June 11, 2012

Dr. Lisa M. Brines
National List Coordinator
USDA National Organic Program
Standards Division
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Re: Petition to Remove Expiration Date from the Authorized Use of Tetracycline for the Control of Fire Blight in Apples and Pears

Dear Dr. Brines:

In accordance with the Federal Register Notice 72 FR 2167 (January 18, 2007), the Washington State Horticultural Association (WSHA) located in Wenatchee, Washington, California Pear Advisory Board (CPAB), located in Sacramento, California, and U.S. Apple Association, located in Vienna, Virginia, (henceforth, the petitioners) request the removal of the expiration date (October 21, 2014) from the authorized use of oxytetracycline for the control of fire blight in apples and pears. We further request reinstatement of oxytetracycline to the sunset process.

We have considerable concern for the proposed expiration of oxytetracycline. The loss of oxytetracycline to control fire blight in organic apples and pears will have broad negative implications throughout the national organic tree fruit industry. This petition to re-list oxytetracycline for control of fire blight in organic apples and pears is based on extensive discussions and feedback from organic growers and others in the industry across the country. Oxytetracycline is the current standard control for fire blight in California and the Pacific Northwest, where the majority of organic apple and pear acres are located. But growers and scientists in other parts of the country support the petition to retain this proven tool while non-antibiotic control regimes continue to be developed, studied, tested, and introduced to growers of organic fruit. Fire blight is one of the most devastating diseases for the pome fruit industry. In jeopardy nationally are 488.2 million pounds of organic apples (20,000 acres) and an additional 43.8 million pounds of organic pears (2,145 acres).[i]

The risk of fire blight disease is such that without proven, equivalent, and accessible alternatives, which the industry currently does not have, many growers will reduce their organic apple and pear production or exit organic tree fruit production. This reduction could be substantial, based on surveys and interviews done in several parts of the country. Fire blight is unique in that it puts at risk whole trees and entire orchards, not just some portion of the year's fruit harvest.

The sunset review process was designed specifically for this type of situation in which growers rely on listed synthetic products, while the search for non-synthetic alternatives continues. We disagree with the conclusion of the NOSB that suitable alternatives are in place, and we disagree with its process of removing oxytetracycline from the sunset review and putting an expiration date on it. This has created considerable uncertainty in the organic apple and pear sector and has triggered additional work and expense for many, including the NOSB, by requiring additional petitions such as this to be drafted, submitted, and reviewed.

We support the recently funded Organic Agriculture Research and Extension Initiative (OREI) project on non-antibiotic fire blight control and believe this project needs to be completed to allow time to examine alternatives and update the science. We respectfully request that the National Organic

Standards Board re-examine the decision to eliminate oxytetracycline use in organic tree fruit production on October 21, 2014, without a viable alternative available.

The critical decision this board must address is *when* antibiotics should be removed from use. If the NOSB takes this action before effective alternatives are <u>fully</u> developed and perfected, growers of organic apples and pears will be forced to choose between using a fire blight control product with proven reliability, *i.e.*, streptomycin and/or oxytetracycline and thereby returning their organic apple and/or pear orchards to conventional production, *or* risking their entire organic pome fruit investment with biological alternatives for fire blight control that, so far, have failed to deliver consistently equivalent performance under severe fire blight pressure compared to antibiotics. Please consider how this decision could adversely affect the livelihood of organic fruit growers and the health of their pome fruit orchards. We request that oxytetracycline be returned to the list and the sunset process.

The petitioners have made an attempt to address the concerns of the NOSB and the Crops Committee. We look forward to working with the NOSB as it reviews this petition and would gladly provide any necessary clarifications.

Sincerely,

WASHINGTON STATE HORTICULTURAL ASSOCIATION

Bruce Grim
Executive Director

CALIFORNIA PEAR ADVISORY BOARD

Chris Zanobini
Executive Director

U.S. APPLE ASSOCIATION

Mark Seetin
Director of Regulatory and Industry Affairs

California Pears
Fresh. Flavorful. Beautiful.
California Pear Advisory Board

U.S. APPLE ASSOCIATION

WASHINGTON STATE HORTICULTURAL ASSOCIATION
1904 100 YEARS 2004
"Representing Orchardists & Shippers Since 1904"

[i] Organic Production Survey, 2007 Census of Agriculture, NASS, USDA 2008

Petition to National Organic Standards Board (NOSB) for Removal of the Expiration Date for Tetracycline

June 11, 2012

Petitioners: **Washington State Horticultural Association**
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Item A: This petition applies to tetracycline, an exempt synthetic substance currently authorized for control of fire blight on apples and pears under §205.601(i)(11) of the National List.

Items B-1 through B-11:

Information required for Items B-1 through B-11 has been previously submitted to the NOSB in the following petition:

- NOP Tetracycline (Oxytetracycline Hydrochloride Complex) Petition, AgroSource, Inc., October 10, 2007.

Item B-12. "Petition Justification Statement"

In 75 FR 38696 (July 6, 2010) the NOP states:

> *"…Though some commenters have requested the removal of the expiration date from the use of tetracycline, the NOP recommends that such interested parties petition the NOSB using the petition process outlined in 72 FR 2167 (January 18, 2007) to have the expiration date removed from the authorized use of the substance."*

The petition herein submitted follows the recommendation by the NOP for interested parties and seeks removal of the expiration date, October 21, 2014, from the authorized use of tetracycline for control of fire blight in apples and pears and requests reinstatement of tetracycline into the sunset process.

Executive Summary

Tetracycline, for control of fire blight in apples and pears, was added to the National List as an exempt synthetic substance under §205.601(i)(11) by final rule on December 21, 2000 (65 FR 80613). This action established October 21, 2007 as the sunset date for tetracycline, subject to review as mandated by the Organic Foods Production Act (OFPA) of 1990 (7 U.S.C 6517(e)) which stipulates that each substance identified in §205.601 is subject to a sunset review process by the NOSB every five years.[1] The first sunset review of tetracycline was completed by the NOSB Crops Committee on April 20, 2006, which recommended (by a vote of 7 in favor and 4 opposed) to renew tetracycline to the National List. Tetracycline was subsequently renewed by the NOSB to the National List by final rule on October 16, 2007, resetting its sunset date to October 21, 2012 (72 FR 58469).

On July 6, 2010 – prior to a second sunset review of tetracycline – §205.601(i)(11) of the National List was amended by the NOSB which replaced the sunset date of October 21, 2012, for tetracycline with an expiration date of the same (75 FR 38693). The replacement of the sunset date for tetracycline with an expiration date preempted a second sunset review and instead removed tetracycline from the National List effective October 21, 2012, without any further analysis of the consequences of this decision. Thus, use of tetracycline for control of fire blight on organically grown apples and pears was determined to be no longer permitted in accordance with NOP rules after October 21, 2012.

In October 2010, Washington State Horticultural Association, a representative of the tree fruit industry of the Pacific Northwest, submitted a proposal requesting that the expiration date be removed for oxytetracycline and it be reinstated to the sunset list. The Crops Committee rejected the petitioner's request. On April 8, 2011, the apple and pear industry submitted a rebuttal to the Crops Committee recommendation with endorsements from organizations representing over 10,000 growers and shippers of tree fruit. At the April 2011, meeting of the NOSB, it was recommended that the expiration of oxytetracycline be extended until October 21, 2014, with the expectation that members of the industry will collaborate and coordinate efforts in preparing for the removal of this material from the national list.

The removal of tetracycline as an exempted substance from the National List via expiration on October 21, 2014, will result in significant disruption to the organic apple and pear growing segment of the tree fruit industry and ultimately result in significantly fewer acres devoted to the growing of organic apples and/or pears in the United States. Over the past decade, the availability of tetracycline to growers of organic apples and pears to control fire blight has been critically fundamental to the growth of that industry segment in the U.S., particularly in California, Washington, Oregon and Idaho. Tetracycline is the only substance with a proven and reliable record of fire blight control in regions where alternative control measures have lost

[1] See at:http://farmlandinfo.org/documents/38361/Federal_Organic_Food_Production_Act.pdf

effectiveness and/or where biological options to tetracycline have yet to attain a comparable level of disease control.

Petitioners contend that the expiration of tetracycline from the National List on October 21, 2014:

1. will likely result in a significant net <u>decrease</u> in acreage devoted to the organic production of apples and pears in the major U.S. apple growing states, e.g., California, Michigan, New York and particularly in the PNW where the majority of organic apples and pears are grown;

2. is unmerited given the lack of any documented adverse impact on humans and the environment;

3. is unwarranted and unwise since biological alternatives to tetracycline currently available to growers of organic apples and pears are unproven, unreliable and/or ineffective under severe fire blight disease pressure;

4. will likely cause economic loss to growers highly invested in organic operations and;

5. lacks support from a broad segment of growers, packers and shippers of organic apples and pears; a wide range of state, regional and national commissions, boards, councils and leagues representing apple and pear growers; and the major university and federal scientists conducting research on fire blight and the exploration of alternatives to conventional antibiotics for fire blight control.

To avoid the adverse consequences likely to fall on organic apple and pear growers as a result of the loss of tetracycline from the National List via expiration, petitioners seek removal of the expiration date of October 21, 2014 and reinstatement of oxytetracycline into the sunset process under §205.601(i)(11) of the National List.

Oxytetracycline

Oxytetracycline is created by naturally occurring soil bacteria (*Streptomyces rimosus*) and is produced in commercial quantities through a fermentation process. However, while the production of oxytetracycline is naturally-occurring, the processes used to extract and purify the substance from the bacteria and growth media during the commercial manufacture of the oxytetracycline formulation are not. The commercial formulations of oxytetracycline calcium or hydrochloride are primarily used in plant agriculture to manage fire blight in apples and pears. Oxytetracycline was first registered for use by the U.S. Environmental Protection Agency in pear orchards for control of the bacterial disease fire blight in 1974. It was approved for use for fire blight management in orchards of susceptible apple cultivars for a number of years under a section 18 emergency registration and fully registered for use on apples beginning in 2007. It has been on the approved materials list of the NOP since the program's inception in 2000.

According to data provided by the USDA/NASS Chemical Use Survey, nationally, from 1993 until 2009, an average of 7% of the U.S. apple crop was treated with tetracycline. The peak treatment year was 2005, when 16% of the apple crop was treated. In 2007, when crop protection chemical use on organic apples was compared to use on conventional apples, 5% of the organic apple acres and 7% of the conventional apple acreage were treated with oxytetracycline. For pears, in the period from 1991 through 2009, an average of 39% of the U.S. pear acreage was treated. Chemical use data was not collected in 2007 for pears. The peak treatment year was 1993 when 53% of the pear acreage was treated. This contrast in use between apples and pears reflects grower recognition of a risk-based treatment determination rather than a prophylactic use of the product. When evaluating the importance of the use of oxytetracycline on apples, the geographical differences in antibiotic use across the country must be considered. Eastern apple growers have historically preferentially used streptomycin for fireblight management. Thus the potential acreage that might be treated with oxytetracycline in the western U.S. represents about half of the total U.S. apple acreage. So, while looking at the analysis in this manner results in a higher percentage of the likely treated acreage, the level of treatment shows that apple growers are not applying regular prophylactic treatments but responding to critical risk situations that vary by variety, location and weather and does not signify that the overall problem is minor.

Petition to Remove Expiration Date for Tetracycline and to Re-instate Sunset Date

Petitioners wish to address several points in support of removal of the expiration date for tetracycline and **reinstatement of a sunset date under §205.601(i)(11).**

I. The loss of tetracycline for control of fire blight in organic apples and pears will result in a significant net reduction in the amount of organic apples and pears produced in major pome fruit producing states such as California, Michigan, New York, but particularly in the Pacific Northwest.

Certified organic acres devoted to apples and pears in the U. S. have risen dramatically since the year 2000 principally in the states of Oregon and Washington. In 2009 (latest year for which figures are available), approximately three-fourths of all organic apples and pears grown in the United States were grown in Washington state, where, in 2000 approximately 4,321 acres of apples were certified organic; by 2009 this figure had grown to 15,735 acres – an increase of 264%. The trend for pears is similar: in 2000, there were approximately 575 certified organic acres in Washington state; by 2009 there were 1,964 acres – an increase of 242%[2]. While a number of factors contributed to these increased acreages, the approval in 2000 of tetracycline by the NOP to the National List as an exempted (naturally derived, semi-) synthetic substance gave organic apple and pear growers, particularly in the PNW and California the assurance that organic growers would have an effective treatment to bring to bear in their efforts to combat this serious disease.

Just how important the listing of tetracycline as an exempt substance on the National List has been to the growth of the organic apple and pear industry in Washington state was made clear in surveys of over fifty organic apple/pear growers conducted in early 2010, 2011 and 2012 by Washington State University Sustainable Agriculture Specialist, David Granatstein[3]. Over the past 5-10 years, organic growers have become increasingly aware of growing pressure to discontinue allowance of tetracycline and/or streptomycin to control fire blight in apples and pears. At the same time growth of the organic pome fruit industry has created market forces spurring significant research into biological alternatives for fire blight control on apples and pears. In this context, Granatstein asked a representative group of organic apple and pear growers the following:

How would the loss of antibiotics, e.g., tetracycline, for fire blight control impact your operations?

Granatstein Survey Results	2010	2011	2012
Little to no effect	24%	21%	8%
Reduce organic pear acreage	13%	16%	4%
Reduce acres of susceptible organic apples	35%	41%	44%
Exit organic apple/pear production	28%	22%	44%

[2] Data summarized from: *Recent Trends in Organic Fruit Production, Washington State, 2009* by Elizabeth Kirby and David Granatstein, Washington State University Center for Sustaining Agriculture & Natural Resources, (WSU-CSANR) and from personal communication from David Granatstein.
[3] Summarized from surveys of organic apple and pear growers in Washington State: *Organic Orchards: Needs and Priorities*, conducted by David Granatstein (WSU-CSANR), Mark LaPierre, Wilbur-Ellis Co., and Nadine Lehrer, WSU-TFRC.

In other words, fully 76% of organic apple and pear growers surveyed in 2010 indicated that without the ability to control fire blight using tetracycline[4], they would either reduce or eliminate completely their organic apple and/or pear production. In 2012, 92% of these same growers responded that they would reduce or exit organic pear/apple production completely.

In 2011, Granatstein also asked this same group of organic apple and pear growers:

"In a severe fire blight year, would you be able to control the disease without antibiotics, e.g., tetracycline?"

In response to this question, fully 82% of the organic apple and pear growers answered *"No"*.

In 2012, Granatstein's survey indicated that 73% of organic growers had tried non-antibiotic regimes to control fire blight. Sixty-seven percent of these growers stated that non-antibiotic regimes were not successful. Ninety–three percent of the growers indicated that another petition should be filed with the NOSB requesting an extension on antibiotics beyond the 2014 expiration date.

If 92% of organic apple and pear growers indicate a reduction or elimination of their production commitments in direct response to the loss of antibiotics, i.e., tetracycline, from their management tools, the clear message is that organic apple and pear growers fully realize that viable alternatives to tetracycline for the control of fire blight under severe disease pressure are simply not yet available to them.

The results from Granatstein's surveys give strong indication that a loss of tetracycline to organic apple and pear growers will bring significant reductions in the amount of these fruit being produced organically. Since over the past 10 years consumers have become more accustomed to – and are now actively seeking – organic apples and pears, Granatstein suggests that if American organic growers exit the market, the likely result will be that a comparable volume of organic apple and pear production would be imported from the few areas (e.g, Chile, Argentina) where fire blight has not yet been identified. [5] Fire blight is now present in 43 countries.[6] Organic apple and pear growers, deprived of at least having the option to use tetracycline, are at risk that eventually a fire blight epidemic will occur and the results will be devastating. Entire orchards can be destroyed under severe fire blight epidemics (see photographs below). In 1998 a severe fire blight epidemic in Washington and Oregon caused an estimated $68 million loss; in 2000 a

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[4] Due to widespread streptomycin resistance in Oregon and Washington State, use of tetracycline is the predominant management tool used in the Pacific Northwest for the control of fire blight.
[5]Personal communication, David Granatstein, 2010.
[6] Fire Blight, *Erwinia amylovora*, by Virginia Barlow, May 7th, 2009, Northern Woodlands, see at: http://northernwoodlands.org/articles/article/fire_blight_erwinia_amylovora/

fire blight epidemic in Michigan killed over a quarter million trees generating a $42 million loss to growers.

Michigan apple orchard (cv 'Gala') killed by fire blight in 2000.
Photo courtesy Mark Longstroth, MSU Extension.

Many European countries have banned or severely limited the use of antibiotics for the control of fire blight in pome fruit production. Such efforts, however, have only increased pressure on growers in their annual battle against fire blight. Serious outbreaks of fire blight occurred during the mid-1990s in Hungary, Romania and Spain. In the Po Valley of northern Italy, fire blight epidemics since 1997 have resulted in the destruction of over 500,000 pear trees in efforts to eradicate *Erwinia amylovora*, the pathogen responsible for fire blight (without success).[7]

[7] Fire blight of apple and pear, on-line review article by Ken Johnson, Oregon State University. See at: http://www.apsnet.org/edcenter/intropp/lessons/prokaryotes/Pages/FireBlight.aspx

Portion of 200-acre apple orchard (cv 'Pink Lady') in Washington State destroyed by fire blight in 2001. Photo courtesy Timothy Smith, WSU Extension

Washington pear orchard destroyed with fire blight (1988). Photo courtesy (WSU Extension) Mike Willett, Northwest Horticultural Council

Other European countries' apple and pear growing regions have also suffered outbreaks of fire blight in recent years. McManus and Stockwell report that "…580,000 pear, apple and quince trees were destroyed in Romania from 1993 to 1997 and 340,000 pear and apple trees were destroyed in Croatia since 1995 in efforts to halt the spread of fire blight in those countries."[8,9] In recognition of the damage inflicted by fire blight, Germany, Austria and Switzerland have permitted the restricted application of streptomycin to orchards for disease control on an emergency basis that is evaluated annually by the European Union.

