National Cotton Council OF AMERICA

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September 21, 2018

Office of Pesticide Programs
Regulatory Public Docket (7502P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW Washington, DC 20460

RE: Docket ID Number EPA-HQ-OPP-2017-0720

Dear Ms. Yu-Ting Guilaran:

The National Cotton Council (NCC), and the undersigned organizations, appreciate the opportunity to provide comments on the Environmental Protection Agency's (EPA) docket "Registration Review: Draft Human and/or Ecological Risk Assessments for Several Pesticides: Notice of Availability." The NCC recognizes the critical importance of acephate, Case 0042, EPA-HQ-OPP-2008-0915, for control of destructive cotton pests in the U.S. Extension cotton entomologists from across the cotton belt have communicated to the NCC that acephate is a critical backbone to cotton IPM practices, and the loss of the product would greatly reduce producers' ability to control plant bug pests across the cotton belt. Particular concerns were expressed for states that have historically experienced high insect pressure from the tarnished plant bug (TPB) (*Lygus lineolaris*). The TPB is a highly polyphagous, very mobile, piercing sucking insect pest of multiple crops. TPB has been ranked among the top 5 pests of cotton for several years. Acephate is a critical mode of action (MOA) in combination with other MOAs to control this pest that has displayed varying levels of resistance to multiple insecticide MOAs.

The NCC is the central organization of the United States cotton industry. Its members include producers, ginners, cottonseed processors and merchandizers, merchants, cooperatives, warehousers and textile manufacturers. A majority of the industry is concentrated in 17 cotton-producing states stretching from California to Virginia. U.S. cotton producers cultivate between 9 and 12 million acres of cotton with production averaging 12 to 18 million 480-lb bales annually. The downstream manufacturers of cotton apparel and home furnishings are located in virtually every state. Farms and businesses directly involved in the production, distribution and processing of cotton employ more than 125,000 workers and produce direct business revenue of more than $21 billion. Annual cotton production is valued at more than $5.5 billion at the farm gate, the point at which the producer markets the crop. Accounting for the ripple effect of cotton through the broader economy, direct and indirect employment surpasses 280,000 workers with economic activity of almost $100 billion. In addition to the cotton fiber, cottonseed products are used for livestock feed and cottonseed oil is used as an ingredient in food products as well as being a premium cooking oil.

