



3 Park Place, Suite 307
Annapolis, MD 21401-3722 USA

Phone: 301-731-4535
Fax: 301-731-4538

esa@entsoc.org
www.entsoc.org

July 30, 2018

Regulatory Analysis and Development, PPD, APHIS
Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Re: Public Input on Environmental Impact Statement regarding the Movement and Outdoor Use of Certain Genetically Engineered Organisms
(Docket No. APHIS-2018-0034)

To Whom It May Concern,

I am writing to you today on behalf of the nearly 7,000 members of the Entomological Society of America (ESA) regarding the “Notice of Intent to Prepare an Environmental Impact Statement; Movement and Outdoor Use of Certain Genetically Engineered Organisms” (Docket Number APHIS-2018-0034).

ESA strongly supports APHIS’s intention to conduct a programmatic environmental impact statement (EIS) on the movement and outdoor use of genetically engineered (GE) organisms, with the intention of updating the regulations that support the Federal Coordinated Framework for the Regulation of Biotechnology. Given the rapidly changing state of art in this field, and that an update has been needed for some time, ESA supports conducting the programmatic EIS. Modern technologies provide an opportunity to effectively contribute to efforts to address a wide range of grand societal and international challenges, but there is a serious need to balance opportunities with risks and to do so in a manner that rests on solid science, rather than emotion and unwarranted fear.

The need for updated regulations is clear and critical to be able to develop and deploy GE organisms safely and effectively well into the future. Although regulations have not been updated significantly in nearly 30 years, the methods, technologies and applications have changed greatly, warranting strong consideration for updates. At this point, GE technology and its implementation are changing more quickly than the science that assesses the impacts of technology. The Federal Register notice states that it will be critical to focus regulations on risks associated with organisms, rather than the methods to produce the organisms. However, the latter must not be ignored. It will be essential that updated regulations consider both the technical aspects as well as the scientific basis for GE technology.

Given the history of safe deployment of many GE organisms—particularly crop plants—a number of species may be exempted from the continuing regulatory processes. However,

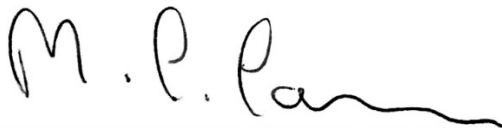
with a broad range of GE organisms deployed throughout entire ecosystems, it will be important to anticipate and understand interactions among primary (target), secondary, and even tertiary (non-target) organisms. With the potential for use of the technology in animals, particularly arthropods, such interactions take on an even greater importance.

The programmatic EIS proposed in Docket No. APHIS-2018-0034 identifies a good list of preliminary aspects for consideration. Because there are many potential consequences—intended and unintended, direct and indirect—the programmatic EIS will need to use a broad perspective when approaching the needed updates to regulations. The recent report issued by the Council for Agricultural Science and Technology (CAST) on “Genome Editing in Agriculture: Methods, Applications, and Governance” (available at: http://www.cast-science.org/file.cfm/media/products/digitalproducts/CAST_IP60_Gene_Editing_D752224D52A53.pdf) touches on a range of topics that are essential for consideration of updated regulations, including the importance of international coordination, economic impacts, and public perception. We encourage APHIS to consider and include the perspectives from the CAST report in the planned programmatic EIS.

We recognize that preparation of a programmatic EIS is only the first step in updating regulations. We also recognize the role played by other federal agencies that, with APHIS, ensure alignment with the Federal Coordinated Framework for the Regulation of Biotechnology. It will be critical that updated regulations are comprehensive yet flexible in implementation, are developed using a risk-based approach, and are based on the best science available.

We thank you for the opportunity to provide comments on this issue. The Entomological Society of America and its many subject-matter experts remain a resource for the Agency, should you need input on any topic of entomological importance.

Sincerely,

A handwritten signature in black ink, appearing to read "M. P. Parrella". The signature is fluid and cursive, with a long horizontal flourish at the end.

Michael Parrella, Ph.D.

President, Entomological Society of America