CENTER FOR FOOD SAFETY

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National Organic Standards Board
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Center for Food Safety Comments to the National Organic Standards Board

The Center for Food Safety (CFS) is a non-profit membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and sustainable agriculture. Our list of True Food Network members has rapidly grown to include over two hundred thousand people across the country that support organic food and farming, grow organic food, and regularly purchase organic products.

Our comments address the following issues: oxytetracycline, polyoxin D zinc salt, excluded methods, sugar beet fiber, other ingredients, confidential business information, and public communications.

Crops Subcommittee

Oxytetracycline

CFS opposes 2016 oxytetracycline extension

CFS does not support the Crops Subcommittee recommendation to extend the use of oxytetracycline until 2016. While the Subcommittee's recommendation includes language early in the document that emphasizes its commitment to phasing-out antibiotic use,[1] the remainder of the text suggests otherwise. The majority position rationalizes the use of antibiotics and minimizes the risks associated with oxytetracycline, presenting an understated and sometimes even misleading picture of the true threats oxytetracycline poses. In addition, the call for "increased support for research"[2] is the same call that the organic community has heard from the NOSB for years, but to no avail. As such, the Subcommittee's recommendation does not convey to the organic community a strong message or

[1] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline. February 5.
[2] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline. February 5.

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commitment by the NOSB to remove antibiotics from organic production. We urge the NOSB to provide language to accompany its final decision on the petition that clearly states the principle that antibiotics do not belong in organic production systems.

CFS supports the minority position to maintain the existing oxytetracycline expiration date of October 2014 and to reject the petition to extend its use until 2016. As the minority position clearly demonstrates, the use of antibiotics for fire blight control in apple and pear production fails the three applicable NOSB material review criteria mandated by the Organic Foods Production Act (OFPA): (i) environmental and health impacts, (ii) compatibility with organic principles, and (iii) essentiality of the material. This clear and objective assessment of the unacceptability of oxytetracycline in organic provides the necessary and sufficient basis for the eliminating oxytetracycline at the earliest opportunity—the current 2014 expiration date. The NOSB has provided ample warning that oxytetracycline would not be available for organic growers indefinitely, as the original listing in 1995 and all subsequent reviews have clearly indicated. We believe that the intervening 18 years has been enough time for skilled growers to identify the workable cultural practices and substitute materials needed to put the organic apple and pear growing industry on the proper course of organic production.

Antibiotic resistance poses human health risks

The main problem posed by the use of antibiotics in organic apple and pear production is the development and spread of genes for antibiotic resistance. Organic production should not be contributing in any way to the serious threat of losing an important drug to fight human bacterial infections, due to bacterial resistance to the drug. While the majority position heavily focuses its discussion on antibiotic residues that may be left on fruit, an important consumer consideration, we believe that line of argument obfuscates the more critical issue—the mechanisms that create resistance in the orchard environment in the first place.[3] The Subcommittee wrongly minimizes this risk in the face of scientific and medical views to the contrary.[4]

Development of antibiotic resistance

Antibiotic use inevitably leads to the development of resistance by bacteria, regardless of the intensity or frequency of its use. When bacteria are exposed to antibiotics, susceptible bacteria die and those with resistance survive and increase the incidence of conjugation with other bacteria, effectively enhancing the spread of antibiotic resistance.[5] With respect to the *Erwinia amylovora* bacteria found in organic apple and pear orchards, resistance will eventually emerge to create the conditions that will render antibiotics ineffective for preventing fire blight. Regardless of the decision to extend the expiration date, organic apple and pear growers will lose oxytetracycline as a tool to control fire blight. It is just a matter of time. Surely, this is no surprise to growers who have already confronted resistance to streptomycin, a tool which has lost its effectiveness against fire blight in many regions.

[3] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.

[4] American Academy of Microbiology. 2009. Antibiotic Resistance: An Ecological Perspective on an Old Problem.; Silbergeld, E., J. Graham, and L. Price. 2008. Industrial Food Animal Production, Antimicrobial Resistance, and Human Health. *Annu. Rev. Public Health*, 29: 151-169.