In short, the European experience provides clear evidence that, with currently available tools, production of organic apples and pears cannot be maintained indefinitely (let alone expanded) without the judicious use of antibiotics[10]. Evidence from current growers of organic apples and pears in the PNW combined with what has been observed when and where antibiotics have been eliminated for fire blight control in Europe indicates that the net result of a loss of tetracycline to the domestic organic apple and pear industry will most certainly be fewer certified organic acres, with corresponding less organic apples and pears being produced, especially in the PNW. Such an outcome seems dramatically inconsistent with the goals and aspirations of the NOP to expand the production and consumption of organic apples and pears.

Summary. The growth of the organic apple and pear industry, especially in the PNW, has been driven over the past decade in no small measure by the fact that tetracycline has been defined as an exempt substance on the National List thus allowing the option for its use by organic apple and pear growers when faced with severe fire blight conditions. Fire blight epidemics have utterly destroyed entire orchards causing millions of dollars in losses in various apple and pear growing regions, not only in the U.S. but in Europe as well. Since the fire blight pathogen (*Erwinia amylovora*) is endemic to the U.S., a full-scale epidemic requires only suitable host plants, e.g., apple and pear trees, and environmental conditions favoring the pathogen's growth – mean temperatures above 60°F and a "wetting event" (light rain, dew, etc.). In view of this reality, the loss of tetracycline from the National List will undoubtedly lead to a significant reduction in organic apple and pear acreage and the reversion of these organic orchards to conventionally-managed orchards simply because, in the face of potential severe fire blight pressure, consistently reliable alternatives to tetracycline for fire blight control are not yet available.

II. U.S. EPA and independent research has not identified an adverse human health or environmental health risk with orchard oxytetracycline agriculture use. The EPA and

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[8] McManus, Patricia and Virginia Stockwell. (2000) Antibiotics for Plant Disease Control: Silver Bullets or Rusty Sabers? APSnet Features, Online. See at: http://www.apsnet.org/publications/apsnetfeatures/Pages/AntibioticsForPlants.aspx

[9] Cvjetkovic, B., Halupecki, E. and Špoljaric, J. 1999. The occurrence and control of fire blight in Croatia, Acta Hort. (ISHS) 489:71-78 http://www.actahort.org/books/489/489_8.htm

[10] Widely available computer models allow apple and pear growers to incorporate current environmental conditions and past fire blight history in order to predict the likelihood and severity of fire blight for any given orchard. Thus, critical real-time information is available to apple and pear growers to guide them in applying materials such as tetracycline only when needed.

the FDA have not made specific rulings on the use of tetracycline that would show there is an adverse effect to the public or the environement.

Environmental Protection Agency

Oxytetracycline calcium complex and oxytetracycline hydrochloride are expressed as oxytetracycline[11]. Oxytetracycline has been available in the United States as a drug for therapeutic use in humans since 1950 and was registered by EPA as a pesticide in 1974. The compound is registered for use on apples, pears, nectarines and peaches in the U.S. under the names of Fireline and Mycoshield.[12] Use of these active ingredients in accordance with approved labeling is not expected to result in unreasonable adverse risk to human health (general U.S. population or to infants and children). Based on EPA's assessment, the typical pharmaceutical exposure of oxytetracycline to humans would be 50,000 to 200,000 times greater than the theoretical dietary exposure (combined food and drinking water exposure) associated with the use of oxytetracycline used in plant agriculture. Potential unreasonable risks to endangered species, beneficial organisms, or the environment are not expected from use of these products in accordance with approved labeling.

Human Health. The Food Quality Protection Act Summary document published in the Federal Register as part of the initial filing for oxytetracycline use on apples has been previously submitted and contains information needed by EPA to assess the potential risks presented by residues of oxytetracycline in or on apples.

Toxicological Profile. EPA has waived all toxicological data requirements for oxytetracycline calcium, the active ingredient in Mycoshield, using instead the data generated from oxytetracycline. Oxytetracycline calcium is of low acute toxicity through the oral route of exposure, and has been placed in Toxicity Category IV indicating the lowest degree of toxicity. Subchronic feeding studies in rats showed no adverse effects. In two-year chronic toxicity studies in rats and dogs, the No Observable Effect Level (NOEL) was the highest dose tested, 2500 mg/kg/day.

Carcinogenicity studies show some equivocal evidence of cancer in male and female rats administered extremely high doses. However, EPA has classified oxytetracycline as a "Group D" carcinogen – one that is "not classifiable as to human carcinogenicity."

One developmental toxicity study in rats showed a high incidence of maternal deaths and ferotoxicity; however highly excessive dose levels were used. No adverse effects were demonstrated in another similar study.

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[11] R.E.D. FACTS for hydroxytetracycline monohydrochloride and oxytetracycline calcium. EPA-738-F-93-001.
[12] Fireline and Mycoshield are formulations of oxytetracycline hydrochloride and oxytetracycline calcium complex, respectively. Fireline is manufactured and registered by AgroSource, Inc.; Mycoshield is manufactured and registered by Nufarm Americas Inc.

Aggregate Exposures and Risks. The Agency's RfD Peer Review Committee has established the reference dose for oxytetracycline as 0.005 mg/kg/day using the NOEL of 0.05 mg/kg/day from the 44-day feeding study in dogs which was based on an antimicrobial effect. The Agency determined that an acute dietary FQPA Safety Factor was not needed for oxytetracycline based on a review of the entire data base.

The risks to people from dietary and occupational exposure to pesticides containing hydroxytetracycline monohydrochloride and oxytetracycline calcium are considered negligible. Chronic dietary risks posed by all food uses of these pesticides are well below the level that would reasonably cause concern.

Dietary Exposure. Tolerances or maximum residue limits (MRLs) of 0.35 ppm are established for residues of oxytetracycline in or on apples, pears, and peaches (including nectarines) (see 40 CFR 180.337). Because oxytetracycline is used in veterinary medicine, FDA has established tolerances for residues in animals as well (see 21 CFR 520, 522, 524, and 558).

Groundwater. The exposure to drinking water is considered minimal. FireLine or Mycoshield will not be applied directly to water.

Residential (Non-dietary) Exposure. There are no registered residential uses of oxytetracycline, so a residential exposure assessment is not needed.

Occupational Exposure. Pesticide mixers, loaders, and applicators can be exposed when oxytetracycline is applied using foliar application methods. No occupational or residential exposure monitoring data are required because the toxicity data for oxytetracycline are below EPA criteria values that would trigger requirements for these studies.

Common Mode of Action. Oxytetracycline, oxytetracycline calcium, and hydroxytetracycline monohydrochloride have a common mechanism with other tetracyclines, but not with other pesticides. There are no known common modes of action with other pesticides.

Tetracyclines bind to bacterial ribosomes and block the binding of aminoacyl tRNAs to amino acids, which results in the inhibition of protein synthesis. Streptomycin, the other bactericide registered for use for fire blight control in Washington (but not currently in use because of widespread resistance) binds to bacterial ribosomes and prevents protein synthesis, the initiation of peptide chains, and the recognition of normal triplets.[13] Both streptomycin and tetracycline inhibit protein synthesis via interaction with the bacterial ribosome but the mechanisms for the development of antibiotic-resistant strains are different. Changing a single nucleotide in a gene

[13] Agrios, G. N. 1988. PLANT PATHOLOGY, 3rd Ed. Academic Press, San Diego.

encoding the bacterial ribosome during normal replication of the chromosome can lead to resistance to streptomycin, but the bacterium will still be sensitive to tetracycline. In laboratory studies, *E. amylovora* does not develop resistance to tetracyclines via spontaneous mutation. While streptomycin-resistant strains of *E. amylovora* are common in the PNW, resistance to oxytetracycline has not been documented in Washington and Oregon despite several surveys over the past 35 years.

<u>Human Pathogen Resistance</u>

Orchard application of antibiotics in 2009 accounted for 0.12% of the total antibiotics used in animal agriculture.[14] Antibiotic resistance in medicine has been recognized as a major threat. However, antibiotics used for orchard application have not been linked to this threat. Stockwell and Duffy[13] make the following points:

1. U.S. EPA standards restrict permissible antibiotic residue on crops and significant residues have not been found in harvested fruit.

2. Based on EPA assessment, the typical pharmaceutical exposure of oxytetracycline to humans would be 50,000 to 200,000 times greater than the theorized dietary exposure (combined food or potentially contaminated water source) associated with the use of oxytetracycline used in plant agriculture.[15,16]

3. U.S. EPA models indicate that direct exposure to humans and their microflora from antibiotics used in crop protection are several thousand-fold less than medical use antibiotics. [15, 16]

4. Antibiotics used in plant agriculture are non-persistent on plant surfaces and lose activity rapidly. Tests have shown that antibiotics are active on plants less than a week. Stockwell et al. discovered in a controlled experiment on treated trees in a screenhouse that when protected from UV radiation and rain, oxytetracycline could not suppress bacterial growth four days after treatment.[17] In a coconut palm study, no oxytetracycline uptake was found using soil drench or foliar spray. Direct injection into the trunk did produce detectable levels in leaves (up to 20 μg/g) with a half-life of two weeks. [18]

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[14] Stockwell, V.O. and Duffy, B., (2011)Use of Antibiotics in Plant Agriculture (in press)
[15] U.S. EPA (2006) Report of the Food Quality Protection Act tolerance assessment progress and risk assessment decision (TRED) for oxytetracycline. Available at:www.epa.gov/oppsrrd1/REDs/oxytetracycline_tred.pdf
[16] U.S. EPA (2008), Oxytetracycline summary document registration review, Initial Docket !2/2008; Docket Number EPA-HQ-OPP-0686, Available at www.regulations.gov
[17] Stockwell, V.O., Temple T.N, Johnson, K.B. and Loper, J.E. (2008), Intergrated control of fire blight with antagonists and oxytetracycline.
[18] McCoy, R.E. 1976. Uptake, translocation, and persistence of oxytetracycline in coconut palm. Disease Control Pest Management 66:1038-1042.

5. Oxytetracycline is not rainfast on leaves:[14]

2-minute simulated rain (44 mm/hr)	67% reduction in oxytetracycline concentration
1-hour simulated rain (44mm/hr)	Oxytetracyline near the limit of detection

6. Oxytetracycline in orchards would not be available to suppress bacteria for 2 days after full sunlight, 4 days under overcast skies or 2 minutes during a heavy rainstorm.

7. Human pathogens are not common colonists of pome fruit flowers, thus the probability of obtaining antibiotic resistance genes directly from phyllosphere bacteria in the tree canopy is reduced.

8. Sprayed antibiotics that land on the orchard floor have not been found to select for antibiotic resistant soil bacteria since antibiotics do not remain active in the soil. [19]

These researchers concluded that antibiotics have been in use for crop protection for over 50 years without documented adverse effects on human health or adverse impact on the environment.

III. Existing Fire Blight Management Systems and the Role of Biologically-Based Alternatives to Antibiotics.

The fire blight *(Erwinia amylovora*) bacterium is native to eastern North America, but has now spread to Europe, the Near East, and New Zealand. *E. amylovora* enters the plant through flowers and wounds, and can be spread by insects, rain, hail, wind and through cultural practices that damage the bark such as pruning or tractor equipment. Once inside the tree, the bacteria multiply and spread through the plant's vascular system. If the bacteria move into the rootstock, fire blight can kill the entire tree. Once an infection is observed, growers typically prune out diseased wood, which is labor intensive and thus expensive (>$1,000/acre).[20] Control is most successful when materials such as antibiotics and copper are used to prevent growth of the pathogen on plant surfaces and subsequent infection. Once infected, no materials will kill the bacteria in the tree. This is in contrast with the use of antibiotics to control established infections in humans and livestock.

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[19] Subbiah, M., Mitchell, S.M., Ullman, J.L. and Call, D.R. (2011) β-Lactams and Florfenicol antibiotics remain bioactive in soils while ciprofloxacin, neomycin, and tetracycline are neutralized, Appl Environ Microbiol. 77(20):7255-60. Epub **2011** Aug 19.
[20] Granatstein, D. (2011) Economic Impact of loss of tetracycline for control of fire blight on organic apples and pears, submitted to NOSB.

Fire blight control in organic apples and pears in the western United States is accomplished through an integrated approach focusing on orchard sanitation, controlling vigor through judicious nitrogen use, temperature-based prediction system to monitor the risk of fire blight infection and evaluate need for control measures and, finally, the application of bactericides or bacteria-stats to reduce the risk of fire blight infections by reducing bacterial populations in the orchards.

In this section we review the use of currently approved fire blight control measures; the potential for EPA-registered biological and biologically-based alternatives to tetracycline to provide adequate control; and the potential for the incorporation of resistant plant material into the fire blight management program.

Sanitation

Sanitation for fire blight management or the removal of infected tissue, either during the growing season and/or during the dormant period, is an important part of a fire blight control program. Regional experts recommend that all visible fire blight infections be removed from the orchard during the winter and that any "strikes" observed during the growing season be removed as soon as the symptoms become visible to avoid spread of the disease in the orchards.[21] Removal of infected host material is the basis for integrated fire blight management as practiced by apple and pear growers.

Predicting Fire Blight Risk

One of the goals of fire blight research over the last 50 years has been to gain a better understanding of the observed relationship between weather and the likelihood of fire blight infection. This research, both basic and adaptive, has resulted in a number of site-specific temperature based tools to allow U.S. apple and pear growers to predict the likely presence and the magnitude of *Erwinia amylovora* populations in their orchards (e.g. Cougarblight, Maryblyt, Thomson-Schroth Average Temperature Model, Zoller Degree-hour model). All of these models allow managers to take into account the risk-status of the orchard (based on recent infection history), the presence/absence of bloom, the growth of bacterial population in open flowers on the trees, the likelihood that weather related (rainfall or dew) events will result in disease and the need to apply an antibiotic to suppress bacterial populations and prevent infection should the correct combination of wetting and warm temperatures occur.

The antibiotic oxytetracycline is one of the primary tool used by conventional and organic growers to prevent fire blight infection of apple and pear trees during periods of high risk. Use

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[21] Smith, T.J.(November 2010) Fire Blight Management in the Pacific Northwest USA.

of these materials is guided by disease models tailored to different regions of the country. Treatments are not applied in those years when the models do not indicate sufficient risk. Growers deploy other practices as part of a fire blight management program, but antibiotics are the last line of defense when infection risk is high. Once infected, no available materials provide a curative effect; the antibiotics act in a preventative mode only.

With the recent availability of low cost environmental monitoring tools, most orchardists have access to remote weather stations as part of computer-based weather networks. Growers can run these models from weather data collected in their orchard or use data from remote stations. Most of these weather networks provide growers with access to one or more of these fire blight models, depending on model validation in a given production area. A complete description of representative model, Cougarblight, can be found in Attachment 4. All of these tools allow growers to assess the potential fire blight risk and choose the most effective tool to address the degree of risk projected.

Alternative Fire Blight Control Materials

Alternatives to antibiotics have been actively pursued by researchers and industry for several decades, with a significant infusion of grower funds for their evaluation. Several biological control materials are now registered for use by organic growers. However, availability does not equate to demonstrated equivalence with the material they are intended to replace, as shown above. At this time, the tools for non-antibiotic control of fire blight for organic apple and pear growers are not sufficiently effective or evaluated as replacements for conventional antibiotics currently used. Some growers have reported success with non-antibiotic regimes, but these regimes have not been widely tested in the diverse growing environments across the country.

The National Organic Program has included antibiotics for use only on fire blight on apples and pears as part of the National List of Allowed Synthetics since the program began in 2000. The National Organic Standards Board has now set October 21, 2014, as the expiration date for their use and has requested information on the status of alternative controls. Research on biological controls of fire blight has been on-going since the 1980s. BlightBan A506 and Serenade were introduced in the 1990s; then BlightBan C9-1 and Bloomtime Biological were put on the market in the 2000s. A new biocontrol material was commercialized in Germany several years ago and is now being tested in the U.S.[22] Blossom Protect is a live formulation of *Aureobasidium pullulans*, a naturally occurring yeast that is commonly found in orchards. Blossom Protect has shown promise in limited field studies and is now registered by the EPA (February 2012), but supplies are limited for the 2012 season. These developments have been supported by over $600,000 in grower funds on research for non-antibiotic controls and practices that would be organic compliant. The

[22] Kunz, S., Schmitt, A., and Haug, P. 2011. Development of strategies for fire blight control in organic fruit growing. Acta Horticulturae 896:431-436.

USDA-ARS supports at least three key research programs on alternative fire blight control (Wenatchee, WA; Kearneysville, WV; Geneva, NY for resistant rootstocks), with a cumulative investment of over $5 million. Other USDA grants funds have totaled over $1 million. There has been no lack of effort and support for developing non-antibiotic alternatives, just a lack of clear success with the alternatives.

The primary three biocontrol products that are EPA-registered for fire blight and that OMRI-approved are BlightBan A506 (*Pseudomonas fluorescens*), Bloomtime Biological (*Pantoea agglomerans*), and Serenade Max (preparations of *Bacillus subtilis* QST 713). Several of the organisms in these products are natural antibiotic producers. These have been tested extensively as standalone replacements for streptomycin or oxytetracycline in different regions of the country. Sundin et al. tested these products over 7 years in Michigan, Virginia, and New York.[23] These materials exhibited low efficacy and high year-to-year and location-to-location variability. They did show promise when used in sequence with antibiotics, and were able to reduce the number of antibiotic sprays needed. Based on their results, the researchers concluded that "…the prospects for biological control of fire blight in the eastern United States are currently not high". The experience has been similar in Washington, Oregon, and California.[24] [25] A complicating factor that has not been extensively explored is the possibly negative interaction between other management practices used by organic growers, such as scab (*Venturia inequalis* and *Venturia pirina*) control or fruit thinning, and the use of these biological control organisms.[26]

Recently, Oregon researchers developed an integrated control concept for fire blight that recognized differential control of the disease when on the stigma versus the nectary of the fruit tree blossom. [27] They defined 'integrated' as the sequencing of a biological control followed by an antibiotic control, based on their hypothesis that the biological materials controlled the pathogen on the stigma in the early stage of bloom, and the antibiotic controlled it when on the nectary later in bloom. They were able to achieve control similar to an antibiotic-only regime, but reduced antibiotic use by half.

In field trials in Oregon, a regime of Bloomtime Biological followed by Blossom Protect provided fire blight control similar to regimes that included antibiotics (K. Johnson, unpublished data).

