

## MEMORANDUM

To: Advisory Panel to Better Understand and Make Recommendations Regarding the Implications of Genome-editing Technology for the Citizens of the State

From: Office of Policy and Legal Analysis Staff

Date: September 21, 2022

Re: **Types of genetic engineering prohibited in organic farming and processing**

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At the second Advisory Panel meeting on September 7, 2022, members inquired about the types of gene-editing technologies prohibited in organic farming under applicable federal regulations.

Regulations promulgated by the U.S. Department of Agriculture's National Organic Program (NOP) direct that "To be sold or labeled as '100 percent organic,' 'organic,' or 'made with organic (specified ingredients or food group(s)),' a product must be produced and handled without the use of . . . (2) Excluded methods, except for vaccines: Provided, That, the vaccines are approved in accordance with § 205.600(a) . . . ." [7 C.F.R. § 205.105\(e\)](#).<sup>1</sup> NOP regulations define "excluded methods" as:

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

[7 C.F.R. §205.2](#). In 2011, the NOP issued a Policy Memorandum regarding genetically modified organisms (*attached*), explaining that inadvertent cross-contamination does not constitute a violation of the excluded methods regulations if organic producers and processors "have verifiable practices in place to avoid contact with GMOs."<sup>2</sup> In addition, a NOP Policy Memorandum from 2013 regarding cell fusion techniques used in seed production (*attached*) demonstrates the complexity of differentiating between emerging technologies the NOP concludes "are not possible under natural conditions" (ex: cell fusion where the donor cells are from different taxonomic plant families) and technologies the NOP concludes are permissible because they have "been a part of traditional breeding programs for many years without being considered genetic engineering" (ex: in vitro fertilization and fusion of cells from the same taxonomic plant family).<sup>3</sup>

The National Organic Standards Board (NOSB), which is comprised of organic farmers and processors, scientific experts and other industry stakeholders, was established by federal law "to assist . . . in the development of standards for substances to be used in organic production." [7 U.S.C. §6518](#) (2022). In November 2016, the NOSB recommended that the NOP "develop a formal guidance document for the determination and listing of excluded methods." This recommendation, which has been refined several times but has not been adopted by the NOP, establishes four criteria to determine whether specific methods should be included in a table of excluded methods developed by the NOSB. The most recent NOSB recommendations (from April 28, 2022) regarding its proposed excluded methods table are attached.<sup>4</sup>

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<sup>1</sup> See also [7 C.F.R. § 205.301\(f\)](#) ("All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not: (1) Be produced using excluded methods . . ."); [7 C.F.R. § 205.670\(b\)](#) (If there "is reason to believe that [an] agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods," "preharvest or post harvest testing" may be required).

<sup>2</sup> Available at <https://www.ams.usda.gov/sites/default/files/media/OrganicGMOPolicy.pdf>.

<sup>3</sup> Available at <https://www.ams.usda.gov/sites/default/files/media/NOP-PM-13-1-CellFusion.pdf>.

<sup>4</sup> Available at <https://www.ams.usda.gov/sites/default/files/media/MSExcludedMethodsFinalRecApril2022.pdf>.