



Policy Memorandum

To: Stakeholders and Interested Parties

From: Miles McEvoy, Deputy Administrator

Subject: Cell Fusion Techniques used in Seed Production

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The USDA organic regulations at 7 CFR 205.105(e) prohibit the use of excluded methods (genetically modified organisms) in organic production and handling. The definition of excluded methods at section 205.2 includes cell fusion as both an allowed traditional breeding technique and as a prohibited method. The National Organic Program (NOP) recently received questions about whether seed varieties produced through cell fusion techniques are allowed in organic production. The NOP stresses the importance of encouraging organic seed production and preservation of genetic diversity in organic crops. Organic farmers also rely on traditional seed germplasm as foundation for new organic varieties and when equivalent organic varieties are not available. This policy memorandum clarifies that use of certain traditional breeding techniques that involve cell fusion should not be considered excluded methods, while those cell fusion techniques that involve recombinant DNA technology or cell fusion of plant cells from different taxonomic families are prohibited for use in organic production. The NOP will consider development of future guidance or regulations if necessary regarding standards for organic seed production, however, this policy memorandum applies to techniques used in seed production in general.

Cell fusion is not defined in the USDA organic regulations but it is included under the definition of excluded methods. Excluded methods are defined at section 205.2 as:

Excluded methods. 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.



“Cell fusion” is a general term that has not been explicitly defined in context of the USDA organic regulations. In the scientific literature, cell fusion is defined as the fusing of two cells to form a single cell. Natural cell fusion is integral to plant growth; egg fertilization is one example. In plant breeding programs, cell fusion is used in many traditional breeding and hybridization programs as well as in general propagation using tissue culture.

In a method known as somatic cell hybridization or protoplast fusion, cell walls of different plants are removed using enzymes, and the protoplasts (naked cells) are then fused with the help of chemical or electric stimuli. The resulting cells have a combination of genetic material from both plants, and are then grown in tissue culture to develop into fully differentiated plantlets.

There are hundreds of plant varieties, particularly in the Brassica family, that have been developed using this technique to confer traits that are useful in hybrid breeding programs, especially the trait of cytoplasmic male sterility. According to plant breeding literature, cell fusion techniques have been used for many years to confer traits of disease and pest resistance in other crops including tomato, potatoes, rice, citrus, and tobacco.

Specific identification of crop varieties that have been produced using cell fusion techniques is not always known, and it may be difficult for producers or seed handlers to identify all varieties that may have had some traits incorporated using a cell fusion technique at some point in their breeding history.

Based upon this information on the use of cell fusion in traditional breeding, the NOP reviewed cell fusion in the context of the excluded methods definition at section 205.2.

1. The first sentence is a general statement of principles and ethics: excluded methods are those not possible under natural conditions, and not compatible with organic production.
 - “Not possible under natural conditions” – does not rule out use of cell fusion within plant families. Traits transferred using cell fusion techniques, such as male sterility, may also be accomplished via natural breeding techniques in many cases, though it is a slower process.
 - “Compatible with organic production” – is a subjective determination. If cell fusion using parent lines of the same plant family is able to produce varieties that are resistant to pest and diseases that are not otherwise available, and does not present harm to ecosystem or human health, it could be considered compatible with organic systems.
2. The second sentence states a list of methods deemed excluded, including cell fusion.
 - Cell fusion, (and two other terms) are not explained or defined. Cell fusion is a broad general term used in medical, animal, and plant science. It means combining of two cells and can occur in natural systems or via human intervention. A literal reading that cell fusion is always prohibited, would mean



that pollination of flowers, and subsequent fusion of pollen tube cells and ovaries is prohibited in organic production.

- The second sentence does provide some guidance that techniques that involve gene deletion, gene doubling, and recombinant DNA technology are considered excluded methods.
3. The third sentence provides a list of practices not considered to be excluded methods; including traditional breeding, hybridization, in vitro fertilization, and tissue culture. All these practices may involve cell fusion, so this sentence helps clarify the meaning of the previous sentence.
- Cell fusion has been a part of traditional breeding programs for many years without being considered genetic engineering. Mutagenesis (treatment of plants with radiation or chemicals to induce random mutation) is considered part of traditional breeding programs.
 - A common cell fusion technique is known as “somatic cell hybridization” to transfer cytoplasmic male sterility into parent lines used in broccoli and cabbage breeding programs; these are used to produce F1 hybrids, and are thus a hybridization technique.
 - In vitro fertilization involves fusion of gametes to produce embryos and would not occur in nature, but is a type of cell fusion.
 - Cell fusion occurs in tissue culture, when undifferentiated callus tissue is treated to induce somatic embryos (asexual reproduction) that develop into normal plants.

Conclusion:

The NOP concludes that cell fusion techniques are an excluded method when the donor cells/protoplasts do not fall within the same taxonomic plant family. Cell fusion is an excluded method when the donor or recipient organism is derived using techniques of recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology), and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism (such as microinjection).

However, the NOP further concludes that cell fusion (including protoplast fusion) is not considered an excluded method when the donor cells/protoplasts fall within the same taxonomic plant family, and when donor or recipient organisms are not derived using techniques of recombinant DNA technology.

Organic operations must continue to provide verification to their certification agents that seeds used on organic operations are not derived from excluded methods. Cell fusion techniques that are considered prohibited include:



- Use of a donor or recipient organism that is derived using techniques of recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology),
- Techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism (such as microinjection).
- Use of donor cells or protoplasts that do not fall within the same taxonomic plant family.

Seeds that are produced using traditional breeding techniques and that do not involve prohibited methods as identified above are not considered excluded and may be used in organic production.