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[23] Sundin, G. W., Werner, N. A., Yoder, K. S., and Aldwinckle, H. S. 2009. Field evaluation of biological control of fire blight in the eastern United States. Plant Disease 93:386-394.
[24] 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.
[25] Zoller, B. 2011. Use of streptomycin and oxytetracycline for fire blight management in organic pear production in California. Unpublished report.
[26] Lindow, S.E., Holtz, B.A., and Elkins, R.B. 2008. Improved biological control of fire blight of pear and apple by introduction of antagonistic bacteria into un-opened flowers. Acta. Hort. 793:451-452.
[27] Stockwell, V.O. , Temple, T.N., Johnson, K.B., and Loper, J.E. 2008.Integrated control of fire blight with antagonists and oxytetracycline. Acta. Hort.793:383-390.

The Bloomtime Biological protected the stigma and the Blossom Protect protected the nectary, following the integrated control concept described above. Interactions of these controls with organic fruit thinning protocols using lime sulfur plus fish oil are being studied as well (Fig. 1).

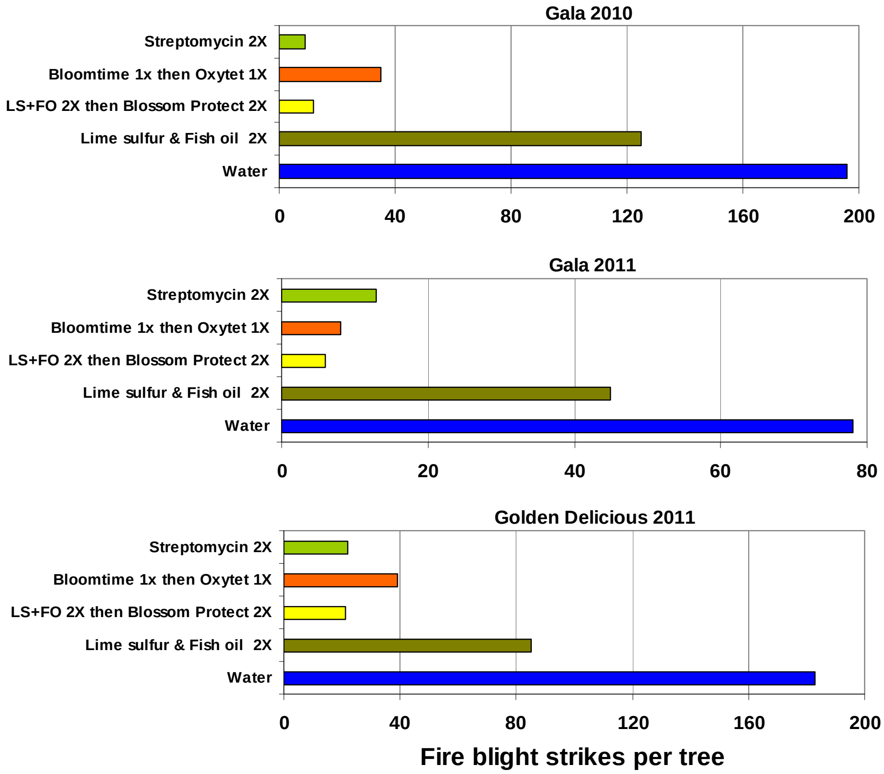

Figure 1. Examples of field trial results with non-antibiotic and integrated control of fire blight, Corvallis, OR (K. Johnson, unpublished data). LS=lime sulfur; FO=fish oil

Field trials in eastern Washington have also evaluated Blossom Protect on apples and found it to provide control similar to oxytetracycline. [23]. One year of testing on pears in California yielded positive results. [28] In Michigan, Blossom Protect (63-64% control) on apples did not provide similar control to streptomycin (97-98% control) in two of three years when disease pressure was moderate and high, using 4 applications of Blossom Protect. [21,29 30]

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[28] Adaskaveg, J.E. and Gubler, W.D. 2010. Evaluation of new bactericides for control of fire blight of pears caused by *Erwinia amylovora*. Annual Report for California Pear Advisory Board. http://www.calpear.com/_pdf/research-reports/JEA%20Fireblight.pdf

[29] Sundin, G.W., Ehret, G.R., and McGhee, G.C. 2009. Efficacy of bacterial antagonists in controlling fire blight on 'Gala' apple, 2008. Unpublished research report.

[30] Sundin, G.W., Ehret, G.R., and McGhee, G.C. 2010. Fire blight control on Jonathan apple with antibiotics in 2009. Unpublished research report.

Because it is a live organism, there are some operational considerations with the use of Blossom Protect which differ from traditional antibiotic use. Growers must be aware that certain fungicides, including copper, must be applied one to two days before or after a Blossom Protect application. Also due to a concern of fruit russetting in wetter production regions, the label also prohibits the use of Blossom Protect when fruit is present. This can limit a grower's options if they are protecting secondary (or rat-tail) bloom from infection. In the western U.S., it is the infection of secondary bloom, which co-occurs with the developing fruit, that results in the greatest amount of fire blight infection during normal years.

A USDA OREI funded project in 2011 (K. Johnson, principal investigator) will continue the work described above in Oregon, Washington, and California to further validate efficacy, design suitable integrated control programs, and educate growers. This is a 4-year activity that will begin with the 2012 field season. It is not reasonable to assume that the project could be shortened to speed the process of obtaining the necessary data.

After a single year of use, it is too soon to determine how Blossom Protect will fit within the tree fruit protection regimes. In terms of evaluating the benefits of Blossom Protect under commercial conditions, the opportunities were limited for the 2012 season. With registration so recently granted, very little of the product is available to growers for testing purposes (limited to treatment of 2000 acres in 2012).

Certain copper products are already used by organic growers during the dormant season to help suppress the development of fire blight bacteria cankers on the trees. New copper formulations are being tested for use during bloom and have shown positive results (Fig. 2). More experience is needed to allay concerns about fruit russetting (which renders the fruit unmarketable), particularly in pears. It is also unknown if these products will be available to organic growers. Long term, coppers are not a suitable replacement for antibiotics. Copper is an essential plant micronutrient, but it is also a heavy metal and potential environmental contaminant that persists in soils. Organic farms in Europe have relied on repeated use of copper for disease control, which led to elevated soil copper levels far above what was considered normal and into ranges where scientific studies have shown potential for inhibition of soil microorganisms. In addition, long term usage of copper products could result in soil levels that could induce heavy metal toxicity to trees, especially new root stocks. This could potentially result in stunted growth and or short term death. Thus, soil monitoring is needed when using these materials.

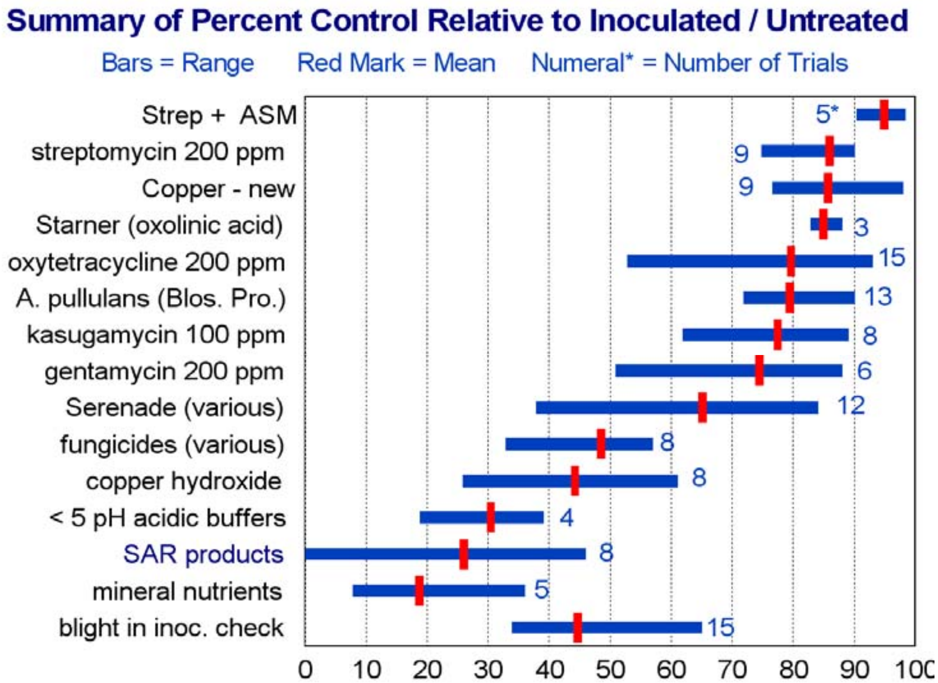

Figure 2. Summary of "percent control" of blossom infection in the past 10 years of similar fire blight control material trials in eastern Washington. [Strep=streptomycin; ASM= acibenzolar–s-methyl; Blos. Pro. =Blossom Protect; SAR=systemic acquired resistance; inoc. =inoculated] Courtesy of Tim Smith, WSU.

Research on the biology of fire blight and other possible controls is on-going as well.[31] [32] [33] This includes identifying stigma exudates and their role as a microbial food source, water dynamics and osmotic adaptation possibilities, and use of bacteriophages attached to other biocontrol organisms (L. Pusey, pers. comm.).

As new materials become available, researchers validate them under different conditions and within overall orchard management systems to reduce the risk of failure or unanticipated side effects by growers. This process is then followed by a period of education and grower experience to again refine the use of the materials in the diverse settings and environments encountered in commercial orchards. The process of moving from a material, such as Blossom Protect being available, to proving its efficacy, to integrating its use into an overall management

[31] Johnson, K. B**.,** Sawyer, T. L., Stockwell, V. O. and Temple, T. N. 2009. Implications of pathogenesis by *Erwinia amylovora* on stigmas of rosaceous flowers to biological control of fire blight. Phytopathology 99:128-138.
[32] Pusey, P. L., Stockwell, V. O., and Mazzola, M. 2009. Epiphytic bacteria and yeasts on apple blossoms and their potential as antagonists of *Erwinia amylovora*. Phytopathology 99:571-581.
[33] Johnson, K.B., Stockwell, V.O., and Sugar, D. 2000. Assessment of environmental factors influencing growth and spread of *Pantoea agglomerans* on and among blossoms of apple and pear. Phytopathology 90:1285-1294.

system, to educating growers, is a multi-year effort (often 5 or more years) that needs to be recognized by bodies such as the National Organic Standards Board when making a decision to phase out a critical control option. Given the time required, it is questionable whether organic apple and pear growers will have in place a suitable and nationally applicable alternative management regime for fire blight by the October 21, 2014 date set by NOSB for expiration of antibiotic use.

Genetic Resistance

The ideal long-term solution for fire blight disease in apples and pears would be a high level of multi-gene resistance, or immunity. Our understanding of the genetic basis of fire blight resistance has increased, and researchers have used molecular biology techniques to enhance the resistance of 'Gala' apple (a cultivar produced using such techniques would not likely be in compliance with the National Organic Program). Past breeding efforts that used crabapple as a source of resistance generally led to cultivars that were not acceptable to consumers. According to apple breeder Henryk Flachowsky (Dresden, Germany), "Only a few varieties have a certain degree of resistance to [fire blight], but these are not grown commercially. Resistance genes are normally found only in wild species, but these tend to have very small fruit." Some apple breeding programs have used 'Red Delicious' or 'Golden Delicious' as a parent for increasing fire blight resistance, while others have conducted their breeding and then simply screened progeny for their resistance. Lists of the fire blight resistance of apple cultivars are compilations from several sources that did not necessarily use the same method for assessing resistance. These lists typically state that none of the cultivars is immune and all will become infected under high risk conditions.

Cultivars and Rootstocks. No domesticated apples or pears are known to have immunity to fire blight. All will become infected under high risk conditions. Once infected, greater resistance (or tolerance) leads to less spread of the disease in the tree and less damage. 'Red Delicious' has the greatest level of resistance of all apple cultivars in wide commercial use, but can still suffer 45-65% infection of blossoms if untreated. Unfortunately, organic consumers have a low preference for this cultivar. As a rule, the older the tree, the more resistant it is to fire blight damage, and older wood on a tree is more resistant than young wood on the same tree. Different plant parts show varying susceptibility. For example, flowers of 'Red Delicious' are very susceptible, but the young wood is not; thus bacteria entering through the flower do not spread very far down the branch and damage is limited.

Most apples used today are grafted trees, so the resistance of both the scion (top) and rootstock must be considered. Fire blight susceptibility in an apple cultivar is increased by grafting to fully dwarfing rootstocks. These rootstocks lead to flowering at an earlier age (when the tree is more susceptible) and to more secondary bloom (which occurs in warmer weather with higher infection risk). Dwarfing rootstocks have essential horticultural characteristics needed for commercial apple production. The dominant dwarfing rootstock used is M.9, which is highly susceptible to fire blight. The new 'Geneva' rootstocks have a high level of fire blight resistance and desirable horticultural qualities, but are not yet commercially available. Rootstock resistance means that a highly infected tree is not likely to be killed clear to the roots by the intra-plant movement of the bacteria, but does not confer resistance to damage in the scion part of the tree.

Pears show less variation in resistance and are generally more susceptible than apples. Many pear orchards are decades old and these large trees may become infected but are less likely to die than young trees. Bosc pear is particularly susceptible to fire blight, and even 15-20 year-old trees can die. But since Bosc produces minimal late bloom, it generally escapes infection with bloom occurring during cooler periods that are not high risk for infection. The "blight resistant" cultivars that have been developed by various pear breeding programs around the world have not been popular with growers or customers, and are more tolerant of blight, not highly resistant.

Plant breeding for resistance. Most apple (and pear) breeding programs have focused foremost on the eating quality of the fruit, as this will determine the economic viability of that cultivar. Breeders are screening for more horticultural traits as well, and with the advent of genome mapping and marker-assisted breeding, it is easier to screen for specific traits such as fire blight resistance. North American apple scion breeders have seldom actively bred for fire blight resistance, while some European breeders have. For example, the apple breeding program at Dresden-Pilnitz has produced several selections in the Re series with enhanced resistance to fire blight and purported commercially acceptable fruit quality. Some of the current work involves the use of molecular biology approaches, but only uses genes from *Malus* species; this is often termed *cis-genic*, versus transgenic. This process allows a known variety with established consumer acceptance to have its resistance increased. It is unlikely such modified varieties would be allowed and accepted in organic production under current NOP standards.

Planting resistant orchards. The life of a modern apple planting is generally 15-20 years, compared with a 30-100 year life for pear orchards. Replanting an orchard is a very expensive process. It costs between $12,000-$22,000 to remove the old trees, remediate the soil, plant new trees and install the support systems. In this scenario, a grower could replace both the scion and rootstock with more fire blight resistant choices if: 1) there is a market for the fruit, 2) the scion is available, and 3) the rootstock is available. A grower must order the specific scion/rootstock combination from a nursery several years in advance. Thus, despite the existence of the 'Geneva' rootstock, supply is very limited, and a grower wanting to replant an orchard could probably not do so with resistant rootstock until 2-8 years from now. Apple growers can cut off the scion and re-graft a new scion at lower cost than removing the trees. This could improve scion resistance but would not affect rootstock.

Apples, and to some extent pears, are one of the few food items sold by cultivar name in the U.S. Therefore, switching to an unknown variety that is fire blight resistant and of good eating quality would entail a significant risk for a grower. Until the consumer market is developed for a new variety, it is not possible to sell significant volume through commercial channels. Developing consumer recognition and acceptance of a new variety is a multi-year and multi-million dollar process, with no guarantee of success. Thus, it is unrealistic to ask organic growers to assume the market risk of planting acreage of a fire blight resistant variety with no consumer recognition. Introducing a fire blight resistant apple or pear variety will need to occur over a period of many years and therefore is not a short-term solution to the antibiotic phase-out planned for organic producers.

IV. Economic impact/loss would adversely affect growers heavily invested in organic operations.

The following tables provide the most recent USDA NASS 2008 survey data for organic apple and pear production (rounded values).

Organic Apples	**U.S. Total**	**Washington** (% of U.S. total)	**California** (% of U.S. total)	**Arizona** (% of U.S. total)	**Colorado** (% of U.S. total)	**Oregon** (% of U.S. total)
Acres	20,009	13,005 (65%)	3192 (16%)	1023 (5%)	426 (2%)	238 (1.2%)
Tons	244,100	212,600 (87%)	11,200 (5%)	8,600 (3.5%)	2,800 (1%)	1300 (0.5%)
$ Value (million)	136.8	118.9 (87%)	6.5 (5%)	4.2 (3%)	1.5 (1%)	0.73 (0.5%)

Organic Pears	**U.S. Total**	**Washington** (% of U.S. total)	**Oregon** (% of U.S. total)	**California** (% of U.S. total)	**Virginia** (% of U.S. total)
Acres	2145	1319 (61.5%)	344 (16%)	212 (10%)	60 (2.8%)
Tons	21,900	17,200 (78.5%)	2,500 (11.4%)	88 (0.4%)	22 (0.1%)
$ Value (million)	16.2	12.8 (74%)	1.4 (8.6%)	0.9 (5.5%)	0.16 (1%)

While oxytetracycline loss would affect all apple and pear growers, Washington, the largest apple and pear producing state, would be disproportionately affected as streptomycin is not used as an alternative. If fire blight develops and results in a complete loss of trees, the 1998 estimated average replacement cost averaged about $12,777 per acre[34]. Newer data from 2010 has determined the establishment cost of an organic Gala apple orchard to be $13,673 per acre.[35] Accumulated establishment costs could range as high as $22,450 in the third year. (Attachment 5)

If only 2% of Washington acres (264 acres) were lost, $3.96 million in orchard establishment costs alone would be born by the growers. Loss of trees would negate future returns on these orchards. The fruit from one acre of Gala or Braeburn apples could be worth $2,250 - $4,500 in

[34] Hinman, H., Williams, K. and Faubion, D. November 1998, Estimated capital requirements and profitability of establishing and producing a high density Fuji apple in Eastern Washington, Pub. No. EB1878, Dept. of Agr. Econ., Washington State University, Pullman.
[35] Galinato, S.P., Granatstein, D., Taylor, M.R. (2011) http://cru.cahe.wsu.edu/CEPublications/FS041E/FS041E.pdf

the first year of production to $20,250 in the tenth year. Fuji's could be worth $3,000-$6,000 during the second year and increase to $27,000 per acre during the tenth year. Pink Lady could return $3,900 - $7,800 during the first year of production and increase to $35,000 per acre during the tenth year. Use of Mycoshield or FireLine Fungicide/Bactericide would protect the investment of many growers and help to ensure market diversification.

