V. CROPS SUBCOMMITTEE

PROPOSAL:

OXYTETRACYCLINE (TETRACYCLINE)

SUMMARY

Reject the petition to add tetracycline to the National List.

Reject the petitioner's request to remove the 2014 expiration date for tetracycline use in organic apples.

Reject the Crops Subcommittee's proposal:

> *Remove the existing expiration date of October 21, 2014 for oxytetracycline and replace that with a new expiration date of October 21, 2016. This would be for use in both apples and pears for control of fire blight.*

The antibiotic oxytetracycline, also called tetracycline, is currently allowed for use in organic crop production only until October 21, 2014. The NOSB voted in favor of specifying this sunset date in 2011.

In order to be approved for use in organic production, synthetic materials such as antibiotics must meet three criteria: They must be **essential** for organic production, **compatible** with organic production practices, and cause no adverse impacts on humans or the environment. We believe that tetracycline fails to meet all these criteria set forth in OFPA.

The "dealbreaker" in reviewing the current petition, for The Cornucopia Institute, is the fact that measurable antibiotic residues can be found in apples and pears treated with antibiotics, which, upon reviewing alternatives, are not essential in organic production.

In response to the petition for continued use of tetracycline the Crops Subcommittee prepared a well-researched proposal—a total of 40 pages, including eight pages of references and endnotes. The majority (five members) voted in favor of extending the expiration date for tetracycline. The minority (three members) opposed the motion. In the discussion, the majority opinion ignores or discounts important and relevant research in several areas. (Some instances of this are noted below.) The minority opinion presents important research to support a prohibition of tetracycline. We agree with the discussion and conclusions presented by the minority, who opposed the extension on the use of antibiotics.

Rationale

- **Tetracycline is not essential for control of fire blight.**
  - Cultural controls are available to manage fire blight.
  - Biological controls are available to manage fire blight.
  - Many orchardists, both in the US and in Europe, grow apples without using tetracycline or other antibiotics.

- **Tetracycline is harmful to humans and the environment.**
  - Tetracycline is a broad-spectrum antibiotic that is active against a wide variety of bacteria, which could have deleterious impacts on biodiversity and the ecosystem.
  - Tetracycline use in orchards may contribute to development of antibiotic resistance, with serious consequences for human health.

Much research has been conducted on apples to demonstrate that the cultural practices and materials available to organic growers are sufficient to manage fire blight without tetracycline. The expiration date for tetracycline on apples should be maintained at October 21, 2014.

Research on pears, however, is more limited. Since pears are naturally more susceptible to fire blight, and there are fewer research studies available to demonstrate effective controls, it may be necessary to consider extending the expiration date until October 21, 2016 for pears only.

BACKGROUND

Tetracyclines are a group of broad-spectrum antibiotics that include chlortetracycline, oxytetracycline, and others. The National List, Section 205.601(i)(12), lists tetracycline as an allowed material for plant disease control; therefore, we use the term "tetracycline" in these comments.

The petitioned use of tetracycline is to control fire blight on apples and pears, caused by the bacterium *Erwinia amylovora*, which infects blossoms of apple and pear trees. If the disease is not controlled, flowers die, resulting in crop loss, and the woody branches can become infected, resulting in loss of limbs or an entire tree.

Tetracycline does not kill the bacteria, it only prevents them from growing and multiplying. Streptomycin has been the antibiotic of choice because it kills the pathogen. Tetracycline, which stops the growth of the pathogens but does not kill existing populations, is less effective than streptomycin. Tetracycline is only used where the pathogenic bacteria are resistant to the antibiotic streptomycin, primarily California, Oregon and Washington.

NOSB proposal for use of antibiotics

Antibiotics are prohibited for production of organic livestock and for most organic crops in the US. The only exception is the use of tetracycline and streptomycin, which are allowed for control of fire blight, a disease of apple and pear trees. They are listed on National List Section 205.601:

> (i) As plant disease control.
>
> (11) Streptomycin, for fire blight control in apples and pears only until October 21, 2014.
>
> (12) Tetracycline, for fire blight control in apples and pears only until October 21, 2014.

