

March 18, 2013

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So, Ag Stop 0268
Washington, DC 20250-0268
Docket: AMS-NOP-12-0070
RE: GMO ad hoc committee

Dear Ms. Arsenault:

Thank you for this opportunity to comment to the NOSB. Nature's Path is North America's first and still largest certified organic breakfast cereal manufacturer, and our highest priority is to keep organic standards strong and to prevent GMO contamination.

Re: Terminology for Excluded Methods

The definition of "excluded methods" in the Organic rule needs to be revised. It needs to be updated to reflect new developments, new understanding, and new concerns that have evolved over a decade after it was first defined in the NOP.

Updating of the definition should seek to clarify it to avoid vague or multiple interpretations being possible. Dissecting the current definition, the following are my comments on each:

Current standard reads:

1. 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.

This sentence of the current definition has two problems:

- a) Use of the word "modify". This word is not commonly used to exclusively describe genetic engineering. All natural breeding includes modifying organisms, thus causing confusion of the meaning.
- b) Referencing "natural conditions" is confusing without a further definition of "natural conditions".

We suggest that this sentence be substantially changed as it does not add significantly to the definition.

Current standard reads:

2. 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).

The list of methods listed needs to be updated to reflect current reality and science. Instead of listing individual techniques, overall classifications need to be made. As new technologies are developed there is a better chance of these being covered.

Current standard reads:

3. Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

This list of methods that are not included needs to be updated to accurately describe the current sciences that would not be prohibited by "excluded methods". Again overall classifications need to be made.

In general Nature's Path supports a definition that clearly draws a line between genetic engineering and natural breeding, (including classical breeding and modern breeding). The defining factor should be that genetic engineering includes removing and inserting genes either between species, among the same species, or in the same organism (moving genes around in the DNA sequence). Technical terms for these methods could include: *Recombinant DNA non conjugating* techniques including transgenic (intraspecific or intergeneric), or sisgenic (intrageneric) transfers of genes*.

What should not be included in the definition of "excluded methods" and thereby not banned from use in organic growing, processing or animal feed/medication would be the results of *all other natural, classical, or modern breeding techniques*. This does not mean that organic operators can use all or any of these other methods for production of certified organic seeds, animals or substances, but if for instance a non organic seed is qualified to be used in organic production through other exceptions in the standard (e.g. commercial availability), it could have been bred using the methods not covered by the "excluded methods" definition.

The fundamental issue with genetic engineering or excluded methods is that this science is not bound by the natural boundaries inherent in nature. These boundaries include

- a) Boundaries between species, e.g. bacteria and corn plants do not cross pollinate, breed or conjugate in any other way.
- b) Moving genes in the sequence of DNA around within a species or single organism, e.g. genes are not able to be manipulated to predictably change position in the

sequence of DNA in any organism through any breeding or conjugation process whether it be all natural or assisted with classical or modern breeding techniques.

These boundaries <u>do apply</u> as limitations to natural, classical and modern <u>breeding</u> techniques. It <u>is the overriding of these boundaries that is objectionable in organic systems</u>. The philosophy that organic is based on is to mimic and strengthen nature. Genetic engineering is clearly a sharp departure from mimicking, and seeks deliberately to interfere and/or alter organisms beyond and without regard for nature's boundaries.

The timeline of the evolution of breeding techniques should not be used as a factor for establishing what is considered GMO and what is not. It should be based on the above mentioned boundaries. The use of methods of genetic engineering, and the presence or not of genes altered through genetic engineering in primary source materials should remain the criteria.

Proposed new definition of Excluded Methods:

Methods that change the genetic material of an organism through recombining DNA**** through laboratory methods and in ways that are not dependent on the use of conjugating, sexual or asexual reproduction methods, including transgenic (intraspecific or intergeneric), or sisgenic (intrageneric) transfers of genes. Methods not included in the definition are; other natural, classical, or modern breeding techniques that depend on movement of genes only through a conjugative, sexual or asexual reproduction method with parent gene material from within the same taxonomic family.

