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November 9, 2020

Environmental Protection Agency
Mike Mendelsohn, Branch Chief
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

RE: Docket No. EPA-HQ-OPP-2019-0682

Dear Mr. Mendelsohn,

The National Cotton Council (NCC) appreciates this opportunity to provide comments regarding the Environmental Protection Agency's (EPA's) "Draft Proposal to Improve Lepidopteran Resistance Management" ("Draft Proposal"). The NCC has carefully reviewed the Draft Proposal and has considered the application of FIFRA in the development of the Draft Proposal. These comments identify numerous concerns identified by NCC and are detailed below.

In particular, the NCC believes the Draft Proposal is predicated on a fundamentally flawed understanding of EPA's power to make a finding of "unreasonable adverse effect" under FIFRA. Generally, Section 3 of FIFRA empowers EPA regulate the distribution, sale, and use of any pesticide "to the extent necessary to prevent unreasonable adverse effects on the environment" and establishes various registration authority. Section 6 of FIFRA empowers EPA to determine whether the use of a pesticide, for which a registration is under review, may have an "unreasonable adverse effect" on the environment. If so, EPA may deny a label to that pesticide or may impose conditions on its use. This authority is based on an expectation that the use of a pesticide might cause harm to the environment. It does not contemplate an expectation that the use of a pesticide would create a *benefit* to the environment, such that the withdrawal of that pesticide from use would be the cause of an "unreasonable adverse effect." With the Draft Proposal, EPA now purports to turn this authority on its head and infer that an "unreasonable adverse effect" would occur from the declining effectiveness of a pesticide due to Bt-resistance. This suggests a farmer shoulders the affirmative responsibility to ensure the indefinite effectiveness – and, thus, the indefinite availability of a pesticide – in order to preserve its benefits. This is not the purpose of FIFRA.

Predicated on this flawed reasoning, and in addition to identifying Bt resistance as an "unreasonable adverse effect," the Draft Proposal would impose several measures the farmer and registrant would not otherwise be reasonably expected to undertake and that exceed the agency's scope of authority. Specifically, the Draft Proposal would:

1. Force registrants to act as points of enforcement;

2. Impose penalties that FIFRA does not authorize; and,
3. Identify cancellation of registrations not consistent with FIFRA.

The NCC urges EPA to withdraw and reconsider the Draft Proposal in light of these deficiencies and provide public review of necessary information that adequately represents proposed processes, mandates, and procedures lending to decisions.

About the NCC

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 10 and 14 million acres of cotton with production averaging 12 to 20 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 $75 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.

Unreasonable Adverse Effect

EPA asserts that authority to require resistance management is granted under FIFRA Section (3)(a) and 6(a)(2), which provides for a finding of "unreasonable adverse effect." FIFRA Section 2(bb) defines "unreasonable adverse effect" on the environment to mean "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."

EPA has conducted multiple Human Health Risk Analysis for Bt crops and has never identified any risk of concern. EPA has also conducted numerous Environmental Risk Assessments for Bt crops and has generally acknowledged that only a narrow spectrum of species are typically impacted, predominantly the targeted pest species. The Human Health and Environmental Benefits are well established and recognized by EPA (see *Benefits of Bt PIPs*, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/insect-resistance-management-bt-plant-incorporated#overview). However, EPA notes that the development of pest resistance to the PIPs could alter the risk-benefit assessment.

The NCC agrees the evolution of pests resistant to pesticides can alter a risk-benefit analysis, and that appropriate stewardship actions can delay resistance development. This is why the NCC encourages stewardship practices to preserve the use of pesticide technologies and supports

efforts to provide clear information necessary for users to effectively engage in resistance management practices.

Nevertheless, proposed measures to manage the evolution of pesticide-resistance in pests must be assessed against the agency's proper scope of authority. The NCC is concerned that EPA's well-meaning activities to mandate resistance management go beyond the scope of authority granted by FIFRA.

