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December 8, 2020

Ann Overstreet
Biopesticides and Pollution Prevention Division (7511P)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

RE: EPA-HQ-OPP-2019-0508

Dear Ms. Overstreet:

The National Cotton Council (NCC) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA's) proposed rule titled "Pesticides: Exemptions of Certain Plant-Incorporated Protectants" (Proposed Rule). The NCC applauds EPA's thorough consideration of factual support for the Proposed Rule, and for the careful and thorough development of a Proposed Rule that provides clarity through definitions, while being transparent in the description of decision processes. The NCC suggests the extensive Proposed Rule is not needed and does not comply with Executive Order (EO) 13874, but instead adds new limitations, constraints, and regulatory burdens beyond existing regulations. However, the NCC will give consideration to the entirety of the Proposed Rule. The NCC requests EPA compare the Proposed Rule and current regulations of 40 CFR § 174.25 and recognize the existing regulation provides greater flexibility, efficiency, and consistency than the Proposed Rule. The NCC suggests a minor edit to 40 CFR § 174.25(a) would expand the rule to include gene modification and achieve greater compliance with EO 13874.

The NCC is the central organization of the United States cotton industry. Its members include producers, ginner, 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 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.

Proposed Rule Considerations

Authority

The basis of this Proposed Rule is to comply with EO 13874 (“Modernizing the Regulatory Framework of Agricultural Biotechnology Products”). EPA explains that its compliance with EO 13874 will “promote innovation and competitiveness by efficiently exempting through regulation qualifying PIPs based on sexual compatible plants created through biotechnology that meets the FIFRA and FFDCa standards for exemption.”

The current regulations state:

“40 CFR § 174.3 – Definitions

“Conventional breeding of plants means the creation of progeny through either: The union of gametes, i.e., syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include use of any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.

“Plant-incorporated protectant means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.”

“40 CFR Part 174 - PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

“40 CFR Subpart B – Exemptions

“40 CFR § 174.25 - Plant-incorporated protectant from sexually compatible plant. A plant-incorporated protectant is exempt if all of the following conditions are met:

“(a) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient plant.

“(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient plant.”

The NCC believes the current regulation is concise and more appropriately aligned with the EO 13874, as well as EPA’s stated intent, than the Proposed Rule. The Proposed Rule would impose new guidelines and restrictions that are not present in the current regulation. The current regulations provide exemption of PIPs derived from sexually compatible source. Rather than increasing efficiency and providing regulatory relief, the Proposed Rule would impose new criteria and regulatory engagement thus amplifying the regulatory burden.

The NCC urges EPA to modify the existing regulation with the broad exemption for PIPs derived from a sexually compatible source as follows:

(a) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is ~~from~~ found in a plant that is sexually compatible with the recipient plant.

The minor edit to 40 CFR § 174.25(a) would sufficiently identify the inclusion of gene modification as well as gene transfer as long as the pesticidal substance and genetic material that encodes for the pesticidal substance are representative of variation presently in the species gene pool.

EPA has provided no comparative explanation indicating greater flexibility, efficiency, timeliness, transparency, predictability, or consistency of the Proposed Rule and the existing regulation. EPA should refrain from creating additional constraints, criteria, and procedures that add complexity without justification.

Phrasing Modification

The NCC urges EPA to rephrase all language stating “*plant product containing PIPs based on sexually compatible plants created through biotechnology*” and consider “*biotechnology used to create plants from sexually compatible parent(s)*.” The NCC suggests caution that some may interpret the first phrasing to suggest the resulting creation is now sexually compatible rather than the requirement of sexually compatible parent(s).

Definitions

The NCC believes EPA’s proposed definitions for 40 CFR § 174.3 adequately convey the intended meanings for *gene*, *native allele*, and *native gene*.