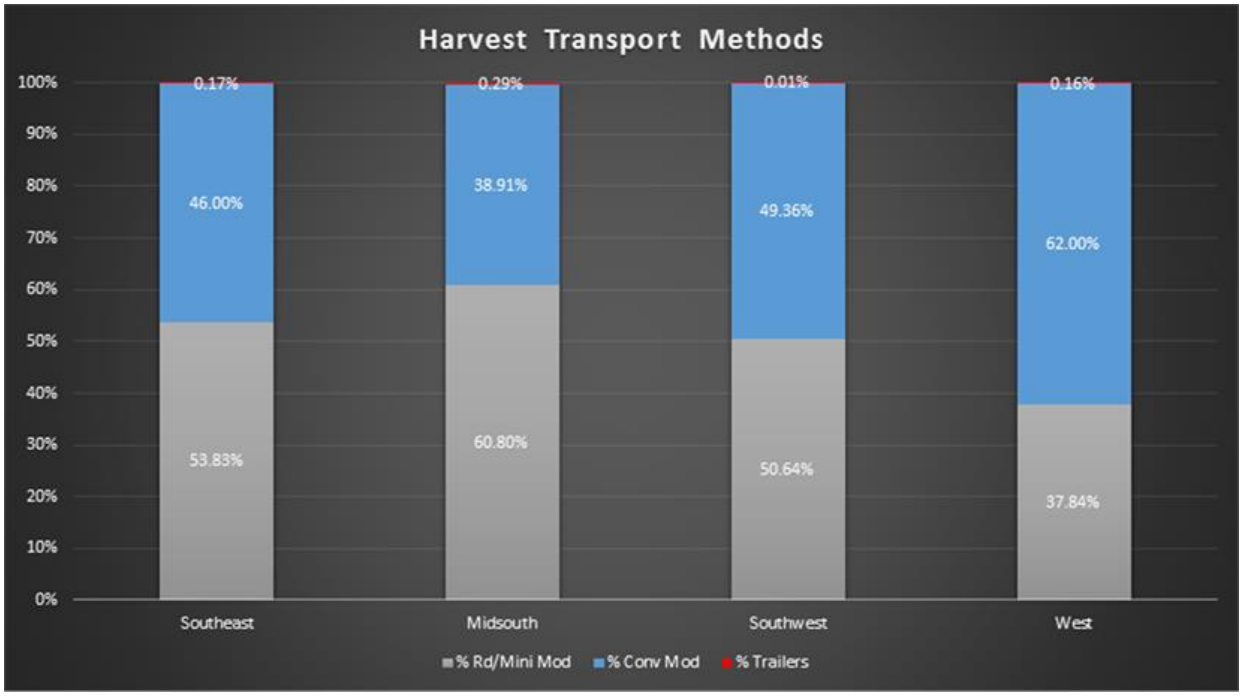
The NCC has thoroughly reviewed EPA's Draft Risk Assessments and appreciates EPA's continued protection of human health as well as balancing the risks/benefits once human health concerns are adequately considered. The NCC was surprised with EPA's Draft Human Health Risk Assessment which significantly deviated from the EPA's 2001 position that "Acephate residues in food and drinking water do not pose risk concerns, and by reducing exposure in homes and through residential lawns, acephate fits into its own "risk cup."" (September 2001, EPA Acephate Facts, EPA 738-F-01-013). EPA notes the decision was made once registrants dropped indoor residential use and certain turf uses, and further notes mitigations that resulted in worker and ecological risk also below levels of concern for registration. The NCC is uncertain and concerned that the deviation is a result of EPA changing the points of departure (POD) and related toxicity adjustment factors (TAFs) for the methamidophos metabolite. The NCC particularly points to EPA's statement "100% conversion of acephate to its more toxic degradate, methamidophos, is **assumed**

in drinking water." The NCC urges EPA to work with registrants to refine the risk assessment based on actual data and not assumptions.

Refined Risk Assessment

The NCC respectfully requests EPA to conduct a refined risk assessment to reflect real world uses as well as removing some obsolete risk concerns. The NCC notes that EPA included exposure risks for anticipated post-application activities and transfer Coefficients for cotton harvesters (Table 8.2.2.7, Revised Occupational and Residential Exposure Assessment for Registration Review). The NCC once again shares with EPA data demonstrating the harvesting technology of the cotton industry has significantly changed and no longer relies on trampers to pack cotton in trailers.

National Cotton Council
December 2016 Gin Survey of Harvest Transport Practices.



A survey was sent to 436 cotton ginning operations inquiring how cotton was delivered to the gin from fields. A total of 152 responses were received and were summarized by region of operation. The survey shows high adoption of new harvest technology utilizing round bale or mini modules cotton harvesters (% Rd/Mini Mod). Many still utilize the conventional module builders that are mechanically packed (% Conv. Mod). For the U.S. cotton crop, the trailer transport method (% Trailers) is only used for a very small % of cotton and most cotton transported in trailers is not packed. The manual packing method is used by a few producers on a very small number of bales.
According to survey respondents (n=152):
0.17% of the harvested cotton is transported in trailers in the Southeast
0.29% of the harvested cotton is transported in trailers in the Midsouth
0.01% of the harvested cotton is transported in trailers in the Southwest
0.16% of the harvested cotton is transported in trailers in the West

Of the 0.17% of cotton transported in trailers in the Southeast, 18.57% is manually packed and 81.43% is not packed. Of the 0.29% of cotton transported in trailers in the Midsouth, 20% is mechanically packed and 80% is not packed. In the Southwest and West regions, 0% of the cotton transported in trailers is packed. The Southeast was the only region reporting the use of trailers and manual packing and the number was very small.
Applying these results to 2016 production to estimated manually packed bales:
3,891,000 bales produced in the Southeast in 2016
0.17% of 3,891,000 bales = 6,615 bales were transported in trailers
18.57% of 6,615 bales = 1,228 bales (which would likely be lower if weighting was applied)

1,228/16,524,000 = 0.00743% of total U.S. bales transported in trailers and manually packed

The use of cotton trailers and trampers has changed to accommodate efficiencies in transportation over greater distances as many small cotton gins closed and consolidated into updated, high efficiency and high output gins. Risk assessments should no longer include occupational risks for trampers.