A review of FIFRA's statutory language and its regulatory history are helpful. Subsection (a)(2) of FIFRA Section 6 ("Administrative Review; Suspension") states:

> *"If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator."*

Thus, subsection (a)(2) imposes on a registrant a continuing requirement to report factual developments that occur after registration. Further, its placement in Section 6 clearly corresponds to the continuing requirement for consideration of future agency actions, including re-registration or cancellation. The gradual encroachment extending authority of FIFRA Section 6(a)(2) extends back at least into the 1990's. PR Notice 92-1 (January 2, 1992) attempted to clarify the agency's approach regarding submission and identification of adverse effects information and also regarding the public notice of rules that implement authority under FIFRA Section 6(a)(2). Paragraph II ("Applicability") states,

> *"Although Section 6(a)(2) does not directly address applicants, 40 CFR 152.50(f)(3) requires applicants for registration to submit with their application any factual information regarding unreasonable adverse effects of the pesticide that would be required to be submitted by registrants under Section 6(a)(2) if the product were registered."*

Page 3, paragraph 3 further states, "The Agency further defines all 6(a)(2) submissions as "health and safety data" subject to the automatic presumption of reliability under FIFRA Section 10(d)(1), …"

PRN 92-1 also provides EPA policy statements describing information to be submitted identifying a 1978 Interpretive Statement, a 1979 Enforcement Policy, and a 1985 Interpretive Rule. EPA promulgated the rule on September 19, 1997 (62 FR 49370), and which became effective on June 16, 1998, superseding all previous policy statements pertaining to FIFRA Section 6(a)(2). PRN 98-3 and PRN 98-4 provided additional guidance intending to clarify 6(a)(2) regulations.

With the first registration of a Bt trait in cotton, EPA expanded the scope to include mandatory Insect Resistance Management (IRM), but only for the Bt PIP. PRN 2017-1 and 2017-2 expanded informational and educational efforts into all pesticide registrations (*see* NCC comments September 1, 2016; Docket EPA-HQ-OPP-2016-0242).

The NCC understands PRN 92-1 to acknowledge that FIFRA Section 6(a)(2) does not apply to application for registration and further to acknowledges that the intent of unreasonable adverse effects relate to "health and safety data" only. Based on this understanding of PRN 92-1, EPA's use of 6(a)(2) would appear to exceed its scope of authority by expanding it into registration requirements.

Similarly, the scope of FIFRA (3)(a) ("unreasonable adverse effects,"), while very broad, does not provide authority to regulate resistance and resistance management. Resistance to a Bt toxin has no harmful impact on humans or the environment. Resistance to a Bt toxin simply means the product is not effective and that its use is futile. From an environmental perspective, the use of an ineffective product is equivalent to *not* using it. In other words, the environment impact of a farmer's use of the ineffective product is no better or worse than the same farmer's decision not to use the product at all. FIFRA provides regulatory authority to EPA to ensure no products are registered for use in a manner that would involve an "unreasonable risk to man or the environment…". But, if there is no human or environmental harm from the registration and use of a product, there is also no human or environmental harm in its absence from the field. To say otherwise is to produce an absurd regulatory result: that the farmer is *compelled* to preserve the effectiveness of a particular product in order to ensure its continued use. EPA possesses neither the statutory nor constitutional authority to compel the affirmative use by a farmer of a particular product. The distinction of mitigation in order to allow safe use of a pesticide product is very different from the distinction of a mitigation to prolong the marketing lifespan of a product that poses no use risks.

Adherence to the scope of authority should take precedent over a consensus of a product's need. While the NCC agrees that resistance management practices are desirable, the NCC does not agree that FIFRA authorizes EPA mandate such practices.

Enforcement authorities

FIFRA Section 26(a) provides that "a State shall have primary enforcement responsibility for pesticide use violations." The NCC considers verifying compliance of EPA's mandate requiring a 20% non-Bt block refuge to be engagement in compliance enforcement. The Draft Proposal offers consideration to require the registrants to visit farms and verify the planting of the block refuge (where required). Such consideration would seem in direct violation of FIFRA as it identifies registrants as enforcement authorities.

Penalties

EPA has offered consideration of two penalties for refuge non-compliance:

1. A producer not planting the block refuge would lose access to the company's (unclear if the trait registrant or seed company) product for two years; and,

2. Seed distributors could lose access to the company's product for sale (time not specified) for failing to achieve 95% compliance of registrant-grower contracts (it is again unclear if the "company" is the trait registrant or the seed company).

FIFRA Section 14 addresses penalties, hearings, determination of penalty, and criminal penalties. Penalties may result in fines and/or imprisonment, but FIFRA does not provide support for EPA to withhold access to a company's product.

Additionally, if the requirement for a refuge is a condition of registration and the registrant requires the grower to sign an agreement to accept responsibility to meet the requirement, then EPA's jurisdiction lies with the registrant. The grower agreement is a contract between the registrant and the grower. It is unclear to the NCC whether FIFRA authorizes the involvement of EPA in a contract between registrants and growers in this way.