This exception to organic standards has been controversial since 2000, when the regulations were being drafted. Antibiotics were added to the National List in 2000, and renewed in 2006. A different form of tetracycline was petitioned in 2008, at which time an expiration date of 2012 was established. A petition submitted in 2011 led the NOSB to extend the expiration date to 2014. One year later, in June of 2012, the Washington State Horticultural Association submitted a petition to overturn this rule, specifically requesting the removal of the 2014 expiration date. Tetracycline would be added to the National List and would be subject to review every five years through the sunset process.

As they reviewed the petition for this NOSB meeting, the Crops Subcommittee split into equal camps—four in favor and four opposed to the motion. A second, “compromise” proposal was then drafted:

> *Remove the existing expiration date of October 21, 2014 for oxytetracycline and replace that with a new expiration date of October 21, 2016. This would be for use in both apples and pears for control of fire blight.*

A majority (five members) of the subcommittee voted in favor of this proposal; a minority (three members) voted against it.

Evaluation for approval of synthetics to be added to the National List

In organic agriculture, synthetic materials such as antibiotics are prohibited unless:

1. The substance is **essential** for organic production.

2. The substance is **compatible** with organic production practices.
3. There are **no** adverse impacts on humans or the environment.

In the following section we discuss reasons why the use of tetracycline in organic agriculture is not essential, is not compatible with organic principles, and is harmful to humans.

TETRACYCLINE IS NOT ESSENTIAL TO CONTROL FIRE BLIGHT

Cultural, biological and chemical controls are available to manage fire blight

The fire blight disease initially infects blossoms of apple and pear trees. Effective management of fire blight must rely on prevention of these initial infections, rather than control after the bacterial populations are high. Fortunately, there are many ways to prevent fire blight infections. <u>This principle of management of diseases by prevention rather than control is one of the organic principles mandated by OFPA</u>. The principles are outlined in section 205.206 *Crop pest, weed, and disease management practice standard*, and explained in the *Guide for Organic Crop Producers*,[11] available for download from the NOP website.

7 CFR 205.206 lists the following as management practices to prevent disease that are applicable to orchardists:

> *(a)(3) "Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases" and*
> *(d)(1): "Disease problems may be controlled through: Management practices which suppress the spread of disease organisms."*

Level A, the systems approach, as outlined in the *Guide for Organic Crop Producers*, includes use of resistant varieties and resistant rootstocks, specifically non-dwarfing rootstocks. The systems approach should be the first line of defense against fire blight, because a properly designed system will have less disease.

Level B, cultural practices, include blossom thinning and canopy management, specifically avoiding high-density plantings to allow greater air flow in the orchard.

Level C, inputs, includes natural materials, biological controls and synthetic materials such as antibiotics. In general, inputs should only be used after other practices have failed to control the disease. If inputs are required, farmers should use natural materials and biological controls before using synthetic materials such as antibiotics.

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[11] Coleman, P. 2012. *Guide for Organic Crop Producers*. National Center for Appropriate Technology, 64 pages. www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101542

Even if cultural practices are not adequate, there are several natural materials and biological controls that can be used to manage fire blight, as we discuss below. With all these cultural practices and materials available, antibiotics have been proven unnecessary for control of fire blight.

Resistant varieties and rootstocks

Selection of a resistant cultivar is the most effective method of controlling fire blight.[12] The relative resistance and susceptibility of different apple cultivars in well-known; university extension specialists in many parts of the country publish this information. To manage fire blight, it is also important to avoid planting apples on susceptible rootstocks. The dwarfing rootstocks, in particular, such as Malling 9 and 26, are highly susceptible to fire blight.[13]

Apple and pear growers have known that antibiotics would likely be prohibited for organic production in the future, either through removal from the National List via the sunset process, or by an expiration date in the listing. Growers taking a proactive approach would plant resistant varieties on resistant rootstocks. This has not been the case. Instead, cultivars with greater susceptibility to the disease, such as Braeburn, Fuji, Gala, and Pink Lady, have been planted.[14]

In 2009 in Washington State, 45% of the organic apple acreage was planted to Gala and Fuji, both of which are susceptible to fire blight.[15] At one point, fire blight primarily was a concern to pear growers only, not apple growers, but the situation has changed: "Now that there are extensive acreages of highly susceptible apple varieties on super-susceptible rootstocks in warmer parts of the state, the possibility of serious fire blight damage in Washington apples has evolved into a reality."[16] The current practice of high-density plantings increases the speed at which fire blight can spread.