The definition proposed for *sexually compatible* does not encompass the situation in which conventional breeding requires an intermediate or bridge species in order to then proceed to the final target plant. For example, diploid *Gossypium* species are not sexually compatible with all tetraploid *Gossypium* species; however, a conventional breeder can identify a *Gossypium* line that would cross with diploid and tetraploid species, thereby allowing conventional breeders to utilize characteristics of diploid species for tetraploid improvements. While it is NCC’s understanding that the Proposed Rule is intended to include the cases where a bridge plant must act as an intermediate step, the NCC does not believe the language clarifies that intent. The proposed language seems to limit the exemption to a host gamete and recipient gamete form a viable zygote.

40 CFR § 174.3 contains the following definition:

“Bridging crosses between plants means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to

cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.”

The NCC would urge consideration of the following definition:

“Sexually compatible, when referring to plants, means a viable zygote can be formed through the union of two gametes, including cases involving bridging crosses between plants, through conventional breeding.”

General Qualifications for Exemption

The Proposed Rule identifies what NCC believes to be the “minimum qualifications” for exemption. The Proposed Rule, in essence, refers to exemptions for host plant resistance (HPR), an identified component of Integrated Pest Management (IPM) that has historically been difficult to capture through traditional breeding programs. Traditional breeding programs require a vast amount of time to transfer the trait and backcross to restore commercial acceptability with competitive growth and yield characteristics. Due to the time involved, many identified HPR characteristics have not been utilized. The evolving science enabling HPR development with minimal time (relatively speaking) and minimal disturbance of growth and yield characteristic should be embraced as a revival of HPR development. The capability to transfer, modify, or remove genes and their associated activities should be embraced as a new frontier that expands IPM. The use of these modern technological advancements based on evolutionary variation in native parental plants should be highly encouraged with minimal regulatory discouragement. The NCC urges EPA to expand its consideration of qualifications to include other uses within the Proposed Rule’s justifiable argument of reasonable certainty of no harm.

The NCC requests consideration, or possibly clarification, of the expression of the protectant substance in non-food tissue of the plant. It is reasonable to consider that a pesticidal substance, currently present in the environment as part of the sexual compatible gene pool, presents no new environmental threat. Therefore, the concern becomes one of human health. Expression of the protectant in tissue not utilized as a food resource would not pose human health risks. In order to encourage scientists to seek plant protection in today’s production varieties by identifying ancestral characteristics/protectant substances, the exemption should broaden the exception recognizing the numerous uses that fall within “reasonable certainty of no harm.” The expression of a protectant below the bark of trees may identify means to preserve the U.S. orange production industry with minimal use of crop protection products. Root tissue of cotton plants (and potentially other row crops) could be protected from the devastation of nematodes without necessary application of crop protection chemistry. These are only two basic examples of uses that pose no human health risks.

The NCC urges EPA to additionally consider the crop protection benefits derived from the use of biotechnology that incorporates the sexually compatible native gene pool. The potential human and environmental benefits are abundant. While there is not likely to be a single characteristic/protectant substance capable of total crop protection, potential combinations would

enhance crop protection, reduce reliance on crop protection chemistry, expand efforts to delay or avoid development of resistant pests, and allow targeted delivery of pest control.

The NCC would urge EPA to consider greater expansion of the exemption rule if the PIP demonstrated target specificity or limited spectrum of activity. IPM has historically considered minimizing disturbance of species diversity, particularly beneficial insects. EPA should encourage research providing target specificity with minimal regulatory burdens.

The NCC would urge EPA to consider potential exceptions to modifications of the coding regions, such as in root tissue, if tissue is not utilized for food purposes and generally not accessible for exposure.

The NCC believes that limiting, within the bounds of reasonable certainty of no harm, regulatory interference with new biotechnology advancement would re-invigorate public breeding programs that are focused on preserving long-term sustainable agricultural production. EPA should consider the potential environmental benefits uniting public priorities.

Intra-Agency Consistency

The NCC continually encourages a consistency of the use of terms between federal agencies, as well as careful review and alignment with accepted English definitions. The lack of consistency with commonly recognized and accepted definitions and alteration of definitions between governmental agencies creates confusion. The public does not operate solely within the scope of EPA, USDA or any other federal agency. The public relies on all agencies. The lack of consistency in definitions diminishes public trust among agencies. The NCC urges greater consistency in definitions addressing the same subject.

