July 5, 2011

The Honorable Lisa P. Jackson
Administrator
Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Administrator Jackson:

We, the undersigned members of the National Academy of Sciences, write today to voice our concern over the latest proposal from the U.S. Environmental Protection Agency (EPA) to further expand its regulatory coverage over transgenic crops in a way that cannot be justified on the basis of either scientific evidence or experience gained over the past several decades, both of which support the conclusion that molecular modification techniques are no more dangerous than any modification technique now in use. The increased regulatory burdens that would result from this expansion would impose steep barriers to scientific innovation and product development across all sectors of our economy and would not only fail to enhance safety, but would likely prolong reliance on less safe and obsolete practices.

Twenty-five years ago, on June 26, 1986, the Office of Science and Technology Policy (OSTP) put forth a policy statement that created a "Coordinated Framework for the Regulation of Biotechnology" in the United States. At the time the Coordinated Framework was articulated, a degree of caution seemed reasonable, while seeking to achieve "a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry". At that time it was acknowledged that the framework should be "expected to evolve in accord with the experiences of the industry and the agencies, and, thus, modifications may need to be made".

Since then, extensive research, coupled with years of experience, led to the conclusion that there is no scientific basis to single out plants produced by transgene insertion for a special regulatory review, nor to distinguish these products from others on the basis of the process used to create them. There is now abundant evidence that the most appropriate regulatory approach would be to require review only of truly novel traits introduced into plants without regard to the methods used for their introduction. Yet the regulatory apparatus in the U.S. has increasingly moved in the opposite direction towards ever greater regulation and increased data requirements for transgenic plants, despite the abundant accumulation of data attesting to their safety.

The scientific community has a strong interest in keeping regulations science-based and commensurate with the risk of the products at issue. This past March, EPA announced in the Federal Register a draft proposed rule to codify data requirements for plant incorporated protectants (PIPs). This draft was forwarded by EPA to the U.S. Department of Agriculture (USDA), Department of Health and Human Services and Congress for review in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act. Based on initial reviews of that draft proposal and recent EPA actions associated with biotechnology-derived crops, it is clear that the Agency is departing from a science-based regulatory process, walking down a path towards one based on the controversial European "precautionary

principle" that goes beyond codifying data requirements for substances regulated as PIPs for the past 15 years.

We are particularly troubled by proposals to expand EPA's current oversight into areas such as virus resistance and weediness that have been adequately addressed by USDA since 1986. Already, EPA has expanded its oversight into virus resistance, which previously had been the purview of USDA's Animal and Plant Health Inspection Service (APHIS) and which EPA prudently proposed in 1994 to exempt from its regulations. With the draft proposed rules, EPA would further expand its regulations and data demands to other areas historically covered by USDA-APHIS without the slightest justification based on either data or experience.

It is most troubling that EPA is also proposing to increase its regulation to cover matters which are still not deemed to be threats even after years of study, such as potential gene transfer from plants to soil microorganisms. In other actions, EPA has expressed its right to regulate plants engineered for altered growth (e.g., by suppression of ethylene production), the same way it regulates synthetic plant growth regulators. The Agency does so based on a generous interpretation of the enabling legislation, despite the absence of any scientifically credible hazard.

Such an expansion in regulatory purview would reverse long established and highly successful policy under the Coordinated Framework. Such a shift would (1) create a duplicative regulatory system for very low risk products delivering substantial, demonstrated environmental benefits; (2) increase costs, reduce efficiency and prolong the review timelines thereby discouraging innovation; (3) dramatically increase the hurdles already facing academic institutions and companies attempting to improve so-called minor use or specialty crops through modern biotechnology; and (4) adversely impact trade in safe and wholesome commodities produced by U.S. growers because of the stigma attached to anything characterized as a "pesticide" — a regulatory label for DNA that is unique to the U.S. — and with no concomitant increase in product safety. In addition, any expansion in regulatory oversight not resulting from documented risk could have global ramifications, as policymakers in other countries routinely consider U.S. policymakers as leaders in the regulation of crops derived from biotechnology.

Indeed, it is astonishing that EPA would attempt such an expansion of its regulatory activity in this sphere. We now have more than 25 years of experience with biotechnology-derived crop plants. None of the hypothetical risks articulated at the dawn of this era has been realized and caused new environmental problems. On the contrary, billions upon billions of meals derived from these crops have been eaten by humans and livestock around the world with no ill effects. Moreover, environmental impacts of production agriculture and the carbon footprint of agriculture have been significantly reduced through the use of transgenic crops. At the same time, farmers have benefited economically, socially, and through improved health. These indisputable results make a compelling case that existing regulatory burdens should be reduced and refocused. There is absolutely no justification in either scientific data or experience for the regulatory expansion proposed by EPA.

Over the last two decades, advances in sequencing and genomic analysis have revealed that biotechnology is more precise and less disruptive to the genome than traditional plant breeding. In point of fact, recent genomic, proteomic and metabolomic comparisons of varieties bred through conventional and transgenic methods demonstrate that transgenic plants with incorporated novel traits more closely resemble the parental variety than do new varieties of the same plant produced by more

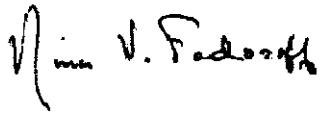
traditional breeding or mutagenesis techniques. These findings confirm that transgene insertion is not inherently risky nor does it present new and greater hazards than conventional plant breeding.

In conclusion, recent EPA actions signal an intent to expand the Agency's regulatory oversight into products regulated by USDA for over two decades and to products for which there has never been a justification for regulation. These actions are not only inconsistent with regulatory directives mandated by the current Administration, they also erode the integrity of the Coordinated Framework. Such expanded regulation would serve only to increase costs, hinder research, undermine the long-term viability of public university research programs, and limit product development from the private sector. The proposed actions would threaten our ability to produce high quality food at an affordable price and feed a growing population. They would also weaken the competitive advantage of U.S. public research programs in the global research arena, all with no increase in safety for consumers, farmers, or the environment — indeed, the contrary would be the case in many instances.

The academic community is committed to ensuring that the environmental and food safety benefits of biotechnology-derived plants continue to accrue, and it is essential that all agencies respect the scientific basis for regulation and division of regulatory responsibilities established by the Coordinated Framework. It is critical that regulations focus on scientifically demonstrated hazards, rather than being driven by issues of perception or political expediency. Therefore, Administrator Jackson, we urge you to reconsider the pending EPA regulatory actions and limit the rulemaking proposal to requirements for substances that have traditionally been regulated by EPA as PIPs, and then to only those requirements that are fully justified on the basis of safety and sound science.

I sign this letter on behalf of the more than 60 members of the U.S. National Academy of Sciences listed below. The list includes many of America' most eminent biological scientists, including Nobel Laureates Dr. James Watson and Dr. Günter Blobel.

Sincerely,



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