Biological controls and other inputs are available to manage fire blight

Even with the planting of susceptible varieties, there is a wealth of materials available to control fire blight without antibiotics. The TR mentions biological controls: Bloomtime Biological, BlightBan C9-1, BlightBan A506 and Blossom

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[12] Johnson, K.B. 2000. Fire blight of apple and pear. *The Plant Health Instructor*. DOI: 10.1094/PHI-I-2000-0726-01. *Updated 2005.*
[13] Ibid.
[14] Johnson, K.B. 2000. Fire blight of apple and pear. *The Plant Health Instructor*. DOI: 10.1094/PHI-I-2000-0726-01. *Updated 2005.*
[15] Kirby, E. and D. Granatstein. 2011. Status of Organic Tree Fruit in Washington State an Other Regions: 2010. Center for Sustaining Agriculture and Natural Resources, Washington State University
[16] Smith, T. 2012. Fireblight Management in the Pacific Northwest USA. Downloaded Nov 2012 from http://county.wsu.edu/chelan-douglas/agriculture/treefruit/Pages/Fire_Blight.aspx

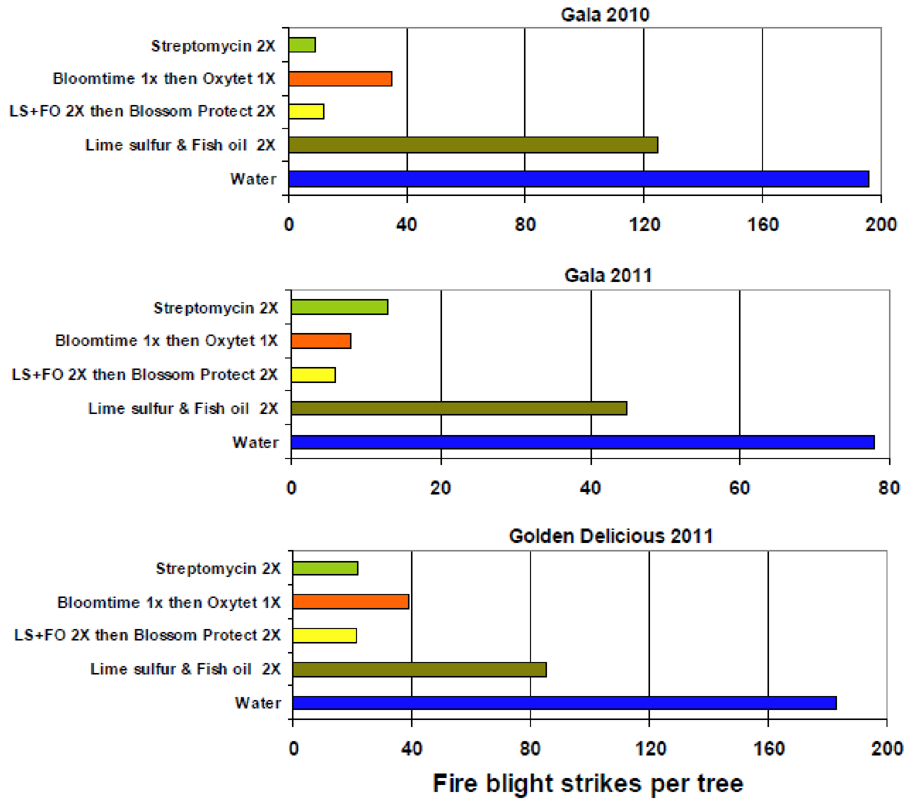
Protect. Other materials available include several brands of lime sulfur, fish oil and copper sulfate. Finally, Serenade Max is an antimicrobial product made from bacteria.