Cancellation of Registration

The Draft Proposal requests that registrants consider the "phase out" of certain traits and certain combinations of traits as equivalent to cancellation of registration. FIFRA Section 6(b) outlines the process for EPA to cancel product registration. When evaluating a product's cancellation, EPA is again required to consider "unreasonable adverse effects on the environment of the pesticide." Thus, again, the Draft Proposal contemplates an action on the basis of a flawed interpretation of EPA's authority with respect to the "unreasonable adverse effects" of a product. The declining effectiveness of a product, and thus of its commercial viability, should be the basis of an affirmative obligation by farmers to preserve it.

Additionally, the NCC notes loss of efficacy for one pest does not imply the product retains no value if multiple pests are targeted by the product. For example, the registration of the first Bt trait for use in cotton highlighted the product met the desired high dose requirements for *Heliothis virescens*. To date, no Bt resistant population of *H. virescens* has been identified. Prior to the first Bt cotton, *H. virescens* had become a dominant major pest of many cotton production areas and had developed resistance to most insecticide active ingredients. A single species' development of resistance to a trait should not be the basis of a decision to cancel a trait's registration when it is still effective for other species.

Other General Concerns

The NCC also notes other areas of concern:

1. The Draft Proposal contains multiple determinations, requirements and generalized considerations without offering a clear or transparent process for stakeholder review. According to the Draft Proposal, the EPA will:

> *"consider all comments received and negotiate a final framework with Lepidopteran Bt corn and Bt cotton PIP registrants to be implemented as revised terms of registration for all affected PIP products. Then EPA will release the finalized IRM framework to the public docket."*

It is unclear how this comment and negotiation process will unfold. Given the complexity of these issues, and the potential impact of the EPA's actions, the proposed measures should have

been released as a pre-proposal, which would have facilitated additional opportunities for stakeholders to understand fully how these measures would be implemented and how they would fulfill FIFRA's purposes before comment opportunities were exhausted. The NCC is concerned that the final proposal may not fully balance the interests of product users versus those of other stakeholders nor fully consider whether the policy can be feasibly implemented.

2. The NCC is concerned the Draft Proposal has not adequately addressed the potential PIP derived by novel gene editing, nor considered the potential change of registrants resulting from novel gene editing. More consideration should be given to how novel PIPs not yet registered should be deployed for maximum lifespan and to how the proposed measures could affect the interests of future registrants.

3. The Draft Proposal identifies a distinction between high dose and non-high dose for target pests and seems to suggest EPA will retain previous requirements for pests receiving high dose from the plant and add to it the Draft Proposal to address pests not receiving high dose. The NCC is aware of variation among target species' susceptibility and expresses concern whether EPA has considered implications for a product's current and future registration. Susceptibility below high dose can vary considerably among species and active ingredient. EPA seems to be considering variation in registration based on efficacy by species. The potential scope of such action is enormous. The Draft Proposal contains an excellent example of insect (corn earworm vs. fall armyworm) by efficacy (Vip 3A vs initial launch of Cry 1Ab).

4. The Draft Proposal identifies multiple "expectations/mandates" of users but provides little information regarding registrants' obligations associated with those user "expectations/mandates." The NCC acknowledges PIPs provide value to producers, but additionally notes the added value comes at additional costs. The NCC is concerned registration requirements are not adequately balanced between registrants and producers. EPA requirements associated with the registration of a product should not be imposed on users solely at the cost of users. The NCC urges EPA to distinguish, with clarity, mandates that are imposed on registrants without ties to users. For example, are mitigation measures such as oversprays the responsibility of registrants or simply additional costs placed on producers?

5. The Draft Proposal considers tillage as a potential mitigation. While registrants may consider tillage to be an appropriate mitigation measure, many producers have contractual obligations with other federal agencies prohibiting tillage. Mitigation measures and their associated costs should identify and account for all obligations obstructing those measures.

6. The NCC urges EPA to address two critical questions pertaining to the entirety of the Draft Proposal:

> (1) In terms of delaying the development of resistant pests, what time period represents success?
> (2) Can EPA and registrants identify activities/actions contributing to, at least in part, active resistance management practices?

The latter question is related to the distinction of measures for safety (human or off-target concerns) versus measures to preserve the longevity of product use (planting a refuge). For example, users must wear appropriate PPE identified on product labels to meet safety standards. Registrants are not able to wear the PPE themselves. However, registrants are capable of planting a refuge (whether through land rental agreements or sharecrop agreements). Such activity directed by EPA avoids multiple layers of confusion with sales staff, dealers, retail distributors, etc. and identifies two parties involved (EPA [mandate imposer] and registrants [mandate impose]).

