying data.
 - c. The 'proprietary' data cited in the assessment are of unclear quality.

RESPONSE: BEAD appreciates the opportunity to clarify and correct the assessment.

a. The methodology BEAD uses in conducting its benefits assessments is standard for understanding the benefits of a technology: in the absence of a technology (*e.g.*, a neonicotinoid seed treatment), what would the user of the technology (*e.g.*, a soybean grower) do and what effect would that have on a relevant measure of benefits (*e.g.*, net operating revenue, defined as the difference between gross revenue and variable costs)? The 'baseline' depends on the perspective one takes. Typically in government regulations, the analyst assesses an action that would restrict the user's choices and would measure the impact of switching from use of the technology to the next best alternative, where the impact is measured in terms of lost revenue and/or increased cost. EPA is not at this time proposing to take an action that would affect the availability of neonicotinoid soybean seed treatments; our goal is to quantify the benefits of the neonicotinoid seed treatments to soybean growers. Hence, BEAD's perspective, as shown in Table 4 of the assessment, is essentially to assess the gains of employing neonicotinoid seed treatments in lieu of the next best alternative in terms of additional revenue and/or decreased cost.

BEAD acknowledges that the terminology used by EPA in the context of pesticide regulation can be confusing compared to the usual cost-benefit terminology where one typically compares the costs and benefits of a regulation. The terminology used by EPA in the context of pesticide regulation stems from FIFRA, which instructs EPA to consider the risks and benefits of a pesticide. In this case, the use of the term 'benefits' is appropriate since BEAD is assessing the benefits provided by neonicotinoid seed treatments to soybean growers. As explained elsewhere, this

benefit is appropriately measured in comparison to alternative pest control strategies, not to a scenario with no pest control.

b. BEAD acknowledges a mathematical error. The average annual soybean yield was reported in Table 1 of the Soybean Assessment as 44.6 bushels per acre, rounded to 45 bu/acre in Table 4 to calculate the benefits. However, from Table 1 of the soybean assessment, average annual production of soybean from 2009 to 2013 was approximately 3,220,826,000 bushels grown on approximately 75,760,000 acres. This implies an average of about 42.5 bu/acre.

As a result of this error, the typical gross revenue per acre used in Table 4 of Soybean Assessment was biased upward by about \$25 per acre, as was the typical net operating revenue for both the neonicotinoid seed treatment scenario and the flubendiamide foliar treatment scenario. The cost differential remains about \$6 per acre; however, that represents a 1.85% increase in net operating revenue with the neonicotinoid seed treatment compared to the alternative, not 1.70% as calculated in the Soybean Assessment.

c. The proprietary data used by BEAD for the Soybean Assessment is of very high quality. These data are not generated by EPA; the data are purchased by EPA from a leading agribusiness market research firm. For decades, the firm has provided market data across various economic sectors to consumer and commercial organizations, including pesticide chemical companies. EPA has purchased access to the data for more than 20 years.

Data are collected by surveys of agricultural producers. The survey participants are selected based on the location and size of the operation to develop a representative sample of producers in the continental U.S. Typically, the data are statistically valid at the state level; in the case of soybean, data are often statistically valid at the level of the Crop Reporting District. Producers may participate in the survey over time, which permits valid comparisons between time periods. Data on pesticide use is collected by product and includes the area treated (including area treated multiple times), application rates, the stage of the crop at application, product price, target pest, *etc.* Information may be verified through complementary surveys, for example, surveys of pesticide distributors to ensure that reported prices are within normal ranges.

These data meet all the relevant quality measures as outlined in EPA's information quality guidelines. The survey methodology ensures that the data are accurate, reliable, and unbiased.

C. Governmental Stakeholders

EPA received comments from the National Association of State Departments of Agriculture and comments from two offices in the U.S. Department of Agriculture, the Agricultural Research Service and the Office of the Chief Economist.

- Comments from Barbara Glenn, Ph.D., National Association of State Departments of Agriculture (NASDA). NASDA represents the Commissioners, Secretaries, and Directors of the state departments of agriculture in all fifty states and four U.S. territories. NASDA's full comments are available at regulation.gov, docket EPA-HQ-OPP-2014-0737, document 0919.
 - a. "... we request EPA engage soybean growers, state agricultural extension offices, state departments of agriculture, and other interested agricultural stakeholders to revisit and improve the scope and methodology utilized in order to accurately determine the benefits of neonicotinoids to soybeans, or any other crop system."
 - b. "We note EPA registered neonicotinoids as 'reduced risk' alternatives to organophosphates and other older classes of chemistry . . ."
 - c. "Across the fifty states and four territories, there are large variations in crop production practices and pest management challenges. This large amount of agricultural diversity requires a robust review of all elements, variables, and scientifically sound data in order to measure the true benefit of an entire class of chemistry to a complete crop system." Cites comments submitted by Cachot et al, " and we recommend EPA undertake a similar, comprehensive review of various factors and elements in any future determination of the benefits of neonicotinoid seed treatments, or any other crop protection tools."

RESPONSE: BEAD appreciates the comments on behalf of NASDA. With regard to engagement of numerous additional stakeholders, the established comment period for BEAD's benefits analysis has elicited numerous comments from the stakeholders NASDA identifies and BEAD concurs with many of the criticisms, comments, and suggestions provided on how to improve our assessment of neonicotinoid seed treatment benefits for soybeans. With regard to the 'reduced-risk' status for a number of neonicotinoid active ingredients, BEAD agrees that in many cases, usage of neonicotinoids in general has displaced a significant amount of usage of older chemical classes across numerous crops and use patterns. However, with specific regard to neonicotinoid seed treatments on soybeans, BEAD notes that very little insecticide usage of any kind was recorded on soybeans prior to 2004. Further, recent usage data (MRD, 2004-2013) show that usage of foliar insecticides, from several modes of action (including organophosphates and synthetic pyrethroids) on soybeans has appreciably increased at the same time that adoption of neonicotinoid seed treatment usage has also increased.

BEAD agrees with the comment about varied production practices and pest management challenges by region. BEAD has revised its characterization of regional pest differences and appreciates that a number of submitted comments have helped to improve BEAD's awareness of these important regional nuances and the factors that affect the relative likelihood of benefits from usage of neonicotinoid seed treatments on soybeans.

- 2. Coordinated comments from USDA-ARS were submitted by Ann Bartuska, USDA Deputy Under-Secretary for Research, Education, and Economics. ARS's full comments are available at regulation.gov, docket EPA-HQ-OPP-2014-0737, document 0943.
 - a. "there is no simple answer to the question of whether neonicotinoid seed treatments have value as a prophylactic treatment in soybeans, and most other crops for that matter. It is a complicated situation with many facets and important nuances that must be considered."
 - b. "Prophylactic use of an insect management tool is not necessarily a bad idea, and such a strategy can play a central role in an IPM program depending on the context host plant resistance is the classic example, because it eliminates or reduces the need for in-season rescue treatments . . . From an IPM point of view, the value to a grower should outweigh this cost, at least when averaged over years, for use to be economically justified. Neonicotinoid seed applications are purported to provide early-season, broad-spectrum pest control, enhancing plant vigor and crop yield potential."
 - c. "Pest complexes and cropping practices vary widely across the U.S. soybean growing regions. The abundance and diversity of different pest populations also vary, even within different production regions . . . Using neonicotinoid seed treatments for protection against a certain pest in one region of the country may be justified much of the time, whereas prophylactic protection against the same pest in another part of the country may be seldom warranted. For example, soybean growers in the southern. U.S. face a much more diverse and serious threat from insect pests than growers in the Midwest, and the value of protection afforded by prophylactic insecticides likely will vary accordingly."
 - d. "Information on pest pressure by scouting is often the best way to assess need for control, but for many of the pests targeted by neonicotinoid seed treatments, especially below-ground insects, scouting is impractical or there is no viable rescue treatment available once a real-time problem is detected. In these cases prophylactic seed treatments may be warranted if predicted risk of damage is high enough."
 - e. "...scenarios putting fields at risk of serious secondary pest pressure are not uniformly distributed in space or time, but neither are they rare.... A one-size-fits-all assessment of value of neonicotinoid seed treatments is not possible except from a very high vantage point that deals with overall averages... and overall averages are not always the best tool for determining the best course of action on the scale of individual farms."
 - f. "We caution that the very widespread use of neonicotinoid seed treatments on soybeans and other crops cannot be taken as direct evidence of their value to growers, because in most cases untreated seed of the varieties desired by a grower is not available for purchase.... We also caution against assuming that non-use of seed treatments will automatically necessitate replacement by some other form of protection against the target pests. The need for any pest control approach depends on pest pressure or, in many cases, the risk of pest pressure, for which national or even regional averages are not sufficiently informative."
 - g. "USDA-ARS scientists and others are actively engaged in synthesizing what is already known that can be of potential use in assessing the value of neonicotinoid

seed treatments for major U.S. crops, and in conducting meta-analyses of relevant published and unpublished data. The results should reveal the most serious knowledge gaps that we (the scientific community) can most profitably address in future research."

RESPONSE: BEAD appreciates USDA-ARS's comments and strongly agrees that a regional analysis would provide a fuller understanding of the benefits of soybean neonicotinoid seed treatments. BEAD acknowledges that some of the specific regional issues identified in the above comment were not adequately understood or addressed in BEAD's assessment. Based upon other submitted comments, particularly Comment #3 in Section II, BEAD has a better understanding of the unique pest control challenges faced by growers in the mid-South, and a more nuanced understanding of the relative likelihood of benefits on a region-by-region basis, particularly for soil-dwelling pests.

