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August 15, 2019

U.S. Environmental Protection Agency
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
Attn: Ms. Tracy Perry
1200 Pennsylvania Ave., NW
Washington, DC 20460

RE: Docket ID Number EPA-HQ-OPP-2019-0185

Dear Ms. Perry:

The National Cotton Council (NCC) appreciates the opportunity to comment on “EPA’s Proposed Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluation of Pesticides.” The NCC appreciates EPA’s continual efforts to identify a transparent methodology that meets the requirements of FIFRA and ESA statutes. The NCC recognizes the conflicting directives of FIFRA and ESA and urges EPA and the Services (Fish and Wildlife Services, and National Marine and Fisheries Services collectively) to identify a workable solution with minimal duplication of work.

The NCC is the central organization of the United States cotton industry. Its members include producers, ginners, cottonseed processors and merchandizers, merchants, cooperatives, warehousemen 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 understands EPA’s obligation under FIFRA and PRIA to conduct thorough and timely registration/registration review decisions for pesticide products. The NCC recognizes EPA’s review process requires large sets of scientific data collected through carefully designed experiments approved by EPA. The NCC acknowledges EPA’s cautious science driven review process for pesticide registration contains multiple processes that overstate the risks in order to reach a “reasonable certainty of no harm.”

The NCC acknowledges that the ESA requires all federal agencies to determine if their actions “May Affect” an endangered species, and if so to initiate a consultation with the Services. With respect to pesticide registration, the consultation would be required if there exists a direct overlap between the endangered species and the labeled pesticide use area, and “May Affect” risks are identified. The NCC believes the statute is clear with regards to when consultation is required, and all federal agencies are obligated to determine if any “May Affect” interface exists.

The NCC believes the proposed revised method outlines an overly conservative approach that increases the probability of a false “May Affect” (MA) and “Likely to Adversely Affect” (LAA), determination that would mandate consultation with the Services. Although the NCC has reservations due to the overly conservative approach, the NCC applauds EPA for producing and describing a transparent methodology utilizing reliable data, probabilistic analysis, and best scientific information available for this risk assessment process. The NCC believes the methodology does outline a clear path for determination of “Not Likely to Adversely Affect” (NLAA) and urges EPA and the Services to utilize the methodology without duplicative determination processes. The NCC urges EPA to further refine the methodology to enhance the ability to determine overlap areas of endangered species and proposed labeled uses of the pesticide while minimizing the likelihood of false “May Affect” determinations. The NCC believes this is an obligation of EPA under ESA in order to minimize false MA assessments that impose costly burdens on the Services.

EPA has outlined a three-step process, with each step incorporating more refinement to the risk assessment. Step 1 and Step 2 outline EPA’s methodology to determine if a consultation requirement is met. Step 3 is noted to be conducted by the Services, with no information of a collaboration agreement. The NCC urges EPA and the Services to clarify Step 3 methodology with a minimum of no duplication of the work completed in Step 1 and Step 2. The NCC urges EPA to consider the following suggestions:

Step 1 – Proposed Method for Differentiating May Affect (MA) from No Effect (NE) Determination

The NCC appreciates the methodology of Step 1 as an initial screening step. Step 1 provides an overly conservative filter that clearly identifies a NE determination. The process of identifying an Action Area by utilizing the overlap between Species Range and Pesticide Use Site plus an Off-Site buffer, all based on available data, is very appropriate.

The NCC would suggest EPA consider the possibility of enhancing the Step 1 screening by utilizing components described in Step 2 such as Dormancy State and Migration Pattern. These components described in Step 2 appear to be an appropriate consideration in Step 1 that would enhance efficiency of the process.

Pesticide use data

The use of the most recent 5-year data representing pesticide usage is a very legitimate approach for an initial screening. The NCC noted criticism that the data does not predict future use and would similarly note the data does not predict use reduction. However, such predictions are not data driven and should not direct public policy. Stakeholder engagement should be sought for additional data to refine pesticide use.

