

## GMO Ad-hoc Subcommittee

### Excluded Methods Terminology

#### **CFS Supports the Current Definition of Excluded Methods**

CFS agrees with the Ad Hoc Subcommittee that the organic community needs additional clarity around the meaning of words used in connection with excluded methods. Even so, it is important to underscore the point that “excluded methods” clearly prohibits genetically engineered organisms and processes. Nonetheless, we believe that before any clarifications are made, it is crucial to understand the extent to which certain technologies are being proposed or used in organic production so that we can focus our energies on conducting meaningfully technology assessments and evaluations of the implications for the organic sector. When the time comes for clarification, CFS urges the NOSB to use non-regulatory vehicles, such as Guidance documents and policy statements, to clarify the rule, as was intended by the drafters of the final organic rule.

*The definition of “excluded methods” in the Organic Rule does not need to be revised.*

The regulatory history of “excluded methods” illustrates the plain intention of the Rule’s drafters to create a broad standard that can be clarified through Guidance and policy statements. It is well known that when NOP released the first draft Organic Rule and invited public comment, the proposed allowance of genetically engineered (GE) organisms in organic farming and handling was vehemently opposed.<sup>30</sup> NOP received an astounding 275,603 comments strongly opposing GE and, accordingly, the NOSB created a special definitional category for GE “in the broad definition of excluded methods.” As the drafters explained: “[s]ince the use of excluded methods in the production of organic foods runs counter to consumer expectations, foods produced with these methods will not be permitted to carry the organic label.”<sup>31</sup>

The broad definition of excluded methods was drafted with the understanding that if and when technologies advanced, the NOSB and the NOP could provide the necessary clarification.<sup>32</sup> Congress also cautioned that “as time goes on, various scientific breakthroughs, including biotechnology techniques, will require scrutiny for their application to organic production.”<sup>33</sup> Therefore, the definition created “a degree of flexibility to ensure that the regulations could continue to accurately reflect industry practices and consumer preferences.”<sup>34</sup>

As the regulatory history illustrates, the definition of excluded methods was never intended to be re-written as technologies advanced; it was intended to be the benchmark against which new and emerging technologies are weighed and considered for allowance in organic production systems. After adequate exploration, discussion, and feedback from the organic community, the NOSB and the NOP can provide clarification through new Guidance documents or policy statement, as is intended by the

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<sup>30</sup> 62 Fed. Reg. 65850, 65875 (Dec. 16, 1997).

<sup>31</sup> 65 Fed. Reg. 13512, 13513-14 (Mar. 13, 2000).

<sup>32</sup> 65 Fed. Reg. 13512, 13521.

<sup>33</sup> 62 Fed. Reg. 65850, 65875.

<sup>34</sup> *Id.*

rule. Of course, this cannot be undertaken without a deeper understanding of the extent to which certain technologies are being used in organic production and any implications, positive or negative, for their use. Examining data on crop varieties called into question by this discussion, as well as surveying farmers and seed breeders about the techniques they are using, is necessary for creating a useful Guidance document that increases organic integrity.

*The terms “natural conditions” and “traditional breeding” should not be replaced. We can look to international definitions for further clarification.*

As this debate ensues, CFS argues that the current definition of excluded methods is a strong definition that is consistent with international regulatory frameworks regulating biotechnology. For example, the Food and Agriculture Organization of the United Nations (FAO) defines genetically engineered organism as: “products...produced by using techniques that alter the genetic material of an organism in a way that does not occur naturally by mating and/or natural recombination. Techniques of genetic engineering include, but are not limited to: recombinant DNA, cell fusion, micro- and macro-injection, encapsulation, gene deletion and doubling. GMOs do not include organisms resulting from techniques such as conjugation, transduction and hybridization.”<sup>35</sup> This definition is substantially similar to the current NOP definition of excluded methods.

