National Cotton Council of America

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August 31, 2020

Office of Pesticide Programs
Regulatory Public Docket (7502P)
U.S. Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

RE: Docket No. EPA-HQ-OPP-2020-0306

Dear Mr. Jonathan Williams,

The National Cotton Council (NCC) appreciates this opportunity to provide comments on the Natural Resource Defense Council's petition on May 4, 2020 requesting the Environmental Protection Agency (EPA) "Revoke all neonic tolerances and comments regarding dietary exposure." The NCC urges EPA to deny the petitioners request. EPA has methodically completed each risk assessment and made the documents available for public comment, occasionally extending the public comment period per the request of stakeholders. EPA has already provided abundant opportunity for relevant data, information, and other concerns through public comment periods that extended beyond the standard time periods.

The NCC appreciates the EPA's compliance with the Food Quality Protection Act (FQPA), the Food Drug and Cosmetic Act (FDCA) and the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and acknowledges the many accomplishments of the EPA that have resulted in enhancing the safety of U.S. food and fiber production for consumers. The NCC does not believe that the general public fully understands the extreme measures employed by EPA to assure crop protection products, when used as labeled, continue to provide the public with affordable, safe food and fiber.

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 are used as an ingredient in food products, as well as being a premium cooking oil.

The pesticide Registration Review process is very transparent with a long history of developmental methodology providing safety for human health and the environment. The methodology has been

vetted by multiple Scientific Advisory Committees and has received guidance from the National Research Academy. EPA has provided many resources outlining the procedural process, components of risk assessments and the multiple opportunities for public review and input. The methodology maintains compliance with multiple laws that intersect during pesticide registration and provides a reliable process of transparent review.

The neonicotinoid registration process was initiated in 2008. Since the initiation, EPA has issued multiple data call-in requests, strengthened several components of ecological risk assessments, and required vast numbers of scientific studies conducted with Good Laboratory Practices (GLPs) for the registration review of the neonicotinoids. EPA has procedurally announced availability of various stages of the risk assessment process and provided (and often extended) opportunity for public comment, input, or additional data. The Preliminary Human Health Draft Risk Assessment, including Acute and Chronic Dietary (Food and Drinking Water) Exposures, was provided for review and comment in 2017, initially with a 30-day comment period which EPA extended to 60 days.

The NCC compliments EPA for a thorough and comprehensive Human Health Risk Assessment of the neonicotinoid chemistries and NCC believes the risk assessment clearly shows that the labeled uses of these products are safe. The EPA procedurally published the Human Health Risk Assessment and complied with an appropriate comment period for public input. The NCC notes multiple opportunities were afforded for public comment, including submission of scientific data relevant to the risk assessment. The NCC believes EPA complied with statutory requirements, has provided numerous opportunities for petitioner's comments, and has appropriately complied with the scientific data requirements of the multiple statutes defining the U.S. risk-based regulatory process.

The NCC believes EPA has appropriately conducted neonicotinoid risk assessments in compliance with multiple statues and could easily argue the assessment is overly conservative. The NCC additionally realizes EPA has authority to review scientific literature, evaluate its merit based upon the standards established for EPA studies and compliance with GLP, and that EPA has established procedural measures to determine actions should new evidence of concern arise. While the NCC does not believe sufficient scientific evidence has been provided to initiate revisions to the Human Health Risk Assessment, the process established does not correspond to the petitioner's request to "revoke all tolerances".

EPA has established tolerances for various neonicotinoids based on risk assessments properly conducted in accordance with multiple overlapping mandates (FIFRA, FDCA, FQPA, PRIA). EPA should not revoke established tolerances before reviewing new evidence that would allow the Administrator to determine if it is sufficient to result in changes to the current, published tolerances. Without a procedural determination by the Administrator, this type of action would allow constant disruption of the regulatory process based on other's assertions of merit, repeatability, appropriateness of data, interpretation of data within the scope of the study, and relevance within the context of established risk assessment methodology.

Denying the petitioners request to revoke all tolerances does not imply EPA will ignore the petitioners' submission arguments and claims of supporting evidence. The NCC urges EPA to retain the established tolerances and review the information provided by the petitioners in order to reach a determination if any new evidence of concern is appropriately supported within the guidelines of EPA data review and risk assessment process. However, if the petitioners have not provided new evidence for evaluation, no additional actions should be taken.

To grant the petitioners request would undermine the registration review process and raise procedural questions within FIFRA and PRIA. In essence, granting the petition in whole jeopardizes the long-standing registration and registration review process by granting one entity (the petitioner) authority to rule that EPA's determination of neonicotinoid safety is "arbitrary and unsupported by substantial evidence".

The NCC appreciates the opportunity to provide these comments to EPA regarding the public notice of EPA's receipt of a "Petition to Revoke All Neonic Tolerances and Comments Regarding Dietary Exposure".

Sincerely,

Steve Hensley
Senior Scientist, Regulatory and Environmental Issues