History has shown that while fire blight risk does not occur every year, an infection risk that warrants treatment occurs every 3 to 5 years for a given block in Washington state.[19] However, fire blight disease is known to have restricted the range of the principle production of some susceptible cultivars to the more arid regions of the U.S. California is often at the warm, wet weather extreme of where major production of some cultivars has been possible, but only with treatments such as oxytetracycline or coppers available for fire blight disease management. In contrast to short bloom duration apple cultivars in some production regions, the California susceptible pear bloom can last two months in some cultivars. Culture of the most important varieties such as Bartlett, Bosc and Starkrimson has required several treatments most seasons according to the degree hour fire blight predictive model. [36]

Infected blocks require additional management measures in terms of cutting out infected wood to prevent further spread in the infected trees and contamination of more of the orchard. This cost was estimated to be at least $1000 per acre by Tim Smith, a fire blight expert with WSU Extension. [19] With WA organic apple acres at 15,021 (organic plus transition, 2011), and organic pear acres at 2,025 (organic plus transition, 2011), from 3,409 to 5,625 acres would be treated in a given year. Without a suitable antibiotic replacement, 75% of these acres might suffer an infection that would otherwise not occur and thus the growers would incur a collective cost of $2.6-4.2 million a year for manual control measures. In California the manual control of fire blight in pear production is an every year effort in conjunction with treatments. Control of the disease over the long term with manual efforts alone would not be economically sustainable. Organic production to supply the current California marketing window would shift to areas of the globe where the disease is not present.

For the 2010 crop, 6.8 million boxes (40 lb) of apples were sold as organic and 649,000 boxes (44 lb) of pears were sold as organic. Using typical price premiums per box of $8.06 for organic apples, and $10.65 for organic pears (average of 2005-2009 crops; Kirby and Granatstein, 2011; http://www.tfrec.wsu.edu/pdfs/P2191.pdf), and assuming a 10-20% reduction in supply based on grower survey response, this would equal a loss of premium income of $6.17-12.34 million per year.

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[36] Zoller, B., in Van der Zwet, T., Orolaaza-Halbrendt, N. and Zeller, W. 2012. Fire Blight History, Biology, and Management. APS Press, p. 355-358.

The above figures do not include any yield loss from fire blight infected trees and blocks, or costs to replant dead trees or blocks. Annual cost for Washington growers alone could range from $8.77-16.54 million per year. This would account for an estimated 80-85% of the national economic impact[20].

In 2006, the industry prepared a Section 18 for the U.S. EPA to request emergency use of oxytetracycline to control fire blight in apples. The EPA requires an assessment of economic loss. The EPA confirmed the projections and granted the emergency use of this product. This document is attached for your review. (Attachment 6)

V. Widespread support in the organic tree fruit community, including

- **growers, packers and shippers of both organic and conventional apples and/or pears,**
- **various university and federal scientists conducting research on fire blight and the exploration of alternatives for fire blight control, and**
- **a broad range of organizations dedicated to research, education, promotion and marketing of both organically and conventionally grown apples and pears.**

In 2010, the petitioners canvassed representatives from among the apple and pear growing industry and asked the following question –

> *"How will the loss of tetracycline in 2012 affect your commitments to* <u>*organic*</u> *production of pome fruit?"*

Respondents to this question ranged from growers with relatively "small" organic acreages (1 - 100 acres) to "medium" organic growers (101 – 250 acres) to "large" organic growers (>250 acres). Representative responses to the above question from each grower size category are reproduced below.

<u>"Small" organic apple/pear growers (1 – 100 acres)</u>

- **Name:** Gary Middleton
  Organization: Middleton Organic Orchards, Washington State
  Position in Organization: Owner/Grower
  Comments: "*I am the owner and grower of a 100 acre orchard on which we grow organic apples, blueberries and cherries. At issue is our 16 acre block of Gala apples. Over the past 5-7 years fire blight has decimated approximately 5-6 acres throughout this block of apples which equates to over 4,000 trees and a financial annual loss of $75K - $90K. Fortunately, we have had the opportunity to utilize Mycoshield [equivalent product: FireLine™, Mycoshield (oxytetracycline)] or the losses certainly would have*

been much greater. Without products such as Mycoshield it is highly likely that our entire Gala block would need to be destroyed. Replanting is not an economical alternative even if the Geneva rootstock was available. Like other orchardists we are anxiously anticipating new organic products to suppress fire blight. However, I am not aware of any products at this time or the near future. We have utilized bacteria control such as Blight Ban and Bloom time with extremely nominal results. These are not viable options however we still utilize them to help suppress the disease. The cost per acre to apply Mycoshield is $147.56 per acre with a maximum of four applications per year. The cost of Blight Ban is $174.87 per acre with a maximum of six applications per year. These do not include the cost of spraying. I cannot emphasize enough how we are concerned about the integrity of the organic products we provide to our consumers. We take pride and ownership in the fruit that we produce. This is a complex matter at best and there are no easy solutions but with confidence I can say that with stringent monitoring and limited use of antibiotics we can continue to move forward until a true organic solution becomes available."

<u>"Medium" organic apple/pear growers (101 – 250 acres)</u>

- **Name**: Luis Hernán Acuña
  Organization: CF Fresh (Fruit broker representing "many growers in Washington and California, selling a significant volume of organic apples and pears across the U.S. and abroad.")
  Position in Organization: Co-President
  Comments: *"Fire blight is a tremendous problem for apple and pear growers. A grower could get wiped out by not having the proper material to control that disease. Organic growers deserve a chance to count on this material or an alternative material that satisfies the requirements of the National Organic Program fully. The NOSB cannot leave us to perish because they think tetracycline is unnecessary. The organic pear market will be destroyed by taking this product."*

- **Name:** Nick Stephens
  Organization: Columbia IPM, Inc., Washington State
  Position in Organization: Production Consultant
  Comments: "*The loss of oxytetracycline would cause irreparable harm to the organic apple and pear industry of Eastern Washington. There is no effective substitute for oxytetracycline that will prevent an epidemic from killing untreated orchards during a severe infection period. No grower can assume the degree of risk that this potential rule change would impose."*

- **Name:** Chet Dufault
  Organization: Emmanuel Enterprises, Inc., Washington State
  <u>Certified Organic Acres</u>
  Apples 105 acres; Cherries 27 acre; Grapes 94 acres

Position in Organization: Manager
Comments: ***"****Discontinuing the use of tetracycline will have a very negative impact on organic apple production. It will leave growers with no effective control against a wide spread fire blight infection. It will force many growers to return to conventional production which in turn could have a negative impact on them financially."*

"Large" organic apple/pear growers (>250 acres)

- **Name:** Cragg M. Gilbert
  Organization: Gilbert Orchards, Washington State
  Position in Organization: General Manager/Farmer
  Comments: "*The loss of tetracycline would result in us pulling the following varieties from organic production: Cripps Pinks and Galas."*

- **Name:** Harold V. Austin IV
  Organization: Zirkle Fruit Company, Washington State
  Position in Organization: Director of Orchard Administration; Washington State Department of Agriculture Organic Advisory Board (member); National Organic Standards Board (member)
  Comments: "*We grow, pack and sell our own fruit, represented as a large producer/handler in the organic program. We currently farm both conventional and organic apples, cherries, pears, and blueberries in Washington State. Oxytetracycline is an extremely important part of our fire blight control program for both apples and pears. There are certain varieties that would most likely not be able to be continued to be farmed organically without oxytetracycline, such as Pink Lady, Honeycrisp, Gala, and Fuji, some of our pollinizer trees, as well as our Bosc and Bartlett pears. There are other products available for use, but none of these compounds come anywhere close to giving us the control aid that we get and rely on from oxytetracycline. These other products do not give us the control or the range of application timing. The only effective "post bloom" product that we currently have is oxytetracycline, the others are extremely in-effective in giving us adequate control of fire blight after bloom. It is our firm belief that without oxytetracycline as one of the tools in our fire blight control program we will not be able to keep certain blocks of fruit in our current organic program. We could easily be looking at removing over 500 acres (minimum) from the organic program. We sincerely urge the NOSB to consider postponing the removal of oxytetracycline from the current proposed deadline, until an effective replacement product can be found. We have all worked too hard to build the organic programs to their current levels (both within our state and nationally) to allow such a huge setback to occur."*

- **Name:** Jim Phipps
  Organization: Stemilt Growers, representing small, medium and large organic apple and pear growers, in Washington and California States

Position in Organization: Food Safety Coordinator
Comments: *"Some varieties in some areas would not be economically feasible to continue production. If conditions were right for a terrible fire blight year and we did not have tetracycline, we could not control an outbreak. Most of the block would have to be destroyed to keep infection from reaching good trees. Of particular concern are: Pink Lady, Gala and Fuji apples and Bosc pears."*

In 2010, the petitioners also canvassed a wide segment of university researchers and state extension personnel/crop advisors having extensive experience in fire blight research and/or investigation into alternatives to tetracycline (or antibiotics in general) for the control of fire blight. The question put forth to these individuals was –

"Is the current level of organic pome fruit production and market share in your region sustainable if tetracycline (assuming strep resistance exists in your region) is lost as a tool to manage severe outbreaks of fire blight?"

Responses to this question were submitted via email to petitioner and are reproduced below:

- **Name**: Ken Johnson, Ph.D.
  Contact information: 541-737-5249, johnsonk@science.oregonstate.edu
  Affiliation: Oregon State University, Corvallis, Oregon
  Position: Professor, Botany and Plant Pthology
  Comments: "*[R]emoving oxytetracycline from the NOP approved materials list is likely have these two impacts: a) some growers may be faced with the tough choice of saving an orchard or losing certification, and b) the diversity of cultivars (and perhaps quantity of fruit) produced under the NOP standard would likely decline. Our research at Oregon State U. has been actively addressing the question of non-antibiotic control of fire blight. We have made some progress in improving control, and expect to make more. Nonetheless, with non-antibiotic materials, achieving the level of control that is obtained with oxytetracycline is a tough goal and likely impossible from a material cost point-of-view. For most cultivars of pear and many newer cultivars of apple, if fire blight attains a moderate level of infection, it has the potential to destroy an entire orchard without intervention with antibiotic materials. As problems in crop protection go, there are very few pests that have this kind of destructive potential."*

- **Name:** David Granatstein, M.S.
  Contact Information: 509-663-8181 ext. 222, granats@wsu.edu
  Affiliation: Washington State University, Center for Sustaining Agriculture and Natural Resources, (WSU-CSANR), Wenatchee, WA
  Position: Sustainable Agriculture Specialist
  Comments: "*While I am not a plant pathologist, I do work extensively with organic tree fruit producers in Washington State, the Northwest, and other parts of the world.*

Currently Washington State provides the large majority of organic apples and pears to the U.S. market. Our climate is relatively conducive to organic pome fruit production compared to more humid regions such as New York or Michigan. However, we do have fire blight disease present in the region. It is a disease that does not occur every year or on every orchard, and thus actual treated area with antibiotics such as tetracycline is not extensive. However, once a tree becomes infected with fire blight, it can kill parts or all of the tree, and provide an inoculum source to further infect the orchard. As growers have switched to newer apple varieties to appeal to consumers, some of the new varieties are significantly more susceptible to fire blight than older varieties such as Red Delicious. And organic consumers appear to prefer the newer varieties over the older ones.

Based on a survey I did in February 2010 at an organic tree fruit grower meeting, growers did indicate that the loss of tetracycline would be a serious impact. While other controls are being developed and tested, growers generally do not consider any of them to be adequate in a severe fire blight infection year. Thus, in their survey responses, they indicated that they would likely reduce their organic acres of susceptible apples and pears, or perhaps exit organic production altogether, due to the increased risk of orchard loss to fire blight. Since Washington State is the primary supplier of organic apples and pears, and since other regions of the U.S. have not proven nearly as suitable for organic pome fruit production, a reduction in organic apple and pear acreage in Washington due to the loss of tetracycline would likely result in either a contraction of supply or an increase in imports of organic apples and pears from other countries that do not have fire blight present.

Growers are comfortable with the antibiotic exception for organic apples and pears being removed once alternatives have been well proven and are commercially available. At this point, the alternatives are not well-proven to the level of efficacy that antibiotics provide, and the risk of significant or total loss of an orchard block to fire blight is large enough that loss of antibiotics will likely lead to contraction of production, based on the responses to my survey and conversations with growers."

- **Name:** David Rosenburger, Ph.D.
  Contact Information: 845-691-7151, dar22@cornell.edu
  Affiliation: Cornell Hudson Valley Laboratory, Department of Plant Pathology and Plant-Microbe Biology, Cornell University, Ithaca, New York
  Position: Professor of Plant Pathology and Plant-Microbe Biology, Superintendent, Cornell University Hudson Valley Lab
  Comments: "*Maintaining registration for tetracycline on organically-produced pome fruits could be a determining factor in whether or not there will ever be a significant acreage of organic pome fruits in Northeastern United States because organic growers need effective tools to prevent fire blight from killing their trees. Organic apple and pear*

producers in New York and New England struggle to control the fungal diseases that are prevalent on pome fruits in this area, but they would find it impossible to control fire blight without access to antibiotics. Farmers would be foolish to invest in organic pome fruit production if they knew in advance that organic standards would limit their access to the antibiotics that provide the only effective means for controlling fire blight. Establishing a new orchard now costs more than $10,000 per acre, and only the perversely foolish person would consider putting that level of investment into an organic orchard if they knew in advance that organic standards might prevent them from controlling a disease that could kill most of their trees within two years.

Yes, biorational products like Serenade are registered to control fire blight, but extensive research has shown that these products have almost no value when used alone and are only marginally effective when used in alternations with standard antibiotic treatments (see Plant Disease 93:386-394 [2009]).

Currently, streptomycin is still working in New York and New England, so streptomycin will be the first choice of antibiotic when growers need to protect blossoms from the fire blight bacterium. However, streptomycin-resistant strains of the fire blight bacterium could appear in New York at any time, and when that occurs, growers will need an alternative that can be accessed immediately. Thus, while loss of tetracycline for organic pome fruit production would presumably have little short-term impact on organic fruit producers in this region, loss of this valuable tool could prove disastrous in the longer-term and could be a determining factor for growers considering investments in organic pome fruit production."

- **Name:** Jim. E. Adaskaveg, Ph.D.
  Contact Information: 951-288-9312, jim.adaskaveg@ucr.edu
  Affiliation: Department of Plant Pathology, University of California, Riverside, California
  Position: Professor
  Comments: "*In California the apple and pear industry has widespread streptomycin resistance in the major production regions of the state. Our surveys conducted with the support of the apple and pear industries of California over the last several years have indicated that approximately 50% of isolates collected from commercial orchards are resistant to streptomycin. Currently, the entire organic and non-organic pome fruit industry is heavily dependent on the use of tetracycline for managing fire blight. This is further demonstrated by the fact that the California Apple Commission has previously supported a Section 18 emergency registration for tetracycline use on apples. If this tool is lost, extensive crop losses may occur under conducive environments and streptomycin resistance will increase. Furthermore, if tetracycline is not available for organic growers, this situation will jeopardize the existence of organic farming of apples and pears in California. Currently, there are no other organic treatments available that have*

the same level of efficacy as tetracycline. Thus I strongly support the continued "organic" status and registration of tetracycline as one of the main tools for managing fire blight in organic and non-organic pome fruit orchards in California."

- **Name**: Timothy J. Smith
  Contact Information: 509-667-6540, smithtj@cahnrs.wsu.edu
  Affiliation: Washington State University, Wenatchee, Washington
  Position: Area Extension Specialist, Tree Fruit
  Comments: "*While we are working to develop alternative organically acceptable materials for the control of fire blight, and there are some products that show great promise, there is no such alternative presently. After all other steps to reduce the chance of infection are taken, products that directly protect the flowers from infection by the disease bacteria must be applied when disease forecasting models indicate high risk of infection. There is nothing to do after the infection event but wait to see how much, if any, damage was done to the orchard. Damage ranges from zero to complete loss of the orchard. If infection occurs, large portions of the tree or the entire tree must be removed. No other tree fruit disease threatens the level of damage that fire blight can inflict on the orchard. Oxytetracycline is a substance derived from nature through the process of fermentation. It is far more natural than many other substances approved for organic production. This product has remained effective for 35 years in Washington due to its unique mode of action against bacteria. Resistance to this substance is unlikely to occur in the* Erwinia amylovora *bacteria, and selection pressure is very slight on other bacteria in the environment. As for human exposure, limit seasonal spraying to the time of season that it is effective, primary bloom to 30 days after, and the residue on food will be infinitesimal."*

- **Name:** Philip Schwallier
  Contact Information: 616-490-7917, schwalli@msu.edu
  Affiliation: Michigan State University Extension, Grand Rapids, Michigan
  Position: District Horticulture Agent
  Comments: "*Fire blight is a devastating disease of apples and pears. Organic producers have few to no good alternatives. Removal of registration would reduce or eliminate production for many growers. I support the continued use of tetracycline for organic fruit production."*

- **Name:** Dan Griffith
  Contact Information: 509-575-8382, dang@gslong.com
  Affiliation: G.S. Long Company, Union Gap, Washington
  Position: Crop Advisor
  Comments: ***"****I am a crop advisor with lots of organic acreage of pome fruits. Losing tetracycline would have a terrible effect on the growers of existing organic apples & pears. The damage would be devastating."*

- **Name**: Broc Zoller, Ph.D.
  Contact Informations: peardoc@pacific.net
  Affiliation: The Pear Doctor Inc., Kelseyville, CA
  Position: Crop Advisor to organic and conventional pear growers.
  Comments: *"The ability to control fire blight has determined the areas in the U.S. where some pear cultivars may be successfully produced. In California the production of organic pears without the antibiotics for fire blight control has been tried and is thought to be limited to the least favorable weather areas. Even in these areas antibiotic use is the preferred method and currently excludes marketing in Europe by grower choice because of the difficulties without antibiotics in control of the disease. Losing oxytetracycline would shift organic production of our cultivars to areas of the globe without the disease."*

In addition to the above testimony from organic growers and researchers involved directly with fire blight, the following table lists organizations, commission, and boards representing apple and pear growers (both organic and conventional) across the U.S. that have reviewed this petition. On behalf of the thousands of apple and pears growers they represent, each organization has endorsed this petition for removal of the expiration date of tetracycline.