Additionally, the NCC has noted that EPA's use scenario assumed maximum application with minimum intervals between applications until the seasonal use of active ingredient was exhausted (Appendix B. Use summary for Acephate, Revised Draft Human Health Risk Assessment (DRA) in support of registration Review). The NCC has held several meetings and email exchanges with state university entomologists across the cotton belt to provide EPA with data representing more realistic high use of acephate. EPA noted (page 42, section 5.4.2, line 4) that the maximum percent crop treated estimates for cotton was 35%. Acephate has a critical fit in cotton IPM practices but is not blanketed across all cotton acreage. Like all pesticides, it has a cost and IPM practices weigh the cost with the anticipated losses/resistance management needs before use. In communicating with state university entomology experts, the NCC believes the highest use area would be represented by the midsouth due to the tarnished plant bug (TPB), *Lygus lineolaris*. Although western areas have similar pests (*Lygus herspeus* and the cotton leafhopper), the population of TPB represents a highly polyphagous destructive pest that can migrate into fields throughout the entire cotton production season with highly variable populations moving from wild hosts. Additionally, the TPB has historically been monitored to report variable resistance to multiple insecticides throughout the season. For this reason, single mode of action (MOA) insecticide applications are seldom made for TPB. Tank mix applications and rotation of MOA's are required throughout the season attempting to reduce TPB populations below damaging economic thresholds.

Although the NCC recognizes different use patterns in other regions and does not detract from the critical value acephate has in the respective regions, the NCC believes EPA desires the high use scenario for risk assessment.

State Entomologists from the midsouth compiled the following information for acephate use in cotton:

Stage	DAP	Use	Rate (ai/A)	Proportion of Acres	Total Acres	Acres Treated	Total AI per Use				acres	
at-plant, or	0	ST	0.036	0.25	1,980,000	495000	17820				625000	MS
at-plant	0	IFS	1	0.03	1,980,000	59400	59400				480000	AR
1-2 leaf	18	F	0.25	0.5	1,980,000	990000	247500				350000	TN
pre-bloom	48	F	0.5	0.33	1,980,000	653400	326700				180000	LA
bloom	69	F	0.75	0.8	1,980,000	1584000	1188000				345000	MO
bloom	79	F	0.75	0.8	1,980,000	1584000	1188000				1980000	
bloom	100	F	0.75	0.6	1,980,000	1188000	891000					
			4.036				**3918420**	**1,980,000**	**1.979**			
		no IST	4				**Total Ai**	**Total Acres**	**Average AI/A**			
		no IFS	3.036									
	ST = Seed Treatment											
	IFS = In-furrow liquid spray											
	F = Foliar											
	WOS = Week of Square											
	WOF = Week of Flower											
	Rate (ai/A) = The rate of acephate only for each application											

Based on the above data (personal meeting with Dr. Jeff Gore, Mississippi State University; Dr. Angus Catchot, Mississippi State University; Dr. Gus Lorenz, University of Arkansas; Dr. Sebe Brown, Louisiana State University; and Dr. Scott Stewart, University of Tennessee, September 7, 2018) and assuming highest use scenario, the NCC would encourage EPA to revise the risk assessments to reflect the appropriate rate and interval between applications. The data do not represent a desire in label change but provide relevant use within label limits for refinement of risk assessments. The state entomologists emphasized unusual situations may require the need for single application maximum of 1 lb. ai per acre, or a shorter interval between two applications, but such occasions are rare. The state university extension entomologists stress that acephate has become so vital to the current IPM programs, that any reduction in active ingredient will have negative consequences requiring more frequent applications of the few MOA's remaining. Additionally, the point was made that the presented acephate use is a tank mix with other products to manage pest densities and pest resistance. Several of the products involved in these tank mixes are

currently involved in EPA's registration review cycle with great uncertainty of availability. Extreme concern was discussed that foliar control of piercing/sucking pests such as the tarnished plant bug is being jeopardized by lack of MOA's and continual reduction of available active ingredients.