[5] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Minority Position. February 5.

The eventuality of fire blight resistance is not addressed in the majority position, which instead argues against the inevitability of *E. amylovora* developing resistance because "there are no examples of acquisition of tetracycline-resistance genes by *E. amylovora* in orchards."[6] Yet, the 2011 Technical Review directly states that "there have been reports of oxytetracycline resistant strains of *E. amylovora* in apple orchards, [although] the extent of this resistance is unknown,"[7] and resistant bacteria have been identified in orchards, especially in those with a history of oxytetracycline use.[8] While fire blight itself is already developing resistance, resistant genes do not need to evolve in the fire blight bacterium in order to transfer resistance to other organisms.

Transfer of antibiotic resistance between bacteria

Horizontal gene transfer (HGT) occurs readily between various species of bacteria and is the main mechanism for spreading antibiotic resistance. The majority position does not adequately present the available science and current thinking with respect to the development of resistance and horizontal gene transfer. The following excerpt from the *Johns Hopkins Magazine* describes the evolving view of microbial genetics and HGT:

> "Bacteria have a remarkable capability for sharing genes, through what is known as horizontal gene transfer. The old view of resistance was Darwinian: In the presence of antibiotics, a mutation would be naturally selected if the mutated gene helped a microbe survive application of the drugs. "That underestimates the brilliance of microbes…," [Dr. Ellen] Silbergeld says. Molecular biologists now understand that within a microbial community, one microbe can acquire genetic material from another microbe, even a microbe of a much different type, then incorporate it in its own genome and thus acquire resistance to an antibiotic it has not yet even encountered. It's as if bacteria are capable of downloading resistance from a gene database."[9]

In contrast, the majority position argues that there needs to be a direct link between microbial species that are human pathogens and exposure to antibiotics sprayed on apple and pear trees. However, this ignores the ability of reservoirs of resistance to develop, even in benign organisms, which can eventually pass resistance on to human pathogens. This situation can contribute to a crisis in antibiotic resistance if the pathogens do not respond to available antibiotics.[10] Thus, development of resistance within an ecosystem can and does contribute to resistance in human pathogens. HGT between unrelated bacteria can pass resistant genes between orchard species and human pathogens or simply create a reservoir of resistance in the environment that can later be passed to pathogenic species. There are a number of mechanisms that can move microbes out of the orchards and into human communities, including dust on fruit, airborne dust, and dirt on workers' shoes.[11] These clear linkages

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[6] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.
[7] ICF International for NOP. 2011. Technical Review: Tetracycline (Oxytetracycline). April 1, 2011. Lines 577-580.
[8] Schnabel & Jones. 1999. Distribution of tetracycline resistance genes and transposons among phylloplane bacteria in Michigan apple orchards. *Appl. Environ. Mircobiol.*, 65: 4898-4907.
[9] Keiger, D. 2009. Farmacology. *Johns Hopkins Magazine*, available at: http://www.jhu.edu/jhumag/0609web/farm.html
[10] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.
[11] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.

between orchard microorganisms and human pathogenic communities exist, even when they are not directly exposed to antibiotics.

Soil ecosystem impacts

Broadcast spraying of oxytetracycline in orchards exposes a wide swath of the orchard to antibiotics, including soil and its microbial population. The impacts of spraying oxytetracycline in orchards contravene OFPA's mandate to 'maintain or improve' the ecosystems where organic farming occurs.[12] Laboratory studies have demonstrated that oxytetracycline application alters soil microbial communities and contributes to oxytetracycline resistance.[13] This alteration in microbial communities is an unacceptable environmental impact in organic systems. When it is applied, oxytetracycline is quickly adsorbed into soil particles and held fairly tightly in the soil structure, but changes in soil conditions (pH, soil organic matter, microbial composition) can eventually result in tetracycline's release into an active form.[14] Thus, the oxytetracycline that accumulates in the soil but remains inactive over a period of time can still have an impact on microbial communities and contribute to further resistance when soil conditions change oxytetracycline into an active form again. Once released into the soil, oxytetracycline can exhibit antimicrobial effects long after it is sprayed. This mechanism for the selection of antibiotic resistance provides a strong argument for phasing out antibiotic use as soon as possible because the effects can persist indefinitely and can be cumulative.

