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March 26, 2019

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-2018-0805

Dear Mr. Keigwin:

The National Cotton Council (NCC) appreciates the opportunity to comment on the petition from the Center for Food Safety (CFS) to the Environmental Protection Agency (EPA) requesting that EPA either initiate a rulemaking or issue a formal EPA interpretation for planted seeds treated with systemic pesticides. The NCC believes EPA has conservatively fulfilled its requirements under FIFRA during the registration and registration review process for pesticide products labeled for use and urges EPA to deny the petition for such action. It is unfortunate that the public does not realize the extent of EPA's overly rigorous review process with multiple risk assessments involving assurance of human safety and reasonable certainty of no adverse effects.

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.

EPA has requested public comments on two major points contained in the petition from the CFS: 1) CFS's request that EPA amend or formally reinterpret the Treated Article Exemption in 40 CFR 152.25(a) to clarify whether the exemption applies to seeds treated with systemic pesticides

intended to kill pests of the plants; and 2) CFS's request that EPA enforce FIFRA's registration and labeling requirements for seed products coated with systemic pesticides.

The NCC notes in 40 CFR §152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.

(a) Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

The NCC believes the language in the regulation is clear and that EPA's current interpretation and use of the treated article is appropriate. The plain meaning of the rule clearly provides an exemption for the article treated if the treatment product is registered for such use. The pesticide product is still subjected to EPA's rigorous risk assessments including Human Health Risk Assessments, Ecological Risk Assessments, Bee Risk Assessments, Aggregate Risk Assessment, Cumulative Risk Assessment, Occupational Risk Assessment, and the multitude of models and intermediate data requirements to accomplish these risk assessments. The NCC believes EPA has fully complied with FIFRA by sufficiently addressing all requirements of pesticide registration of products labeled for use as seed treatments. The NCC cannot find any justifiable benefits of adding duplicative risk assessment of the treated article as if it were a pesticide.

The NCC further requests that EPA recognize the long-standing authority (1940, revised 1998) of USDA's jurisdiction under the Federal Seed Act (FSA, 7 U.S.C. 1551-1611). Within Title I of FSA, Congress included the term "treated" defined as follows:

Title I, Sec. 101, (23) *The term "treated" means given an application of a substance or subjected to a process designed to reduce, control, or repel disease organisms, insects or other pests which attack seeds or seedling growing therefrom.*

The NCC believes the commonality of these definitions recognizes the basic scientific understanding of a seed as a biological organism of form. A viable seed is a form of a seedling (embryo) in nature's protective packaging (seed coat) with stored nutrients (cotyledon) until environmental conditions are suitable for release (germination) from the protective seed coat. The cotyledons provide sufficient nutrition for the seedling to unfold, emerge from the soil, and sufficiently grow until physiological development allows photosynthesis to sustain the plant. The NCC notes the purpose of the FSA was to require those selling seed to disclose expectations for seed purchasers including seed quality tests for percent germination into a viable, nondeformed seedling. The NCC believes the FSA demonstrates the long-standing legislative recognition that a seed is a living organism, and purchasers of seed should be provided a level of germination and crop establishment from the planted seed.

The most critical component of crop production is the establishment of an adequate plant stand. Multiple factors affect establishment of a plant stand. As recognized by the FSA, plant seed should be viable with an expected germination quality. However, once a seed is planted in soils, the seed and the internal embryo are subjected to soil dwelling pests (insects, pathogens, etc.). In many cases, the seed is destroyed by pathogens or insects before germination. Often these pests are not detectable because the seed is below ground level. Germination is the process in which a viable seed begins to unfold, or sprout, releasing the seedling contained inside. Many members of the academic community across the cotton belt (university and federal) have conducted trials involving various seed treatments (both systemic and non-systemic). The weight of the evidence from these studies indicates that treated seeds provide many benefits - often including reduced number of subsequent foliar applications. The causes of these benefits vary greatly. Agronomists, plant pathologists, and entomologists have long recognized the critical need to protect the seed/seedling in order to achieve a sufficient plant stand. It is also well-established that protection from soil pests must be initiated at planting due to the inability to deliver "rescue" treatments during post planting. Prior to seed treatment technology, the delivery of protection for seeds/seedlings included various field level handling and application methods such as infurrow granular applications, in-furrow T-band liquid applications, band at planting applications, hopper box treatments, and field level treatments of seed. The development of seed treatment technology upstream provided a more reliable application technology, reduced needs for field level handling of products, and provided quality assurance with extensive reduction in potential exposure to handlers and application errors at the field level. The NCC urges EPA to recognize the multiple benefits of treated seed technology.