BEAD agrees that for soil-dwelling pests, scouting is difficult and that preventative treatments may often be warranted for areas with known instances of damage or a history of pest pressure (see Section I.4). BEAD also agrees with USDA-ARS's comment that usage in and of itself does not constitute evidence of any specific benefit (Section I.C.6), and shares the expressed concerns about the availability of untreated seed to growers. This comment, in particular, runs counter to claims by other commenters and registrants and indicates that there is some controversy among stakeholders as to the actual/practical availability of untreated seed for growers.

- Coordinated comments from USDA's Office of the Chief Economist (OCE) were submitted by Robert Johansson, USDA Acting Chief Economist. OCE's full comments are available at regulation.gov, docket EPA-HQ-OPP-2014-0737, document 0942.
 - a. "As a whole, USDA disagrees with [BEAD's] assessment. We believe that pest management strategies are made in consideration of pest pressures, climate, landscape, and numerous other factors. Growers should have the ability to use the best tools available to manage pests that include choices in seed treatment and pest management tactics. Each knows best what works for his or her individual situation."
 - b. "... it is unlikely that most farmers would be purchasing seed treatments if there was no value to them. For example, extension agents at the University of Mississippi [*sic*]point out that adoption of neonicotinoid seed treatments for soybeans in MS has risen from 2 percent in 2007 to 90 percent today. That pace is more rapid than adoption of herbicide resistant soybeans and has been driven by the value MS soybean producers place on the protections afforded by neonicotinoid seed treatments." "In general, USDA would suggest that farmers are efficient and would not use management practices that did not generate expected benefits that were at least as great as the cost of that management practice ... In this case, employing a menu of pesticide practices that includes seed treatments is balanced against the costs of using those practices." "USDA agrees that in some situations different pesticide methods may be equally effective as seed treatments in a given year. And it is likely that in some soybean growing regions, there are more cost-effective pest management

treatments. However in other situations or regions, environmental conditions would likely favor the efficacy of seed treatments over those afforded by foliar spraying."

- c. "EPA has had to make several broad generalizations and to rely on scarce and limited data that are not public. For example, EPA assumes that foliar spraying of pesticides is done by all producers who are purchasing seed treatments, that such spraying does not incur additional costs in management or equipment purchases, and that such spraying can address the same pests over the same time window as seed treatments.
- d. "EPA did not consider any potential environmental consequences of foliar spraying The EPA analysis assumes that foliar spraying is environmentally preferable to using seed treatments." "Environmental or ecological consequences of neonicotinoids may not be as great as other traditional insect control, especially with regard to unintended mortality of beneficial insects since, in soybeans, it does not persist to the period when most beneficial insects are most active."
- e. "EPA's conclusions are not supported by complete data nor analysis", citing labor/management savings, effectiveness of seed treatments in challenging weather conditions where foliar sprays are not possible, control of soil pests, additional regulatory expenses by landowners ("such as costs to revise pesticide permit applications, or costs to submit new applications for foliar spraying"), year by year benefits of seed treatment via rotation of multiple crops. OCE's proposed sensitivity analysis indicates "EPA's calculations could be understated by more than a factor of 10 for soybean producers in certain regions."
- f. "USDA is disappointed that EPA published this report in such a preliminary format without offering USDA an opportunity to help EPA reframe their analysis and correct the misrepresentation of economic costs and benefits that underlie this report . . . As such, it is inappropriate to draw conclusions about the entirety of soybean production across regions of the United States under different environmental conditions by simply looking at national averages over several years."
- g. "...yield enhancement is not the only consideration for using neonicotinoids in crop production, including in soybeans. Those insecticides may have benefits in soybeans to help produce seed without mottling by reducing virus transmission by beetles, especially around edges of fields. Seed producers get 'docked' for mottled seed."
- h. "USDA suggests that EPA revise their study to evaluate the full costs and benefits of neonicotinoid seed treatments in all crops and regions. Furthermore, because EPA has relied on data currently unavailable to the public, USDA requests that EPA include more survey results from the recently released reports that indicate that farmers are using neonicotinoid seed treatments for a variety of reasons."
- i. Additional Specific Comments:
 - i. "USDA suggests EPA reframe their analysis to consider the full costs or benefits of neonicotinoid seed treatments as it would typically do under its FIFRA requirements.
 - ii. The potential change in use for neonicotinoid seed treatments assumed in EPA's analysis is economically significant.
 - iii. The report does not consider the environmental benefits of neonicotinoid seed treatments for soybeans.
 - iv. Preventative seed treatments are likely to be more or less effective under certain conditions and regions.

- v. Seed treatments minimize the management and labor investment required for scouting and foliar spraying.
- vi. EPA's use of limited data to support their analysis is unfortunate, when they were aware that several other studies on this topic would be released at roughly the same time. Those additional data could have been used to augment the limited data cited by EPA in their report.
- vii. EPA's Table 4 should show sensitivity analysis as it is standard practice for cost-benefit analysis.

RESPONSE: BEAD appreciates USDA's Office of the Chief Economist (OCE) comments. BEAD agrees that growers need to make use of multiple tactics and BEAD reiterates that this analysis is focused on benefits of neonicotinoid seed treatments on soybeans and does not constitute a risk assessment or risk management proposal. BEAD agrees that widespread use of a pesticide can be indicative of benefits to the use of the pesticide (or application method). However, widespread use is not necessarily correlated with the magnitude of benefits on a per-acre or per-farm basis. Moreover, in the case of seed treatments, farmers may not have complete choice in the seed treatment package that is used on certain varieties of seed. BEAD concurs that its original assumptions about foliar spraying and tank-mixing were incomplete and has revised its new impact estimates accordingly to account for the costs of additional passes over fields. BEAD concedes that its benefit estimates focus on economic benefits to growers, it does not include non-monetary advantages, such as convenience of use, etc. Such considerations are generally beyond the scope of an analysis of the benefits of the use of a pesticide. BEAD notes that the publication of its draft assessment has elicited numerous comments and brought about valuable input from additional stakeholders that has helped BEAD to refine its estimates. This is precisely the point of a public comment process and BEAD appreciates the input it has received. With regard to the relative risks associated with alternative insecticides, please refer to Section I.D.

BEAD acknowledges the importance of neonicotinoid insecticide seed treatments for the control of BLB and mitigation of BPMV on soybeans and has revised its benefit estimates accordingly (see Section III) to incorporate additional data and input from registrants and other commenters. Further, EPA has revised estimates with regional considerations for the mid-South and Midwestern U.S.

D. Comments from Agricultural Extension Programs

EPA received comments from several groups of agricultural research and extension experts at land grant university systems. These experts have specialties in pest management problems in specific regions, including the Northeast, Midwest, and Northern Plains; the upper Midwest; the Southeast; and the Mid-South.

1. A group comment (Bailey et al., EPA-HQ-OPP-2014-0737-0331) was submitted from extension programs in Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, Pennsylvania, South Dakota, Wisconsin.

- a. "Given our collective research and extension experience in soybean entomology, we confidently state that widespread, prophylactic use of neonicotinoid seed treatments is unnecessary and ill-advised in our region. There are often temporal and spatial inconsistencies between deployment of seed treatments and target pests; farmers thus gain little pest management or economic benefit from widespread, prophylactic use of these treatments. This conclusion is borne out by multiple years of research in the northern soybean producing region, which reinforces the recent EPA report. However, neonicotinoid seed treatments on soybean are valuable for managing certain insect pests in targeted, high-risk situations."
- b. "In the northern region, most of the below-ground insect pests (e.g., seedcorn maggot, white grubs, and wireworms) targeted by neonicotinoid seed treatments do not reach economically-damaging levels in the majority of fields, and soybean producers benefit from this relative scarcity of early season pests."
- c. "There is a temporal mismatch between the typical timing of soybean aphid colonization (often late vegetative into bloom stages) and the short-lived window of insecticidal activity in plants. In addition, early-season aphid infestations can be suppressed by a suite of predators and parasitoids. Scouting and threshold-based foliar insecticide applications are the most effective and economical approach for soybean aphid management."
- d. "They [seed treatments] increase the risk of resistance through the widespread, repeated use of a single insecticide class. This is an understudied issue for neonicotinoid seed treatments that deserves more attention."
- e. "Targeted use of neonicotinoid seed treatments is advised for fields or parts of fields at high risk of economically-significant infestation of seed or seed-feeding pests, particularly for those soil-borne pests with no rescue treatments. In our experience, however, these situations are uncommon. Furthermore, risk of infestation by these pests is usually predictable based on field history and conditions." A list of situations is provided where seed treatment usage is most likely warranted.
- f. Three points of emphasis regarding seed treatment use on soybeans:
 - a. "Early-season economic infestations of insects in soybean are uncommon in most fields across the northern region."
 - b. "Soybean is an extremely resilient crop, tolerating early-season stand losses and defoliation from insects without suffering economic loss."
 - c. "When pest problems do occur, management should be based on an integrated approach including host plant resistance, cultural control, conservation of natural enemies, scouting, and threshold-based insecticide applications."
- g. "The current widespread, prophylactic use of neonicotinoid seed treatments in soybeans is currently unjustified."