7. The NCC notes EPA engaged in extensive resources to convene a Scientific Advisory Panel (SAP) to address and provide suggestions to "charges" identified and presented by EPA. However, the Draft Proposal seems to be influenced by information outside the SAP's suggestions. The NCC requests clarification of EPA's procedures and identification of all sources of information gathered following the release of the SAPs final report, as it is understood that ABSTC provided unsolicited comments following the SAP's report. In order to ensure transparency, the NCC recommends that EPA consider an open comment period following the final release of an SAP document and prior to initiation of a draft proposal, thereby granting all stakeholders opportunity to provide input supporting or objecting to the SAP positions.

Resistance Definition for Non-High Dose Pests

The Draft Proposal defines heightened risk of resistance to represent the baseline for all non-high dose pests of Bt, regarding which the NCC notes the following:

1. On page 11, EPA notes "other resistance requirements for high dose pests remain unchanged (see US EPA 2010)." The NCC would urge EPA to include such notes at the beginning of documents with the discussion of developing a new plan for non-high dose pests.
2. The base line for each non-high dose pest differs among pest species and varies greatly even within pest species. EPA does not clarify if the baseline will be pest specific or if the baseline will be based on least/greatest susceptible pest species. EPA does not provide any procedure to understand how this baseline is established, variability around the baseline, or how population density may relate to the baseline.
3. The NCC would suggest EPA consider focusing on major pests at a national level. The loss of efficacy to minor or occasional pests would not be as negative compared to loss of efficacy to a major pest.

Refuge Compliance (occurs at planting)

Increasing Percent Refuge in Seed Blend Products

EPA proposes to increase the percentage of non-Bt seed blended into the Refuge-In-A-Bag (RIB) with Bt seed from 5% to 10% nationwide and maintain current requirements to plant a separate 20% block of non-Bt corn in cotton production states.

The NCC notes the following:

1. EPA has noted the major concern is non-compliance with the 20% non-Bt block in cotton production states. As mentioned above, EPA retains the 20% non-Bt block requirement but increases the non-Bt seed in the RIB nationwide. The NCC does not follow the logic of this consideration and is concerned about damage from corn rootworm in the majority of the corn states. The NCC notes that RIB is a viable resistance management strategy assuming that the planted Bt variety is truly a pyramid. The past releases of Bt traits has allowed each trait to be subjected to extended high selection pressure before the addition of another trait. Under such circumstances, one must question if any products marketed today are pyramid products or if the efficacy relies on the last added trait.

   EPA acknowledges that the SAP recommended prohibition of RIB in cotton production states, and proposed prohibition of Vip3A RIB in cotton production states. Scientists in the cotton production regions support the prohibition of corn varieties with Vip3A noting lack of economic return and the greater selection placed on VIP3A when contained in corn and cotton varieties. EPA has excluded areas and states from other registrations in the past, but the risk was one of harm rather than preservation of a product. The NCC believes EPA's prohibition of Vip3A corn varieties in the south (given the number of other Bt traits already granted registration in the south) could be viewed as a violation of FIFRA and potentially some commerce laws. Again, this demonstrates the lack of resistance management authority in FIFRA.

2. Ideally, EPA should be including a focus on the appropriate registration requirements for the next set of Bt toxins, e.g. any new product must contain two unique modes of action (MOA) prior to release.

3. The NCC offers the following alternatives for consideration by EPA to ensure compliance with the 20% non-Bt block refuge requirement in states producing cotton; states without cotton production may retain the current % RIB or block options.

   a. Registrants provide producers elite non-Bt corn seed and reimburse producers the difference between total farm yield average of Bt corn and field average of elite non-Bt corn on a per acre basis.
   b. Registrants contract with producers to plant elite non-Bt corn blocks with agreements to reimburse the producers the difference in average yield of elite non-Bt corn and the farm average yield of Bt corn on a per acre basis.
   c. Registrants offer an incentive program (or rebate/reimbursement) upon submission of a non-refundable proof of purchase of enough seed to provide the 20% non-Bt corn refuge block.
      EPA evaluates the merits of providing an option for southern states with cotton to allow RIB corn blends of 80-20 (Bt-non-Bt). Does the science support the 80-20 blend approach as an improvement to the current block refuge compliance concerns?