Worker exposure to antibiotics and resistance

Spray applications of antibiotics also provide ample opportunities to expose workers who are mixing and applying the antibiotics. While direct contact with oxytetracycline is not likely to pose an acute hazard, agricultural workers may be more prone to developing and harboring antibiotic-resistant bacteria.[15] This is a direct link between human bacteria and the antibiotics. Even though a direct exposure is not required to build resistance among human pathogens, workers in the orchards can expose human bacteria to antibiotics, contributing to the pool of resistance. If resistant strains do develop, workers can pass these on to their family members and the greater community. While this pathway has not been fully evaluated in the orchard environment, studies from animal agriculture suggest that agricultural workers exposed to antibiotics are at a much higher risk of contracting resistant bacteria.[16]

Alternative fire blight controls

Relying on antibiotics is inconsistent with the spirit of organic production. While there is variation in the severity of fire blight in different years and regions depending upon weather patterns, rain, and humidity, antibiotics are not essential to organic apple and pear production. Oxytetracycline is not strong enough to kill fire blight once infection sets in so it is primarily used prophylactically. The use of other control products when conditions suggest a fire blight infection is imminent can help directly

[12] 7 CFR 205.200

[13] Popowska, M., A. Miernik, M. Rzeczycka, and A. Lopaaciuk. 2010. The impact of environmental contamination with antibiotics on levels of resistance in soil bacteria. *J. Environ. Qual.,* 39: 1679-1687.

[14] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.

[15] ICF International for NOP. 2011. Lines 568-573.

[16] Silbergeld, E., J. Graham, and L. Price. 2008. Industrial Food Animal Production, Antimicrobial Resistance, and Human Health. *Annu. Rev. Public Health*, 29: 151-169.

replace the use of oxytetracycline as a preventative measure. There are a variety of other ways that fruit growers can protect their orchards from fire blight and reduce its spread, including planting resistant cultivars and rootstocks, adequate tree spacing, and the use of alternative control products.[17] As part of a holistic approach to disease control in orchards, there are also a number of existing and emerging alternative products available. Some of the alternatives that can be used include foliar nutrient sprays, copper materials while trees are dormant, lime sulfur, and Serenade MAX.[18] The recent registration of Blossom Protect, a natural yeast product with promising results, adds to the alternatives available to growers. The most effective alternative controls require an integrated approach including cultural practices, attention to fire blight prediction models, and alternative biological control products.

Growers who sell to the European Union and Canada also do not use antibiotics because it is prohibited in tree fruit production there. This includes almost one third of Washington State's organic apple producers in 2011.[19] The success of these growers shows that antibiotics are not an essential input in organic systems, but the challenge for those who still use oxytetracycline is to learn how to adapt such tried and true practices to fit their own growing conditions. The inconsistency is also an issue for equivalency agreements with other countries' organic programs. Once organic growers cease using antibiotics, these markets will be open to all American growers. The NOSB should allow the use of antibiotics to expire in order to bring U.S. regulations in line with the international community's regulations on antibiotics.

Consumers demand organics without antibiotics

Consumers choose to buy certified organic food because they want to support systems of production that protect and enhance human health and the environment. They also expect their organic food to be grown without the use of antibiotics, growth hormones, genetically engineered organisms, and synthetic herbicides and pesticides.[20] Spraying organic apple and pear orchards with oxytetracycline, a drug that the World Health Organization (WHO) has labeled a "critically important" [21] antibiotic for human health, undermines the spirit and intent of organic consumer expectations. Despite the fact that oxytetracycline has been on the National List (NL) for several decades, few people other than NOSB insiders know that antibiotics are used in organic apple and pear production. But, this latest petition for extension, coupled with the Subcommittee's faulty scientific assessment that minimized the threat of antibiotic resistance, has sparked a public discussion about why antibiotics are being used in organic at all. This little-known fact about organic that now has been made public has the potential to not only tarnish the organic apple and pear industry, but also to tarnish the organic label and reputation of the wider organic sector.