Blossom Protect is a biological control agent made from *Aureobasidium pullulans* (note: the name of this microorganism is misspelled in the TR; it is spelled correctly here). Field trials in eastern Washington have found that Blossom Protect provided control similar to oxytetracycline.[17]

Ken Johnson, in a webinar in March 2012, presented his research on materials that provided **"a fantastic level of control" of fire blight**. He stressed that management is vitally important—growers must begin to manage fire blight early in the season, when pathogen populations first start to build up. He suggested that growers begin with copper products, to delay the onset of disease. When trees begin to bloom, several different materials must be used at the appropriate times, first to reduce the number of infection sites, then to protect the remaining blossoms with biological controls.

Blossom thinning to remove flowers is essential because the bacteria that cause fire blight will initially infect the stigmas of the flowers. When flowers are removed, there are fewer places where bacteria can cause fire blight infections. Blossom thinning also reduces the crop load, reduces stress on the tree, and results in larger and more marketable apples. In Johnson's research study, he used lime sulfur (LS) and fish oil (FO) for blossom thinning. The remaining flowers were sprayed with Blossom Protect, a microbe that colonizes the flowers. Results in the graph below indicate that those treatments were as effective as antibiotics, even on Gala apples, a susceptible variety. The experiment was repeated in 2012, with the same results, showing the effectiveness of lime sulfur plus fish oil followed by Blossom Protect.[18]

[17] Smith, T. 2011. Improving the management of two critical pome fruit diseases. Final Project Report, WA Tree Fruit Research Commission Project Number CP-09-904
[18] Granatstein, D. 2012. Fire Blight Update. Organic Tree Fruit Industry Work Group. Presented at the NOSB Meeting, Providence, Rhode Island, 10/16/2012



Johnson also tested the use of Bloomtime Biological early in the season, followed by Serenade Max, which resulted in "very good to excellent control." In a recent webinar, Johnson[19] presented results of additional research, and verified that effective non-antibiotic control of fire blight can be achieved on apples through an integrated control program. Johnson was also able to achieve fire blight control on pears, although reliable control is expected to be more difficult than on apples.

Although these biological products control infections as well as antibiotics, they must be sprayed more frequently—four sprays instead of two. As long as antibiotics remain allowed in organic agriculture, growers are more likely to use them rather than biological controls, as a cost-saving measure. If antibiotics are prohibited, cost of apple production may increase slightly. However, cost is not a factor, by law, in deciding which materials to allow. We believe that organic consumers, who already expect to pay a price premium for organics in order to avoid harmful inputs, including antibiotics, will be willing to pay the extra price, if any, to avoid the harmful effects of antibiotics on humans and the environment.

[19] Johnson, K. 2013. Research Update on Non-antibiotic Control of Fire Blight. Webinar date March 19, 2013. www.extension.org/organic_production

Many orchardists grow apples without using antibiotics

Europe does not allow antibiotics in organic production of apples or pears, yet there were approximately 57,582 acres planted to organic apples in Europe in 2008.[20]

Many organic apple growers in Washington State grow fruit to be exported to Europe, and do not use antibiotics on those trees. As of March 2011, approximately one-third of the organic apple producers in Washington had not used antibiotics for at least three years, because they were certified to sell apples to Europe.[21]

A national poll of organic apple and pear producers, conducted by The Cornucopia Institute in early 2013, shows a wide disparity in the use of antibiotics. The poll results, being compiled in March 2013, will be presented to the NOSB at their spring meeting in Portland, Oregon.

Tetracycline is not compatible with organic production practices

NOP regulations prohibit the use of antibiotics on livestock for meat or milk production. Antibiotics may not be used on any organic crops, other than apples and pears.

Tetracycline is prohibited by international standards. It is not allowed for organic production in Canada, Europe or Japan. It is not allowed by the CODEX Alimentarius Commission, or the International Federation of Organic Agriculture Movements (IFOAM).[22]

Antibiotics represent an input-substitution mentality

As discussed above, fire blight is a serious disease that has been aggravated by the planting of vast acres of susceptible apple varieties on susceptible rootstock at high densities. Growers who have ignored preventative practices are relying on inputs for disease control.