The NCC recognizes the current label allows up to 1 pound of active ingredient per single application and urges EPA to understand that although that may not be the standard use rate, it does allow producers and crop consultants to shift their use if needed for unusual situations. Similarly, the re-treatment interval of 7 days is seldom used, but provides flexibility under extreme population explosions.

As shown in the table above, the proportion of midsouth acres treated with acephate at a seasonal high use-scenario is small. On a cotton belt scale, the use becomes less as noted in EPA's Draft Risk Assessment. Additionally, western and southeastern areas of the cotton belt have different target pests and different use patterns that represent lower use of acephate. The current label provides for the variation among regions but is not represented appropriately in the draft risk assessment assuming maximum use at minimum intervals until seasonal limit is reached. Revising the risk assessment to reflect field level use rates will increase degradation and lower risks of concern. Combining use rate with more appropriate points of departure (POD) and related toxicity adjustment factors (TAFs) for the methamidophos metabolite and revising the assumption of 100 percent conversion of acephate to methamidophos in water will greatly improve the risk assessment.

FQPA Safety Factor

The NCC is aware of the September 15, 2015 memo claiming justification to include a 10X Food Quality Protection Act (FQPA) safety factor for risk assessment of all organophosphates (OP's). The determination to include the safety factor represented a major policy change that did not engage stakeholders in a public notice procedure thereby eliminating any transparency. It has been clearly acknowledged that EPA had already conducted the health risk assessment with the inclusion of the 10X FQPA Safety Factor referred to in the September 15, 2015 memo. It is also clear from page 2 of the memo that the use of this safety factor will greatly impact the risk assessment of many extremely valuable, if not critical, pesticide products for agriculture.

The NCC continues to question the EPA's imposition of an additional 10X Safety Factor on all OP's. EPA's unprecedented internal review and adoption of a new risk procedure with no public notice or opportunity for stakeholder engagement implies an end to transparency.

For registrants, the EPA has set rigorous professional standards for methodology, data submission, and Good Laboratory Practices (GLP) (EPA often develops the protocols for the studies required and the studies are often conducted by independent third-party contractors). However, there appears to be a bias where extremely relaxed data requirements, a low standard for methodology, and no required GLP studies are required for claim submissions by anti-chemical activists. The EPA at times talks about the weight of the evidence but grants greater weight to studies that were not mandated by the EPA and were not conducted in a manner consistent with the EPA's quality requirements of the mandated studies. EPA seems to not only discount the vast required studies conducted as the EPA specified, but in its review, seems to place greater weight on the fewer studies of lower quality and without being granted access to the data by the investigator. The EPA appears to be taking action more closely resembling the precautionary approach practiced by the European Union authorities. Such an approach eliminates the balance of progressive commerce while protecting societal concern but rather implements constraints on commerce with conjectures not scientifically proven to exist. The NCC believes such an example is demonstrated in the adoption of the additional 10X Safety Factor for organophosphates.

The EPA's argument for including the additional 10X safety factor relies predominately on a study conducted at Columbia University. EPA notes other studies that suggests associations and speaks of correlations of various studies, but EPA is aware that scientifically correlations do not demonstrate cause and can easily be flawed by the inclusion of inappropriate variables or omission of relevant variables.

Many examples have been developed to demonstrate how correlations can result in absurd conclusions and do not identify the real causal affect. For that reason, it would seem mandatory for EPA to have complete access to study data before giving the study sufficient credibility to adopt a major policy change.