Proposed addition of definition for Conjugation*:

- (1) The process whereby two ciliates come together in a temporary fusion to exchange micro-nuclear material, then separate, each being a fertilized cell.
- (2) A form of sexual reproduction in certain algae and fungi where a male gamete unites with a female gamete resulting in the union of their nuclei and the subsequent formation of a zygote.
- (3) The temporary joining together of two bacterial cells to transfer genetic material via the plasmid (either as solitary or as part of a chromosome) from the donor cell to the recipient cell.

Proposed addition of definition for sexual reproduction**:

A mode of reproduction involving the fusion of female gamete (ovum) and male gamete (spermatozoon), which forms a zygote that potentially develops into genetically distinct offspring.

Proposed addition of definition for asexual reproduction***:

A form of reproduction that does not involve meiosis, ploidy reduction or fertilization, and the offspring is a clone of the parent organism; because of no exchange of genetic material.

- * http://www.biology-online.org/dictionary/Conjugation
- ** http://www.biology-online.org/dictionary/Sexual reproduction
- *** http://www.biology-online.org/dictionary/Asexual reproduction
- **** http://en.wikipedia.org/wiki/Recombinant DNA

Re: GMOs and Seed Purity

The NOP organic standards were based on standards that were developed before the advent of genetic engineering. Since GMOs entered the agricultural landscape, NOP added them as an excluded method, but did not add any other specific guidelines for how to deal with it. Certifiers simply had to react and find a way to deal with it in the practical world. The common way to address GMOs was to assume that since it's a prohibited material in organic food production, similarly to *synthetic pesticides or fertilizers*, the same approach was superimposed on dealing with GMOs. At this point 17 years after the commercial introduction of GMOs in agriculture, it's time to evaluate this in more detail.

The most concerning shortcoming of the current standard is that even though it does prohibit GMOs in organic food production, it does not prescribe the use of the necessary tools to prevent GMO contamination from increasing in organic. This must be addressed so we don't allow uncontrolled contamination to start creeping into organic food production.

We find that even though there are similarities between other prohibited substances and GMOs, there are significant differences, which we believe means that the standards must also treat GMOs differently. One of the basic differences is that other substances prohibited in organic are passive in that they do not multiply in the environment, they disperse and dilute over time. They also degrade and decompose into other substances over time (some longer than others). This is why it makes sense to regulate these prohibited materials in organic agriculture by focusing on banning the practices that add the substances deliberately, and prescribe practices aimed at preventing deliberate or adventitious contamination from known sources (process based standard versus a purity based standard). Genetic engineering on the other hand is not a substance, but rather the building blocks of life-forms that have been artificially altered. These resulting living organisms do not dilute, diminish or degrade over time; however they do carry the GMO feature forward through breeding where the offspring carries forward the altered gene sequences in their DNA. This breeding can be intentional such as when grains are planted and new grains (seeds)

that are viable are the result. Also GMOs can be increased in the environment through unintentional breeding with feral crops or weeds or through cross pollination with organic crops, for instance through wind-born pollen, birds, bees, or seed spills.

Other prohibited substances are effectively dealt with by the prescribed practices (process based) standard. If they are not intentionally added, and cross contamination exposure is limited, over time they will disappear from organic production units to the background levels.

We feel it is very important that this distinction is understood, and that the NOP is modernized to reflect this reality. Currently the NOP is dealing with GMOs as if they are on the same level of threat to organic integrity as synthetic pesticides or fertilizers. In order to correct this, the NOP needs to add two specific tools which are essential in order to require reasonable practices to protect the organic integrity of products. These two tools are needed precisely because of the feature of GMOs being artificial alterations made to living and reproducing organisms. If this was not so, it would remain adequate to treat GMOs in the same way as other prohibited substances.

We are not proposing that the principle of the organic standard being a "process based standard" is faulty or that it should be departed from. Rather we are arguing that no meaningful "practice or process" has been required to safeguard organic from GMO contamination.