And, in case there is any doubt that widespread consumer market rejection could happen, it would behoove those pushing for another extension to recall the so-called "Alar apple scare" that swept the

[17] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Minority Position. February 5.
[18] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Minority Position. February 5.
[19] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Minority Position. February 5.; ICF International for NOP. 2011. Lines 222-230.
[20] Organic Trade Association. 2011. U.S. Families' Organic Attitudes & Beliefs, 2011 Tracking Study. Page 13.
[21] World Health Organization. 2009.

country in 1989. A *60 Minutes* program exposed the dangers of spraying the toxic chemical, Alar, on apples to make them ripen longer on the tree before falling to the ground. That exposé ushered in one of the country's most widespread and costly food scares, which resulted in the collapse of the apple market, virtually overnight. Researchers found residues of the probable human carcinogen in several brands of baby food, which marked the last straw for consumers. They stopped buying apples, apple juice, and products containing apple ingredients. Prices plummeted, and the nation's largest apple growing region, Washington State, claimed losses of $100M and a slew of small grower bankruptcies. EPA finally banned Alar shortly thereafter, citing the "unacceptable public health risk" as the justification for its decision.[22] Although the apple industry eventually bounced back, it was at a huge cost to growers. There are no guarantees that this would be the case with respect to antibiotics in organic apples and pears.

While admittedly the controversy surrounding oxytetracycline use is different because the public health concern is the development of antibiotic resistance, not toxic pesticide residues in fruit, the outcome of consumer rejection could be the same if action is not taken. Organic production systems depend upon the existence of organic markets for their economic survival, and given the fact that 24,545 people have signed CFS's petition to oppose the extension thus far, the organic apple and pear market could be at risk if growers again strongly protest the 2014 phase-out date.

The non-therapeutic use of antibiotics in organic production systems also presents an unacceptable public health risk. It contravenes the NOSB's stated Principles of Organic, which emphasize promoting and enhancing "biological cycles" and "the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials."[23] As the problems associated with antibiotic resistance and the potential for reduced effectiveness of this important drug for curing human infections, the obvious question that must be asked is why antibiotics are being uses by organic growers in the first place. Isn't it antithetical to the principles of organic? A strong commitment from the NOSB to uphold the 2014 expiration date would send a meaningful signal to organic consumers that the NOSB is committed to continual improvement, as per the regulatory charge of the National Organic Program.[24]

No need to wait for EPA review

Most materials that are approved by EPA as pesticides are not permitted in organic production because they fail to meet the strict review criteria under OFPA. Oxytetracycline pesticides are currently under registration review with the EPA, which requires new data gathering and analysis and is scheduled for completion in 2014.[25] The majority position suggests that an extension until 2016 will allow NOSB to evaluate new EPA data, but this is unnecessary to fulfill OFPA's stricter review criteria. While some of the findings from the registration review may help expand the understanding of tetracycline's impacts, the EPA review process is not reason enough to delay action at the NOSB. The information that is already available on tetracycline use and persistence in orchards provides a

[22] Gordon, W. 2011. The True Alar Story: Part I. Available at: http://www.onearth.org/blog/the-true-alar-story; Environmental Working Group. 1999. Ten Years Later, Myth of 'Alar Scare' Persists. Available at: http://www.ewg.org/node/8005

[23] NOSB. October 17, 2011. "NOSB Principles of Organic Production and Handling.

[24] 7 CFR 205.200.

[25] NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline. February 5.

sufficient scientific rationale for the NOSB to take precautionary action and support the expiration of oxytetracycline for use in organic apple and pear production.

Conclusion
CFS urges the NOSB to vote against extending the use of oxytetracycline to 2016. Increasing, documented incidence of antibiotic resistance and the threat of losing oxytetracycline as a tool for combating infections in humans, alone, is reason enough to prohibit its use in organic at the earliest opportunity.