Organization	No. Growers* Represented
California Apple Commission	70
California Pear Advisory Board	Approx. 180
Columbia Gorge Fruit Growers	440
Northwest Horticultural Council	Approx. 3,700
New York Apple Association, Inc.	Approx. 700
Pear Bureau Northwest/USA Pears	Approx. 1,550
Tilth Producers of Washington	Approx. 400
U.S. Apple Association	Approx. 7,500
Washington Apple Commission	Approx. 2,200
Washington State Horticultural Association	Approx. 1,500
Washington Growers Clearing House	2,200+
Washington Tree Fruit Research Commission	†
Washington Growers League	407
Wenatchee Valley Traffic Association	‡
Yakima Valley Growers and Shippers Assoc.	‡

*Figure includes both organic and conventional growers of apples and pears.
†The Washington Tree Fruit Research Commission (WTFRC), though not directly representing growers as other organizations listed here, is a grower-funded, state commodity commission serving apple and pear growers through on-going research and education into a variety of areas related to tree fruit, including fire blight research and management.

‡This organization serves both the Washington Apple Commission and the Pear Bureau Northwest with a combined membership of approximately 3,750 growers.

Finally, both manufacturers and registrants of agricultural tetracycline (oxytetracycline) for control of fire blight in apples and pears fully support this petition to the NOSB (see table below).

Manufacturer	Tetracycline (Oxytetracycline) Product Trade Name
AgroSource, Inc.	FireLine™ 17 WP
Nufarm Americas Inc. USA	Mycoshield®

Based on comments received by the petitioners in this matter, a broad segment of pome fruit growers view the expiration of tetracycline from the National List as having serious repercussions to their commitments to continue producing organically grown apples and/or pears. They base their opinion on the inescapable reality that fire blight epidemics continue to occur each year and consistently reliable alternative biological control measures in the face of a full-scale fire blight epidemic are not yet available to them. This point is further substantiated by the written testimony from a wide range of pomologists, field research scientists and state extension agents across the U.S. familiar with the current state of fire blight research and with the local conditions in which they conduct their research. Testimony from those most involved in fire blight research does not support the action taken by the NOSB to remove tetracycline from the National List based on the logic that alternative measures are available. In addition, various commissions, councils, research groups, boards and trade associations devoted to the research, production and promotion of apples and pears, collectively representing thousands of small, medium and large apple and pear growers, both organic and conventional, have endorsed this petition because they clearly recognize the adverse impact the loss of tetracycline will have on their grower members.

Summary and Conclusions

To maintain a complete document, attached is a response addressing published concerns of the NOSB Crops Committee recommendation of March 2011 after its review of the WSHA petition. This response has been previously provided to the NOSB as a rebuttal to the conclusions reached by the Crops Committee on this matter. (Attachment 7)

The United States Department of Agriculture (USDA), Agricultural Marketing Service, 7 CFR, Part 205 – National Organic Program, Subpart G – Administrative, contains the National List of Allowed and Prohibited Substances (the National List) for use in organic agriculture. Within the National List §205.601 establishes that certain synthetic substances may be used in organic crop production provided the "…use does not contribute to contamination of crops, soil, or water." The Organic Foods Production Act (OFPA) of 1990 mandates that each substance identified in

§205.601 is subject to a sunset review process by the NOSB every five years. The first sunset review for tetracycline was conducted by the NOSB – Crops Committee in 2006 prior to its sunset date of October 21, 2007. On April 20, 2006, the NOSB-Crops Committee voted to recommend renewal of tetracycline as an exempted substance on the National List. Subsequently, tetracycline for fire blight control was renewed to the National List on October 16, 2007. With a new sunset date of October 21, 2012, tetracycline would be removed from the National List pending a sunset review as per OFPA, a majority vote to recommend renewal by the Crops Committee as an exempted substance under §205.601, a vote by the NOSB to accept the recommendation and final rule adoption.

On July 6, 2010 final rule action amended §205.601(i)(11) replacing the sunset date for tetracycline (October 21, 2012) with an expiration of the same date. This action circumvented the OFPA-mandated sunset review process for tetracycline and removed it from the National List as without due process. In April 2011 the NOSB ruled that the use of tetracycline for control of fire blight on organically grown apples and pears is no longer permitted in accordance with NOP rules after October 21, 2014.

Approval of tetracycline through the petition process to the NOP National List in 2000 gave apple and pear growers the confidence to expand acreages devoted to these crops while facing possible outbreaks of fire blight. The result for the past decade has been a greater abundance of organic apples and pears for consumers and greater participation and acceptance on the part of apple and pear growers to the National Organic Program as well as many state organic programs. Should the expiration date for tetracycline be allowed to stand, the result will be <u>a net reduction</u> in the number of acres devoted to growing organic apples and pears simply because the risk of growing these fruit crops without the option of tetracycline to control a fire blight epidemic is too great for most growers to bear. In the end, the loss of tetracycline will mean many – perhaps a majority – of organic apple and pear orchards will be <u>converted back</u> to conventionally managed orchards.

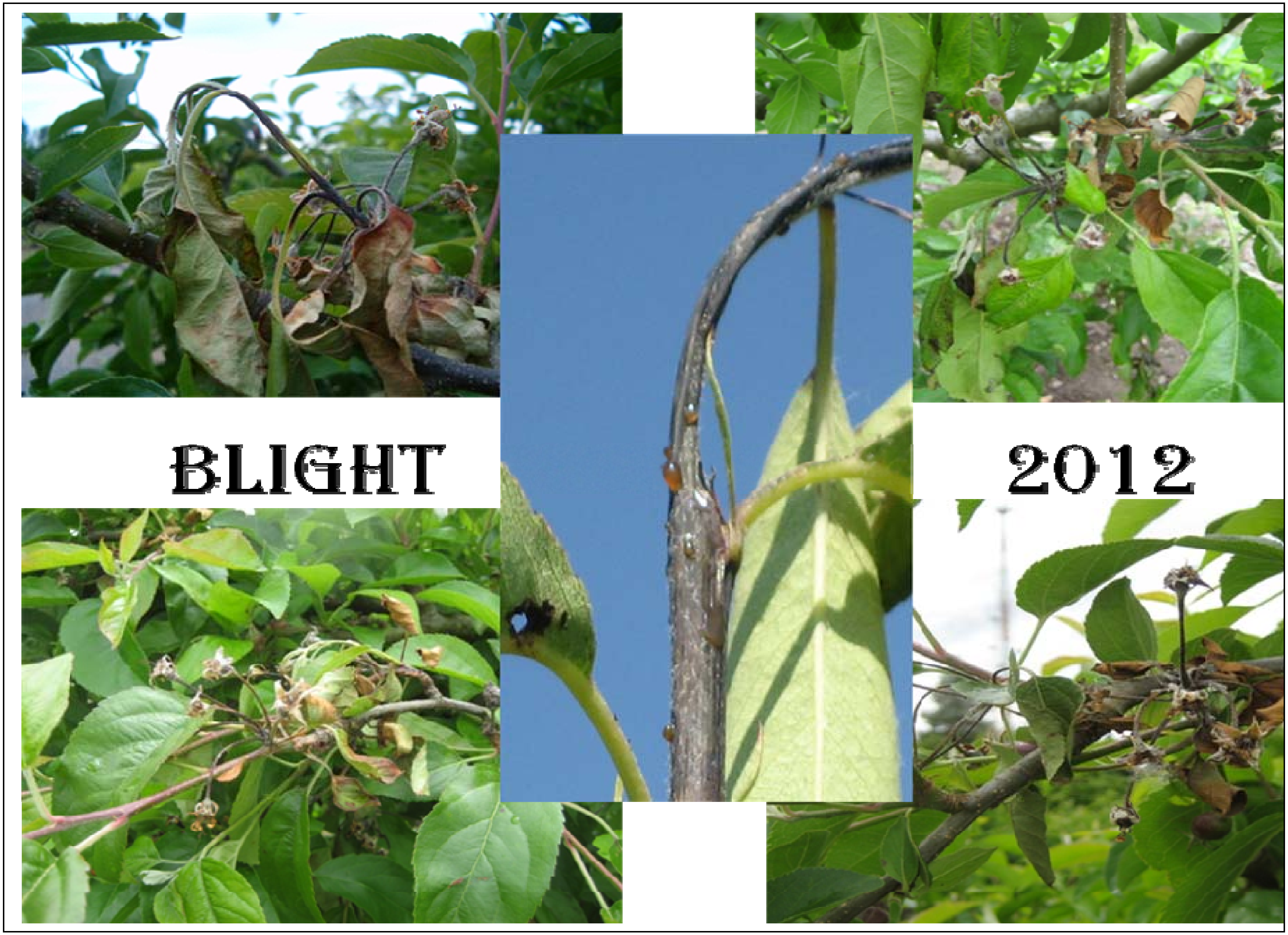
By the rule changes adopted on July 6, 2010 and April 2011, a process to remove tetracycline from the National List has been set in motion that fails to give adequate regard to the adverse consequences such action will have on organic apple and pear growers in the United States. The critical matter this board must address is *when* antibiotics should be removed from use. If the NOSB takes this action before effective alternatives are <u>fully</u> developed and perfected, growers of organic apples and pears will be forced to choose between using a fire blight control product with proven reliability, *i.e.*, streptomycin and/or oxytetracycline and thereby returning their organic apple and/or pear orchards to conventional production, *or* risking their entire organic pome fruit investment with biological alternatives for fire blight control that, so far, have failed to deliver consistently equivalent performance under severe fire blight pressure compared to antibiotics.

Petitioner requests an amendment to remove the expiration date and re-instate tetracycline into the sunset process under §205.601(i)(11) of the National List. A reinstatement of tetracycline to the National List for approved substances will give growers of organic apples and pears throughout the United States confidence to continue their production commitments and future plans while development of biological alternatives for the control of fire blight continues to advance. The rapid growth in organic apple and pear acreage, especially in the PNW, over the past ten years has justified significant research efforts to develop biological alternatives for the control of fire blight. Therefore, maintaining tetracycline on the National List is vital to not only existing growers of organic apples and pears in their annual battle with fire blight but for the continuation of multiple research efforts underway to develop viable biological alternatives to tetracycline for the control of fire blight in apples and pears.

Following are snapshots 2011/2012 fireblight damage.

Because of the large document size, attachments can be found in a separate file.

1. NOP Tetracycline (Oxytetracycline Hydrochloride Complex) Petition, AgroSource, Inc., October 10, 2007. Redacted CBI version. (previously provided)
2. AgroSource Fireline™ Label and MSDS
3. NuFarm Mycoshield® Label and MSDS
4. WSU- The Development and Use of Cougarblight Model
5. 2010 Cost Estimates of Establishing and Producing Organic Apples in Washington
6. Section 18. Emergency use of oxytetracycline (Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline) to control fire blight in apples (2006)
7. WSHA, April 8, 2011, Re-listing Tetracycline, AMS-NOP-11-0014



Courtesy of Aaron Avila, G.S. Long, Yakima, WA

Courtesy of Aaron Avila, G.S. Long, Yakima, WA

Courtesy of Aaron Avila, G.S. Long, Yakima, WA

CALIFORNIA BLIGHT 2011

Courtesy of Broc Zoller, Kelseyville, CA

Mycoshield®

FOR THE CONTROL OF FIRE BLIGHT OF PEAR AND APPLE AND BACTERIAL SPOT OF PEACH AND NECTARINE

ACTIVE INGREDIENT:	
Oxytetracycline Calcium complex:	
(Equivalent to17% oxytetracycline)	31.5%
OTHER INGREDIENTS:	68.5%
TOTAL:	100.0%

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KEEP OUT OF REACH OF CHILDREN

WARNING / AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

SEE INSIDE BOOKLET FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

Manufactured For
NUFARM AMERICAS INC.
AGT DIVISION
150 Harvester Drive
Burr Ridge, IL 60527

EPA REG. NO. 55146-97
EPA EST. NO. _________

NET CONTENTS: 2.0 POUNDS

FIRST AID	
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING / AVISO

Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes, on skin, or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Protective eyewear.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users Should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Engineering Controls Statement

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d) (46)], the handler PPE requirements may be reduced or modified as specified in the WPS.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the high water mark. Do not contaminate water when disposing of equipment washwater.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry internal. The requirements in this box only apply to uses that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Protective eyewear

This product contains the antibiotic oxytetracycline. To reduce the development of drug resistant bacteria and maintain the effectiveness of this and other antibacterial products, this product should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

This material is not to be used for medical or veterinary purposes.

CHEMIGATION

Do not apply this product through any type of irrigation system.

APPLICATION PROCEDURES

For best results, apply this product using an airblast sprayer with enough water to provide full coverage. Thorough coverage is essential.

MIXING PROCEDURES

MIXING:

To avoid possible pesticide contamination, use only clean metal or plastic containers in preparing all solutions.

CONCENTRATION DESIRED	QUANTITY MYCOSHIELD PER VOLUME OF WATER		
ppm*	**50 gals.**	**100 gals.**	**500 gals.**
150	6 oz.	12 oz.	3 ¾ lbs.
200	8 oz. (½ lb.)	16 oz. (1 lb.)	5 lbs.

*ppm = parts per million oxytetracycline base in prepared solution.

CROP USE DIRECTIONS

Use of predictive models for fire blight threshold treatment conditions will minimize the number of applications of this product. Thorough spray coverage is essential.

CROP	DISEASES CONTROLLED	USE RATE	APPLICATION INSTRUCTIONS
Peaches **Nectarines**	Bacterial Spot *(Xanthomonas campestris pv. pruni)*	• 0.75 - 1.5 lbs. per 50 - 200 gals. water per acre	**Ground Application:** Apply at 7 day intervals beginning at petal fall (<5% shuck split) through first cover. After first cover, application interval can be extended to 7 - 10 days depending on weather conditions. Use the higher rate early in the season and during periods conducive for disease. Use a pressure sprayer capable of delivering the spray at a minimum of 250 lbs. pressure per square inch through a hand-held single nozzle gun, or 150 lbs. pressure per square inch using an airblast sprayer. For best results with airblast sprayer, do not exceed 3 miles per hour ground speed or 100 miles per hour spray velocity. Do not apply within 3 weeks of harvest. Do not apply more than 12 lbs. product per acre per year.
Apples **Pears**	Fire Blight *(Erwina amylovora)*	**Ground Application:** Apply a 200 ppm solution per acre which is equivalent to: • 1.0 lb. Mycoshield / 100 gals. water **Aerial Application:** • 1.0 lb. Mycoshield / minimum 10 gals. water	**Ground Application:** Apply using airblast sprayer. Ensure good coverage of plant parts. Apply beginning with 10% bloom and continue at 3 - 6 day intervals or apply when blight favorable weather is expected during apple bloom. Do not exceed 5 applications per year. **Aerial Application:** Application by air is not a direct replacement for applications by ground. Use aerial application only in those orchards in which optimal coverage can be achieved by air. Even with optimal coverage, the extent of control may be reduced. Apply by ground within 3 to 6 days subsequent to an aerial application. Begin spray application at 10% bloom and continue at 3 - 6 day intervals, or apply when blight favorable weather is expected during apple bloom. Spray coverage of blossoms is essential. **Restrictions:** DO NOT apply more that 1.0 lb. of product per acre per application. DO NOT exceed a total of 5 applications of oxytetracycline per year using either ground or aerial methods of application. DO NOT apply within 60 days of harvest. DO NOT use treated crop or by-products for feed. DO NOT allow livestock to graze on treated orchards. **NOTE:** Use of this product may cause phytotoxicity to the fruit and/or foliage of sensitive pear varieties, especially Asian varieties.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Open dumping is prohibited.

PESTICIDE STORAGE: Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative of the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

Paper Bags: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

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If you do not agree with or do not accept any of the directions for use, the warranty disclaimers, or limitations of liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV081811)

BATCH CODE: ________________

FireLine™

17 WP

This document has been prepared to meet the requirements of U.S. OSHA Hazard Communication Standard, 29, CFR 1910.1200. The information contained herein is for the concentrate as packaged unless otherwise indicated.

MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

TRADE NAME: Fireline™ 17 WP fungicide/bactericide
PRODUCT NUMBER: 1001
EPA REGISTRATION NUMBER: 74896-4
ACTIVE INGREDIENT: Oxytetracycline Hydrochloride
CAS NUMBER: 2058-46-0
CHEMICAL NAME: 2-naphthacenecarboxamide, 4-(dimethylamino)-1, 4, 4a, 5, 5a, 6, 11, 12a-octahydro-3, 6, 10, 12 dioxo-monohydrochloride, 12a pentahydroxy-6-methyl-1, 11-dioxo-monohydrochloride
ANSI COMMON NAME: Oxytetracycline
MOLECULAR FORMULA: $C_{22}H_{24}N_2O_9HC_1$ (oxytetracycline hydrochloride)
CHEMICAL CLASSIFICATION: Antibiotic
USE: Control of bacterial diseases on agricultural crops.
MANUFACTURER:
AgroSource, Inc.
P.O. Box 1341
Mountainside, New Jersey 07092-0341
U.S.A.
General Information: (908) 931-9001

EMERGENCY TELEPHONE NUMBERS:
IN CASE OF EMERGENCY CALL INFO TRAC
(800) 535-5053 or (352) 323-3500

SECTION 2 - COMPOSITION, INFORMATION ON INGREDIENTS

Component	%w/w	CAS Number	OSHA PEL**	ACGIH TLV**
Oxytetracycline (hydrochloride)	17	2058-46-0	Not Established	Not Established
Quartz		14808-60-7	0.1 mg/cu m Respirable Dust	0.1 mg/cu m Respirable Dust
Inert Ingredient		Not Available	3 mg/cu m Respirable Dust	3 mg/cu m Respirable Dust
Inert Ingredient		Not Available	10 mg/cu m Total Dust 5 mg/cu m Respirable Dust	10 mg/cu m Total Dust 5 mg/cu m Respirable Dust

* Unidentified inert ingredients are proprietary and/or non-hazardous.
** Permissible Exposure Limits (PEL) & Threshold Limit Value (TLV) are 8-hour time weighted average (TWA).