RESPONSE: BEAD appreciates the insights into our benefits analysis, particularly noting the consensus opinion that many of the key soil-dwelling pests of importance to soybean production occur infrequently in the regions of soybean production. This observation is of key importance for informing uncertainties about regional variability in the benefits of neonicotinoid seed treatments for soybeans. BEAD also agrees that in areas of known pest pressure from the soil pest complex, that neonicotinoids are very effective materials for control of these pests and for prevention of yield losses. BEAD concurs with the statements about past field and site history offering insights, (albeit with limited predictive power) for the relative likelihood risk of soil pest pressure for soybean growers. This finding should inform not only specific pest management decisions by growers, but also inform interpretation of national-scale meta-analyses of yield protection data. It is logical and intuitive to understand that the relative likelihood of yield benefits from seed treatments will be higher in areas where soil pest pressure is more likely to be significant. BEAD also appreciates the expert insights into the relative importance of seed treatments for soybean aphids, which as stated by the commenters, most often occur at times that do not match up well with the period of highest bioactivity in soybeans. BEAD appreciates the concerns expressed regarding widespread selection pressure due to area-wide prophylactic use and agrees that more study on this particular issue is warranted. BEAD acknowledges and agrees with the statement on the relative resilience of soybeans as a crop. It is well-established that soybeans can withstand substantial levels of early season defoliation without significant impacts on yield.

- 2. Dr. Adam Gaspar, a scientist in the Department of Agronomy at the University of Wisconsin in Madison, submitted a short comment and provided three of his scientific publications to support his statements. (EPA-HQ-OPP-2014-0737-0349).
 - a. "My concern ... is with the general sweeping statement offered in the first line of the conclusion that reads "This analysis provides evidence that U.S. soybean growers derive limited to no benefit from neonicotinoid seed treatments in most instances". ... My published research from the state of Wisconsin... suggests that there is evidence of efficacy based on increased stand counts over the untreated check and fungicide only checks with the use of some of the neonicotinoid insecticides."
 - b. "Furthermore there are instances when growers receive a positive return on investment and reduced economic risk when some (not all) of the neonicotinoid insecticides are used."
 - c. "To be clear I am not suggesting that I recommend that [every] acre of soybean in the United States or WI for that matter receive a neonicotinoid insecticide, however I also do not want to see this class of chemistry banned or over regulated to the point that soybean growers do not have the option based on localized pest issues or seasonal production challenges."
 - d. Three research papers were submitted: Gaspar et al. (2014a), Gaspar et al. (2015), Esker and Conley (2012).

RESPONSE: BEAD appreciates the submitted comments from Dr. Gaspar along with three notable papers germane to the probability of grower benefits from use of neonicotinoid seed treatments on soybeans. BEAD addresses the concern regarding national-level estimates on numerous occasions here and in the concluding sections. BEAD concurs that it would not be desirable for preventative neonicotinoid seed treatment usage to be adopted on all soybean acreage in the U.S. or any one state, and further concurs that there are instances where seed treatments on soybeans deliver significant benefits to growers, based upon control of pests that are present in fields. BEAD emphasizes that seed treatment efficacy for target pest control is well-demonstrated and widely supported by available evidence.

BEAD staff reviewed the articles provided by Dr. Gaspar, as well as some of the related extension advice available at the Wisconsin Soybean Extension Program website (see http://coolbean.info/soybean_research/soybean_research.php).

The research cited by Dr. Gaspar involved comparisons of seed treatments including different types of pesticides and neonicotinoid insecticides, mainly in terms of the effects on soybean plant stand density and yields. The research also evaluated the impact of various such seed treatments on crop profitability with both typical and reduced rates of seeding. All trials were conducted within one state (Wisconsin), and included many locations, multiple years, a range of pest species and population pest pressures, as well as different climate conditions. Aside from the tested seed treatments, the researchers used in-season pest management recommendations provided by the University of Wisconsin. The insect pests involved were the soybean aphid, the bean leaf beetle, and/or the seedcorn maggot (species composition varied, depending on year and location). In one study (Gaspar et al., 2014a), several combinations of pesticides were tested, including three fungicides, a nematicide, and three separately utilized neonicotinoids (clothianidin, imidacloprid, and thiamethoxam). There were no insecticide-only seed treatments-each was combined either with a fungicide (one of three different AIs) or the nematicide. In another study (Gaspar et al., 2015), treatments included (1) two fungicides (used alone and in combination) and (2) a combination of thiamethoxam and one of the fungicides. These treatments were applied along with different seeding rates in several locations with varying pest pressures within Wisconsin.

Results of this research suggested that there are unpredictably variable, but sometimes positive effects of including a neonicotinoid seed treatment in the planting regime for Wisconsin soybeans. In addition, at reduced seeding rates only the thiamethoxam plus fungicide treatment ("CruiserMaxx") increased yield and profits. In addition, to paraphrase the abstract from Gaspar et al. (2014b): plant stands were consistently increased when any neonicotinoid was added to either a fungicide or a fungicide plus nematicide combination, but yield increases were variable across years and locations. Seed treatments only increased yields over the untreated control in one year (2013). This indicates that yield increases due to these treatments are dependent on other unpredictable factors. Another aspect to the results was that imidacloprid was generally less effective in increasing yield, as compared to either thiamethoxam or clothianidin.

Taken together, these results suggest that the addition of a neonicotinoid seed treatment is sometimes helpful (in terms of increasing yield and, if thiamethoxam is used, doing so even with reduced seeding rates) under certain growing conditions. Unfortunately, there seems to be no way of reliably concluding from this work exactly what these conditions are. It seems prudent to conclude that this work supports the inclusion of certain neonicotinoids (thiamethoxam and clothianidin) where pressure from the insect pests evaluated (the soybean aphid, the seedcorn maggot, and/or the bean leaf beetle) is expected or reliably known to be high every season. Other issues exist in these studies – e.g., they were conducted in only one part of the Midwest, and did not compare

neonicotinoid seed treatments with either foliar alternatives or non-neonicotinoid seed or soil treatment options.

Generally speaking, the probabilistic approached presented by Gaspar et al. (2015) and Esker and Conley (2012) shows variability in the yield response for soybeans grown in Wisconsin. Further, the conclusion projects that the probability of benefits is highly correlated with both the baseline yield for a given site, and also with the soybean commodity price, whereby the likelihood of a seed treatment investment providing a break-even return are much more likely under conditions of high soybean prices and high baseline yields, and the likelihood of returns decreases as these variables decrease. However, for sites with known pest pressure, BEAD concurs with the general conclusion that soybean seed treatments are very effective at protecting seeds from soil-dwelling pests and that yield is protected under conditions of high pest pressure. BEAD also concurs that taking this efficacy into account can allow for high soybean yields using lower planting densities that lower the costs per acre for growers. BEAD recognizes that along with use of alternative control tactics (i.e., permethrin seed treatment) or cultural practices (such as tillage), it is feasible to mitigate some pest damage (and yield loss) by increasing seeding densities in the absence of available neonicotinoid seed treatments. Since seed treatments protect the seeds and preclude the need for higher seeding rates, it is possible to achieve a desired yield at a lower seeding rate. BEAD projects that the benefit of over-seeding as a yield protection tactic likely falls somewhere below BEAD's revised (see Section III) upper-bound impact scenario for the mid-South, which addresses the yield losses associated with soil pests in the absence of an effective seed treatment.

3. Several commenters discussed the important benefit of preventing transmission of the bean pod mottle virus (BPMV) which is vectored by the bean leaf beetle (BLB). Citations were provided discussing the importance of this factor and it was noted that control of the adult overwintering generation is key to stopping transmission of this virus by providing an early season mitigation of BLB populations. This, can often preclude the need for later foliar treatment of subsequent BLB generations.

RESPONSE: BEAD is very appreciative for the submitted information and citations regarding transmission of BPMV by BLB. Available data indicate that losses from BPMV infection, which impact both yield and quality of beans, can be quite significant. BEAD did not previously take BPMV transmission into account when analyzing comparative efficacy of seed treatments vs. foliar spraying for BLB control. While overall control of BLB (both adults and the immature stages from subsequent generations) is not significantly different between foliar sprays and neonicotinoid seed treatments on soybeans, review of the cited and submitted information makes it clear that the most effective way to control spread of BPMV is by controlling the overwintering adult population of BLB adults that feeds on soybean plants soon after crop germination and emergence. Because this overwintering adult population would typically be active in soybean fields immediately after planting, neonicotinoid seed treatments offer particular advantages for BLB control during this period of time, given the systemic movement into the emerging soybean plant, and bioavailability of neonicotinoid residues for the first 3-4 weeks after planting. Also, because wet conditions can often occur in the time period

during or immediately after planting, it can be difficult for growers to make foliar applications of insecticides during this important control window. Protecting the emerging soybean seedlings by use of a neonicotinoid seed treatment ensures adequate protection against BLB during this critical control window without the need for the additional expense of applying foliar insecticides. BEAD concurs that the neonicotinoid seed treatments thus provide an important benefit for areas at high risk for infection from BPMV and where overwintering BLB adult populations are expected to be high. BEAD concurs that it is advantageous to utilize neonicotinoid seed treatments in such areas (particularly Iowa and other Midwestern states), based upon established site history, evidence of past BPMV infections nearby, and known presence of significant BLB populations. BEAD has incorporated the potential impact of and importance of BPMV and the associated vector control in a revised impact estimate that will be discussed later in this document. Furthermore, for the revised analysis of impact, BEAD will project alternative costs based upon an additional foliar insecticide spray applied to soybeans to control overwintering BLB in the Midwest, assuming acreage that currently receives a soybean seed treatment.