Refuge Compliance

EPA notes its "sole focus is on the registrant's obligation under the terms and conditions of the registration." The NCC would refer EPA to the above alternative (3) that outlines a clear and transparent process whereby EPA would have sole focus on the registrant achieving registration compliance. Additionally, the above process would eliminate expectations/mandates of users and additional dependence on people not employed or representing the registrants. Again, the NCC notes the distinction that the requirement is an obligation of the registrant for the preservation of the registrant's technology and differs from other mitigations on users for protection from harm.

The NCC recognizes EPA's concerns about insuring availability of non-Bt elite corn hybrids for refuge. The NCC believes there is a disconnect between producer awareness and/or knowledge of elite non-Bt corn and cotton varieties and cooperative solutions should be identified. The NCC believes availability alone does not provide market awareness. Additionally, seed companies are limited in their ability to provide comparisons with competitors.

It is worth noting that, at least in the cotton belt, many universities conduct and report annual variety trials. The trials allow registrants, for a fee, to submit a reasonable number of top varieties to be included in the university variety trial. University staff plant the variety trials at multiple locations across the state. These reports show yield comparisons for each variety by location, notes of management practices and soil type at the locations. Producers utilize these publications as indicators of varieties that are most likely to perform well on their farm. Since the introduction of Bt and herbicide traits, companies no longer submit their non-traited varieties in trials comparing yields with traited varieties.

The NCC offers the following considerations:

1. ABSTC could conduct reasonably similar variety trials for non-Bt (or non-traited) cotton and corn, or ABSTC could contract universities to conduct a smaller scale variety trial exclusively for non-Bt (or non-traited) cotton and corn.
2. The results could be reported by the states in a similar fashion to the State (university) Variety Trials.
3. The National Corn Growers of America (NCGA) could provide links to state variety trials or provide a complete report of all state variety trials for non-Bt (non-traited) corn. Similarly, the NCC could provide links or a complete report for non-Bt cotton variety trials.
4. The NCC and the NCGA have discussed the need of centralized locations with performance information for non-Bt cotton and corn varieties. Both organizations agree they should cooperate with seed companies to provide producers information regarding available non-Bt varieties. Additionally, both organizations would likely hear from members if listed varieties were not available.

The NCC has considered utilizing web-based technology that would document site visits and activity for the web site providing non-Bt variety data in order to evaluate the sites value to producers and identify deficiencies.

The NCC does not support:

1. Registrant verification of user compliance through farm visits (enforcement action);
2. Any means of auditing seed dealers handling of grower contracts (enforcement and the contract is separate from the registration thus between the registrant and grower, separate from EPA authority); or,
3. Prohibiting growers' access to registrant/company product. (The NCC notes particularly vague language of the Draft Proposal; the NCC is not certain if EPA was identifying the registrant, seed company, or dealership regarding restricting access. Each entity represents a different distinction of what would not be available. Given the number of pyramid trait varieties with traits owned by various registrants, the rule could potentially prohibit access to all varieties. Regardless, the NCC acknowledges this to represent a penalty not supported by FIFRA.)

Resistance Monitoring and Unexpected Injury/Damage and Practical Resistance

The Draft Proposal outlines a two-pronged approach for monitoring:

1. ABSTC will be responsible for annual late-planting of sweet corn sentinel plots in high risk areas throughout the cotton belt (may collaborate with academics). Each sentinel plot will include hybrids producing Cry2Ab and Vip3A alongside respective non-Bt isogenic hybrids.

2. At each Sentinel Plot, damage and survival evaluations will occur at the milk stage. Data will include date, location, and evaluator. Thirty (30) corn plants will be examined for stalk tunneling, ear shank tunneling, exit holes in ears, presence of larvae (second instar or above), and identification of each larvae (*Helicoverpa zea*, *Ostrinia nubilalis or Diatrea grandiosella*).

Growers will continue to report unexpected damage found in their fields. Cotton fields will be sampled from 100 bolls/fruit/squares for specific injury levels and presence of larvae (second instar or greater).

Unexpected Injury/Damage and Practical Resistance

The Draft Proposal provides a new term, "Practical Resistance," defined as injury or damage above what would be expected. Its purpose is to set a sensitive criterion that would allow proactive response to eliminate pests that may indicate early development of population resistance. Eliminating the individuals potentially resistant to the toxin, theoretically, could delay the prevalence of the resistant allele in the population. Unexpected Injury (UXI) detections in fields could provide a sensitive measurement for local populations and allow actions to eliminate those individuals prior to adult dispersal movement that may spread the resistant allele in the greater population thereby making it more difficult to detect and mitigate.