The following graph shows how the risk of fire blight increases in the spring.[23] As bacterial populations increase, the risk of disease increases. In order to manage the

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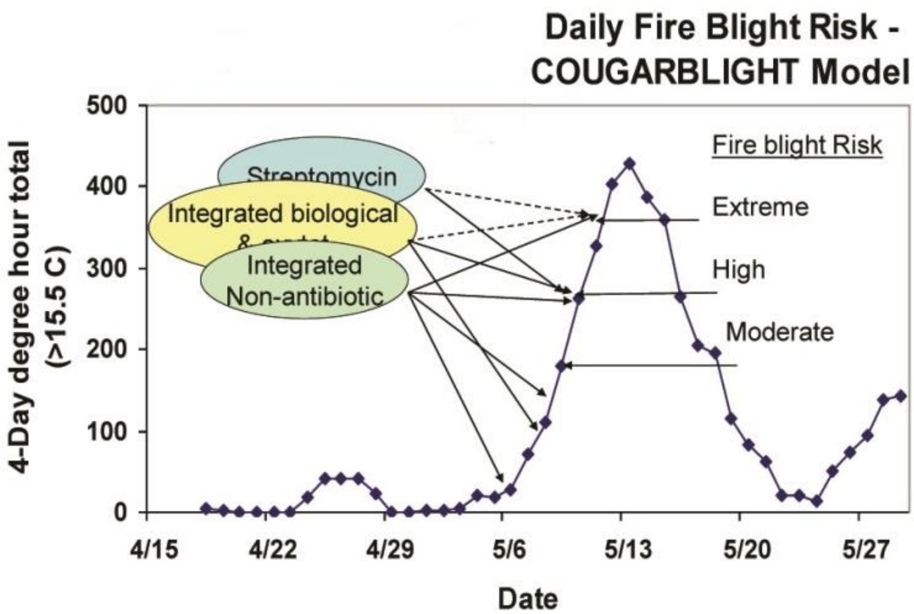
[20] Kirby, E. and D. Granatstein. 2011. Status of Organic Tree Fruit in Washington State an Other Regions: 2010. Center for Sustaining Agriculture and Natural Resources, Washington State University

[21] Washington State Department of Agriculture. 2011. *International Organic Program—EU Compliant Operations, March 10, 2011*. http://agr.wa.gov/FP/Pubs/docs/wsda_eu_compliant.pdf

[22] ICF International. 2011. Tetracycline (Oxytetracycline) Technical Evaluation Report, April 1, 2011

[23] Johnson, K. 2012. Fire Blight Control in Organic Pome Fruit Systems Under the Proposed Non-antibiotic Standard. Webinar date March 13, 2012. *www.extension.org/organic_production*

disease without antibiotics, growers must use integrated control measures early in the spring, when the pathogen population is starting to build. However, if antibiotics are available, this investment in a proactive approach is less important. As Dr. Johnson said in his webinar, "When streptomycin was effective, for us on the west coast, we could ignore the whole pathogen build-up phase…. We could come in with streptomycin at fairly high levels of risk and … we could get good control." This philosophy relies on treating the disease after it becomes serious. An organic philosophy should rely on management to prevent the disease from becoming serious.



Effects on humans and the environment

Tetracycline is a broad-spectrum antibiotic; therefore, the environmental effects of tetracycline are significant. Application of tetracycline involves aerial spraying. Although the tetracycline is needed only on the flower surfaces, the spraying applications ensure that it lands on the tree leaves, tree trunk, cover crops in the orchard and soil, as well as the flowers. Rain washes some tetracycline off the plant surfaces, into the soil. There is evidence to indicate that tetracycline can also be taken up by plants and translocated through their tissues.[24]

Antibiotic residues may be detected in or on the apple fruit. When apple trees at blossom stage were sprayed with streptomycin, residues were found on the apple fruit sampled 86 days later.[25] The Environmental Protection Agency has found detectable residues of tetracycline on apple fruit up at 49 to 61 days after application.[26]

Tetracycline in the soil

As reported in the TR (lines 296-307), several studies demonstrated that tetracycline degrades very slowly in the soil, remaining present and retaining antimicrobial activity for up to ten months.[27,28,29] Antibiotics, including tetracycline, have been found to reduce the numbers of bacteria in the soil, under field and laboratory conditions.[30,31,32,33] The Technical Review (lines 469-490) provides details of these studies.