The study in question did not originate in an agricultural setting, but rather in an urban residential setting where a particular organophosphate once held a legal use for control of household pests. It should be noted that most of the organophosphates were never registered for household use. It is clearly understood that conditions in a home limit the degrading process of pesticides as compared to agricultural environment conditions. Sunlight, soil organisms, moisture, and many other factors of degradation are greatly reduced in home settings. Similarly, movement in home settings greatly increases the likelihood of contacting treated areas. The epidemiology study conducted by scientists at Columbia University reportedly focused on chlorpyrifos exposure in home settings and utilized a prenatal sample to document the exposure level. The study reportedly followed the development of the children for the subsequent 7 years and conducted an IQ test. The study reported a correlation in decreased IQ and exposure to chlorpyrifos as measured from the prenatal sample 7 years prior. While this is admittedly a crude synopsis of a complex study, it does demonstrate why the study should be questioned openly before EPA uses it to claim justification of policy change. EPA's own assessment of the study identified numerous flaws and limitations that are critical to its interpretation to justify a 10X Safety Factor. For example, no data was obtained after the prenatal sample to ensure additional exposure did not occur. Were there other potential exposure concerns such as heavy metals (example lead based paint) in the study homes? Was there subsequent use of stored pesticides that resulted in exposure level above those measured? Were demographic variables sufficiently controlled? How do the study conclusions relate to vast number of mandated EPA studies specifically designed to scientifically evaluate causal effects? What evidence in the study scientifically shows the cause is a general mechanism of all organophosphates? Additionally, the NCC does not find where the EPA compared the study to the vast number of required studies in order to weigh the contrast among conclusions. Such an approach would seem necessary given that EPA has stated they can find no causal relationship between chlorpyrifos and these effects.

While the NCC is not refuting the Columbia University study, or other cited studies with suggested associations, the NCC believes the action of EPA to implement an additional 10X Safety Factor on all organophosphates - most of which are used only in agricultural settings – represents a major policy change that ignores transparency and scrutiny before being utilized to conduct multiple risk assessments. However, the EPA has taken a different course by conducting multiple risk assessments with the 10X Safety Factor and announcing all simultaneously without separate consideration for the adoption of the 10X Safety Factor. Of equal importance, these studies should be held to the same standards of transparency and scientific rigor required of registrants.

The NCC supports the protection of human health. Unfortunately, the NCC is concerned that EPA is inferring harm beyond the scope of scientific data. The NCC refers to EPA's own Scientific Advisory Panel telling EPA the study should not be used for policy decisions due to the high limitations and flaws of the study. The NCC urges EPA to return to the historic path of reliance on credible scientific data and require all studies be evaluated based on scientific quality and merit.

The NCC acknowledges EPA's statement that even without the safety factor, acephate does not pass the human health dietary risk assessment. However, the NCC will continue to disagree on the inclusion of the safety factor for all OP's based on a study that implies an unknown mechanism of action with only one OP. Scientific justification for applying the study to all OP's is absent when the mechanism of action is unknown.

Acephate Task Force

The NCC is aware that the Acephate Task Force will be presenting EPA with updated data, refinements for the risk assessments, and elimination of some modeled uses that are outdated carry-overs from the past but are not used today (example: granular in-furrow cotton application). The NCC encourages EPA to refine

the risk assessments based on the best available data and engage stakeholders if additional refinements are needed.

Thrips, Lygus and Stinkbugs

In 2016, lygus, stink bugs, and thrips (Williams, 2016) were ranked the top three cotton insect pests in the U.S. Although there are geographical differences in species composition, collectively, these sucking insects have become the dominant pests of U.S. cotton for several years.

Thrips typically move into cotton fields early season, often shortly after germination of cotton seedlings. In general, neonicotinoid seed treatments have shown to greatly decrease the need for foliar control of thrips. Environmental factors (for example cool temperatures that delay the cotton plant growth thereby extending the period of time the plant remains susceptible to thrips injury) and some reports of thrips resistance to particular seed treatments require continued monitoring of seedling cotton for thrips and the ability, if needed, for foliar control applications. In the absence of organophosphates like acephate, thrips would be a greater pest threat and more difficult to control. Without acephate, producers would rely more on other organophosphate insecticides.

Lygus sp. (plant bugs) and stink bugs are highly mobile adults that feed on numerous alternative plant hosts and often move into fields from native vegetation near the cotton fields. The movement can occur throughout the cotton growing season and may require multiple applications during one growing season. This is an important point that is often not captured in EPA's consideration identifying "alternatives". Multiple applications during a single growing season can often mean you are making an application late season and potentially have used limits of proposed alternatives; therefore, you have no alternatives. Selection of an insecticide product targeting these pests MUST consider species complex, previous history of the area and any previous MOA's application.