Regardless of the conditions of the refuge or measurement of the general pest population the proposed UXI limits are as follows:

For *H. zea* OR *S. Albicosta* in **corn** with:

1. Vip 3A toxin, damage cannot exceed
    a. 10% of ears with second instar OR exit holes AND
    b. An average of 2 damaged kernels per ear OR more than 2.5 cm^2 injury with second instar larvae present OR exit holes

2. Cry 2A toxin, damage cannot exceed
    a. 50% of ears with second instar larvae OR an exit hole AND
    b. An average of 20 damaged kernels per ear OR more than 8 cm^2 with second instar larvae present OR exit holes

For *Ostrinia nubilalis* and *Diatrea grandiosella* {high dose pests} in Corn:

1. Damage cannot exceed more than 2 places WITH more than 2 inches of tunneling in stalks, ears, or ear shanks.
2. Note other resistance managements for high dose pests remain unchanged (see US EPA 2010).

For H. Zea in **cotton** with:

1. Vip 3A toxin, damage cannot exceed 6% injury fruiting stages (squares, blooms, bolls) AND the presence of one second instar larvae
2. Cry2 toxin, damage cannot exceed 12% injury of fruiting stages (squares, blooms, bolls) AND the presence of one second instar larvae

Exceeding these damage limits triggers classification of "Practical Resistance."

The NCC offer the following considerations:

1. Who is EPA requiring to conduct the monitoring? The Draft Proposal's monitoring language seems to indicate partial responsibility is to be placed on registrants, with partial responsibility on users.

2. Monitoring aspects of the Draft Proposal lack clarity of procedure. If users of the product are partially responsible for monitoring, then the Draft Proposal should identify adequate procedures for frequency of sampling, information to report and who should receive the report. What documentation is necessary to report damage above the UXI? Presence of 2^{nd} instar larvae? What liability is being placed on the user? Is there a verification process of the report, or will the user be at risk of legal recourse disputing the report?

3. Second instar larvae are very small. What level of confidence (and liability) will be placed on the identification by a user (or user's crop consultant) reporting presence of larvae?

4. Most corn and cotton varieties available for production contain multiple traits. How do pyramid crops accomplish the desired monitoring by trait designation?

5. The Draft Proposal says registrants will plant sentinel plots in high risk areas. What is the definition of "High Risk Area," and does that definition change by pest species?

6. What criteria/methodology will determine the number of sentinel plots needed and the distance between sentinel plots given the mobility of the pest species?

Triggering "Practical Resistance"

Damage above the UXI values is identified as "Practical Resistance." Practical Resistance automatically invokes mitigation measures. The Draft Proposal defines the area that will be classified as being in "Practical Resistance" as the "Region," which is defined as the field (or sentinel plots) that exceeded the UXI, the entire county that contains the field (epicenter), and all adjacent counties. **The classification of the Region as "Practical Resistance" would remain in perpetuity unless:**

The individual registrant chooses to conduct F2 screens to demonstrate low resistance allele frequency and thus discontinue resistance mitigation efforts. The F2 screens are optional for the individual registrant in order to refute resistance based on UXI.

Specifically:

a) Registrants will collect insects from the UXI fields and surrounding fields. Each population collection shall attempt to target 400 insect genomes, but a successful population collection will contain a minimum of 100 genomes. The collection may include larval collections and/or collection of adult mated females.
b) Registrants shall standardize F2 screening techniques for appropriate bioassay procedures (Andow and Alstad 1998).
c) If the estimated resistant allele frequency from the F2 screen is less than 2% the pest population will no longer be considered at practical resistance and mitigation actions will be withdrawn. Otherwise, the F2 screen has supported practical resistance and the observed resistance is heritable.
d) F2 screen results will not be accepted from subsequent years to refute resistance claims in the area where UXI occurred due to the capacity of the pests for high dispersal.
e) Alternative bioassays may be accepted subject to EPA approval prior to use.
f) Bioassay protocols for high dose pests and the trigger for mitigation (US EPA 2010) remain unchanged.

Additionally, EPA strongly encourages industry to provide standard toxin stock and traited seed to private sector research for independent confirmation of resistance. Experience has shown that the refusal to follow these requirements increases controversy, speculation, and an increased distrust of registrant reporting. Collaboration between registrant scientists and the academic sector is important for early detection, verification, and public confidence.