In addition to the FSA, EPA's use of the treated article exemption is also consistent with the Plant Protection Act (PPA, 7 U.S.C. 7702), which includes the supporting definitions:

7 U.S.C. §7702. Definitions (13) Plant

The term "plant" means any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed. (14) Plant pest

The term "plant pest" means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

(A) A protozoan.
(B) A nonhuman animal.
(C) A parasitic plant.
(D) A bacterium.
(E) A fungus.
(F) A virus or viroid.
(G) An infectious agent or other pathogen.
(H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

The NCC further notes that 40 C.F.R. §174.3 "Definitions" includes:

Living plant means a plant, plant organ, or plant part that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers, and pollen. The NCC urges EPA to refrain from actions that would result in creating conflicting definitions among federal agencies and regulations. The NCC believes EPA's current risk assessment methodology complies with FIFRA and recognizes the biological significance of seed. Any deviation beyond that obligation would impose additional costs with no justifiable benefits. Conversely, such action could easily result in reducing environmental and safety benefits currently afforded with "treated" seeds.

Potential Costs

The NCC is concerned about what alternative EPA would utilize without the "treated article" exemption. Would EPA equate a bag of treated seed to a container of concentrated pesticide? The NCC believes such an action would impose significant regulatory burdens on producers at their expense, impose additional burdens on the ability to order seeds for planting, and dramatically increase costs as a result of additional, duplicative studies. Such action would likely disrupt commerce activities associated with production, storage, sales, distribution logistics, delivery, and planting of seed for multiple years. Faced with additional costs and regulatory burdens for treated seed, producers would be forced to revert to previous practices utilized prior to seed treatments.

It is important to recognize the value of technology in terms of lowering risk for humans as well as reducing agriculture's environmental footprint. The agricultural community is seldomly portrayed accurately for the many advances in technology and production practices that continually reduce potential risks to the agro-ecosystem and farm workers, who are often the producers and family members themselves. Seldom are producers publicly recognized for innovations and stewardship practices that have preserved and enhanced agricultural land production per acre capacity while simultaneously reducing agriculture's environmental footprint.

Occasionally, regulatory actions create conflicts that discourage or inhibit a producer's continued adoption of reduced risk technologies. The NCC urges EPA to recognize that regulating a pesticide product until it is applied to a seed provides overwhelming benefits when compared with the potential risks that would arise without the treated article exemption. Current practice enhances human and environmental safety by enabling producers to consider the history of their fields, identify pests of concern, and purchase seed already containing the diluted pesticide dose necessary at the single seed level. These steps eliminate multiple layers of potential exposure and removes the potential human error that can occur when pesticide applications are mixed and applied at the field level. The NCC believes that increasing regulations on treated seeds would result in duplicative regulatory burdens that would eliminate the incentive to utilize the advanced technology. Producers would revert to the purchase of concentrated products to mix and apply at the field level. One can easily understand that having fewer handlers of concentrated products greatly reduces the chance of error and significantly reduces potential human and environmental exposure. The NCC urges EPA to avoid regulations that diminish the adoption of enhanced safe-use of crop protection products.

The NCC thanks the EPA for the opportunity to provide comments and urges EPA to deny the petitioners request. EPA has complied with FIFRA and associated pesticide regulatory legislation. Additional levels of regulatory action beyond the treated article would not provide

justifiable benefits but would increase risk by forcing producers to abandon the more advanced, reduced-risk methodology of protecting seeds/seedlings for adequate plant stand emergence.

Regards,

Roece Langley

Reece Langley Vice President, Washington Operations National Cotton Council