Polyoxin D Zinc Salt

CFS supports the Crops Subcommittee recommendation to deny the petition for listing polyoxin D zinc salt to be used as a fungicide. We agree with the Crops Subcommittee that the zinc salt added to the compound should be considered synthetic because its origin is not specified as mined or recycled. Polyoxin D zinc salt (PDZ) fails to meet the criteria for listing on the National List because it has negative environmental impacts, it is incompatible with organic systems, and it is not essential. CFS believes that the compound is inconsistent with organic production.

PDZ inhibits the chitin synthetase in fungus and can have detrimental impacts on other beneficial insects.[26] As it is a broad spectrum fungicide, CFS has real concerns about its residual negative effects in soil and its adverse impacts on beneficial soil organisms. Fungi serve important functions within soil ecosystems, particularly as decomposers that help to maintain soil structure and break down organic matter and in making nutrients available to crops. These crucial soil organisms would also be affected by the use of products that inhibit chitin formation, even if they are targeting plant pathogenic fungi. PDZ has been shown to affect chitin synthetase in studies on cockroaches as well, suggesting a potentially negative impact on beneficial insects that have a chitin exoskeleton.[27] Without the full ability to synthesize chitin, insects that rely on chitin as a major exoskeleton component will be adversely affected because their structure will not develop properly.

Organic pest management systems rely on interactions of beneficial organisms to provide controls for plant pathogens in a system that "promotes and enhances biological diversity, biological cycles, and soil biological activity."[28] Introducing the synthetic PDZ input would unnecessarily and adversely affect these natural cycles. Polyoxin D zinc salt is also not essential for organic production in that there are several readily available alternative products and practices identified in the technical review. These include crop rotation, nutrient management, sanitation, and selection of resistant species and varieties.[29]

We urge the NOSB to reject the petition for listing polyoxin D zinc salt.

[26] NOSB. 2013. Crops Subcommittee Petitioned Material Proposal: Polyoxin D Zinc Salt. Jan. 29. 2013.
[27] The Organic Center for NOP. 2012. Technical Evaluation Report: Polyoxin D Zinc Salt. Lines 257-262.
[28] NOSB. 2001. Principles of Organic Production and Handling: Section 1.1. October 17.
[29] The Organic Center for NOP. 2012. Technical Evaluation Report: Polyoxin D Zinc Salt. Lines 367-382.

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.[30] 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."[31]

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.[32] Congress also cautioned that "as time goes on, various scientific breakthroughs, including biotechnology techniques, will require scrutiny for their application to organic production."[33] Therefore, the definition created "a degree of flexibility to ensure that the regulations could continue to accurately reflect industry practices and consumer preferences."[34]

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

[30] 62 Fed. Reg. 65850, 65875 (Dec. 16, 1997).
[31] 65 Fed. Reg. 13512, 13513-14 (Mar. 13, 2000).
[32] 65 Fed. Reg. 13512, 13521.
[33] 62 Fed. Reg. 65850, 65875.
[34] *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."[35] 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."[36] 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."[37] 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.[38] 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

[35] FAO. Section 2: Description and Definitions. Available at: http://www.fao.org/DOCREP/005/Y2772E/y2772e04.htm.
[36] Convention on Biological Diversity. 2013. The Cartagena Protocol on Biosafety. Available at: http://bch.cbd.int/protocol.
[37] *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
[38] 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.[39] 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." [40] 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.[41] Other technologies should be evaluated if, after

[39] 65 Fed. Reg. 13512, 13521.

[40] 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.

[41] 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[42] 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."[43] 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.[44] 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

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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.

[42] 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.[42] 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.

[43] Excluded Methods definition, 7 CFR §205.2 Terms Defined.

[44] 7 U.S.C. § 6517(c)(1)(A)(i)-(iii)

the environment."[45] The Technical Evaluation Report (TER) could not be any clearer—both sugar beet production and beet sugar production have adverse effects on the environment.