The NCC encourages collaboration with the academic sector in developing a standardization of testing measures that will refine the capability to detect early indications of resistance development. Such collaboration expands the available participants across multiple locations for rapid response necessary to collect insects from populations that exceed the UXI in a timely manner before growers treat the field with a foliar application. Additionally, the multiple locations could aid in isolating populations simultaneously developing resistance and determine if the different populations demonstrate the same or different mechanisms of resistance. The NCC supports the engagement of the academic sector and appreciates their independent contributions for the preservation of production agriculture.

Mitigation

The Draft Proposal clearly acknowledges that "Practical Resistance" would trigger the need for mitigation. EPA stipulates an intent to enhance mitigation strategies and defines measures to reduce the likelihood of "Practical Resistance" spreading. Mitigation seemingly applies to the "Region" although the action for the "Region" seems vague. The proposed use of best management practices (BMPs) for the "Region" outlines the registrant's responsibility to communicate "Practical Resistance" throughout the Region to inform extension, crop consultants, growers, university cooperators, as well as state and federal authorities. The registrant will review the grower's IPM lepidopteran management program and provide recommendations to the grower. If a determination is made during an in-season period that allows for mitigation action, management options are recommended which include:

1. Apply an appropriate foliar chemical insecticide (only if economically viable in corn);
2. If additional pest management is needed, additional control tactics as appropriate (e.g. additional foliar insecticide applications, tillage practices, etc.).

For the next growing season, the producer must review compliance obligations, reminding everyone identified above, and recommend:

1. Switch to a different Bt mode of action or planting non-Bt;
2. Encourage timely planting;
3. Encourage intensified scouting;
4. Use appropriate timed foliar insecticide applications based on field scouting; and,
5. If additional pest management is needed, implement additional control tactics as appropriate (e.g. additional foliar insecticide applications, tillage practices, etc.).

The NCC supports the communications plans, and offers the following additional considerations:

1. Growers, consultants, extension entomologists, and agricultural media have close relationships that build a network for rapid notification of all within a Region, as well as those outside the Region.
2. The BMPs recommend management options vaguely represented and noting "not limited too." Again, the NCC expresses concern that the refinement of the Draft Proposal should be published for an additional comment period due to the vague information and potential for multiple additions that would not include stakeholder representation if EPA

proceeded with its apparent intent to address comments and publish a final rule. The NCC believes stakeholders are critical to the success of this Draft Proposal and should have input on refinements, additions, and procedural components before it is finalized.

3. The NCC notes the Draft Proposal recommends mitigation BMPs for the Region. The NCC does not believe the Draft Proposal clearly articulates the recommended mitigation action. Is EPA proposing that the communication and recommended actions of "foliar chemical insecticide" apply to the entire Region? Does one field exceeding the UXI mean foliar treatment of all fields in the Region? If not, then why did EPA define the Region that would be under "Practical Resistance" thus triggering the mitigation?
4. The NCC does not support a proposal to require the registrant reviewing the grower's lepidopteran management plan. The grower and his crop consultant are very aware of alternative measures to protect the grower's crop. But a grower most likely will ask why they should pay to protect their crop as a result of the failure of the purchased product not performing as claimed by the product seller (registrant or seed company). Again, consideration must be given to determining who is subject to and paying for EPA's mandated conditions of registration.
5. The NCC urges EPA to understand that it is imperative that the concerns of growers are reflected in revisions to the Draft Proposal in order to verify the practicality of compliance. For example, the potential for BMPs that include tillage is not practical for many growers. Many growers have contracts with other federal agencies that prohibit tillage in order to improve soil health and protect lands subject to soil erosion. The consequences of breaking those contracts would expose the growers to financial penalties. Promoting mandates on producers that increase their potential liability will most likely create grower animosity rather than enhance support for resistance management concepts.
6. The NCC notes the rotation of Bt traits seems to imply the development of single trait products but the Draft Proposal fails to outline a procedure by which producers could usefully assess the benefits from the rotation of pyramid traits.
7. Has EPA scientifically evaluated (*i.e.* modeled) the delay of resistance development if one foliar application of insecticide were required on all Bt crops during the late season peak of the pest population? Conceptually, any potential development of Bt resistant genotypes during the early to mid-growing season would be eliminated by the change in MOA. This would minimize the overwintering of resistant genotypes and could create sufficient special separation that the probability of two resistant individuals locating each other for mating is also minimized. Such models should be explored and considered based on the impact of extending the Bt efficacy. Foliar treatments may not provide economic return for the given year, but the collaboration with registrants could minimize the costs to incentivize compliance. Additionally, EPA should compare model outputs with alternating treatment years (*e.g.* treat every other year).