EPA's Specific Comment Requests

1. *Whether a clarifying exemption specific to loss-of-function traits would be helpful, although EPA considers these traits to be included under the current exemption at 40 CFR 174.25 and the proposed exemption at 40 CFR 174.26.*

The NCC believes EPA has clearly stated the intent for loss of function to be covered by the exemption in 174.26(a)(2)(iv).

2. *The Agency requests comments on whether there are any inert ingredients other than the intermediary substances described in the 2001 quote that will remain in the final plant product containing PIPs based on sexually compatible plants created through biotechnology.*

The NCC is not aware of other inert ingredients at this time but would urge EPA to consider a process to rapidly include potential inserts that may arise as the biotechnology capabilities advance.

The NCC would strongly urge EPA to cease use of the phrase "*plant product containing PIPs based on sexually compatible plants created*

through biotechnology” and consider in its place the phrase “biotechnology used to create plants from sexually compatible parents.” The NCC is concerned that some members of the public could incorrectly interpret the first phrase to suggest the resulting product is sexually compatible rather than the requirement of sexually compatible parent(s).

3. *The Agency requests comments as to whether the inert ingredients in PIPs based on sexually compatible plants created through biotechnology require the proposal of an exemption that would be specific to those created through biotechnology and would allow developers flexibility in the nucleic acid sequence (see Unit VII.A.)*

The NCC urges EPA to allow more flexibility closely aligned with conventional breeding. EPA should minimize any differences in regulatory handling of conventional breeding and biotech utilization of native gene pools.

4. *However, the Agency seeks comments on the use of the term “native” in the names of the “native gene” and “native allele” and associated definitions as the Agency does not mean to imply with the term “native” that genes which originate through conventional breeding techniques like mutagenesis would somehow be excluded from the proposed exemptions.*

The NCC asks consideration of the following modification of the definition:

Native gene – a gene that is identified in the recipient plant or plants that are sexually compatible with the recipient plant *through evolutionary processes*; and has never been derived from a source that is not sexually compatible with the source plant.

The addition of “*through evolutionary processes*” seems to align with EPA’s intent while retaining the exclusion of genes that are derived from methods other than evolutionary processes.

5. *EPA seeks comment on whether the use of the phrase in the proposed definition of “native gene” is clear.*

See number 4 above.

6. *What process should the agency use to provide notice that a PIP no longer meets the criteria for exemption if new information is provided?*

The NCC would argue that the exemption criteria support “reasonable certainty of no harm” and thereby reduces the unnecessary burden of substantial costs (both for registrant and EPA staff hours). Should information reasonably imply otherwise, EPA should respond in a manner

similar to a conditional registration. If the exemption criteria no longer support the exemption, then EPA should proceed with data call-in as a conditional registration product unless the new information provides reasonable certainty of imminent harm. In the event of reasonable certainty of imminent harm, EPA should proceed with actions under FIFRA's Section 6, Administrative Review; Suspension.

7. *Should EPA consider other approaches for its confirmation process (p108).*

The NCC applauds EPA confirmation approach, and the clarity provided for the process in the proposed rule. The NCC supports the presently stated confirmation process while urging EPA to seek additional expansion and ways to minimize costs and regulatory burdens.

8. *Is EPA's intent behind the use of the term "native" and "never derived" clear?*

See number 4 above.

9. *The Agency seeks comments on whether alternative phrasing rather than "native" would be more appropriate.*

See number 4 above

10. *The Agency seeks comments on whether a definition for "native gene" or "native allele" is necessary, or if the criteria included in these definitions should instead be incorporated into the exemption text.*

The NCC believes the inclusions of the definition are important and would urge EPA to retain their inclusion with consideration of suggestions in number 4 above.