Like most conventionally farmed crops, conventional sugar beets rely heavily on monoculture, have a limited rotation, and use fertilizers and pesticides that may be harmful to the environment and that reduce ecological biodiversity. The U.S. Environmental Protection Agency has created thresholds for 57 different pesticides found in sugar beet pulp or roots.[46] In fact, "pesticide pollution from sugar beets is a global concern."[47]

In Sweden, where the petitioner obtains and processes its sugar beets, the sugar beet seeds are commonly treated with imidacloprid, a controversial neonicotinoid pesticide thought to be dangerous to pollinators. Neonicotinoids are systemic, meaning that they are taken up by the plant through the plant's vascular system and are expressed throughout the plant's tissues, including flowers, pollen, and nectar.[48] Neonicotinoids work by destroying the central nervous systems of insects, including bees and beneficial pollinators.[49] Because neonicotinoids are persistent, bees and beneficial pollinators are chronically exposed to residue of such pesticides.[50] Thus, the use of imidacloprid and other herbicides "reduce[s] biodiversity in and around the farms where sugar beets [are] cultivated."[51]

It doesn't stop there. Sugar beet production relies on applications of the toxic fumigant methyl bromide.[52] Methyl Bromide is injected directly into soil before sugar beets are planted and covered with a tarp, sterilizing the soil, and killing a wide spectrum of pests, soil-borne fungi, nematodes, weeds, insects, mites and rodents.[53] It negatively affects both target and non-target pests. Methyl bromide slowly seeps into the atmosphere once it is injected into soils and then more rapidly once the tarp is removed. Deleterious human health effects from exposure to methyl bromide gas include central nervous system failure; respiratory system failure; and severe damage to lungs, eyes, and skin.[54]

Methyl bromide is also regulated as a notorious ozone depleting chemical. Its use in industrialized nations was outlawed in 2005 in accordance with the Montreal Protocol (Montreal Protocol on

[45] 7 C.F.R. § 205.600(b)(2)
[46] TER at 6.
[47] TER at 9.
[48] *See* Joe Cummins, *Requiem for the Honeybee*, 34 Inst. for Sci. in Soc'y 37 (2007).
[49] Eric Hoffmann & Steven Castle, *Imidacloprid in Melon Guttation Fluid: A Potential Mode of Exposure for Pest and Beneficial Organisms*, 105 J. ECON. ENTOMOLOGY 67 (2012).
[50] Henk Tennekes, *The Systemic Insecticides: A Disaster in the Making* (Weevers Walburg Communicatie, Zutphen, The Netherlands) (2010)*, available at* www.disasterinthemaking.com.
[51] TER at 8.
[52] TER at 9.
[53] Pesticide Action Network-UK, *Europe Turns the Tide on Methyl Bromide*, 79 Pesticide News 11, 11 (2008) *available at* www.pan-uk.org/pestnews/Issue/pn79/pn79pp11-13.pdf.
[54] Pesticide Action Network-UK, *Europe Turns the Tide on Methyl Bromide*, 79 Pesticide News 11, 11 (2008) *available at* www.pan-uk.org/pestnews/Issue/pn79/pn79pp11-13.pdf.

Substances that Deplete the Ozone Layer (Montreal Protocol)).[55] Now, nearly eight years later, the U.S. continues to extend its use by applying for "critical use exemptions" on behalf of growers who have yet to find alternatives and phase it out. This is certainly not the type of production system that organic should support under any circumstances.