The majority opinion expressed in the oxytetracycline proposal states that the report by Thiele-Bruhn and Beck refers to European soil, not US soils. It does not seem reasonable to believe that an antibiotic would decrease soil bacterial populations in Europe, but would not decrease soil bacterial populations in the US. We agree with the scientific validity of the minority opinion. Tetracycline is harmful

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[24] Kong, WD, Y.G. Zhu,,, Y.C. Liang, J. Zhang, F.A. Smith, and M. Yang, 2007. Uptake of oxytetracycline and its phytotoxicity to alfalfa (*Medicago sativa* L.). Environmental Pollution, Volume 147, Issue 1, May 2007, Pages 187-193

[25] Mayerhofer, G, I Schwaiger-Nemivora, T Kuhn, L Girsch, F Allerberger. 2009. Detecting Streptomycin in apples from orchards treated for fire blight. J. Antimicrob. Chemother. 63(5):1076-1077

[26] EPA (United States Environmental Protection Agency). 2005. Oxytetracycline. Section 3 Use on Apples. Summary of Analytical Chemistry and Residue Data. HED Records Center Series 361 Science Reviews, File R104981. Washington, DC.
http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-006304_3-Jan-05_a.pdf

[27] Thiele-Bruhn, S. 2003. Pharmaceutical antibiotic compounds in soils – a review. J. Plant Nutri. Soil Sci. 970 145-167

[28] Aga, D.S., O'Connor, S., Ensley, S., Payero, J.O., Snow, D., Tarkalson, D. 2005. Determination of the persistence of tetracycline antibiotics and their degradates in manure-amended soil using enzyme-linked immunosorbent assay and liquid chromatography-mass spectrometry. J. Agric. Food Chem. 53: 7165-7171

[29] Cengiz, M., Balcioglu, I., Oruc, H.H. 2010. Detection of oxytetracycline and chlortetracline residues in agricultural fields in Turkey. J. Biol. Environ. Sci. 4(10): 23-27

[30] Thiele-Bruhn, S., Beck, I-C. 2005. Effects of sulfonamide and tetracycline antibiotics on soil microbial activity and microbial biomass. Chemosphere 59: 457-465

[31] Piotrowska-Seget, Z., Engel, R., Nowak, E. 2008. Successive soil treatment with captan or oxytetracycline affects non-target microorganisms. World J Microbiol Biotechnol 24: 2843-284

[32] Colinas, C., Ingham, E., Molina, R. 1994. Population responses of target and non-target forest soil organisms to selected biocides. Soil Biol. Biochem. 26: 41–47

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

to the environment, and reduces biodiversity in the soil, with particular damage to bacterial populations.

Tetracycline may retain its antibiotic activity in the soil, where it may influence the selection of antibiotic resistant bacteria.[34] When tetracycline was applied to three soil types in a laboratory setting, researchers were able to isolate several strains of bacteria that were resistant to tetracycline.[35] Antibiotic resistance is a significant issue, as discussed in the next section.

Tetracycline use in orchards may contribute to development of antibiotic resistance

We agree with the sentiment expressed by Beyond Pesticides in their formal comments to the Board—it is shocking that some members of the Crops Subcommittee are willing to downplay the risk of tetracycline resistance in human pathogens. The World Health Organization includes chlortetracycline, oxytetracycline, tetracycline and streptomycin antibiotics on its list of critically important antimicrobials. They state, "**It is critically important to prevent resistance to these antibiotics due to non-human antimicrobial use**."[36] Since tetracycline resistance has not yet occurred, as stated by the Crops Subcommittee proposal, that is all the more reason to prohibit tetracycline use in all agricultural settings to prevent resistance from occurring.