11. *Should EPA issue a clarifying exemption for loss-of-function traits that result in pesticidal effects?*

In the event that loss-of-function traits result in a pesticidal effect, the most logical reasoning would imply a loss of attractiveness. A loss of attractiveness provides no logical effect that would be contrary to "reasonable certainty of no harm" but would logically enhance the benefits of such natural characteristic that reduces the need for pesticide intervention. The NCC urges EPA to minimize any regulatory cost discouraging loss of function without evidence suggesting harm.

12. *EPA request comments as to whether a clarifying exemption specific to "loss-of-function PIPs," where the genetic material is a pesticidal substance, would aid in reducing ambiguity over the use of the term "pesticidal substance" in the regulatory text.*

The “loss-of-function” or “reduced expression” does not bring to mind a need to differentiate between “substance” and “pesticidal substance.” The mere fact that the source is present in the evolutionary gene pool, and the desire is to reduce or remove the function should not warrant any additional regulatory involvement. It does not seem logical that a desire would be to reduce a toxicant or remove it, but if that action is desired it follows that the potential risk previously accepted has been lower; thus there is greater “reasonable certainty of no harm.” The NCC suggests “the substance, pesticidal or not” should not change the exemption for loss-of-function or reduction of expression.

13. *EPA also requests comments on how to separate exemption or exemption (if any) specific to loss-of-function PIPs might be implemented. Should such separate exemption(s) be technique-specific, or should there be one exemption that covers loss of function PIPS regardless of the technique used in their creation?*

The NCC refers to number 12 above and urges EPA to have one exemption that covers loss of function PIPs regardless of the technique used in their creation.

The NCC is encouraged by EPA’s practical approach that acknowledges evolutionary defense mechanisms exist in ancestral native plants that are not present in current production cultivars resulting from centuries of plant breeding. Traditional breeding practices have relied on a lengthy process of crossing plants with a focus on a narrow number of characteristics to incorporate into the production cultivars. Predominantly, these characteristics have focused on yield enhancement, quality improvements, and plant durability characteristics. However, scientists have known of many pest defense mechanisms in native cultivars that are not present in commercialized breeding lines. The complexity and lengthy process of plant breeding does not easily lend itself to incorporate native pest defense mechanisms that may initially reduce yield components and add numerous years of back crossing to restore yield. Unfortunately, commercialized plants without these native evolutionary defense mechanisms often require chemical intervention to provide the plant protection. The NCC appreciates EPA’s recognition that advancements in technology can expedite the incorporation of native plant mechanisms into production cultivars and exempt these resulting plants from regulatory exercises due to their natural presence in the environment. The development of plants derived from advanced genetic tools and procedures increases the efficiency of traditional plant breeding. The mere difference from conventional breeding is the use of modernized tools. The use of modernized tools alone should not impose regulatory scrutiny of new PIPs. Existing regulations already identify the exemption based on sexual compatibility and employ sound reasoning and avoidance of unnecessary costly review procedures thus reducing cost for taxpayers and registrants. Additionally, the exemption is expected to enable smaller companies and public breeding programs to engage in enhancing commercialized plants, increasing competition by removing unnecessary federal regulation with exorbitant costs. Additional constraint and complexity of the Proposed Rule would be contrary to the intended compliance with EO 13874 and should not be pursued given the existing exemption regulation of 40 CFR § 174.25 with the minor proposed edit.

The NCC appreciates the opportunity to comment on EPA's Proposed Rule. While the NCC respectfully objects to the implementation of the Proposed Rule, we acknowledge the quality of the document as a Proposed Rule. The organization of the material is transparent, comprehensive, and outlines decision processes. The NCC appreciates EPA's presentation of a Proposed Rule with sufficient clarity and defined process to allow public commenters adequate information to consider.

Sincerely,

A handwritten signature in black ink that reads "Steve Hensley". The signature is written in a cursive style with a large, sweeping initial "S".

Steve Hensley
Senior Scientist, Regulatory and Environmental Issues
National Cotton Council