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May 18, 2020

U.S. Environmental Protection Agency
EPA Docket Center, Office of Research and Development Docket
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460

RE: Docket No. EPA-HQ-OA-2018-0259: Strengthening Transparency in Regulatory Science

The National Cotton Council (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.

NCC appreciates the opportunity to comment on this Supplemental Notice of Proposed Rulemaking (SNPR). NCC believes that regulatory transparency is of the utmost importance and we have encountered incidences in the past where the industry was not allowed to study raw data that was being used as justification to regulate agriculture. On the other hand, EPA's offices rely on proprietary databases (e.g. health data) and confidential business information integral to data that industries supply for EPA to study in their regulatory process. While NCC is not

clear on where to draw the line, we do ask that EPA take a carefully balanced, thoughtful approach to carrying out this transparency project that is desperately needed.

In addition, we ask that the agency avoid the precautionary principle approach to regulatory action. Thus, we believe the agency should be very transparent with those datasets that seek to establish the precautionary approach for a product or for all regulations within the U.S. This approach is the antithesis to a true scientific method.

In addition, models should reflect real-world data when that data is available for comparison. The agency should not accept model results that contradict actual sample data. Furthermore, different offices within the agency or different agencies should not have models that suggest wildly different result-scenarios for the same test subject. For example, one model for the spread of a pesticide should not show a result of a potential risk of low-level drifting into populated areas while a model for the same subject, but in a different office, shows that the pesticide rises quickly and affects the ozone layer. We are pleased to see that the SNPR proposes that these provisions would apply to data and models, not only dose-response data and dose-response models.

We are concerned that data not be allowed to be declared proprietary resulting in only summaries being subjected to agency scrutiny. Full data sets need to be provided for analysis and if not, the study should be rejected until all underlying data is provided. Stakeholders cannot have trust in the regulatory process when the data they are to be regulated by has not been subjected to review and properly critiqued.

We also believe when data is being used to make what industry believes is a significant change or affect, the data should be reviewable by the affected entity after redactions for confidential business purposes. Industry can quite often find errors in data located on the public docket and it benefits no one to be regulated based on incorrect assumptions.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) govern the Environmental Protection Agency's pesticide registration process. This process has never been considered to be a "significant regulatory action" and therefore data submitted for pesticide registrations has been excluded. The balance between registration transparency and confidentiality are supposed to be accomplished through FIFRA and FFDCA.

The SNPR proposes to expand the rulemaking to include "influential scientific information" as well as "significant regulatory actions." Given that much of the data is confidential and that there have been problems with data review in the past, NCC requests that data transparency be applied to that process as much as possible.

The NCC appreciates EPA's continued protection of human health and the environment based on scientific data of merit.

Respectfully,

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

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