The increase in apple acreage, and the increase in high-density plantings of susceptible varieties, only increases the likelihood of resistance to tetracycline. An article published in *ASM News*, by the American Society for Microbiology, states, "Although antibiotic use on plants is minor relative to total use, application of antibiotics in the agroecosystem presents unique circumstances that might influence the buildup and persistence of resistance genes in the environment. Antibiotics are applied over physically large expanses. In regions of dense apple and pear production, antibiotics are applied to hundreds of acres of nearly contiguous orchards. Moreover, the past decade has seen a dramatic increase in the planting of apple varieties and rootstocks that are susceptible to the devastating bacterial disease fire blight."[37]

The tree fruit industry has already experienced a problem with antibiotics—bacterium *Erwinia amylovora* has developed resistance to streptomycin. Since tetracycline is now being used in the same way that streptomycin was used, it is

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[34] Chander, Y, K Kumar, SM Goval, and SC Gupta. 2005. Antibacterial Activity of Soil-Bound Antibiotics. Published online Oct 12, 2005

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

[36] World Health Organization (WHO). 2009. Critically Important Antimicrobials for Human Medicine, 2nd Revision

[37] McManus, P. 2000. Antibiotic Use and Microbial Resistance in Plant Agriculture. ASM News

likely that *Erwinia amylovora* will develop resistance to tetracycline as well. This resistance can easily be transferred to human pathogens.

Although there is no research that proves conclusively that use of tetracycline in apple orchards will cause resistance to tetracycline in human pathogens, there are numerous studies to prove that the use of antibiotics in agriculture has increased the prevalence of antibiotic-resistant bacteria.

The threat of tetracycline-resistant bacteria is a serious one, and we need to use the precautionary principle. Scientists must assume antibiotic resistance will occur in the future, because we know that it has happened in the past. Bacteria that develop antibiotic resistance typically remain resistant for a long period of time.[38]

CONCLUSION

Cornucopia agrees with the concerns about tetracycline use in agriculture expressed by the minority view of the Crops Subcommittee. We applaud their research efforts and agree with the scientific validity of their views. We chose not to repeat their findings in detail, since they are already clearly expressed.

The research that has been conducted on the control of fire blight in apples indicates that fire blight can be managed in apples without the use of antibiotics.

We do recognize that pears are highly susceptible to fire blight, and there has been relatively little research done on alternatives to antibiotics on pears. Due to these differences, we suggest that the regulations be written differently for apples and pears. This would allow removal of antibiotics from apple production without impacting pear growers, while further research can be conducted. Eventually all uses of antibiotics on organic crops should be prohibited.

Prohibition of antibiotics on organic apples is essential to maintain consumer confidence. Parents feed large numbers of apples to their children in the form of applesauce, apple butter, fruit leathers, juice and of course, apples. Given the prohibition against antibiotics in all other areas of organic food production, consumers expect that fruit is also grown without antibiotics, especially antibiotics that are important in human medicine.

[38] Levy, SB, and B Marshall, 2004. Antibacterial resistance worldwide: causes, challenges and responses. Nature Medicine Supplement, Published online 30 November 2004; doi:10.1038/nm1145

PROPOSAL:
POLYOXIN D ZINC SALT (Polyoxin DZS)

SUMMARY

Reject the petition to allow polyoxin D zinc salt in organic crop production.

Rationale

- Production process is not available for review by NOSB members and organic stakeholders.
- The petition does not give enough information to determine if polyoxin DZS is synthetic.
- Polyoxin DZS is not compatible with organic production.
- Polyoxin DZS is not essential.
- Potential post-harvest uses have not been clarified.

Cornucopia agrees with the Crops Subcommittee majority opinion:

- Polyoxin DZS is synthetic.
- Polyoxin DZS should **not** be added to the National List at Section 205.601.

BACKGROUND

Polyoxin D zinc salt was petitioned as a disease control material to be used in organic crop production. It is currently used as a pre-harvest foliar spray on conventional crops to control fungal diseases. There are possible additional uses as a post-harvest material.

Polyoxin D inhibits the growth of fungal cell walls. It does not kill the fungus or the fungal spores; it simply stops the growth of hyphae.