- 3. A group comment (Buntin et al. EPA-HQ-OPP-2014-0737-0944) was submitted from extension programs in Alabama (coastal plain), Georgia, North Carolina, South Carolina, Virginia.
 - a. "We concur with the EPA-BEAD conclusion that neonicotinoid seed treatments do not provide clear or consistent economic benefits across the majority of southeastern soybean production systems . . . The scientific consensus in the southeastern states (VA, NC, SC, GA, AL coastal plain) is contradictory to the mid-southern states (northern AL, AR, LA, KY, MS, OK, TN, TX, and MO boothill). This is a significant departure from the assessment, which broadly groups every state from Virginia to Texas into a group titled "southeast."
 - b. "While we acknowledge that responses in several mid-southern states (specifically LA, MS, and TN), a majority of the southeastern land-grant university entomologists have not shown such a finding in their respective geographic region.
 - c. ".. growers in southeastern states rarely encounter treatable populations of bean leaf beetle, soybean aphid, or three-cornered alfalfa hopper in the first three to four weeks from planting when seed treatments are active. Reasons for differences between regions are likely because growers in mid-southern states typically start planting in March, whereas the majority of soybeans in the Southeast are planted between 15 May and 30 June ... where this early (planting) system is neither possible nor profitable.
 - d. "Southeastern land-grant university soybean entomologists are concerned that unilateral prophylactic use of neonicotinoid seed treatments in southeastern soybean production will exacerbate currently evolving insecticide resistance. Southeastern growers already utilize neonicotinoid seed treatments on every acre of corn and cotton.
 - e. "... previous research shows that these (seed) treatments may adversely affect nontarget organisms. Many of our growers realize that beneficial organisms (predators and parasitoids) provide appreciable caterpillar and aphid suppression that will not be

present when insecticides are applied. There is mounting evidence that neonicotinoids negatively affect natural enemy life history."

f. "Although we do not support prophylactic neonicotinoid usage patterns in soybean, we do favor continued labelling of neonicotinoid seed treatments on soybean. Seed treatments need to remain in the soybean pest management toolbox and, indeed can be an appropriate solution in cases where significant risk is demonstrated . . . While uncommon, there are specific conditions, areas, and situations where neonicotinoid seed treatments are important tools in an acceptable integrated pest management program."

RESPONSE: BEAD appreciates the clarification and correction regarding the geographic delineations for discussing the most common pests and production practices in the Southern U.S. BEAD has revised its assumptions about "southeastern" production areas (and the subsequent identification of relative uncertainties). BEAD acknowledges that the mid-South states (i.e., Mississippi Delta region) should be recognized as distinct from the production region further east that encompasses Virginia, North Carolina, South Carolina, Georgia, Alabama, etc. Based upon earlier comments and discussions with researchers from the mid-South, BEAD now has a better understanding about that region's particular practices of early planting, agronomic conditions, and overall pest pressure from soil pests. BEAD appreciates the nuanced discussion of how production in the southeast does not adopt similar early planting practices and how pest pressure from soil pests, BLB, and alfalfa hoppers is relatively lower in comparison. Similar to the regional information from the Midwestern commenters, this is very useful in informing uncertainties about regional pest differences as well as the results of national-level metaanalyses. It is logical and intuitive to understand that the relative likelihood of yield benefits from seed treatments will be higher in areas where soil pest pressure is more likely to be significant. BEAD also agrees that in areas of known pest pressure from the soil pest complex, that neonicotinoids are very effective materials for control of these pests and for prevention of yield losses.

4. Several commenters from the mid-South (including Arkansas, Louisiana, Mississippi, Missouri, and Tennessee) provided information related to the particular pest management needs of the Mississippi Delta growing region, with accompanying citation of a draft meta-analysis of seed treatment yield impacts for mid-south soybeans. [BEAD initiated a phone discussion with one of the authors of this submission in late 2014 to obtain additional information about agronomic practices specific to soybean production in the mid-South.]

RESPONSE: In analyzing the benefits of seed treatment usage of neonicotinoid insecticides on soybeans, BEAD discussed some of the important regional variation in cropping practices, target pests, and agronomic practices across the United States. This submission from the mid-South, and also accompanying information from other comments (particularly the submission from Buntin et al., EPA-HQ-OPP-2014-0737-0944, which will be discussed in more detail later) have made it clear that BEAD's regional analysis (discussed as 'uncertainties) did not adequately capture the unique pest control challenges encountered in the mid-South United States. Beyond a

misunderstanding of the geography of mid-South soybean production (BEAD initially lumped the mid-South in with other Southeastern states such as Georgia, Virginia, and the Carolinas), there were also a number of production assumptions and uncertainties that caused an inherent under-estimation of likely seed treatment benefits for the mid-South.

Of primary concern with regard to seed treatment benefits is the more recent practice of early soybean planting for yield maximization. The author presented evidence of a clear yield effect of earlier planting, whereby earlier planting had a significant impact on soybean yields in this particular region. Such early planting necessitates planting into cooler, wetter soil conditions where seeds and early emerging seedlings are more susceptible to attack from soil pests. Furthermore, due to the increased adoption of no-till and cover-cropping approaches in this region, seeds are being planted into a soil environment that tends to have much higher pest pressure-as compared to soil that is tilled prior to planting. Further discussion with the author indicated that scouting for and identification of particular soil pest damage is exceedingly difficult, particularly at the early planting dates now preferred by growers. There is extensive evidence of widespread damage to untreated seeds that is conferred after planting, but it has proven nearly impossible as of yet to develop scouting methods or predictive models that can anticipate such pest problems prior to a planting decision. Therefore, given the known widespread presence of soil pests (exacerbated by agronomic practices) and the difficulty of scouting for such pests, BEAD concurs that the benefits of a preventative seed treatment are higher in the mid-South, relative to other regions with lower pest pressure, later planting dates, and more varied agronomic practices and that this benefit likely spans the entire mid-South soybean growing region. More details will be discussed in Section IV.

It became clear after communications with one of the authors of this submission, as well as other soybean Extension experts from around the country, that this early-planting situation and particularly some of the cover-cropping practices that exacerbate wireworm and seed maggot pressure are mainly unique to the mid-South United States. While it is difficult to precisely calculate the specific benefits of prophylactic soil pest control under such conditions, BEAD concurs with the authors that from a probabilistic standpoint, the likelihood of problems from soil pests is much higher in this region of production relative to other regions of the U.S. (see Comment #6 in Section I). This information is valuable in providing additional pest risk characterization to the 'uncertainties' identified in BEAD's initial draft.

BEAD would add that since the pest control needs in the mid-South United States are mainly driven by soil pests such as seedcorn maggots and wireworms, the previously identified alternative permethrin seed treatment, if available for use, likely constitutes a viable and effective alternative to neonicotinoid seed treatments for control of these pests.

Finally, BEAD appreciates the submission of a region-specific meta-analysis. BEAD considered this potential benefit, as well as those projected by the conclusions of other meta-analyses that were either submitted or discussed in the comments related to this analysis, and this is discussed further in Section IV.

III. REVISED BENEFIT ASSESSMENT: CLARIFICATIONS, REVISIONS, AND REMAINING UNCERTAINTIES

Clarification of Purpose and Scope

BEAD received a number of helpful comments, which have helped in resolving uncertainties, informing BEAD's assumptions, and providing useful guidance in refining BEAD's impact/benefit estimates.

For clarification on the purpose of this document, BEAD reiterates its response to a number of public commenters and media reports regarding this assessment: BEAD's analysis of benefits for neonicotinoid seed treatment insecticides on soybeans was not a discussion of efficacy, but rather a consideration of the likelihood of benefits for growers. The scientific evidence and expert input is overwhelmingly in agreement that neonicotinoid seed treatments have very good pest control efficacy and are effective at controlling the intended target pests for soybeans for the intended and limited period of bioactivity. Nowhere in BEAD's original assessment nor in this response to comments document does BEAD imply that neonicotinoid seed treatments are not effective at controlling pests when populations of those pests are present in fields.

Furthermore, BEAD also reiterates that its benefit analysis did not, and does not constitute a risk management proposal. BEAD does not analyze the relative risks of alternative pest control tactics such as applications of foliar insecticides to soybeans. While the risk assessments of neonicotinoids are forthcoming, BEAD's analysis was strictly focused on an examination of the benefits of neonicotinoid seed treatments by comparing the current situation of their use to a hypothetical situation where neonicotinoid seed treatments do not exist.

Finally, while BEAD appreciates public comments on the more broadly categorized benefits of neonicotinoids as a class of chemicals, and agrees that neonicotinoid usage has significantly displaced usage of broad-spectrum insecticides from older chemical classes, BEAD's analysis was strictly focused on seed treatments for one crop. This is of particular note when drawing comparisons between BEAD's analyses and, for example, the analyses conducted by AgInfomatics, which sought to characterize multiple benefits (both economic and non-monetary benefits) of all neonicotinoid usage on a much wider variety of crops, and also included qualitative assessments based upon grower interviews.

Probabilistic Approaches and National-Level Meta-analyses

BEAD appreciates the data and suggestions that were shared by multiple commenters regarding area-wide meta-analysis approaches to estimating yield benefits from usage of neonicotinoid insecticide seed treatments on soybeans, including submissions from AgInfomatics, Bayer, Syngenta, DuPont, mid-South researchers, Adam Gaspar, etc. Because raw data and specific statistical methodologies were not submitted, BEAD did not attempt to reproduce or independently verify the results of these analyses. However, BEAD does recognize that there are

inherent limitations to an analysis based solely upon review of independent, small-plot field trial data as is done with the soybean benefit assessment.