Lygus hesperus is common in the western regions of the U.S. and *Lygus lineolaris* is ubiquitous in the midsouth and southeast. Leigh et al. (1977) documented organophosphate resistance in *L. hesperus* in California and Cleveland and Furr (1980) documented *L. lineolaris* resistant to organophosphates in Mississippi. During a similar time, Schuster et al. (1987) reported *L. lineolaris* control failures in Texas. Snodgrass and Scott (1988) documented variation in resistance levels to dimethoate based on time of year and location but reported little tolerance of *L. lineolaris* to acephate. Studies have continued to monitor the development of *Lygus* resistance to organophosphates, pyrethroids and other chemistries with much documentation demonstrating *Lygus* tolerance to the multiple chemistries and with variation during a given year and/or location (Parys et al., 2017, Luttrell et al. 2018). Because of the variation of *Lygus* resistance to multiple MOA's, many university extension scientists recommend tank mixing of MOA's for resistance management purposes. However, each tank mixing application often increases the cost of the application and reduces the amount of two MOA's that can be used for the remainder of the season due to label restrictions. Luttrell et al. (2018) reported that total foliar sprays for plant bugs in the midsouth cotton region ranged from 3.4 to 5.8 applications per year (2008-2015). Considering that at least some of these applications were tank mixes with more than one MOA, increases the cost per application. These points illustrate the importance of multiple MOA's for resistance management purposes and for control of damaging cotton pests. Additionally, the above points illustrate the critical importance of taking the entire growing season into account rather than a snap shot view. You cannot simply conclude pyrethroids and other organophosphates are alternatives. The recommendations by local university extension specialists and the producer's pest management strategies must have flexibility to adapt to variation in effectiveness of control strategies and thereby must have multiple tools available to make necessary adjustments. Benefits analysis should incorporate the need for multiple MOA's and recognize yield loss due to documented resistance of products identified as alternatives. NCC urges EPA to recognize the lack of alternatives because the alternatives are already incorporated into the seasonal management strategies. The loss of acephate would result in a greater reliance on other organophosphates, pyrethroids, and neonicotinoid foliar treatments.

The NCC notes that while control of *L. lineolaris* populations has been a greater challenge in the midsouth, similar experiences have been reported in recent years for parts of the southeast, particularly North Carolina (Dominic Reisig, North Carolina Cooperative Extension Service Entomologist, personal communication).

There are multiple species of stink bugs that may infest cotton, and brown stink bugs require different management strategies than other stink bug species (https://cottonbugs.tamu.edu/fruit-feeding-pests/stinkbugs/). However, if you have more than one species present in the field, control product selection becomes more difficult. The presence of multiple pests (for example bollworms, moderate aphid pressure, and stink bugs) adds to the complexity of the producer's pest control decisions. Add to that pest control applications made previously during the growing season, and the producer is limited on remaining available pest control options (either due to IRM strategies or in compliance with label restrictions that limit amount of product per year or period).

The NCC urges EPA to recognize the critical value of acephate to the cotton production system. The NCC appreciates EPA's continued protection of human health and the environment based on scientific data of merit and the engagement of stakeholders to review and address misconceptions or other relevant comments to ensure appropriate decisions are made.

Thank you for your consideration.

Respectfully,

National Cotton Council
Alabama Cotton Commission
Agricultural Council of Arkansas
Arizona Cotton Growers Association
Arizona Farm Bureau Federation
Blackland Cotton and Grain Producers, Inc
California Cotton Ginners and Growers Association
Cotton and Grain Producers of the Lower Rio Grande Valley
Cotton Producers of Missouri
Delta Council
Georgia Cotton Commission
Georgia Farm Bureau
Louisiana Cotton and Grain Association
Mississippi Farm Bureau Federation
North Carolina Cotton Producers Association
Oklahoma Cotton Council
Plains Cotton Growers, Inc.
Rolling Plains Cotton Growers, Inc.
St. Lawrence Cotton Growers Association
SJV Quality Cotton Growers Association
Southern Rolling Plains Cotton Growers
Southern Cotton Growers
South Texas Cotton and Grain Association
Trans Pecos Cotton Association
Virginia Cotton Growers Association