SECTION 3 - HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

IMMEDIATE CONCERNS:
- Free flowing yellow to tan powder
- Thermal decomposition and burning may form toxic by-products
- For large exposures of fires, wear personal protective equipment

POTENTIAL HEALTH EFFECTS: Effects from over exposure may result from either swallowing, inhaling or coming into contact with skin or eyes. Symptoms of oxytetracycline hydrochloride exposure include gastrointestinal irritation, nausea and vomiting. Exposure may cause allergic reaction and anaphylaxis to occur in sensitive individuals. Eye contact may cause moderate eye irritation. As with other antibiotics, it has the potential to change the micro flora of the intestine and allow overgrowth of non-susceptible organisms.

MEDICAL CONDITIONS AGGRAVATED: Excessive exposure to any dust may aggravate pre-existing respiratory conditions. May cause allergic reaction and anaphylaxis to occur in individuals with allergic history or pre-existing dermatitis.

SECTION 4 - FIRST AID MEASURES

EYE CONTACT: If in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

SKIN CONTACT: If on skin or clothing, take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

INHALATION: If inhaled, remove to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor immediately for further treatment advice.

INGESTION: If swallowed, call a poison control center or doctor immediately for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTES TO PHYSICIAN: Treat symptomatically. There is no specific antidote. Emesis may be indicated in recent substantial ingestion unless the patient is or could rapidly become obtunded, comatose or convulsing. Is most effective if initiated within 30 minutes. Plasma tetracycline levels are not clinically useful. No specific lab work (CBC, electrolyte, urinalysis) is needed unless otherwise indicated. Anaphylaxis may be managed with appropriate supportive measures including securing an adequate airway, epinephrine and diphenhydramine.

SECTION 5 - FIREFIGHTING MEASURES

EXTINGUISHING MEDIA: In case of fire use water spray, dry chemical, foam or CO_2 extinguishing media.

FIRE FIGHTING PROCEDURES: Wear full protective clothing and self-contained breathing apparatus. Evacuate non-essential personnel from the area to prevent exposure to fire, smoke, fumes or products of combustion. Prevent use of contaminated buildings, area and equipment until decontaminated.

FIRE AND EXPLOSION HAZARDS: None known. As with all dry powders, it is advisable to ground material equipment in contact with dry material to dissipate the potential buildup of static electricity.

FLASH POINT: Not Applicable

AUTO IGNITION TEMPERATURE: Not Available

FLAMMABILITY: Not Available; Limits - Not Applicable

HAZARDOUS DECOMPOSITION PRODUCTS ASSOCIATED WITH FIRE: May emit carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride gas.

SECTION 6 - ACCIDENTAL RELEASE

SPILL AND DISPOSAL PROCEDURES: Control the spill at its source and prevent it from spreading, contaminating soil, or entering sewage or drainage systems or bodies of water. Clean up spills immediately and use suitable protective equipment (Section 8). Keep unnecessary persons away. If emergency response personnel are unavailable or unwarranted, clean up a solid spill by carefully sweeping up the material (avoid creating dust) and using a proper tool to place it into an appropriate disposal container. If liquid, cover the spill with an absorbing material and follow the same procedure used for a solid spill. Scrub the area with a hard water detergent. Pick up liquid with absorbent material and follow the same procedure used for a solid spill. Dispose of or treat all spill residues according to applicable local, state and federal regulations (Section 13). Use suitable protective equipment (Section 8). Follow fire prevention procedures (Section 5).

SECTION 7 - HANDLING AND STORAGE

ENGINEERING CONTROLS: Local exhaust ventilation sufficient to control dust is recommended.

HANDLING PROCEDURES AND EQUIPMENT: Avoid generating dust. Use respiratory protection in the absence of adequate ventilation controls (Section 8). Wash skin thoroughly after shift exposure. Keep containers closed when not in use. Clean up spills promptly (Section 6).

HANDLING AND STORAGE: Store in a cool, dry place and protect from moisture. Avoid contact with skin or eyes. Do not breathe dust or spray. Do not ingest. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Do not store food, beverages or tobacco products in the storage area. Protect containers from damage. Use entire contents of packages, do not store open packages. Keep out of reach of children and domestic animals. For agricultural crop uses only.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION

NOTE: The following recommendations for exposure controls and personal protection are for the manufacturing, formulating or packaging this product. For commercial application and/or on-farm use, consult the product label.

INHALATION: Use MSHA/NIOSH approved dust/mist respirator with any R, P, or HE filter. Do not breathe dust or spray.

SKIN CONTACT: Wear chemical resistant (e. g. nitrile or butyl) gloves, coveralls, socks and chemical resistant footwear. For overhead exposure, wear chemical resistant headgear.

EYE CONTACT: Safety glasses required. Use chemical splash goggles if potential exists for direct exposure to dust, splashes or sprays. Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

INGESTION: Prevent eating, drinking, tobacco usage and cosmetic application in areas where there is potential for exposure. Wash thoroughly with soap and water after handling.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Free flowing, yellow to tan powder

ODOR: Odorless to faint odor.

MOLECULAR WEIGHT: 496.9 (Oxytetracycline hydrochloride)

SOLUBILITY IN WATER: Streptomycin sulfate is soluble in water (>20g/l).

PH: 2.5-4.0

VOLATILE COMPONENTS (% w/w): < 8% (water)

DENSITY (lb./cu ft): 42.7 loose, 63.7 compacted

BOILING POINT (degrees C/degrees F): Not applicable

FREEZING POINT (degrees C/degrees F): Not applicable

MELTING RANGE (degrees C/degrees F): Not available

VAPOR PRESSURE (mm Hg @ degrees C/degrees F): Not applicable

SECTION 10 - STABILITY AND REACTIVITY

STABILITY: Stable under normal storage and use conditions. Hygroscopic; moisture can cause decomposition.

HAZARDOUS POLYMERIZATION: Should not occur.

HAZARDOUS DECOMPOSITION: None known.

INCOMPATIBILITIES: Decomposed by strong acids and alkalis.

STORAGE CONDITIONS: Hygroscopic, protect from moisture. Sensitive to air, light, heat and bases so protect from exposure. Keep containers sealed and avoid damage.

SECTION 11 - TOXICOLOGICAL INFORMATION

Oxytetracycline

Test	Species	Result
Oral LD_{50}	Mouse	6,646 mg/kg, Practically Non-Toxic
Dermal LD_{50}	Rabbit	>2,000 mg/kg, Slightly Toxic
Eye	Rabbit	Moderately Toxic
Skin	Rabbit	Non-Irritating
Skin	Guinea Pig	Sensitizing

MUTAGENIC POTENTIAL: None observed.

REPRODUCTIVE HAZARD POTENTIAL: Possible risk of congenital malformation in the fetus.

CHRONIC/SUB-CHRONIC TOXICITY: Gastrointestinal irritation with nausea, epigastric pain and burning, vomiting, abdominal pain, transitory yellowish-brown discoloration of the tongue, anorexia and diarrhea have been reported following oral administration. Blood disorders (delay in coagulation) have been reported. Possible hypersensitization and super-infections due to overgrowth of organisms not affected by the antibiotic agent. Three types of renal disease is associated with over exposure: Acute Non-Oliguric Renal Failure (individuals with pre-existing pancreatitis or fatty liver), Uremia (individuals with pre-existing impaired renal function), and Reversible Nephrotoxicity (due to out-dated or degraded tetracyclines).

CARCINOGENIC POTENTIAL: Not classifiable based on its IARC, ACGIH, OSHA, NTP or EPA.

INERT INGREDIENTS

Note: Crystalline silica (quartz and cristobalite); inhalation of high dust levels can cause pneumoconiosis, silicosis or pulmonary fibrosis. Listed by IARC as a Group 2A carcinogen (lung) based on limited evidence in humans and sufficient data in animals. Listed by the NTP as a substance reasonably anticipated to be a carcinogen.

SECTION 12 - ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE: Oxytetracycline is unstable to light and heat, it should not accumulate in the soil.

OTHER: This product is a pesticide. Avoid contact of spilled materials and runoff with soil and surface waterways.

SECTION 13 - DISPOSAL CONSIDERATION

DISPOSAL: Do not reuse product containers. Dispose of product containers, waste containers and residues according to local, state and federal health and environmental regulations.

Characteristic Waste: Not Applicable

Listed Waste: Not Applicable

SECTION 14 - TRANSPORT INFORMATION

U.S. DOT (Department of Transportation) CLASSIFICATION: Not regulated by DOT

REPORTABLE QUANTITY (RQ): None

SHIPPING FREIGHT DESCRIPTION: Insecticides or Fungicides, Agricultural, N. O. S.

ICAO/IATA CLASSIFICATION: Not available.

IMDG CLASSIFICATION: Not available.

SECTION 15 - REGULATORY INFORMATION

TOXIC SUBSTANCES CONTROL ACT (TSCA) CLASSIFICATION: Exempt. Oxytetracycline is a non-hazardous, non-restricted substance. It is listed in the TSCA inventory but is not regulated. Subject to FIFRA.

RCRA HAZARDOUS WASTE CLASSIFICATION (40 CFR 261): Not Applicable.

CERCLA/SARA 302 REPORTABLE QUANTITY (RQ): None

EPCRA SARA Title III Classification:

Section 311/312: Acute Health Hazard & Chronic Health Hazard.
Section 313: Toxic Chemicals: Not Applicable.

SECTION 16 - OTHER INFORMATION

NFPA HAZARD RATINGS: Health 1, Flammability 0, Instability 0 (0-Minimal, 1-Slight, 2-Moderate, 3-Serious, 4-Extreme)

HMIS HAZARD RATINGS: Health N/A, Flammability N/A, Reactivity N/A (0-Minimal, 1-Slight, 2-Moderate, 3-Serious, 4-Severe)

IMPORTANT: While the descriptions, data and information contained in the Material Safety Data Sheet are presented in good faith and are believed to be accurate as of the date indicated, AgroSource, Inc. makes no warranty with respect hereto and disclaims all liability from reliance thereon. The Material Safety Data Sheet is provided for guidance only. Many factors may affect the product during processing, application or use. Therefore, it is recommended that packagers, handlers and users test to determine suitability under their specific conditions.

Fireline is trademark of AgroSource, Inc.

AGRO SOURCE™

Original Issued Date: 01/16/98; Revision Date: 07/07/11; Replaces: 11/15/04

This is a specimen label, intended for use only as a guide in providing general information regarding use of this product. As labels are subject to revision, always carefully read and follow the label on the product container.

FireLine™ 17 WP

Fungicide/Bactericide
Agricultural Oxytetracycline

GROUP	41	FUNGICIDE

- **For control of Fire Blight on pear and apple and Bacterial Spot on peach and nectarine.**

Active Ingredient:

Oxytetracycline Hydrochloride*	18.30%
Related Compounds	0.17%
Other Ingredients:	81.53%
	100.00%

*Equivalent to 17% oxytetracycline

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

EPA Reg. No. 80990-1
EPA Est. No. 39578-TX-1
Product Number 1001

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and undamaged, and the purchase price will be refunded.

AgroSource, Inc.
P.O. Box 1341
Mountainside, New Jersey 07092-0341

REV 80990-1
(1121708 1087013-3363)

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If In Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If On Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact InfoTrac at 1-800-535-5053 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes or clothing. Do not breathe spray mist. Prolonged or frequently repeated exposure may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary or human purposes.

Personal Protective Equipment (PPE):
Some materials that are chemical resistant to this product are listed below. If you want more options, follow the instructions for Category A on an EPA chemical resistant category selection chart.

Applicators and other handlers must wear:
- long-sleeved shirt
- long pants
- chemical-resistant gloves made of any waterproof material
- shoes plus socks
- NIOSH approved respirator with any N, R, P or HE filter

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Control Statements:
When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations:
Users should:
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box apply to uses that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, wear:
- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Protective eyewear

Do not apply this product through any type of irrigation system.

This product contains the antibiotic oxytetracycline. To reduce the development of drug-resistant bacteria and maintain the effectiveness of this and other antibacterial products, this product should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

This material is not to be used for medical or veterinary purposes.

Resistance Management Statements: FIRELINE™ 17 WP Fungicide/Bactericide Agricultural Oxytetracycline contains a Group 41 (fungicide/bactericide). Fungal isolates/bacterial strains with acquired resistance to Group 41 may eventually dominate the fungal/bacterial population if Group 41 fungicides/bactericides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by **FIRELINE™ 17 WP** Fungicide/Bactericide Agricultural Oxytetracycline or other Group 41 products.

To delay fungicide/bactericide resistance consider:
- Avoiding the consecutive use of **FIRELINE™ 17 WP** Fungicide/Bactericide Agricultural Oxytetracycline or other target site of action Group 41 fungicides/bactericides that have a similar target site of action, on the same pathogens.
- Using tank-mixtures or premixes with fungicide/bactericides from different target site of action Groups as long as the involved products are all registered for the same use and are both effective at the tank mix or prepack rate on the pathogen(s) of concern. Do not use any product that has a prohibition on tank mixing and follow the more restrictive use directions.
- Basing fungicide/bactericide use on a comprehensive IPM program.
- Monitoring treated fungal/bacterial populations for loss of field efficacy.
- Contacting your local extension specialist, certified crop advisors, and/or manufacturer for fungicide/bactericide resistance management and/or IPM recommendations for specific crops and resistant pathogens.

Treatment of Apples, Pears, Peaches & Nectarines:

MIXING: To avoid possible pesticide contamination, use only clean metal or plastic containers in preparing all solutions.

MIXING INSTRUCTIONS			
Concentration Desired	**Quantity FIRELINE™ 17 WP Fungicide/Bactericide Agricultural Oxytetracycline Per Volume of Water**		
ppm*	**50 gals.**	**100 gals.**	**500 gals.**
150	6.0 oz.	12.0 oz.	3 ¾ lbs.
200	8.0 oz.	16.0 oz.	5 lbs.

*ppm = parts per million

Crop	Disease	Recommended Concentration or Rate	Use Directions
Apples	Fire Blight	200 ppm	Begin applications at the start of bloom at a dosage of 50 to 150 gallons of spray solution per acre. The recommended method of application is by airblast sprayer. Repeat spray applications at 3 to 6 day intervals until the end of bloom. One additional application is permitted after the end of bloom. Do not apply more than a total of 6 applications per year. Do not apply more than 150 gallons of spray solution per acre per application or more than 1.5 lb. of **FIRELINE™ 17 WP** Fungicide/Bactericide Agricultural Oxytetracycline per acre per application. Do not apply within 60 days of harvest. Use of **FIRELINE™ 17 WP** Fungicide/Bactericide Agricultural Oxytetracycline may cause phytotoxicity to the fruit and/or foliage of sensitive varieties of apples.
Pears	Fire Blight	200 ppm	Begin spray application at 10% bloom at a rate of 50-100 gals. of solution per acre. Repeat applications at 4 to 6 day intervals. This may involve up to 8-10 applications. Do not apply within 60 days of harvest. Use of **FIRELINE™ 17 WP** Fungicide/Bactericide Agricultural Oxytetracycline may cause phytotoxicity to the fruit and/or foliage of sensitive varieties of pears, especially Asian varieties.
Peaches & Nectarines	Bacterial Spot	150 ppm	Begin application with shuck split using a rate of 3 gallons per tree (240 gals. spray solution per acre based on 80 trees per acre). Apply spray solution to point of runoff. Gallons of spray per acre may be increased for larger trees. Do not exceed 500 gals. of spray solution per acre. Use pressure sprayer capable of delivering the spray at least 250 lbs. pressure per square inch through a hand-held single nozzle gun, or 150 lbs. pressure per square inch using a wind-blast sprayer. For best results with air-blast sprayer, do not exceed 3 miles per hour ground speed or 100 miles per hour spray velocity. **Note:** The spray application schedules are based on a definite biological growth period for peaches, the shuck split. Shuck split stage for peaches varies North to South by state, in individual states and by varieties. Applications are weekly after shuck split stage. This may involve up to 8 or 9 applications. Do not apply within 3 weeks of harvest.

Additional information regarding use of **FIRELINE™ 17 WP** Fungicide/Bactericide Agricultural Oxytetracycline may be obtained from your local Agricultural Extension Agent or State Experimental Station.

Use of **FIRELINE™ 17 WP** Fungicide/Bactericide Agricultural Oxytetracycline may cause phytotoxicity to the fruit and/or foliage of sensitive varieties of pears, apples, peaches and nectarines.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
Pesticide Storage: Keep tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (<77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
Container Disposal: Nonrefillable Container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer bag for recycling if available or dispose of in a sanitary landfill, by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

EMERGENCY TELEPHONE NUMBER:
InfoTrac: 1-800-535-5053

Conditions of Sale and Limitation of Warranty and Liability

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials, resistant strains or other influencing factors in the use of the product, which are beyond the control of AgroSource, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold AgroSource, Inc. and Seller harmless for any claims relating to such factors.

AgroSource, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or AgroSource, Inc., and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, AGROSOURCE, INC. MAKES NO OTHER WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

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Fireline is a trademark of AgroSource, Inc.

Active ingredient made in China. Formulated and packaged in the USA by AgroSource, Inc.

January 25, 2006

Mr. Dan Rosenblatt, Chief
Minor Use, Inerts and Emergency Response Branch (7505C)
U.S. EPA, Office of Pesticide Programs
Document Processing Desk
Crystal Mall No. 2 - 2nd Floor
1801 Bell Street
Arlington, VA 22202

RE: Emergency use of oxytetracycline (Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline) to control fire blight in apples.

Section 18 of the amended FIFRA provides the Administrator may exempt a state or federal agency from provisions of FIFRA if a determination is made that emergency conditions exist which require such exemption. The Washington State Department of Agriculture (WSDA), the Idaho Department of Agriculture (IDA), and the Oregon Department of Agriculture (ODA) are applying for a specific exemption for the use of oxytetracycline (Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline) to control fire blight in apples. This is the tenth year that the request has been submitted for a regional exemption with Idaho and the fifth year with Oregon.

Information required in 40 CFR 166.20 (a) is presented hereunder.