While there was general criticism regarding BEAD's use of a 'vote count' (a term used by commenters) approach in its analysis of publicly available efficacy data that measured yield, BEAD is concerned that an oversimplification can occur when multiple studies are aggregated to determine an overall mean. Without careful statistical treatment of various confounding sources of variability, some of the proposed meta-analytical approaches attempt to draw meaning from small numerical differences in spite of statistical insignificance for many of those comparisons. Therefore, BEAD would note that a meta-analysis approach has its limitations and pitfalls as well.

BEAD also notes that individual grower choices in pest control tactics are ideally driven by a knowledge of site-specific factors, rather than broad probability-based metrics. BEAD emphasizes that while meta-analysis can be a useful methodological tool for use in assessment, the results of a meta-analysis are not likely appropriate as a decision-support system for a grower deciding whether or not to utilize seed treatments on a particular site. A good working knowledge of a site's history regarding pest presence and abundance, and past experience is typically expected to form the basis of such decisions. While a nation-wide meta-analysis might be useful from the standpoint of identifying a baseline probability for expected yield protection in general, the specifics of this likelihood are much further informed by site-specific information known mostly by individual growers and their pest control consultants. It seems to make little sense for a grower of soybeans in an area where there has never been a high likelihood of soil insect pressure or past issues with BPMV or early-season defoliation damage from BLB to choose to spend money on seed treatments based simply on a hypothetical national probability. And conversely, for a grower with a known history of pest pressure, it is likely that site-specific estimates of benefits are far more useful in choosing a control tactic than a generalized average likelihood of yield losses based on a hypothetical national baseline probability. This need for site-specific information in the development of pest management decision-making is underscored by comments submitted by a host of leading national experts in soybean production, as well as by USDA-ARS's submitted comments.

Site variability, which can be driven by climatic differences, different soil types, different variety choices, different agronomic practices, different pest pressures, etc., must be properly identified and addressed before any global averages can be reported as a useful, meaningful result. The valid criticism of EPA's original approach being too generic and not adequately nuanced by region could equally be applied to the proposed meta-analyses discussed here, as all have attempted to amalgamate national data and develop an overall yield impact average, rather than present averages for distinct areas of the country. BEAD does acknowledge that the work cited by Gaspar et al. is regionally focused to the upper-Midwest and the mid-South analysis was focused on the Mississippi Delta region. However, BEAD is unsure if adequate data are available for a similar regional refinement of other submitted meta-analysis data. For the purposes of estimate refinement, BEAD will assume that the results of submitted meta-analyses from the mid-South and elsewhere are generally correct and thus, for its newly refined impact analysis (presented here for the mid-South), BEAD provisionally uses an estimate of 2.5 bushels

per acre impact in the absence of neonicotinoid seed treatments on soybeans in the mid-South. BEAD's original analysis did not project any yield losses.

Revision Summary

BEAD's original assessment concluded that, because of the often low likelihood of the presence of pests targeted by neonicotinoid seed treatments and because much of the usage of seed treatments appeared to be done in a preventative/prophylactic manner without regard to pest pressure, the expected benefits of using neonicotinoid seed treatments for most growers is low. For this revision, BEAD is adopting more standard terminology and is estimating the loss a soybean grower who uses neonicotinoid-treated seed might incur in the absence of the seed treatment. BEAD has updated yield and price information over the five-year period from 2010 to 2014 (USDA NASS, 2010-2014) and variable cost information from USDA Economic Research Service (2012-2013). That is, the national average yield for soybeans from 2010 to 2014 is 43.4 bushels/acre (previously 42.5 bu/acre), the price per bushel averages \$12.26/bu (previously \$12.03/bu), and average variable costs in 2012 and 2013 are \$180/acre (previously \$173/acre).

For comparison purposes, we present the estimated loss per acre, given the original assessment conclusions that yield loss would be negligible and growers may switch to a foliar application of another insecticide, in Table 2. For this estimate, flubendiamide was identified as the most costly alternative insecticide¹. It was assumed that flubendiamide would be applied in combination with another pesticide; no additional application costs were considered. According to market survey day, a neonicotinoid seed treatment costs about \$8/acre while flubendiamide costs about \$14/acre (MRD, 2009-2013). Thus, a grower switching to a foliar application of flubendiamide in the absence of neonicotinoid seed treatments would incur additional costs of production of about \$6/acre. This represents about 1.7% of the calculated net operating revenue of \$344/acre, based on average yields and prices and estimated variable production costs.

	Neonicotinoid Seed Treatments Scenario	Flubendiamide
Yield (bu/A)	43.4	43.4
Price (\$/bu)	\$12.26	\$12.26
Gross Revenue (\$/A)	\$532	\$532
Insecticide Costs (\$/A)		
seed treatment	\$8	
foliar spray		\$14
Other Variable Costs (\$/A)	\$180	\$180
Total Variable Operating Costs (\$/A)	\$188	\$194
Net Operating Revenue	\$344	\$338

 Table 2: Estimated Impacts to Soybean Growers without Neonicotinoid Seed Treatments,

 original assessment conclusions.

¹ Since the analysis was conducted in 2014, the time-limited registration of flubendiamide expired. At the time, ten other insecticides were available at lower cost, implying lower impacts.

	Neonicotinoid Seed Treatments Scenario	Flubendiamide
Change in Net Operating Revenue		- \$6

Numbers may not add due to rounding. Calculations have been adjusted from Myers and Hill (2014) to reflect the most current reported production data and variable costs. Production data represent a national five-year average (USDA NASS, 2010-2014). Active ingredient cost represents national costs as a five-year average (MRD, 2009-2013). Variable costs are reflective of the 2012 and 2013 national average and account for seed; fertilizers; chemicals; custom operations; lube, fuel, and electricity; repairs; purchased irrigation water; and interest on operating capital (USDA Economic Research Service, 2012-2013).

BEAD also highlighted a number of uncertainties about the benefits of preventative use for certain areas of the United States where pest pressure (particularly pressure from soil pests) was potentially higher than average, citing the example of the Southeastern United States. After reviewing comments and submissions in response to that assessment, BEAD now has information to capture the significant regional variation in climate, agronomic practices, and relative pest pressure that is often observed. Based on information and data submitted by commenters, key refinements are as follows:

- 1. BEAD is identifying three regions of the country for analysis, based on comments describing unique pest control challenges:
 - a. The mid-South (Arkansas, Louisiana, Mississippi, Missouri, and Tennessee). States of the Mississippi Delta region have clarified the reasons for their early planting practices, have discussed the agronomic practices that often exacerbate pest pressure from soil insects, and have explained the reasons that their production practices differ from the rest of the South and the United States as a whole (Section II.3).
 - b. The Midwest (Illinois, Iowa, Minnesota, Nebraska, North and South Dakota, and Wisconsin). These states report the potential for substantial damage due to the Bean Leaf Beetle (BLB). While soybean yield is typically quite resilient to early season defoliation from such pests, the BLB can vector the Bean Pod Mottle Virus (BPMV), making early season control important (Section II.4).
 - c. All other soybean growing states.
- 2. Alternative foliar insecticides may not be effective in reducing pest pressure in the mid-South; therefore, it is only assumed that effective alternative foliar insecticides are available for use on soybeans in regions outside of the mid-South.
- 3. BEAD assumes that there will be no mixing of a foliar insecticide (used as an alternative to seed treatment) with another existing foliar pesticide (e.g., fungicide or herbicide) application that would already be routinely applied to a field. Thus the cost of an additional pass over the field will be incurred.

Commenters also noted differences in scouting costs may exist when using treated versus untreated seeds. BEAD disagrees with the implication that seed treatments significantly reduce scouting costs for soybeans. While the need for scouting might be somewhat reduced during the

time immediately after planting when using treated seeds (i.e., the time of highest bioactivity in emerging soybean seedlings), scouting is still necessary in soybeans for weeds, foliar diseases, nutrient management, and insect pests that fall outside the activity spectrum of neonicotinoid seed treatments. Therefore, BEAD does not project that scouting costs will significantly decline for soybeans with treated seeds versus untreated seeds.

BEAD also recognizes that along with the use of alternative control tactics (i.e., permethrin seed treatment) or cultural practices (such as tillage), it is feasible to mitigate some pest damage (and yield loss) by increasing seeding densities in the absence of available neonicotinoid seed treatments. Since seed treatments protect the seeds and preclude the need for higher seeding rates, it is possible to achieve a desired yield at a lower seeding rate. BEAD projects that the loss in net operating revenue from the cost of extra seed while accounting for the benefit of overseeding as a yield protection tactic likely falls somewhere below BEAD's revised (see below) estimated impacts for the mid-South, which addresses the yield losses associated with soil pests in the absence of an effective seed treatment.

Revised Partial Budget Analyses

BEAD is revising the Myers and Hill (2014) partial budget analysis to account for the three refinements listed above. Revisions are provided for each affected region, followed by an estimate of the overall national impact.