The Cartagena Protocol definition (also adopted by Codex Alimentarius) states that “[a] living modified organism is defined as any living organism that has a combination of genetic material obtained through the use of modern biotechnology, namely: (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in conventional breeding and selection.”<sup>36</sup> While this language is more specific, the underlying theme of the definition is the same. However, the distinctions presented by the Cartagena protocol definition could also be used to inform a newly created Guidance document.

For example, there has been much debate over the inclusion of the term of “cell fusion” in the existing NOP definition. Some argue that excluded “cell fusion” should be restricted to “cell fusion outside the taxonomic family.”<sup>37</sup> Others argue that restricting cell fusion to the taxonomic family still allows for crosses that would not be permissible “in nature”, since most families include genera that cannot cross with each other.<sup>38</sup> The Cartagena protocol definition of modern biotechnology has adopted the narrower definition, which excludes only cell fusion outside the taxonomic family. The NOP’s recent Policy Memorandum on cell fusion techniques used in seed production also adopts this view.

Notably, the Subcommittee’s discussion document argues that the phrase “not possible under natural conditions or processes” has become problematic in the context of traditional breeding methods that involve disruption of normal plant cell growth, such as mutagenesis. Yet the drafters of the rule recognized the phrases “natural conditions or processes” and “not considered compatible with organic

<sup>35</sup> FAO. Section 2: Description and Definitions. Available at: <http://www.fao.org/DOCREP/005/Y2772E/y2772e04.htm>.

<sup>36</sup> Convention on Biological Diversity. 2013. The Cartagena Protocol on Biosafety. Available at: <http://bch.cbd.int/protocol>.

<sup>37</sup> See Miles McEvoy. 2013. Cell Fusion Techniques Used in Seed Production. February 1, 2013. Available at: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5102380>

<sup>38</sup> Martha Crouch, Ph.D. February 13, 2013. Personal communication by phone.

production” may be subject to interpretation. But, they decided to retain the language because it was consistent with other earlier NOSB and American Organic Standards definitions, both of which were the result of consultation with organic industry and consumer stakeholders and, thus, accurately reflected current industry practices as well as consumer preferences.<sup>39</sup> CFS takes no issue with “natural conditions” or “traditional breeding” and believes this language is consistent with national and international standards. However, the FAO definition could help clarify the underlying idea — “techniques that alter the genetic material of an organism in a way that does not occur naturally by mating and/or natural recombination.”

Additional clarity will come when the organic community agrees upon what exactly it is about a genetic modification process that is objectionable in the organic context. It may be useful to start with the NOSB Principles of Organic Production and Handling adopted October 17, 2001. The principles state that organic agriculture “tak[es] into account that regional conditions require locally adapted systems.” Locally-adapted varieties possess a range of genetic traits that allow them to thrive in under a wide range of local conditions. That is because they belong to the system in which they are grown, both evolutionarily and ecologically. Conversely, GE organisms are developed for specific traits, ignoring both pleiotropic effects of the genetic manipulations and the genetic vigor that evolves through whole organism selection.

Another objectionable aspect of GE is that it decreases the biological diversity of seeds available in the market place, and it inhibits local seed breeding because farmers are prohibited from saving and adapting GE seeds for their local planting conditions. Again, this contravenes the NOSB’s Organic Principles which stress “the enhancement of biological diversity,” as a central, defining characteristic of ecological production systems of organic agriculture.

*There are terms beyond those in the discussion document that should be addressed in the context of excluded methods.*

Several new methods of plant breeding are being used that are not listed in the discussion document, and to that end, CFS has also submitted to the docket three articles that discuss new technologies that are “tiptoeing around transgenics.”<sup>40</sup> Some of these methods employ recombinant technologies that obviously fall within the excluded methods definition. For example, a class of new technologies involves using genetically engineered plants for specific purposes such as faster growth or maintaining a parental line early in the breeding process, but leaving the transgenes behind at some stage before seeds are provided to growers, so that the crop itself does not contain engineered genes. Examples include FasTrack fruit trees and SPT hybrid corn.<sup>41</sup> Other technologies should be evaluated if, after

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<sup>39</sup> 65 Fed. Reg. 13512, 13521.