In order to prevent increasing levels of GMO contamination in organic it is not enough to forbid intentional use and limit exposure to contamination. If it diminished, diluted and degraded over time this would be adequate, however because GMOs reproduce and increase once released, a methodical reduction of GMO contamination can only happen through:

- a) Accurate routine detection (testing)
- b) Limiting below a set level (threshold)

Without accurate detection methods GMOs cannot be seen. Unlike pesticides that come in jugs with labels, GMOs are unmarked and cannot even be detected without destroying them. There is no way currently to, for instance, take a handful of corn and pick out the GMO seeds from the rest. What this means is that if we do not consistently utilize modern scientific testing methods a farmer cannot know if he/she is planting a GMO contaminated crop or not or to what level the contamination is present. Without mandated testing for GMOs in organic there is no way of knowing if GMO contamination is increasing year by year through GMO contaminated seeds cross-breeding with the uncontaminated part of crops.

Once testing is required, organic farmers must be protected. Unfortunately the reality today is that even organic farmers cannot fully escape GMO contamination, yet it is not allowed by the current standards. What liability is it to an organic farmer to have GMO contaminated crops then? How much does that liability increase with increased levels of contamination? Even though the standards don't currently set a threshold, we all know that organic consumers are not going to accept significant levels of GMO contamination even if it is unintentional. The threshold we are proposing is primarily for the purpose of protecting the organic farmer, so there is an "organic farmer safe zone" where they will not be penalized. After all this is not caused by the organic farmer and we must not make them the ones taking on full liability of the problem, and at the same time help farmers reduce contamination to the absolute minimum. The other thing that a threshold accomplishes is to set a goal which will have the effect of driving contamination down below the level set.

Neither of these two tools are currently prescribed by the NOP organic standards, and we propose that they need to be. In order to keep organic products as a current and viable option for consumers both domestically and abroad, the standards need to be updated to deal with new realities.

If the organic standards are not updated, organic will lose its place as the Gold Standard for environmental and personal health, and standards such as the Non GMO Project will start to capture more consumer trust, thus eroding the effectiveness of the organic system. At Nature's Path we do not feel the current organic standards are sufficient to address the GMO problem, nor of ensuring product integrity to consumers, therefore we have enrolled our products for Verification with the Non GMO Project.

Testing methods:

The methods available today for detection of GMO contamination and quantification are *Strip tests* and *Laboratory PCR* test. We have been testing all our GMO risk ingredients for many years now, using the Lab-PCR method. We also utilize strip tests at various stages of the supply chain to reduce surprise spikes, however we only consider the PCR test as fully reliable. Strip tests are also useful, but some GMO events are not detectable by this method, making it unreliable for a total guarantee of levels present. These tests are capable of detecting levels down to 0.01%. We strongly propose that the NOP should prescribe the use of this common PCR system of detection, and that maximum contamination levels (for the protection of farmers) should be expressed in the common language of percent. The committee proposed system of calculating number of seeds in a sample seems convoluted and we have to wonder if this will not confuse consumers? We favor clear up front communication. It's already well established by the Non GMO Project Standard that 0.9%, or less is

easily understood, and achievable. Reinventing a new system for expressing contamination levels will only serve to alienate consumers from organic.

Considerations for setting a threshold:

- The purpose: to protect farmers so they have a safe space to operate without penalties.
- Level: Our multi-year experience tells us that 0.9% in ingredients is achievable, but does require significant diligence, and rejections have not been uncommon.
- To achieve 0.9% in ingredients, seed thresholds probably need to be set at 0.5%.
- Setting the threshold too low will cause hardship for farmers. Setting the threshold too high will negatively affect our product purity and consumer acceptance.
- A threshold is not a tolerance or acceptance of GMOs. We do not think organic should accept or tolerate any level of GMO contamination. A threshold is a practical way to ensure farmer protection, and to make it possible to measure and achieve continuous improvement.
- As soon as possible the threshold should be reduced until the day GMOs are eradicated.

Thank you for the opportunity to comment.

Respectfully,

Dag Falck

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