As background, BEAD uses a partial budget analysis to place the consequences of neonicotinoid seed treatments no longer being available to soybean growers in the context of grower revenue. Impacts are compared to net operating revenue, which is defined as the difference between gross revenue and variable operating costs on a per-acre basis. This approach does not account for fixed costs, which are highly dependent on land ownership and the size and diversity of the grower's operation, making them difficult to define on a per-acre basis. As such, results of this analysis may understate the impacts as a percentage of grower income. In particular, small growers may be impacted relatively more than large growers from increased costs because fixed costs are likely to be larger per acre when growers have less acreage across which they may spread the fixed costs of operation. On the other hand, because a farm may produce multiple crops, a single crop analysis could also overstate the impacts as a percentage of grower income.

Mid-South United States per Acre Impacts

A revised impact scenario is presented in Table 3 for the mid-South United States, which includes the Mississippi Delta regions of Missouri, Tennessee, Arkansas, Mississippi, and Louisiana (Arkansas is used as a representative state for the partial budget analysis). While BEAD cannot independently confirm the cited meta-analysis (see Section II.3) of yield benefits for this region, it is notable that the results of that analysis were very close to the results presented by other commenters, including other independent researchers, registrants, etc. Therefore, BEAD revised its previous impact estimate and uses a mid-South baseline scenario (Arkansas), which takes into account the potential yield losses from soil pests in the absence of any effective seed treatment options in line with the results of the meta-analyses, at 2.5 bushels per acre. This is intended to represent a scenario where pressure from soil insect pests is high and

no insecticidal seed treatment is available to control these pests. Considering the yield loss from uncontrolled soil pests, impacts are estimated to be about \$23 per acre or a loss of about 8.4% of net operating revenue (Table 3).

Access to Any viable beeu fica	iment options to control bon	I COCO
	Baseline Scenario:	Effective Seed Treatments
	Neonicotinoid Seed	not Available
	Treatments Available	(2.5 bu/acre yield loss)
Yield (bu/acre)	42	39.5
Price (\$/bu)	\$12.24	\$12.24
Gross Revenue (\$/acre)	\$514	\$483
Insecticide Costs (\$/acre)		
Seed Treatment	\$8	
Other Variable Costs (\$/acre)	\$233	\$233
Total Variable Operating	\$240	\$233
Costs (\$/acre)		
Net Operating Revenue	\$274	\$251
Change in Net Operating		- \$73
Revenue		- \$25

 Table 3: Estimated Impacts to Soybeans Grown in the Mid-South (Arkansas) Without

 Access to Any Viable Seed Treatment Options to Control Soil Pests.

Numbers may not add due to rounding. Arkansas production data represents a five-year average (USDA NASS, 2010-2014). Active ingredient cost represent national costs as a five-year average (MRD, 2009-2013). With 89% of total harvested soybean acres in Arkansas being irrigated (USDA Agricultural Census, 2013), a budget specific to furrow irrigation practices was used for this scenario. Variable costs are reflective of Arkansas Enterprise Budget variable costs associated with seed; fertilizers; chemicals; custom operations; lube, fuel, and electricity; and repairs; and interest on operating capital (University of Arkansas, 2015). No costs were reported for purchased irrigation water by University of Arkansas (2015) or by the USDA Economic Research Service for this region (2012-2013).

Midwest United States per Acre Impacts (Areas of BLB/BPMV Pressure)

A revised impact scenario is presented for the Midwestern United States (using Iowa as a representative state for the partial budget analysis) in Table 4, which commenters indicated was an area with the highest likelihood of incidence of BPMV vectored by BLB. Because foliar insecticides are effective at controlling overwintering BLB adults, BEAD projects that in most cases, one foliar insecticide application would be an equal substitute to a neonicotinoid insecticide seed treatment on soybeans. However, in certain limited situations, a second application of insecticides may be required. The second application could further target BLB, or could be used to control an unusual early-season infestation of soybean aphids that otherwise might have been mitigated by usage of a seed treatment.

BEAD finds that in the case of one additional field pass, net revenue would decline \$4 per acre (approximately 1.0% of net operating revenue). Two field passes would result in a \$16 per acre decline in net revenue (3.8% of net revenue) for soybean growers in the Midwest facing significant BPMV pressure combined with early-season aphid infestations (Table 4).

Table 4: Estimated Impacts to Soybeans Grown in the Midwest (Iowa) Without Access to Viable Seed Treatment Options to Control Bean Leaf Beetle (One Foliar Insecticide Application) and/or Bean Leaf Beetle Followed by and Early-Infesting Soybean Aphid (Two Foliar Insecticide Applications).

	Baseline Scenario:	One foliar Insecticide	Two Foliar Insecticide
	Neonicotinoid	Application (lambda-	Applications (lambda-
	Seed Treatment	cyhalothrin) requiring	cyhalothrin) requiring
	Available	one additional field	two additional field
		pass	passes
Yield (bu/acre)	48.8	48.8	48.8
Price (\$/bu)	\$12.25	\$12.25	\$12.25
Gross Revenue (\$/acre)	\$598	\$598	\$598
Insecticide Costs			
(\$/acre)			
Seed Treatment	\$8		
Foliar Insecticide		\$5	\$9
Cost of an Additional		\$7	\$15
Field Pass (\$/acre)			
Other Variable Costs	\$163	\$162	\$162
(\$/acre)			
Total Variable	\$170	\$174	\$186
Operating Costs			
(\$/acre)			
Net Operating Revenue	\$428	\$424	\$412
Change in Net		¢1	- \$16
Operating Revenue		- 34	- \$10

Numbers may not add due to rounding. Production data represents Iowa state five-year average (USDA NASS, 2010-2014). Active ingredient cost represent national costs as a five-year average (MRD, 2009-2013). Variable costs are reflective of Iowa Enterprise Budget variable costs associated with seed; fertilizers; chemicals; custom operations; lube, fuel, and electricity; and repairs; and interest on operating capital seed (Iowa State University, 2015). Additional field pass information represents AgInfomatics (2014) field pass estimates for the Midwest region, updated with 2015 estimates. No costs were reported for purchased irrigation water by Iowa State University (2015) or by the USDA Economic Research Service for this region (2012-2013).

All other Soybean Acres Currently Utilizing Neonicotinoid Seed Treatments, per Acre Impacts

As mentioned, BEAD expects that soybean acres currently utilizing neonicotinoid seed treatments outside of the Midwest and mid-South would not incur any yield losses in the absence of neonicotinoid-treated seed. Because soil pests are highly sporadic, many growers are unlikely to employ the use of foliar treatments. However, some growers may require one additional foliar insecticide application (likely of a pyrethroid or organophosphate) to fields in the absence of any effective seed treatment options. As shown in Table 5, BEAD finds that in the case of one additional field pass, net revenue is expected to decline \$4 per acre (a 1.3% decline in net revenue). Note that this slightly differs from the impacts presented for the Midwest as national level production data and variable costs are used.

Table 5: Estimated Impact for Soybeans Grown in Areas Outside of the Midwest and Mid-South that Currently Utilize Neonicotinoid Seed Treatments (One Foliar Insecticide Application).

	Baseline Scenario: Neonicotinoid Seed Treatment Available	One foliar Insecticide Application (lambda- cyhalothrin) requiring one additional field pass
Yield (bu/acre)	43.4	43.4
Price (\$/bu)	\$12.19	\$12.19
Gross Revenue (\$/acre)	\$529	\$529
Insecticide Costs (\$/acre)		
seed treatment	\$8	
foliar spray cost for additional passes		\$5
Cost of an Additional Field Pass (\$/acre)		\$7
Other Variable Costs (\$/acre)	\$180	\$180
Total Variable Operating Costs (\$/acre)	\$188	\$192
Net Operating Revenue	\$341	\$337
Change in Net Operating Revenue		- \$4

Numbers may not add due to rounding. Production data represents national five-year average (USDA NASS, 2010-2014). Active ingredient costs represent national costs as a five-year average (MRD, 2009-2013). Variable costs are reflective of 2012 and 2013 national averages and account for seed; fertilizers; chemicals; custom operations; lube, fuel, and electricity; repairs; purchased irrigation water; and interest on operating capital (USDA Economic Research Service, 2012-2013). Additional field pass information represents AgInfomatics (2014) field pass estimates for Midwest region, updated with 2015 estimates.

Revised Estimates of National Impacts

As described in the region-specific analyses, the absence of neonicotinoid-treated seed could result in the following impacts:

- \$0 to \$23 (0% to 8.4%) loss in net operating revenue in the mid-South if a 2.5 bu/acre yield loss is incurred,
- \$0 to \$4 (0% to 1%) loss in net operating revenue in the Midwest if one additional field pass is needed,
- \$0 to \$16 (0% to 3.8%) loss in net operating revenue in the Midwest if two additional field passes with a foliar insecticide are needed, and
- \$0 to \$4 (0% to 1.3%) loss in net operating revenue for all other soybean acres in the United States that are currently utilizing neonicotinoid treated seed if one additional field pass with a foliar insecticide is needed.

BEAD determined average national per acre net revenue losses and total national net revenue losses by accounting for the proportion of total national acres that would be impacted by each region-specific scenario. The following explains the methodology used in determining these impacts.

As shown in Table 6, nationally, on average from 2010-2014, approximately 78 million acres of soybeans were grown annually (USDA NASS, 2010-2014). During the same time period, on average, in the mid-South approximately 13.3 million acres of soybeans were grown annually (17% of total national acres) and 41.9 million acres were grown annually in the Midwest (54% of total national acres). The remaining 22.8 million acres of soybeans (29% of total national acres) are grown in other areas of the United States. Neonicotinoid-treated seed is used on part of the national acres grown. Market research data indicate that, on average from 2009-2013, approximately 27 million acres of soybeans were planted with neonicotinoid treated seed, including 4.4 million acres of soybeans in the mid-South and 15.6 million acres of soybeans in the Midwest. Overall, 35% of soybean acres in the United States utilized neonicotinoid treated seed seed annually during this time period.