Annual Reporting

The NCC supports annual reporting as stipulated in FIFRA.

Phase out of Non-Functional Traits and Trait Pyramids

The Draft Proposal notes a consensus of the SAP that the following lepidopteran pests have evolved resistance to specified Bt toxins:

1. *H. zea* resistant to Cry 1 and Cry 2 toxins;
2. *S. frugiperda* resistant to Cry 1F toxins; and,
3. *S. Albicosta* resistant to Cry 1F toxins.

EPA seeks comments on the phaseout of certain Bt traits beginning with single trait varieties (within 3 years) and progressing to pyramid varieties (within 5 years).

The Draft Proposal identified two single trait products in corn (cotton single trait products have been phased out) Cry 1F alone and Cry 1Ab alone.

For Pyramids, the Draft Proposal identified the following for phase out:

Cry 1F + Cry 1Ab
Cry 1Ac + Cry 2Ab
Cry 1A.105 + Cry 2Ab2
Cry 1A.105 + Cry 2Ab2 + Cry 1F
Cry 1Ab + Cry 2Ae

The Draft Proposal listed several pyramids that were not being considered for phase out. The NCC notes one, Vip 3A + Cry 1Ab + Cry 1F, for the following consideration. What criteria identified this product to be retained if EPA is arguing Cry 1F should be eliminated; Cry 1 Ab should be eliminated; and Cry 1F + Cry 1Ab should be eliminated? That logic would imply support of a single trait Vip 3A product.

The NCC offers the following comments:

1. EPA has offered no evaluation procedure that supports any eliminations.
2. While the market might eliminate ineffective products, and registrants might offer volunteer cancellation of a product, phasing out a product otherwise would represent cancellation of a registration, thereby subject to cancellation requirements of FIFRA.
3. The NCC realizes the frequency of fields requiring an overspray for *H. zea* has increased and understands the Bt toxins did not represent high-dose strategies at the initial commercial registration of the Bt traited crops. The NCC urges EPA to distinguish between occasional pests and major pests, recognizing major pests should be the species of focus.
4. If EPA is content to consider phasing out traits, the NCC would urge consideration of the proposal's value for future Bt toxins. Perhaps EPA should establish consensus that moving forward, all registered traits, once used singularly, will be presumed to have compromised efficacy due to previous use and will not be considered of value to qualify as "pyramids." Future pyramids would then have to represent two unique MOAs released simultaneously and may include previous traits if desired.

5. The NCC notes that the development of resistance in a species as conceded by the SAP does not necessarily indicate no activity in that or another species. Without evidence of cross resistance, EPA has shown no support for the concerns they could prompt resistance to other toxins. Conversely, the NCC would urge EPA to evaluate the benefit of retaining the various combinations. If the Vip 3A toxin controls the majority of a population, and then survivors are subjected to multiple alternate MOAs, would the additional MOAs as a combination provide enough pest mortality to delay the evolution of resistance to VIP 3A?

The NCC realizes much of the Draft Proposal highlights the current lack of refuge compliance and the uncertainty of practical test measurements for early Bt resistance monitoring. The NCC urges EPA to consider paths that engage the least number of individuals necessarily involved to achieve compliance. Some of the alternative options offered for EPA's consideration identify clear paths to achieve compliance and minimize complexities associated with passing the costs and responsibilities and costs of compliance on to the user. The costs and responsibilities of compliance can be shouldered by registrants and would enable registrants to maximize the life of their product in collaboration with all stakeholders through cost-shared stewardship.

The NCC urges EPA to withdraw the Draft Proposal and replace it with a proposal that provides more clarity and addresses the concerns raised in these comments. The NCC appreciates the opportunity to share these alternative considerations.

National Cotton Council of America
Alabama Cotton Commission
California Cotton Ginners and Growers Association
Cotton Producers of Missouri
Delta Council
Georgia Cotton Commission
Georgia Farm Bureau
Louisiana Farm Bureau Federation, Inc.
Mississippi Farm Bureau Federation
North Carolina Cotton Producers Association
Oklahoma Cotton Council
Plains Cotton Growers, Inc.
Rolling Plains Cotton Growers
South Texas Cotton and Grain Association
Southern Cotton Growers Inc.
Southern Rolling Plains Cotton Growers Association