Beet sugar production degrades the environment

Beet sugar extraction is equally destructive. It is among the vegetable processing operations cited as responsible for high levels of pollution, and long has been noted for voluminous wastewater with a high biological oxygen demand (BOD).[56] Air pollution and emissions are other concerns for beet sugar extraction.[57] Sugar beet processing facilities contain high levels of formaldehyde,[58] as well as a number of other synthetic substances that are not included on the National List (inlcuding α-alkyl- omega -hydroxypoly-(oxyethylene), Linear undecylbenzenesulfonic acid, dialkanolamide, monoethanolamine, triethanolamine, ethylene dichloride, ethylene glycol monobutyl ether and tetrasodium ethylenediaminetetraacetate).[59] Finally, the sugar beet fiber itself may also be chemically treated with a number of different substances in order to remove undesirable color, odor, and flavor.[60]

Transgenic contamination is bound to happen

Genetic engineering is prohibited in organic production. In order to meet the requirements of 7 C.F.R. § 205.105, non-organic sugar beets would have to come from identity preserved non-engineered sources. This prospect seems unlikely. In the United States, 95 percent of all sugar beets grown commercially are genetically engineered to be resistant to Monsanto's herbicide Roundup.[61] It is unclear how the NOP would enforce a requirement that sugar beet fiber contain no genetically engineered material considering the prevalence of engineered sugar beets.

Even if sugar producers source non-genetically engineered sugar beets, transgenic contamination is so prevalent that it is likely that some genetically engineered sugar beet fiber would make its way into organic consumers' shopping bags. Genetically engineered sugar beets can cross-pollinate with conventional sugar beets (as well as other *Beta* crops such as organic and conventional chard and table

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[55] Methyl Bromide Questions and Answers, Environmental Protection Agency, http://www.epa.gov/ozone/mbr/qa.html (last updated Jan. 8, 2011). In 1987, twenty-seven countries, including the United States, signed the Montreal Protocol on Substances that Deplete the Ozone Layer. Both the Convention and the Montreal Protocol are dedicated to protecting the earth's ozone layer by reducing or phasing out the use of ozone depleting substances such as Methyl Bromide. The United States has not completely phased out the use of Methyl Bromide—many crops are granted critical use exemptions to the treaty.

[56] TER at 8.

[57] TER at 8.

[58] TER at 8.

[59] 7 CFR 205.605(b)

[60] TER at 4.

[61] Glyphosate-based herbicides, such as Monsanto's Roundup brand, kill plants by inhibiting an enzyme that is necessary for the conversion of sugars into amino acids. *Monsanto v. David*, 516 F.3d 1009, 1011 (Fed. Cir. 2008). Glyphosate-based herbicides are non-selective and therefore kill virtually all plants, weeds, and crops. *Monsanto v. David*, 516 F.3d 1009, 1011 (Fed. Cir. 2008). Monsanto created Roundup Ready crops so that when its glyphosate-based Roundup herbicide is applied to crops, it will kill all the weeds while the genetically engineered crop survives. *See generally id*. at 1011-1012. The increasing reliance of glyphosate-based herbicides on Roundup Ready crops in recent years has led to an epidemic of glyphosate-resistant weeds, commonly known as "superweeds," now found on millions of acres of farmland.

beets). The sugar beet industry's own evidence demonstrates that transgenic contamination is likely to occur, leaving growers, sellers, and consumers of other, non-GE beets at significant risk of contamination. The NOSB must protect organic consumers from sugar beet fiber contaminated with genetically engineered genes.

Sugar beet fiber is not essential—alternatives exist
Sugar beet fiber is not "essential for the handling of organically produced agricultural products."[62] While it is used to increase the soluble fiber in foods, it is not essential to the production of any food.

The Technical Evaluation Report lists several alternatives to sugar beet fiber. First, there are other sources of organic vegetable fiber. In many situations other fibers—oat bran, rice bran, barley fiber, wheat bran, citrus pulp, and psyllium—could be used as substitutes for the sugar beet fiber needed. There are also several "functional and commercially available fiber sources that already appear on 7 CFR 205.605, including alginates, gellan gum, and low-methoxy pectin."[63] "Fructooligosaccharides (FOS), gum Arabic, guar gum, oligo-fructose enriched inulin and high methoxy pectin currently appear on 7 CFR 205.606."[64]

The basic tenets of organic production require organic production systems to integrate "cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."[65] Non-organic sugar beet production systems promote just the opposite, and cannot be part of an organic farming and handling system. We urge you to reject the petition to allow conventionally grown sugar beet fiber because its system of production goes against the principles of organic and it is not an essential food ingredient.