 Table 6: Soybean Acres Grown and Neonicotinoid Seed Treated Acres in the United States,

 by Region (2009-2013 Average)

	Mid- South ¹	Midwest ²	Remaining Regions	U.S. Total
U.S. Soybean Acres (in 000s)	13,276	41,900	22,777	77,953
Neonicotinoid Seed Treated Soybean Acres (in 000s)	4,378	15,633	7,337	27,349

Numbers may not add due to rounding. USDA NASS (2010-2014); MRD (2009-2013).

1 States in this region include MO, TN, AR, LA, and MS.

2 States in this region include IA, NE, SD, ND, MN, IL, and WI.

Of the 78 million acres of soybeans grown, 50.6 million acres of soybeans will face no impact as they are not currently using neonicotinoid-treated seed while the remaining 27.3 million soybean acres that utilize neonicotinoid seed treatments may face some impacts. As an upper-bound estimate of national impacts in the absence of neonicotinoid seed treatments, all soybean acres in the mid-South currently using neonicotinoid-treated seed (4.4 million acres) are assumed to face an average loss of 2.5 bushel per acre in the greatest potential cost scenario. Similarly, all 7.3 million acres outside the mid-South and Midwest are assumed to incur a \$4 per acre loss in higher pest control cost. In the Midwest example, however, some Midwest soybean acres may need one additional field pass utilizing an alternative foliar insecticide application while others will need two additional field passes.

EPA relied on proprietary pesticide use data (MRD, 2009-2013) to determine the frequency with which acres in the Midwest would need to make one versus two field passes of foliar insecticide applications. Data indicate that 93% of soybean acres treated with chlorpyrifos and/or a synthetic pyrethroid, the most likely alternatives for BLB, received one foliar application (MRD, 2004-2013). It is notable that this figure includes the entire growing season and accounts for all pests targeted with alternative foliar insecticides throughout the year—not just those targeted with neonicotinoid seed treatments. Thus, it is likely an overestimate of the number of acres that

would need two additional field passes. Given this information, BEAD estimates that at most 7% of the treated acres in the Midwest, or almost 1.1 million acres, would be treated twice with alternative foliar insecticides. The remaining 21.9 million acres of neonicotinoid seed-treated soybean acres nationally—that is, 14.5 million acres in the Midwest and 7.3 million in the rest of the country—are expected to need one additional pass (see Table 7).

	Acres Affected (in 000s)	Baseline Net Revenue per Acre: Neonicotinoid Seed Treatments Available	Per Acre Impact in the Absence of Neonicotinoid Seed Treatment Options	Total Impact in the Absence of Neonicotinoid Treatment Options (in 000s)
Mid-South acres impacted (2.5 bu/acre loss)	4,378	\$274	\$23	\$99,063
Midwest acres receiving one additional field pass with an alternative insecticide	14,539	\$428	\$4	\$64,859
Midwest acres receiving two additional field passes with an alternative insecticide	1,094	\$428	\$16	\$17,913
Remaining U.S. acres currently utilizing neonicotinoid seed treatments receiving one additional field pass with an alternative insecticide	7,337	\$341	\$4	\$32,724
U.S. Total	27,349	\$344 ^{1,2}	\$7.85 ¹	\$214,559

Table 7: Estimated Average Impact S	Soybeans Grown in the United States wit	hout
Neonicotinoid Seed Treatment.		

Numbers may not add due to rounding. Regional impacts calculated as the per-acre impact multiplied by the affected acreage. Average per acre impacts for the United States are calculated as the total impact divided by the total acres affected. See footnotes of Tables 3, 4, and 5 for additional information on calculations and data sources. 1 Represents average per acre estimates.

2 U.S. net operating revenue from Table 2.

Overall, across all soybean acres currently utilizing neonicotinoid-treated seed, impacts to soybean growers are expected to average less than \$8 per acre (approximately 2.3% of net operating revenue). According to USDA NASS (2010-2014), the average total value of production across all soybean acres produced is \$40.7 billion annually. Total industry impacts are expected to be at most \$215 million or 0.53% of the average value of soybean production in the United States. This relatively small change is unlikely to result in price effects. However, as indicated by the study conducted by AgInfomatics (2014), an increase in price due to reductions in the supply of soybean would benefit growers at the expense of processors and consumers.

It should be noted that across all scenarios, it is expected that the presented per acre impacts are likely overstated. First, permethrin seed treatments are registered and may offer equivalent efficacy to neonicotinoid seed treatments at a comparable price. Second, the pests being targeted by neonicotinoid seed treatments tend to occur sporadically and may not affect every soybean acre currently utilizing neonicotinoid-treated seed. Third, alternative practices such as higher seeding rates could reduce yield loss, albeit at the cost of extra seed. Finally, in the Midwest scenario, some growers may be able to apply an additional foliar insecticide as a tank mix with other chemicals, thus avoiding the cost associated with an additional field pass.

Input from National LGU experts and USDA-ARS

BEAD appreciates the constructive input offered by USDA-ARS, and Land-Grant-University (LGU) researchers and Extension experts from around the nation that have specific expertise in the production realities and pest control issues for soybeans. This includes the helpful questionnaire responses cited in the original analysis (which was coordinated by the North Central IPM Center) and the numerous comments submitted in response to the publication of BEAD's assessment.

While BEAD has been criticized by numerous commenters here and elsewhere for failing to reach out to growers, consultants, extension experts, registrants, state departments of agriculture, etc. for additional data and input into its original benefits assessment, the purpose of soliciting public comments on the draft assessment was to obtain input more broadly. Furthermore, BEAD re-iterates that LGU experts constitute a group that is both in close contact with all of the above listed stakeholders and is the most likely group to have objective evidence to support a benefits assessment. LGU experts are in close contact with growers and understand, particularly on a regionally specific basis, the major production and pest management concerns of growers making use of neonicotinoid seed treatments. LGU experts also collaborate closely with registrants and the pesticide industry to develop field plot data that independently evaluates the efficacy of numerous agrochemical products. LGU experts routinely interact with state and federal regulatory agencies. LGU experts are on the cutting edge of the latest advancements in knowledge of insect biology, agro-ecology, and pest management science, and it is generally their goal to synthesize their research results, their knowledge of external factors, and their regionally specific knowledge of production/economic realities, into science-based publications, recommendations, and expert input and disseminate current, peer-reviewed, science-based information on the usage of pesticides in agriculture.

BEAD therefore places a strong emphasis on the input from this group with regard to the methodology and conclusions from our analyses. BEAD notes here that on the whole, the consortia of LGU experts that signed onto two letters submitted as comments to BEAD's assessment, while offering constructive criticism on methodology and regional differences, were largely supportive of BEAD's overall conclusions on neonicotinoid seed treatment benefits for soybeans. LGU experts were also largely skeptical of the need for area-wide prophylactic seed treatment usage, particularly for areas such as the upper-Midwest and the eastern United States where incidence of soil-dwelling insect pests are generally low and only rarely occur at levels that cause economic damage. Finally, these commenters were in near unanimous agreement that

while seed treatments serve a very valuable pest management function, their actual benefits to growers are likely to be sporadic, non-uniform, and clustered in areas with known incidents of high pest pressure and/or presence of BPMV, and that on the whole, when viewed nationally, benefits for most growers were indeed likely to be low.

CONCLUSIONS

BEAD is in agreement with numerous commenters that its original analysis on the benefits of neonicotinoid insecticide seed treatments on soybeans did not adequately capture regional differences. BEAD has sought herein to address these criticisms and has reassessed the impacts for regions where usage of neonicotinoid seed treatments is likely to have benefits that are higher than what was estimated for the United States, on average. Based upon the totality of comments, including those from USDA-ARS and numerous LGU experts, BEAD concludes that the benefits of neonicotinoid seed treatments on soybeans can vary considerably by region. The benefits of neonicotinoid seed treatments on soybeans, in comparison to other available pest control practices, are expected to be low for most soybean growers in the United States. However, in situations where pest pressure is known and expected to be high, such as the mid-South, neonicotinoid seed treatments provide better and less costly control than alternative practices.

BEAD's original assessment (Myers and Hill, 2014) estimated that, on average, soybean growers that are currently utilizing neonicotinoid-treated seed could realize up to a \$6 per acre benefit (1.7% of net operating revenue) in comparison to the use of foliar applications of alternative pesticides. For most growers, BEAD concluded that foliar applications of alternative pesticides are as cost-effective as neonicotinoid seed treatments. However, BEAD acknowledged that there could be regional differences and that neonicotinoid seed treatments may provide benefits to some growers, particularly in the Southeast of the United States. The total value of neonicotinoid seed treatments was estimated to be \$52 million per year.

BEAD's revised assessment now estimates an average benefit across the 27 million soybean acreage planted with neonicotinoid treated seed to be less than \$8 per acre (2.3% of the net operating revenue). Soybean growers in the Mid-South obtain benefits of as much as \$23 per acre (8.4% of net operating revenue). BEAD estimates national impacts to be at most \$215 million or 0.53% of the average value of soybean production in the United States.

