

September 28, 2021

Ms. Michelle Arsenault  
Advisory Committee Specialist  
National Organic Standards Board  
USDA-AMS-NOP

1400 Independence Ave. SW Room 2642-S, Mail Stop 0268  
Washington, DC 20250-0268

Via Regulations.gov Docket # AMS-NOP-21-0038 NOP-21-05

RE: Materials Subcommittee Excluded Methods Discussion Document August 12, 2021

Dear Ms. Arsenault and members of the National Organic Standards Board:

The American Seed Trade Association (ASTA) represents over 700 member companies involved in seed production and distribution, plant breeding, seed treatment and related industries in North America. Our members produce seed for row crops, vegetables, grasses, and cover crops, and for conventional, genetically engineered, and organic seed markets. ASTA's mission is to enhance the development and movement of quality seed worldwide.

ASTA welcomes the opportunity to provide comments to the Materials/GMO Subcommittee Discussion Document, Excluded Methods Determinations August 12, 2021. Please see below ASTA's comments to the specific questions posed by the discussion document.

**1. Should the NOSB prioritize developing additional criteria for excluded methods determinations before continuing to work on the remaining TBD list techniques?**

We do not support the NOSB developing additional criteria for excluded methods determination. ASTA remains concerned that the NOSB criteria for excluded methods determination exceed the scope set out by the Excluded Methods definition as codified in 7 CFR 205.2. In specific, intellectual property protection (IP) for a particular variety or technique should have no bearing on determining whether a method is an excluded method. The IP protection in relations to organic production was not considered in the Organic Foods Production Act, nor was the issue raised during the NOSB meetings and deliberations (1992-2009) on excluded methods prior to the issuance of the proposed rule. Many conventional varieties including those used widely in organic production may have various intellectual property (IP) protection, such as Plant Variety Protection, utility patents and licensing agreements. The ability to have IP on newly developed varieties is one of the primary means to provide incentives to breeders to develop new varieties and cultivars that meet the specific needs desired by producers, including organic producers.

**2. Is Policy Memo 13-1 complete and applied consistently in organic systems, i.e., do cell fusion and protoplast fusion need to remain on the TBD list or can they be moved to the**

**excluded method section with the notes that allowance is made for these techniques when employed within taxonomic plant families?**

ASTA supports the determinations specified in Policy Memo 13-1. The memo examined cell fusion and protoplast fusion against the definition of excluded methods in section 205.2, and concluded decisively that cell fusion, including protoplast fusion, within the same taxonomic plant family is not an excluded method. The memo further detailed instances when cell fusion techniques are prohibited from the National Organic Program.

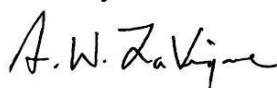
**3. As the NOSB makes excluded methods determinations on the remaining TBD list techniques, should this organic system include allowance for historical use and a time frame for phasing out excluded uses?**

We believe that the excluded methods discussion should be considered in conjunction with NOSB's initiative to strengthen the use of organic seed in certified organic agriculture. In past ASTA comments to the NOSB, ASTA voiced support for efforts, specifically with regards to the proposed Organic Seed and Planting Stock Guidance, to encourage the additional use of organic seed by organic producers. ASTA supports prioritizing the necessary updates to the Guidance to improve organic seed regulation. ASTA also support the timely closure of the on-going NOSB discussion on criteria for excluded method determination, the listing of excluded methods and TBD methods. In particular, the list of TBD methods creates uncertainty and unpredictability for entities that may wish to invest in organic seed development and production.

Planting breeding to bring new improved varieties to growers is a continual process that builds, year upon year, on existing varieties. The development of plant varieties currently in use for organic production and for organic seed development are based on older varieties that are derived from certain methods on the TBD list, for example cell fusion and induced mutagenesis. To fully appreciate the implications of the excluded methods lists for certified organic agriculture, NOSB should seek to better understand how breeding methods may have already been used in the development of seeds used in organic productions. It is important that the excluded methods discussions and recommendations consider the historic use of breeding methods, and do not unintentionally diminish the selection, quantity, and quality of seeds available for organic production.

Thank you for the opportunity to comment.

Sincerely,



Andrew W. LaVigne  
President & CEO