International organic regulations

Polyoxin D zinc salt is not allowed in Canada, Europe, or Japan. It is not listed on IFOAM or CODEX Alimentarius (TER, 2012).

CONCERNS WITH POLYOXIN D ZINC SALT

Production process is not available for review by organic stakeholders

The description of the production of polyoxin DZS is withheld as Confidential Business Information. The petition states that it is produced by a microorganism (*Streptomyces*) in a fermentation process.

The NOSB Manual states that Board members have a responsibility to:

> *Be reasonably informed—It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board.*

When the needed information is kept confidential, it is not possible for Board members to exercise this duty. The authors of the Technical Review (TR) did have access to the confidential information, but their conclusions should not be used as a basis for decision-making. To further complicate the matter, the authors' names, and possible conflicts of interest, are not disclosed. Any petition that contains Confidential Business Information should be declared insufficient for review by the NOSB.

In order to evaluate this material, all information about the manufacturing process needs to be disclosed to the public, including, but not limited to, answers to the following questions:

- Is this strain of *Streptomyces* genetically engineered?
- What are the ingredients in the growth medium for *Streptomyces*?
- Are any ingredients in the growth medium genetically modified? How is this monitored?
- What is the process for extracting the polyoxin D zinc salt from the growth medium?
- Are inerts used in the final pesticide formulation? If so, which ones?

The petition does not give enough information to determine if polyoxin DZS is synthetic

The petitioner believes that this is a non-synthetic material and therefore its use should be allowed without going through the petition process. The determination on whether a material is synthetic or natural must be made by the NOSB, not by the petitioner.

Because the petitioner refused to supply the needed information the NOSB must rely on the TR, which states that PDZS "may" be synthetic.[39]

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[39] Technical Review: Polyoxin D Zinc Salt. 2012. Compiled by The Organic Center

The definition of "synthetic" states that: *"such term shall not apply to substances created by naturally occurring biological processes."* Composting, for example, is a naturally occurring biological process. All microbial growth is a **biological** process. However, growing one microbe in a controlled environment, and feeding it with a chemical soup, is not a **naturally occurring** process.

Polyoxin DZS is not compatible with organic production

This material is a broad-spectrum fungicide that acts by inhibiting synthesis of the fungal cell walls. It prevents growth of both disease-causing fungi and beneficial fungi, according to the TR.

A long list of the proposed uses of this fungicide is included in the petition, pages 6-8. This is evidence that the fungicide has broad-spectrum activity; in other words, it is harmful to many kinds of fungi. This is not consistent with the organic principle that requires farmers to maintain biodiversity on the farm.

It appears that this fungicide will be used both as a foliar spray to control leaf diseases and a soil application to control soil-borne diseases. Therefore, the reduced biodiversity may occur both on above-ground surfaces and in the soil. Soil biodiversity is particularly critical for decomposition and nutrient cycling.

Polyoxin DZS is not essential

The Organic Materials Review Institute (OMRI) lists many materials available to organic growers for plant disease control. These materials include copper, sulfur, oils and other products. With all these other options available, polyoxin DZS is not essential and should seldom be necessary.

There are many practices available to prevent or minimize fungal diseases, such as increased plant spacing, reduced water use, resistant varieties, nutrient management, sanitation and crop rotation. If cultural controls are not adequate, biological controls and non-synthetic materials are available for disease control. If, and only if, these practices are insufficient to manage the disease, synthetic materials can be used.

Potential post-harvest uses have not been clarified

The petition discusses potential post-harvest uses, but does not clarify the crops or method of use. The petition states:

> *Proposed new uses are summarized in Confidential Appendix 1.*[40]

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[40] Kaken, 2012. Petition to Amend 7 CFR §205.601 to Add Polyoxin D Zinc Salt as a Synthetic Substance Allowed for Use In Organic Crop Production

All uses must be explicitly stated before a material can be added to the National List.

CONCLUSION

Cornucopia agrees with the majority opinion: polyoxin DZS should **not** be added to the National List at Section 205.601.

In the future, any petition that contains Confidential Business Information should be returned to the petitioner as insufficient. This will save time for the volunteer NOSB members and the government employees of the NOP.