REFERENCES

AgInfomatics. 2014. Value of Neonicotinoids in North American Agriculture. http://growingmatters.org/

Cachot, A., Gore, J., Cook, D., and Musser, F., 2014. Do Neonicotinoid Seed Treatments Have Value Regionally in Soybeans? Mississippi State University Extension Service. <u>http://www.mississippi-crops.com/2014/10/31/do-neonicotinoid-seed-treatments-have-value-regionally-in-soybeans</u>. EPA, PMRA, CDPR. 2014. Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs, U.S. Environmental Protection Agency; Heath Canada Pest Management Regulatory Agency; and California Department of Pesticide Regulation. June 19. 59 pp. Available at <u>https://www.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance</u>

Esker, P.D., and Conley, S. P., 2012. Probability of Yield Response and Breaking Even for Soybean Seed Treatments. Crop Sci, 52:351-359.

Gaspar, A., Conley, S., and Gaska, J., 2014a. Economic Risk and Profitability of Soybean Seed Treatments at Reduced Seedling Rates. University of Wisconsin Extension. http://coolbean.info/soybean_research/soybean_research.php.

Gaspar. A.P., D.A. Marburger, S. Mourtzinis, and S.P. Conley. 2014b. Soybean seed yield response to multiple seed treatment components across diverse environments. Agron. J. 106:1955–1962.

Gaspar, A.P., P.D. Mitchell, and S.P. Conley. 2015. Economic Risk and Profitability of Soybean Fungicide and Insecticide Seed Treatments at Reduced Seeding Rates. Crop Sci. 55:924–933.

Hammond, R. B. 2002. Seedcorn Maggot Control with Seed Treatments on Soybean, 2001. Arthropod Management Tests 27:F100.

Iowa State University. 2015. Estimated Costs of Crop Production Iowa: Soybeans (Herbicide Tolerant Soybeans Following Corn). https://www.extension.iastate.edu/agdm/crops/html/a1-20.html

MRD (Market Research Data). Various years. Data collected and sold by a private market research firm. Data collected on pesticide use for about 60 crops by annual surveys of agricultural users in the continental United States. Survey methodology provides statistically valid results, typically at the state level.

Myers, C. T. and E.S. Hill, 2014. Benefits of Neonicotinoid Seed Treatments to Soybean Production. Biological and Economic Analysis Division, Office of Pesticide Programs, U.S. EPA, October 15. Available at https://www.epa.gov/sites/production/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf.

Stevens, S. and Jenkens, P. 2014. Heavy Costs: Weighing the Value of Neonicotinoid Insecticides in Agriculture. Center for Food Safety. March 2014. http://www.centerforfoodsafety.org/files/neonic-efficacy_digital_29226.pdf

University of Arkansas. 2015. Soybean Enterprise Budget, Cooperative Extension Service. http://www.uaex.edu/farm-ranch/economics-marketing/farm-planning/budgets/cropbudgets.aspx USDA Agricultural Census. 2013. Irrigated Soybean Acres in Arkansas. http://www.nass.usda.gov/Quick_Stats/

USDA Economic Research Service. 2012-2013. Soybean Production Costs and Returns per Planted Acres, Excluding Government Payments. http://www.ers.usda.gov/data-products/commodity-costs-and-returns.aspx

USDA National Agricultural Statistics Service (USDA NASS). 2010-2014. Soybean Production: Yields and Prices. http://www.nass.usda.gov/Quick_Stats/

APPENDIX. PUBLIC COMMENT RESPONSE REFERENCE TABLE. Public comments received by EPA in response to BEAD's Benefits of Neonicotinoid Seed Treatments to Soybean Production [Docket ID: EPA-HQ-OPP-2014-0737] that are not specifically cited, but have been addressed in Section I or II of this document. Comments addressed in Sections III and IV are specifically cited within the body or the document.

Generalized Comment and Response Location in Document (Section & Number)	Docket Con Number (EPA-HQ-0 2014-0737-	mment OPP- -XXXX)	Synopsis of Generalized Comment
n/a	0018 0020 0022 0023 0024 0037 0048 0052 0058 0072 0074 0077 0077 0077 0092 0099 0119 0121	0122 0123 0166 0192 0211 0220 0228 0233 0263 0308 0348 0349 0741 0777 0897 0901 0905	Anecdotal submissions where growers, contract researchers, etc. provided estimates of benefit based on unpublished data, personal experience, etc., including claims of ~5-33% yield protection from use of seed treatments.
n/a	000 024 089	04 42 68	Anecdotal submissions were cited where growers, contract researchers, etc. claimed that there are no benefits of seed treatment usage, based on unpublished data, personal experience, etc.
n/a	0009 0269 0347 0868 0900	0909 0910 0911 0935	Comments offered a general defense and broadly defined benefit descriptions for neonicotinoid on other crops and argued generally for the value of growers having multiple options in their respective pest management tool boxes for control of insect pests on agronomic and specialty crops.
I.A.1	0006 0909 0917 0926	0934 0936 0928	EPA's release of a benefit assessment prior to release of a risk assessment is unusual, improper, invalid, politically motivated, etc.

Generalized Comment and Response Location in Document (Section & Number)	Docket Comment Number (EPA-HQ-OPP- 2014-0737-XXXX)	Synopsis of Generalized Comment
I.A.2	0868 0935	EPA should not wait for the registration review process to proceed before conducting benefit analyses for neonicotinoid use on other crops and OPP should not wait to take regulatory action on the neonicotinoids, based upon established risks.
I.A.3	0785 0789	BEAD did not follow Presidential Guidance on scientific integrity.
I.A.4	0015 0352 0026 0354 0027 0354 0030 0862 0034 0910 0043 0911 0050 0914 0075 0914 0075 0917 0301 0919 0309 0919 0344 0936	BEAD was too selective and narrowly focused in their data analyses and did not take into account data on benefits from registrants and the contracted analysis done by AgInfomatics.
I.B.1	0216 0228 0305 0313 0315 0322 0322 0324 0322 0324	BEAD's scope of inquiry was too narrow and BEAD should have discussed the costs and benefits of alternatives.
I.B.2	0345 0868 0910	BEAD should release reviews for other crops, especially corn and canola.

Generalized Comment and Response Location in Document (Section & Number)	Docket Comment Number (EPA-HQ-OPP- 2014-0737-XXX)	Synopsis of Generalized Comment
I.C.1	0006 026 0007 028 0024 028 0033 028 0036 029 0041 029 0053 029 0062 029 0094 029 0120 029 0125 032 0138 033 0139 034 0151 036 0171 069 0181 074 0193 089 0196 090 0243 091	Neonicotinoid seed treatments are the only viable option for controlling soil pests in soybeans, which are very difficult to scout and are often sporadic in occurrence/economic importance. This was particularly emphasized for soybeans in the Mid-South U.S., due to various agronomic factors occurring in that growing region.
I.C.2	0053 021 0114 028 0117 030 0189 030 0208 030	Seed treatments allow for early planting into cool and/or wet soils.
I.C.3	0012 0013 0041 0088 009 012 022	Seed treatments preclude the need for foliar sprays.
I.C.4.a	0209 0899	Prophylactic applications are not a favorable approach for integrated pest management (IPM).
I.C.4.b	0123	Prophylactic pest control tactics can be a legitimate and useful tactic within a larger integrated pest management (IPM) framework, and just because target pest populations aren't always known at the time of planting, does not mean that seed treatments are unnecessary or without benefits.

Generalized Comment and Response Location in Document (Section & Number)	Docket Comment Number (EPA-HQ-OPP- 2014-0737-XXXX)		Synopsis of Generalized Comment
I.C.5	0029 0037		Seed treatments preclude the need for soybean re-planting.
	0094 0120 0361		Seed treatments allow for reduced tillage systems to be effective.
I.C.6	0017 0069 0079 0141 0165	0168 0184 0190 0244 0334	Seed treatments confer increased convenience.
I.C.7	0019 0105		The high adoption rates of seed treatments are themselves indicative of benefits; i.e., If growers didn't see real benefits from use of seed treatments, they wouldn't use them on such a large scale.
I.D.1	0897		Seed treatments provide jobs in the seed treatment sector.
I.D.2.a	0011 0013 0017 0019 0033 0042 0069 0088 0141 0157 0165 0167	0168 0184 0192 0198 0244 0321 0334 0334 0789 0897 0934	Seed treatments pose lesser/fewer risks to pollinators and workers than foliar alternatives.
I.D.2.b	0183 0293		Seed treatments have minimal off-site drift in comparison to foliar alternatives.

Generalized Comment and Response Location in Document (Section & Number)	Docket Comment Number (EPA-HQ-OPP- 2014-0737-XXXX)		Synopsis of Generalized Comment
I.D.2.c	0004 02 0042 03 0108 03 0151 03 0157 03 0211 03 0232 03 0236 03 0245 03 0245 03 0245 07 0264 07 0265 07 0285 09	298 502 508 515 518 519 521 538 540 582 739 739 739 739 739 711 917	BEAD did not discuss risks of neonicotinoid seed treatments and their alternatives.
I.D.2.d	0004 01 0011 01 0013 01 0017 01 0019 01 0033 02 0042 02 0062 03 0069 03 0096 07 0116 07 0121 08 0141 08 0157 09 0165 09	167 168 184 192 198 244 283 321 334 353 732 789 368 397 934 935	BEAD should incorporate environmental costs and benefits (i.e., value of ecosystem services, tri-trophic disruptions) and also more specifically, should take the yield benefits of bee pollination into account with our benefit assessment.