Other Ingredients

CFS believes that the Handling Subcommittee proposal on other ingredients does not comply with the criteria laid out in OFPA. The 'baseline criteria' proposed in the recommendation are not as strict as the requirements of OFPA. "Other ingredients" should be reviewed in the same manner that all ingredients are for organic production, based on the review criteria for human health impacts, environmental harm, essentiality, and compatibility with organic. There is no special provision under OFPA to allow for a secondary, less stringent review process for any ingredients entering products labeled organic. Contents of organic food must either be organic or included on the National List for that purpose.

[62] 7 C.F.R. § 205.600(b)(6).
[63] TER at 10.
[64] TER at 10.
[65] 7 C.F.R. § 205.2.

Materials Subcommittee

Confidential Business Information

In contrast to conventional food production systems, transparency is the bedrock of the organic system. Consumers buy organic food because they know what is in it and how it is grown. So, the question of allowing confidential business information (CBI) to be a part of the materials review process is a tricky one. Nonetheless, we are particularly persuaded by the argument that in order for innovation to occur and thrive in organic, some very limited and prescribed amount of CBI may be necessary. But, the question of what aspect(s) of production should be allowed to be CBI still remains.

CFS firmly believes that some materials can never be allowed in an organic system and some products can never be produced organically, due to the adverse environmental and health impacts associated with their production or use. And, in order for the NOSB to make that determination, it is essential that all materials used in the production of organic products and all processes used to produce a given product must be subjected to a high level of scrutiny that only a fully transparent materials review system can provide. Moreover, we believe that ingredients and materials used and incorporated into food products must be fully disclosed and they can *never* be claimed as CBI.

Nonetheless, we understand that a fine line may be able to be drawn, as explored in the Subcommittee's document that allows innovators to maintain CBI for very specific reasons. Allowance for CBI, for example, could be tightly restricted to formulas and recipes only. We support the idea of allowing market research and financial business data to be considered CBI as another area where the NOSB could draw a line in the sand for acceptable confidentiality claims. Yet, even if some exceptions for CBI are made, as noted in the Subcommittee document, petitioners should be directly notified about the unique nature of the organic materials review process and that the materials process is not a pro forma process where materials are automatically allowed on the National List. On the contrary, petitioners must make their case, explain how their materials meet the NOSB evaluation criteria, and ensure their material use is as transparent as possible or risk the rejection of their petition.

We do not support the idea of allowing the NOSB, but not the public, to see CBI materials. Given the close and somewhat interdependent relationship between the NOSB and the public, this could create an unworkable and confusing situation that would set up the Board for a failed process. It could be extremely awkward for NOSB members to reach out to their constituencies for their input while at the same time keeping secrets from them, all the while being unsure exactly where to draw the line. In the end, this could lead both to unintentional breaches of CBI or a tendency to withhold information and limit consultation with the public to prevent such a breach. This would serve to undermine the valuable public participation process that remains the center of organic regulatory development. In any case, once the CBI is in the hands of the NOSB, it is FOIAble and the strict confidentiality of CBI may not be able to be maintained.

Obviously, the Subcommittee does not have complete clarity about the best path forward or the exact parameters for allowing CBI, but the discussion document provides a solid basis for an extended conversation on the issue.

Policy Development Subcommittee

Public Communications

As a public interest group with over 200,000 supporters nationwide, CFS takes seriously our responsibility to actively participate in public policy discussions that affect the work we do on organic, and to inform and involve our supporters whenever possible. As such, we have repeatedly expressed to the Board the need for an official channel, to be open year round, through which we can regularly communicate with the NOSB between meetings. We wholeheartedly support the Policy Development Subcommittee's proposed *Policy for Public Communication between NOSB Meetings* and we thank the Subcommittee for its responsiveness to our requests and to those of the wider organic community to make it happen.

We thank the Board for the important work that it does on behalf of the organic community and for its consideration of our remarks.

Respectfully submitted by,

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