<sup>40</sup>Kuzma J, Kokotovich A (2011) Renegotiating GM crop regulation. EMBO reports 12: 883–888; Podevin N, Devos Y, Davies HV, Nielsen (2012) Transgenic or not? No simple answer! EMBO reports 13: 1057 – 1061; Waltz E (2012) Tiptoeing around transgenics. Nature biotechnology 30: 215–217.

<sup>41</sup> Waltz E (2012) Tiptoeing around transgenics. Nature biotechnology 30: 215–217. The FasTrack system involves engineering fruit trees such as plums with genes from poplar trees so that they flower when they are younger, thus allowing them to be bred earlier. Similarly, Dupont/Pioneer is using a new technology for hybrid corn production that they

surveying growers, they could be<sup>42</sup> or are currently being used in organic systems, as discussed previously. In the interest of preserving the integrity of organic, CFS strongly recommends that the NOSB take precautionary action and adopt a moratorium on techniques that have yet to be evaluated until clarification is possible.

### *Conclusions*

CFS appreciates the efforts of the GMO Ad Hoc Subcommittee to clarify those thorny issues that pertain to “the use of GE organisms” and other technologies that “influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production.”<sup>43</sup> However, the original definition of “excluded methods” must be left intact in the Rule, and any clarifications that NOSB makes to encompass new and emerging technologies must be contained in Guidance or policy statements. We believe that this is in the best interest of protecting organic integrity, holding organic to the highest production standards, and ensuring consumer confidence in the National Organic Program and label.

## **Handling Subcommittee**

### **Sugar Beet Fiber**

According to the Organic Foods Production Act, the National List may provide for the use of substances in an organic farming and handling operation that are otherwise prohibited under the Act, *only if* the Secretary determines that the use of such substances: (i) would not be harmful to human health of the environment; (ii) is necessary to the production or handling of the agricultural product because of the unavailability of a wholly natural substitute; and (iii) is consistent with farming and handling.<sup>44</sup> Sugar beet fiber woefully fails to meet these factors. Sugar beet production and beet sugar extraction are both chemically-intensive and environmental destructive processes. Allowing the byproduct of these processes in organic foods directly conflicts with the principles of organic production and handling. Moreover, no evidence has been presented either by the petitioner or Subcommittee to demonstrate that sugar beet fiber is essential in organic production—it must remain off the National List.

### *Sugar beet production degrades the environment*

A critical factor in determining whether a production or handling substance should be added to the national list is whether “the substances manufacture, use, and disposal [will] have adverse effects on

call SPT (Seed Production Technology). Pioneer developed a genetically engineered “maintainer line” that restores fertility in order to be able to self the lines and recover seeds. This engineered maintainer line is only used to maintain the female inbreds, and the transgenes do not appear in hybrid production fields or in the seeds sold to farmers.

<sup>42</sup> For example, some of the new technologies are designed to create specific mutations in the existing genes of a crop. Recombinant DNA is often used to create the mutations, but this DNA degrades within the initial plant cell and is not present in regenerated plants and subsequent crops. This is being used by Cibus in a process they call RTDS (Rapid Trait Development System), and crops are already being field-tested that were produced with this method.<sup>42</sup> A case study with details of how this system works, including a few possible end results, such as potatoes with virus resistance and corn with drought tolerance, would be useful in determining how the organic community feels about targeted mutagenesis, electroporation of DNA into microspores, and other new methods of plant breeding.

<sup>43</sup> Excluded Methods definition, 7 CFR §205.2 Terms Defined.

<sup>44</sup> 7 U.S.C. § 6517(c)(1)(A)(i)-(iii)