1. Type of Exemption: Specific

2. Knowledgeable Contact Experts:

Washington

Dr. Chang-Lin Xiao
Associate Professor of Plant Pathology
Washington State University (WSU)
Tree Fruit Research Center
1100 North Western Avenue
Wenatchee, WA 98801
Telephone: (509) 663-8181
Fax: (509) 662-8714
E-mail: clxiao@wsu.edu

Timothy J. Smith
WSU Cooperative Extension
303 Palouse Street
Wenatchee, WA 98801-0000
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Dr. Michael Bush
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Ted Head
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1333 Burr Ridge Parkway, Suite 124A
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Phone: (708) 754-3330
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Email: Ted.head@us.nufarm.com

Oregon

Dr. Jay W. Pscheidt
Extension Plant Pathologist
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3. Description of the Pesticide:

Brand Name: Mycoshield
Registrant: NuFarm Americas Inc
EPA Reg. No.: 55146-97 (Attachment 1)
Active Ingredient: oxytetracycline, 17.5% active ingredient (equivalent to 31.5% oxytetracycline calcium complex active ingredient)
CAS Registry Number 15251-48-6 (OPP Chemical Code 006321).

Brand Name: FlameOut Fungicide/Bactericide Agricultural Terramycin
Registrant: Cerexagri, Inc
EPA Reg. No.: 80990-1-4581 (Attachment 2a)
Active Ingredient: oxytetracycline, 17.5% active ingredient (equivalent to 18.3% oxytetracycline hydrochloride active ingredient).
CAS Registry Number 2058-46-0 (OPP Chemical Code 006308).

Brand Name: FlameOut Fungicide/Bactericide Agricultural Oxytetracycline
Registrant: Cerexagri-NISSO LLC
EPA Reg. No.: 80990-1-82695 (Attachment 2b)

4. Description of the Proposed Use:

a) Site to be Treated:

Washington:
<u>Ground Application</u>: Adams, Benton, Chelan, Douglas, Franklin, Grant, Island Kittitas, Klickitat, Okanogan, San Juan, Skagit, Skamania, Spokane, Walla Walla, Whatcom, and Yakima Counties.

<u>Aerial Application (Eastern Washington only)</u>: Adams, Benton, Chelan, Douglas, Franklin, Grant, Kittitas, Klickitat, Okanogan, Skamania, Spokane, Walla Walla, and Yakima Counties.

Idaho: Canyon, Gem, Payette, Owyhee (northwest tip), and Washington (southwest corner within 5 miles of the Snake River) Counties.

Oregon: Hood River, Jackson, Josephine, Morrow, Umatilla, Union and Wasco Counties.

b) Method of Application:

<u>Ground</u>: Apply Mycoshield, FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline in 50 to 100 gallons of water per acre as a foliar spray using ground equipment. An application volume of 100 gallons of finished spray solution per acre is preferred for ground application.

<u>Aerial</u>: Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline may be applied using aerial methods in Eastern Washington only (Adams, Benton, Chelan, Douglas, Franklin, Grant, Kittitas, Klickitat, Okanogan, Skamania, Spokane, Walla Walla, and Yakima County). Application of Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline by air is not a direct replacement for application of this product using ground methods, because spray coverage of blossoms is essential.

c) Rate of Application:

<u>Ground</u>: Apply a 200 ppm solution of oxytetracycline (0.5 pound Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline per 50 gallons of water per acre or 1 lb. of Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline per 100 gallons of water).

<u>Aerial (Eastern Washington only):</u> Apply 1 lb of Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline in 10 gallons of spray per acre.

d) Maximum Number of Applications:

A maximum of five applications of Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline may be made per acre per year (three applications during bloom and two to prevent infection of vegetative tissues). Begin application at 10% bloom and continue at 3-6 day intervals or apply when weather favorable for fire blight is expected.

Use of predictive models for fire blight threshold treatment conditions is recommended and encouraged to minimize the number of applications of Mycoshield or FlameOut Fungicide/Bactericide. The Cougarblight model, which was developed during the 1980's has been the standard Fire Blight Risk Model in Washington and Oregon throughout the 1990's. The model requires the user to recognize specific and ever-changing local events and aspects of their orchard that may increase or decrease fire blight risk relative to other orchards in the region (Attachment 11). The model requires the user to assume there is a risk of fire blight infection whenever blossoms are present on the trees, especially during the petal fall and "post bloom" period, when scattered blossoms may remain on many apple and pear varieties. The model user is asked to carefully assess the situation on their specific site and to initiate control measures if blossoms are present, risk levels are "High" or "Extreme," and blossom wetting is likely to occur sometime during the next 24 hours. The "Cougarblight 2002F" model is available on the web at http://www.ncw.wsu.edu/treefruit/fireblight/2000f.htm (Attachment 10).

e) Total Number of Acres to be Treated: 34,000 acres

Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline is never applied to all of the apple acreage in Washington, Oregon and Idaho.

Washington:	28,000
Idaho:	1,500
Oregon:	4,500

f) Total Amount of Pesticide to be Used:

A maximum of 23,120 lbs ai oxytetracycline (e.g. 136,000 lbs Mycoshield) may be used (assuming 34,000 acres treated at 1 lb per acre with an average of 4 applications). The actual amount should be much lower due to the use of predictive models.

Washington:	19,040 lbs ai (e.g 112,000 lbs Mycoshield product)
Idaho:	1,020 lbs ai (e.g. 6,000 lbs Mycoshield product)
Oregon:	3,060 lbs ai (e.g. 18,000 lbs Mycoshield product)

g) Use Period: April 1, 2006 through August 1, 2006.

The critical use period will be during the bloom period of April 1 through May 31. Timing of application will depend upon weather conditions, variety, and elevation. Most new blight-susceptible apple varieties, particularly those planted on M9 or M26 rootstocks, also produce secondary blossoms into early summer. If other susceptible tissues (i.e. leaves or rat-tail bloom) were physically damaged, then two later applications will be needed between June 1 and August 1, 2006. Harvest of apples begins in late July and extends into mid-November, depending on the variety and area.

h) Other Applicable Restrictions: (in addition to provisions stipulated on the current federal label).

- Do not apply more than 5 pounds of Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline per acre per season.
- Do not apply within 60 days of harvest.
- Do not apply more than 1 pound of Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline or 100 gallons of finished spray solution per acre per application.
- Do not apply this product through any type of irrigation system.
- Do not apply this product by air in Idaho or Oregon.
- Avoid drift onto non-target crops/areas.
- Do not allow livestock to graze on treated orchard ground cover.
- Do not allow livestock to feed on treated crop by-product.
- Do not enter or allow worker entry into treated areas for 12 hours following application. Coveralls, waterproof gloves, shoes plus socks, protective eyewear are required for early entry to treated areas and that involves contact with anything that has been treated, such as plants, soil, or water.
- A copy of the section 18 label must be in the possession of the user at the time of application in Washington and Oregon only.

5. Alternative Methods of Control:

a) Registered Pesticide Alternatives:

Streptomycin Sulfate is the only bactericide registered for fire blight control on apples in the Northwest. However, the pathogen has developed extensive resistance to this antibiotic, as reported in past section 18 requests (Attachment 4). Resistance has been documented in both major apple-growing districts of Oregon--Hood River and Milton-Freewater. Post-bloom applications of streptomycin are largely ineffective in controlling secondary infections and spread of the disease. Dr. Krishna Mohan, University of Idaho has done some sampling and found at least a low level of Streptomycin resistance in Idaho orchards (Personnel communication, Tom Lyon, 1/16/2005).

Copper fungicides, which are registered for control of fire blight, can russet fruit if applied beyond the delayed-dormant stage of bud development and render the fruit unsuitable for fresh marketing. Copper is recommended for use in Hood River and Milton-Freewater orchards in Oregon to reduce disease inoculum, but severe fire blight infections can still occur. Early season application provides some relief from overwintering inoculum, but is not an economic option for management of post-infections.

Fosetyl-Al (Aliette) does not control fire blight (Dr. Gary Grove, Plant Pathologist, WSU-IAREC, Prosser, WA).

***Pseudomonas fluorescens* A506** (Blight Ban) provides limited and variable control of fire blight. The product should be used in conjunction with antibiotics. More importantly, the material is ineffective for blight control after primary bloom. Most of the past fire blight epidemics have started during secondary bloom.

Harpin Protein (Messenger) has limited commercial use in the Northwest because this preventive treatment must be applied 5-7 days prior to onset of the disease and may be useful only as an "aid in management" of fire blight.

Serenade (*Bacillus subtilis*, QST713 strain) provides suppression, but not control of fire blight. The Washington Tree Fruit Research Commission does not have enough information on the effectiveness of Serenade to encourage its widespread use.

The commercial efficacy of Sonata (***Bacillus pumilis* strain QST 2808**) is unknown in the Pacific Northwest, and its use is not currently recommended.

Mancozeb, which is registered for fire blight control, has not shown effective control of fire blight in apples.

Phosphorous acid is not recommended for fireblight on apples because efficacy is not high, too variable and the materials are not compatible with copper products (Attachment 7).

b) Alternative Methods of Disease Management:

Fire blight control results from the integration of chemical and cultural control practices, neither of which is very effective alone (Attachments 5, 8). The most commonly recommended post-infection practice for fire blight management is cutting out and destroying infected tissue in the tree at a point between one and four feet below the last visible symptoms (in healthy looking tissue). This practice is extremely expensive in terms of labor and of crop loss, but is not adequate to prevent outbreaks of the disease. It is virtually impossible to remove all cankers from an infected orchard and there is always some "carryover" inoculum.

Therefore, there are no acceptable, effective means of controlling fire blight during and after bloom period when large-scale tree infection periods and subsequent tree loss are likely. Without the requested emergency use of oxytetracycline, apple growers in the Northwest will face the prospect of further economic losses from fire blight in 2006.

6. Efficacy Data:

The effectiveness of oxytetracyclines for control of fire blight on both apples and pears has been well documented (Attachment 4 and 9). Mycoshield is registered for control of fire blight on pears and bacterial blight on peaches and nectarines in Washington, Oregon and Idaho. The registration on pears was in response to the development of streptomycin resistant strains of the pathogen *E. amylovora*.

7. Residue Data:

An IR-4 study for this compound on apples was conducted in Washington in 1991. IR-4 submitted a tolerance petition to EPA for oxytetracycline on apple along with two volumes of residue data on June 26, 1997 (PP7E4855). These two volumes of data were assigned MRID numbers 44314701 and 44314702 (Attachment 16). All residues were below the proposed tolerance of 0.35 ppm. The petition is still pending at EPA. Registration of oxytetracycline on apples is on EPA's Workplan, however, registration is not expected in time for the 2006 use season.

8. Risk Data:

Oxytetracycline calcium complex and oxytetracycline hydrochloride are expressed as oxytetracycline (Attachment 12). Oxytetracycline has been available in the United States as a drug for therapeutic use in humans since 1950 and was registered by EPA as a pesticide in 1974. The compound is registered for use on other tree fruit crops (i.e. pears and peaches) grown in the Pacific Northwest. Use of these active ingredients in accordance with approved labeling is not expected to result in unreasonable adverse risk to human health (general U.S. population or to infants and children) because the anticipated residues resulting from crop uses are 5-fold less than the therapeutic dose.

Potential unreasonable risks to endangered species, beneficial organisms, or the environment are not expected from use of these products in accordance with approved labeling. Technical experts from the Washington State University and Oregon State University will continue to educate growers in the use of predictive systems for fire blight in order to limit the use of antibiotics in orchards. The Cougarblight fire blight risk model (Attachments 10, 11, and 14) has been developed to calculate the daily fire blight infection risk in the orchard. This model has been evaluated and validated for use in Oregon by Dr. Bob Spotts (Hood River) and Dr. David Sugar (Medford).

The risk of infection during the bloom period is temperature-dependent and is assessed using the daily temperatures for the previous three days plus the projected temperatures for the fourth day. Antibiotic sprays are necessary during warm, moist weather in order to control bacterial population growth on blossoms. Sprays are most effective if applied prior to blossom wetting, especially during "extreme risk" conditions. Mycoshield is most effective during the first 12 hours following the onset of blossom wetting.

A. Human Health:

The FQPA Summary Document published in the Federal Register as part of the initial filing for oxytetracycline use on apples has been previously submitted and contains information needed by EPA to assess the potential risks presented by residues of oxytetracycline in or on apples.

1. <u>Toxicological Profile</u>

EPA has waived all toxicological data requirements for oxytetracycline calcium, the active ingredient in Mycoshield, using instead the data generated from oxytetracycline. Oxytetracycline calcium is of low acute toxicity through the oral route of exposure, and has been placed in Toxicity Category IV indicating the lowest degree of toxicity for this effect. Subchronic feeding studies in rats showed no adverse effects. In two-year chronic toxicity studies in rats and dogs, the NOEL was the highest dose tested.

Carcinogenicity studies show some equivocal evidence of cancer in male and female rats administered extremely high doses. However, EPA has classified oxytetracycline as a “Group D” carcinogen – one that is “not classifiable as to human Carcinogenicity.”

One developmental toxicity study in rats showed a high incidence of maternal deaths and ferotoxicity; however excessive dose levels were used. No adverse effects were demonstrated in another similar study (Attachment 12).

2. Aggregate Exposures and Risks

The Agency’s RfD Peer Review Committee has established the reference dose for oxytetracycline as 0.005 mg/kg/day using the NOEL of 0.05 mg/kg/day from the 44-day feeding study in dogs. An extra 10-fold factor was not necessary due to the extensive human safety data.

The risks to people from dietary and occupational exposure to pesticides containing hydroxytetracycline monohydrochloride and oxytetracycline calcium are considered negligible. Chronic dietary risks posed by all food uses of these pesticides are well below the level that would reasonably cause concern.

Dietary Exposure – Tolerances or maximum residue limits are established for residues of oxytetracycline in or on pears and peaches (see 40 CFR 180.337). Tolerances of 0.1 ppm in or on tomatoes and cherries are pending (Attachment 12). Because oxytetracycline is used in veterinary medicine, FDA has established tolerances for residues in animals (see 21 CFR 520, 522, 524, and 558).

Groundwater – The exposure to drinking water is considered minimal. Mycoshield or FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline will not be applied directly to water.

Residential (Non-dietary) Exposure – There are no known outdoor residential uses of this product in Washington, Oregon and Idaho.

Occupational Exposure – Pesticide mixers, loaders, and applicators can be exposed when oxytetracycline is applied using foliar application methods. No occupational or residential exposure monitoring data are required because the toxicity data for oxytetracycline are below EPA criteria values that would trigger requirements for these studies.

Common Mode of Action – Oxytetracycline, oxytetracycline calcium, and hydroxytetracycline monohydrochloride have a common mechanism with other tetracyclines, but not with other pesticides. There are no known common modes of action with other pesticides.

Tetracyclines bind to bacterial ribosomes and block the binding of aminoacyl tRNAs to amino acids, which results in the inhibition of protein synthesis. Streptomycin, the other bactericide registered for use for fire blight control in Washington (but not currently in use because of widespread resistance) binds to bacterial ribosomes and prevents protein synthesis, the initiation of peptide chains, and the recognition of normal triplets (Agrios, *Plant Pathology*, 1988). The modes of action are apparently slightly different or mechanisms for the development of antibiotic-resistant strains are different because resistance to oxytetracycline has not been documented in Washington despite several surveys.

Timing of Crop Harvest – Apple harvest in the region begins in late July, depending on the variety and location. Harvest is usually completed by the end of November, again depending on the variety and site.

B. Environmental Issues:
EPA has previously waived all environmental fate data requirements for these oxytetracycline ingredients based on the availability of published literature. Use of oxytetracycline calcium and oxytetracycline hydrochloride in accordance with approved labeling is not expected to result in unreasonable adverse effects to the environment (Attachment 12).

Ecological Risk and Endangered Species
Acute toxicity studies in the published literature indicate that oxytetracycline is practically non-toxic to birds, fish, aquatic invertebrates, and non-target insects such as honeybees (Attachment 12). The toxicity values (LC50) for hydroxytetracycline to freshwater fish (bluegill sunfish) and invertebrates are >95 ppm and 102 ppm, respectively.

9. Notification of Registrant:

Nufarm Inc. and Cerexagri, Inc are aware of this request and support the regional Section 18 emergency exemption for this use of Mycoshield and FlameOut Fungicide/Bactericide Agricultural Terramycin or FlameOut Fungicide/Bactericide Agricultural Oxytetracycline, respectively (Attachment 3).

10. Notification of Other Agencies:

The US Fish & Wildlife Service Offices in Washington, Oregon and Idaho and the Washington State Departments of Ecology, Health and Fish & Wildlife have received copies of this request. Any comments received from any of the listed agencies will be forwarded to the US EPA.

11. Enforcement Program:

The Washington, Oregon and Idaho Departments of Agriculture have adequate authority for enforcing provisions of Section 18 Emergency Exemptions and have been doing so for many years. We would be glad to answer any specific questions regarding our enforcement program.

Private and commercial applicators keep records of application use and acreage. The requestor, manufacturers, and Washington State University will be responsible for reporting use and efficacy of oxytetracycline (Mycoshield / FlameOut Fungicide/Bactericide) on apples under this exemption in Washington. The Hood River Grower/Shipper Association, the Fruit Growers League, the manufacturers, distributors, dealer representatives, and Oregon State University will be responsible for reporting use and efficacy of oxytetracycline (Mycoshield / FlameOut Fungicide/Bactericide) on apples under this exemption in Oregon.

12. Previous Use Under Section 18:

2005 Mycoshield Use Report on Apples

State	EPA File Symbol	Acres Treated	No. of apps.	Estimate pounds used on apples
OR	05-OR-08	3,282	1.1	3,000
WA	05-WA-08	25,310	1.5	22,000
ID	05-ID-07	504	1.1	432
Regional Total		29,096		25,432

13. Progress Toward Registration:

The tolerance petition submitted by IR-4 is pending at EPA (Attachments 3, 16). On June 2, 2004 a draft label with the apple use was submitted to the EPA at the EPA's request. In addition, the Notice of Intent has been submitted as well as the $50,000 Fees For Service (letter dated September 30, 2004). According to the New Fee schedule, this action was coded as an R17, New Food Use and the Agency has up to 38 months from 9/30/04 to make a decision.

