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National Organic Standards Board
USDA-AMS-NOP 1400 Independence Ave., SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

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RE: Materials/GMO Subcommittee Discussion Document: Induced Mutagenesis and Embryo Transfer in Livestock

Thank you for the opportunity to provide comments on the Materials/GMO Subcommittee's discussion document on induced mutagenesis (February 12, 2019). Organic Seed Alliance (OSA) is a mission-driven organization that works nationally to advance ethical seed solutions to meet food and farming needs in a changing world. Our research, education, and advocacy programs foster seed systems that are responsive to the needs of organic agriculture, resulting in more organic seed and more skilled organic seed producers.

OSA appreciates the subcommittee's effort to clarify which plant breeding methods should be excluded from organic production. The methods at issue in this discussion document are those that induce mutations in plants, including heat, UV light, chemicals, irradiation, and x-rays. Providing recommendations regarding these various methods is very difficult because the organic community doesn't readily know the following:

- How frequently these various methods are used in plant breeding programs;
- The extent to which organic growers rely on varieties developed with these methods
- How difficult it would be to create a system for tracing these methods to finished varieties in the marketplace; and
- What ramifications there would be on variety options available to organic growers should induced mutagenesis be wholly excluded.

The answers to these questions are important from an enforcement standpoint since the Crops Subcommittee's proposal, "Strengthening the Organic Seed Guidance April 2019," at **4.1.2** recommends that "Certified operations may use non-organic seed and planting stock only if equivalent organically produced varieties of organic seeds and planting stock are not commercially available, **and the conventional replacement variety can be documented as being produced without the use of excluded methods.**" Seed companies would be greatly challenged to provide, and at times would be unable to provide, this documentation for methods that have already been determined, or may soon be determined, as excluded, including varieties developed through induced mutagenesis. The lack of clarity both in terms of methods still listed

as TBD and what breeders and companies are supposed to do in instances where excluded methods can't be traced in the pedigrees of their material could prove very disruptive to plant breeders and seed companies. Variety development requires years of investment and advance planning and this kind of uncertainty could lead to a chilling effect on organic breeding, especially if there are crop sectors where mutagenesis had been widely used historically. Unlike some of the more modern techniques, induced mutagenesis has a long history of use.

OSA's current position on induced mutagenesis is that it's too soon to exclude these methods without more information, including having adequate answers to the questions bulleted above.

While many questions remain, what we do know is that plant breeders and seed companies serving organic farmers need more clarity on which methods the National Organic Program considers excluded. Ideally this clarity would be coupled with practical routes for fostering transparency and communication between breeders, seed companies, and organic farmers.

In addition, more attention must be given to how allowable plant breeding methods can be better embraced and enhanced. The issue of excluded methods brings into sharp relief the question of how we use our plant breeding resources. We should answer this question through the lens of needing more genetic diversity in the field and seed marketplace. We need to focus our investments in areas where we'll get the most gain, and plant breeding investments aimed at developing a robust organic seed system must be guided by the same principles that underpin organic agriculture: diversity, health, care, and fairness.

1. Using the NOSB recommendation on the criteria to determine a technology as genetic engineering, please provide information on which technologies that result in induced mutagenesis could be considered an excluded method under organic production and why? These would include induced mutagenesis caused by irradiation, x-rays, heat, UV light, and a variety of chemicals.

The criteria listed in the discussion document are prefaced with: "In 2016 the NOSB recommended the following criteria be used to assess emerging technologies and determine if they should be excluded from organic production." Our understanding is that the criteria is to be used to determine whether a method should be excluded, not whether it fits the definition of genetic engineering – these are two different things. The question isn't clear, and we're unprepared to answer it at this time.

2. Using the NOSB recommendation on the criteria to determine a technology as genetic engineering, please provide information on which technologies that result in induced mutagenesis could be considered not an excluded method under organic production and why? These would include induced mutagenesis caused by irradiation, x-rays, heat UV light, and a variety of chemicals.

Same answer as above.

3. Should the random or targeted aspects of induced mutagenesis be considered when determining if a technology should be excluded?

There are no methods of mutagenesis that never cause any non-random mutation, although gene-editing techniques (e.g., CRISPR-Cas9) are claimed to have a lower frequency of random events. The current gene-editing technologies have already been determined by the NOSB to be

excluded. Generally speaking the various forms of induced mutagenesis fit onto a spectrum in terms of random versus targeted, with irradiation causing random mutations, chemicals inducing not entirely random mutations (different classes of compounds induce different mutations), and gene editing tools, such as CRISPR-Cas9, providing site-specific mutations, but sometimes to other sites in addition to the targeted site. Whether a mutation was targeted or not shouldn't be a defining factor – the actual method should be. Furthermore, it's not entirely clear to us how "targeted" is defined, since activating transposable elements under drought or heat stress, for example, could be considered a targeted mutation. Is "targeted" defined as desirable?

4. How do epigenetic implications affect the determination of whether the method is to be excluded? Are there some types of epigenetic methods that could be allowed or not allowed?

Scientists are still learning about the spectrum of tools available and used to influence epigenetics. We need more specificity on the proposed epigenetic tools to comment.

5. Would there be any effects on currently accepted varieties, cultivars, or breeds if induced mutagenesis was determined to be excluded? Be specific.

We know that organic growers rely on varieties that were developed using induced mutagenesis. Should some forms of mutagenesis be excluded in the future, it will be necessary, in our view, to consider varieties that organic growers currently rely on, that were developed with these methods, as grandfathered in to ensure no disruption to their operations, especially given the inability to trace these methods in all cases. It is also important to remember that plant breeding is an iterative process, and desirable traits are passed along from one variety to the next through continual cross-pollination. While a variety could theoretically be excluded from use in organic production, it would be very hard to ensure that the particular traits found in that variety do not appear in other varieties simply through traditional plant breeding processes. It is the traits themselves (such as leaf color, disease tolerance, or skin thickness) that are potentially altered by technologies such as mutagenesis. How widely they are then disseminated in multiple varieties once the trait is developed is very hard to determine.

Finally, if some forms of induced mutagenesis are determined excluded in the future, we suggest there be a reasonable sunset period and that the NOSB consider the appropriateness of excluding these methods in organic seed, conventional seed, or both.

Summary

We're grateful for the subcommittee's efforts to unpack such a complicated area of plant breeding. This area of excluded methods requires much more conversation with affected stakeholders. We look forward to future opportunities to work with you on ensuring a strong decision-making process for excluded methods that provides more clarity for the organic community and supports the ongoing growth and integrity of the organic seed sector.

Sincerely,



Kiki Hubbard

Director of Advocacy & Communications