Off-site target transport zone

The NCC agrees with EPA that spray drift estimates generated by the AgDRIFT model are conservative, although NCC may argue overly conservative. However, the data would appropriately address Step 1 screening for NE. The NCC supports EPA's use of less than 1% overlap as a NE determination based on EPA's explanation. Given the conservative nature of AgDRIFT, the NCC would argue EPA's use of 1% overlap is highly conservative for species protection.

The NCC agrees with EPA regarding the lack of value to use the Downstream Dilution tool as it would not likely affect the removal of species from consideration.

Toxicity thresholds

The NCC understands EPA's rationale for its "belief that growth is an important sublethal endpoint" influencing survival; however, NCC notes the inclusion of growth is a conservative approach that will expand the MA determination for species protection. The NCC urges EPA to exercise caution in any additional sublethal effects without quantitatively linking the effects to survival. For example, growth regulators used in cotton impact vegetative growth allowing the plant nutrient resources to be directed to fruiting sites without any detriment to plant survival. The NCC applauds EPA's position to include the information for the Services consideration if necessary.

The NCC believes EPA's approach to consider impacts on an individual of listed species complies with ESA Section 7 with a very conservative methodology. The NCC understands the objective of Step 1 is to exercise an extreme conservative assessment that clearly identifies NE determinations. The NCC believes EPA has outlined extreme conservative endpoints that clearly identify some NE, but recognizes that many false MA will be suggested. Although the methodology achieves the initial screening purpose, it is so conservative that it increases the workload requiring additional refinement. The NCC urges EPA to refrain from any expansion beyond those presently proposed for direct and indirect effects. With the multiple conservative approaches, the assumption that 50% decline in biomass of the most sensitive tested aquatic species and the 25% decline in the most sensitive terrestrial species would constitute an effect that is meaningful to survival, EPA has greatly increased the workload requiring further refinement at Step 2. The NCC believes the Step 1 process will contain numerous cases later determined to be NE due to the overly cautious approach. While NCC understands the importance to capture all MA, the NCC believes the presented process lacks costs efficiency due to extreme caution and should not be expanded further.

Step 2 – Proposed Method to Differentiate May Affect and Likely to Adversely Affect (LAA) from May Affect and Not Likely to Adversely Affect (NLAA)

The NCC appreciates EPA's Step 2 method for further refinement of Step 1's conservative approach. The NCC urges EPA to consider Figure 4, 2c that indicates decreased growth suggests LAA (discussed previously related to growth regulators that do not influence survival). NCC also restates its suggestion that species range and active/dormant status should be part of Step 1. The NCC appreciates the refinement considerations in Step 2 and urges EPA to seek additional refinements based on scientific data. For example, dietary assessment should reflect natural behavior utilizing multiple food sources rather than limiting the diet consideration to no choice but treated crop.

The NCC appreciates the use of probabilistic analysis and simulations rather than deterministic approaches that do not represent available variation in environments. The NCC urges EPA to consider the probability of exposure carefully to determine if the weight of evidence suggests reasonable likelihood that the species would be affected. Simulations could be designed to evaluate various percentages of population exposure and species affect. Such simulations would allow further refinement based on population behavior studies.

It is the NCC's understanding that Step 1 (crude review) and Step 2 (refined review) will be conducted by EPA for determination of consultation engagement with the Services. The NCC believes EPA has outlined a very transparent process that meets the requirements under ESA.

The NCC recognizes the crop impacts and costs associated with various levels of pests and continues to emphasize the judicious use and critical need for safe and effective pest management tools. The NCC is encouraged that EPA is addressing ESA consultation requirements in an appropriate, conservative manner and looks forward to the implementation of a revised method.

Thank you for the opportunity to provide comments regarding "EPA's Proposed Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluation of Pesticides." The NCC looks forward to additional stakeholder engagement.

Sincerely,

A handwritten signature in black ink that reads "Steve Hensley". The signature is written in a cursive, flowing style.

Steve Hensley
Senior Scientist, Regulatory and Environmental Issues