Information as required in 40 CFR 166.20 (b) is presented hereunder.

1. Pest(s) to be Controlled:

Fire blight (*Erwinia amylovora).*

2. Events which brought about the Emergency Condition:

An emergency condition exists because there are no effective, registered products available to manage this disease following infection, which has become resistant to streptomycin. The presence of inoculum, highly susceptible apple varieties, together with warm weather and moisture during bloom are critical factors that contribute to fire blight epidemics. The path of fire blight infection, which is a complex bacterial disease (Attachment 5), is primarily through open flowers.

Fire blight infection conditions were high to (very) extreme in many parts of the state during the spring of 2005, especially in parts of North Central Washington. (Attachment 6). According to Tim Smith, WSU, blight was especially bad in orchards where 2004 cankers were missed during winter pruning, and blight bacteria were both early and numerous going into the infection periods. The risk of blight damage is expected to be much higher in 2006 due to the wide-spread infections in 2005 and because missed blight cankers will be much more common.

Fire blight epidemics occurred in Washington in 1993, 1997, and 1998. All years were characterized by unseasonably warm weather during the bloom period. Epidemics generally occurred in areas composed of orchards with varieties that had extended bloom periods, produced secondary bloom, and had a prior history of fire blight. Fire blight disease pressure was moderate in 2001 in the largest Oregon apple growing districts due to disease incidence in previous years. In 1997 and 1998 unseasonably warm temperatures during primary and secondary bloom in the Hood River area resulted in extreme fire blight risk. Infection was widespread in 1997 (pears) and 1998 (apples and pears), despite careful monitoring of infection risk, dissemination of that information, and generally timely application of antibiotic materials. At least 16 acres of high density, high-value apple orchards in Hood River County were removed in 1998 as a result of fire blight infection.

The precise time and intensity of the emergency (i.e. when an infection period occurs and therefore when chemical control procedures need to be applied) will be monitored using models developed for fire blight prediction. Growers are currently using the Cougarblight model (Smith), which is based on the presence of flowers, moisture, and degree-day accumulations during the period from green tip to petal fall. The model is slightly over predictive, but provides a significant reduction in chemical usage when compared to treatment based on a "calendar" system. The calendar approach could involve up to 8-10 applications because this spray schedule starts at 10% bloom and continues at 4-6 day intervals. Moreover, the predictive models may indicate little risk of infection during bloom and no material would be applied in this case.

3. Additional Benefits Information:

Fire blight-sensitive cultivars comprise an increasing percentage of overall production each season. Impacts to the economy in Washington are tremendous. Any reduction of apple production due to crop losses from fire blight will result in a corresponding reduction in business volume and employment of growers, apple packinghouses, and sales agencies. Additionally, the section 18 approval of oxytetracycline would be of benefit to organic apple growers, which a growing sector of apple production (Attachment 17).

4. Discussion of Economic Loss:

Washington

An estimated $40 million dollars were lost in 1998 due to the fire blight epidemic. If a major fire blight epidemic develops on apples in Washington during 2006 and results in the complete loss of trees, then the estimated replacement cost could average about $12,777 per acre (Attachment 15). In addition, the annual production loss per year would amount to about $6,630 per acre of mature, high-density apples.

If all of this acreage were lost to a fire blight epidemic, it would result in a loss of $345 million in orchard establishment costs alone. Loss of entire trees would negate future returns on these orchards. The fruit from one acre of Gala or Braeburn apples could be worth $2,250 - $4,500 in the first year of production to $20,250 in the tenth year. Fuji's could be worth $3,000-$6,000 during the second year and increase to $27,000 per acre during the tenth year. Pink Lady could return $3,900 - $7,800 during the first year of production and increase to $35,000 per acre during the tenth year. Use of Mycoshield or FlameOut Fungicide/Bactericide would protect the investment of many growers and help to ensure the diversification and competitiveness of Washington's apple industry. It is estimated that only 10% control can be achieved using streptomycin sulfate in Washington because of widespread resistance. For this reason, up to 65% losses in yield could result from a fire blight epidemic. Copper bactericides cannot be used during bloom and therefore would be of little help in managing a severe fire blight epidemic. If used at the appropriate time, Mycoshield or FlameOut Fungicide/Bactericide should provide 90-95% control.

The December 2002 price per box of Washington Extra Fancy grade Fuji apples was about $21.15. Yields from these orchards planted with 9-year old Fuji apples average about 810 packed boxes per acre. This amounts to a $17,131 per acre gross return to the grower. Without the use of Mycoshield or FlameOut Fungicide/Bactericide a fire blight epidemic would have a significant economic impact upon apple growers when based on these returns and coupled with the orchard establishment costs.

Table 1. Five-Year History - Washington Economic Data: (Fuji Extra Fancy)

Year	Yield per Acre (tons)	Price per Ton ($)	Gross Revenue ($) / Acre	Cost per Acre ($)	Net Revenue Per Acre
2001	16.3	$463	$7,546	$6,630	$916
2002	12.7	$622	$7,924	$6,630	$1,294
2003	13.0	$527	$6,851	$6,630	$221
2004	15.0	$571	$8,565	$6,630	$1,935
2005 (est)	14.1[2]	$546[3]	$7,289	$6,630	$656
Average	14.1	$546	$7,679	$6,630	$1,049
2006 Estimates					
With oxytetracycline	14.1	$546	$7,679	$6,630	$1,049
Without oxytetracycline[1]	9.1	$546	$4,991	$6,630	($1,639)

[1] Assumes 35% yield loss without Mycoshield or FlameOut Fungicide/Bactericide on affected acreage.

[2] Based on USDA/NASS October 2005 Forecast of 11% decrease in production compared to 2004.

[3] Price per ton for 2005 based on an average price between 2001-2004.

Oregon
In 1998, conservative estimates of overall fire blight cost to growers in the Mid-Columbia and Milton-Freewater Districts equaled $4,000,000. A total of 320 acres of primarily young trees were removed due to severe infection. This figure represents only the costs of reestablishing the removed trees and does not consider lost production for the three to four years it takes for the replaced trees to come into full production. Losses were minimal in 1999 and 2002 and moderate in 2000 and 2001. In 2000, growers in the Milton-Freewater lost 60 acres of apples at an estimated loss of $600,000. Apple orchards remain at risk in 2006 due to the presence of fire blight bacteria from past high infection periods, and the potential for weather conditions that are conducive to infections during the critical bloom period.

Control over the last five years has been excellent (better than 90%) where both chemical and cultural controls have been implemented. There have been cases where growers did not spray, did not make applications at the right time, or did not cut out active strikes or holdover cankers. Losses have been high in these orchards. In years when weather conditions were not favorable for blight development there were no losses to fire blight.

Table 2. Five Year History - Oregon Economic Data

Year	Yield per Acre (tons) [1]	Price per Ton [1] ($)	Gross Revenue / Acre	Cost per[2] Acre	Net Revenue Per Acre
2001	9.4	$332	$3,121	$3,496	($375)
2002	12.1	$380	$4,598	$3,496	$1,102
2003	11	$571	$6,281	$3,970	$2,311
2004	13.7	$484	$6,631	$3,970	$2,661
2005 (est) [3]	10.3	$400	$4,110	$3,775	$355
Average	**11.3**	**$433**	**$4,895**	**$3,741**	**$1,154**
2006 Estimates					
With oxytetracycline	**11.3**	**$433**	**$4,895**	**$3,741**	**$1,154**
Without oxytetracycline[4]	8.5	$433	$3,668	$3,741	($73)

[1] Yield and price data are based on OSU-ES Commodity Data Sheet 5105-99
[2] Production cost data are based on Enterprise Budget, Red and Golden Delicious Apples, EM 8491 (revised June 1997)
[3] 2005 Estimates provided by Tom Darnell, OSU
[4] Assumes 35% yield loss

If oxytetracycline is available under Section 18 exemption, then infection should be reduced to 10% of susceptible acreage (control estimated by Dr. Jay Pscheidt, OSU). If oxytetracycline is not available under a Section 18, then infection could reach as high as 100% of susceptible acreage. Losses would then be in the millions of dollars in farm-gate value. Neither of these scenarios considers losses in future income or additional management costs in the current year.

Table 3. Five Year History - Idaho Economic Data

Year	Yield per * Acre (tons)	Price per Ton * ($)	Gross Revenue / Acre	Cost per** Acre	Net Revenue Per Acre
2000	12.3	$214	$2,632	$5,125	$(2,493)
2001	7.0	$282	$1,974	$5,125	$(3,151)
2002	7.0	$388	$2,716	$5,125	$(2,409)
2003	7.5	$340	$2,550	$5,125	$(2,575)
2004	7.5	$340	$2,550	$5,125	$(2,575)
Average	**8.3**	**$313**	**$2,484**	$5,125	**($2,641)**

* Yield and price data are based on personal communication from industry (2003) and 2003 Idaho Agricultural Statistics

** Cost per acre data is from University of Idaho Cooperative Extension System EBB2-Fu-98 “Fuji Apple Production”

If you have any questions, please contact this office at (360) 902-2030 or Steve L. Foss at (360) 902-2049 or e-mail sfoss@agr.wa.gov.

Sincerely,

PESTICIDE MANAGEMENT DIVISION

Ted Maxwell, Program Manager, Registration Services

SLF:jh

cc: Alan Schreiber, ADG, Inc.
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Cheryl Niemi, WDOE
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Jay Davis, USFWS
Marco Gaske, Yakama Nation
Royal Schoen, WSDA

ATTACHMENTS

1. Proposed section 18 labels for Mycoshield (Idaho, Oregon and Washington).

2a. Proposed section 18 labels for FlameOut Fungicide/Bactericide 80990-1-4581 (Idaho, Oregon and Washington.)

2b. Proposed section 18 labels for FlameOut Fungicide/Bactericide 80990-1-82695 (Idaho, Oregon and Washington.)

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CougarBlight 2010, a Significant Update of the CougarBlight Fire Blight Infection Risk Model

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Keywords: Fire blight, model, infection, Cougarblight, CougarBlight 2010, apple, pear

Abstract

The CougarBlight fire blight flower infection risk model was developed in the early 1990s following the rapidly evolving understanding of the infection process, limited scientific data on the growth rate of *Erwinia amylovora* (*E.a.*) relative to temperatures, and the study of weather conditions leading up to numerous isolated outbreaks of fire blight (Smith, 1993, 1999; Thomson, 1986). Rather than daily mean temperatures (Mills, 1956), hourly temperature values over the four day period leading up to flower wetness were measured to quantify infection risk. Total temperature value accumulation necessary for infection thresholds were set up empirically. The presence of fire blight or its recent history in the neighborhood was used to differentiate temperature value accumulation thresholds dependent on potential inoculum level. Subsequent studies (Thompson and Gouk, 2003; Pusey and Curry, 2004) have supported the four day accumulation of temperatures, but relatively new research has provided an opportunity to improve the values assigned to various hourly and daily high temperatures as they relate to population sizes on flower stigmas. Temperature values are now based on the increase in population size of the pathogen per hour on flower stigmas at any specific temperature, divided by 1,000. Total daily values for forecasting daily risk are based on an average of the sum of 24 individual hours relating to daily high temperatures of numerous example days. The new version of the model will be called Cougarblight 2010, and can be found in its most current version on a website listed below. While past versions of the CougarBlight model are still functional, this new version is recommended for all future risk assessment.

INTRODUCTION

Erwinia amylovora infects the host primarily through the flowers after colonizing the stigma, building to critical population size, and then moving to the nectaries with the aid of water (Thomson, 1986; Pusey, 2000). Some of the components of this infection process are well studied, and potentially quantifiable, such as the growth rate of *E. amylovora* as influenced by temperature. Others are recognized, but not quantifiable; for example, population size at the time of initial colonization of stigmas. Other factors, such as possible variation in cultivar flower susceptibility, remain uncertain. While aspects of the infection process are unclear, experience clearly shows that fire blight is far more serious in some seasons than others, and varies greatly from one orchard to another in any specific year. An effective model can be used by growers and their advisors to differentiate the conditions that lead to blossom infection and serious fire blight outbreaks. This may help them determine where control procedures should be initiated or intensified (Johnson et al., 2004). If growers understand the infection process, and have a model that helps define the orchard and weather conditions that have, in the past, been followed by fire blight outbreaks, they are far more likely to time their preventative sprays to better match actual infection events (Buban et al., 2002).

The CougarBlight model was developed to help apple and pear managers in the Pacific Northwest USA recognize specific weather conditions that have preceded blight infections. The basic concepts of the model have not changed since 1995. However, there are significant alterations to the 2010 version of this model relating to the growth rate of *E.a.* on stigmas, discussed below. In the past, the CougarBlight model temperature risk numbers were based on the growth rate of *E.a*. in broth culture (Schouten, 1987), far different conditions than those found in nature.

The basic components and assumptions of the CougarBlight fire blight infection risk model are:

1. Orchard fire blight history: There are important differences among orchards relating to the potential of blossom contamination and initial population size of the pathogen on the stigma. These neighborhood differences are directly related to the presence, proximity and number of active fire blight cankers (van der Zwet and Keil, 1979). The weather condition leading to fire blight infection are far more easily met in areas where fire blight cankers have carried over from the previous year's infections. The grower is asked to first select an orchard fire blight history that most closely describes the orchard. It is assumed, if there was fire blight nearby the previous season, some cankers were most likely missed during wintertime sanitation, and may be present and active during the current year. If there was no fire blight in the neighborhood the previous season the grower is allowed to assume that infection thresholds will be more difficult to reach, and therefore use higher temperature risk value thresholds.

2. Flower life / colony growth: In the range of temperatures that are likely to lead to fire blight infection, a flower is assumed to be open and receptive to contamination and infection for a total of four days. In Cougarblight 2010, pear growers are given the option of assessing a five day temperature risk value total. When a flower is wetted, the temperature conditions during all of the four or five days prior to that event are considered when assessing risk of infection.

3. Bacterial growth rate: Temperatures have a strong influence on the growth rate of the *E.a.* on stigmas. The relationship of hourly temperatures during any given day to growth rate of the pathogen on stigmas is quantified in this model. The temperature risk value numbers in Cougarblight are not degree hours; they were based on the average *pathogen* growth rate per 24 hours, which was then divided by 24 to derive an hourly growth rate at any given temperature, then once again arbitrarily divided by 1000 to make the model numbers easier to use (Table 2). These hourly-by-temperature values are assigned to each hour of the day, and totaled for the four days leading up to the wetting event. For forecasting purposes, numerous days of similar high temperature were evaluated for total value and an average daily value was assigned to each specific daily high temperature (Table 3).

4. Wetting as a trigger to infection: Wetting of the flowers by rain, dew of two hours or more duration, mist from sprinklers, or any other situation that results in flowers being wet for two hours or more is considered a potential infection event. At the time of blossom wetting, if the temperature total risk value exceeds certain thresholds, then conditions leading to fire blight outbreaks in the past have occurred. In practice, actual fire blight development after a wetting event during a Cougarblight high risk period is dependent on the presence or absence of flowers and the presence or absence of *E. amylovora* contamination.

A current Excel version of this model may be downloaded from the following website: http://www.ncw.wsu.edu/treefruit/

MATERIALS AND METHODS

Below is a description of the methods used to formulate the various aspects of the Cougarblight fire blight flower infection risk analysis model:

1. Orchard fire blight history: The three fire blight history scenarios were derived empirically by studying numerous individual fire blight outbreaks. Most of these outbreaks were in the Pacific Northwest USA; however, data from other regions of the USA, such as Utah, California, Michigan, New York, and Eastern and Western Canada were included in the study. Growers and industry advisors cooperated by reporting local orchard outbreaks, allowing author inspection, and by recounting recent fire blight history in their neighborhood.

Specific outbreaks in seasons where fire blight infections were widely scattered and limited to between 50 and 100 meter width zones in specific orchards were used as examples to set the lowest range of thresholds (blight history scenario 3). The low temperature risk thresholds were based on the observation that live cankers are often missed by growers cutting out blighted branches, and these cankers lead to localized blight outbreaks the next spring, even after relatively cool blossom seasons. Under these conditions, a temperature risk value of 100 or higher indicates a "high" risk of infection. Growers who had blight problems the previous year (and their near-by neighbors) should use this scenario when assessing risk.

Thresholds for scenario 2 were set by analyzing outbreaks in regions that have fire blight to some degree almost yearly, with some years far worse than others. It was assumed that live cankers are likely scattered across the region every spring, but not necessarily near the orchard where infection risk is being evaluated. This blight history has a temperature risk value of 200+ as the lower threshold for "High" risk of infection.

Outbreaks in areas that have fire blight, but infrequently, were used as examples for setting the high-range thresholds. This scenario can be used only when fire blight was not a problem the previous year in the contiguous region. This scenario is common in many regions with relatively cool spring temperatures. However, it should not be used in any region where fire blight is a significant problem more frequently than once every eight or ten years. This blight history (scenario 1) has a temperature risk value of 500 as the lower threshold for "High" risk of infection.

Thresholds of infection risk relative to fire blight history scenario are as follows: For scenario 1, risk categories and temperature risk value ranges are: Low 0 - 150, Caution 150 – 500, High 500 – 800, Extreme 800-1000, and Exceptional 1000+. For scenario 2, risk categories and temperature risk value ranges are: Low 0 - 100, Caution 100 – 200, High 200 – 350, Extreme 350 – 500, and Exceptional 501+. For scenario 3, risk categories and temperature risk value ranges are: Low 0 (there is no low risk in an infected orchard), Caution 0 – 100, High 100 – 200, Extreme 200 – 300, and Exceptional 301+.

The meaning of risk category terminology:

Low: Wetting of flowers during these temperature conditions has not resulted in new flower blight infections in past years. The flowers within a few meters of an active canker may be an exception.

Caution: Wetting of flowers under these temperature conditions is not likely to lead to infection, but the possibility increases as values approach the upper range. Weather forecasts and risk values should be carefully monitored. If antibiotic materials are not being used, blossom protection with other materials should be initiated three or four days prior to entering a high infection risk period. Continue appropriate protective sprays until the infection risk drops below the "high" threshold.

High: Under these temperature conditions, serious outbreaks of fire blight have occurred. Orchards that recently had blight are especially vulnerable. The risk of severe damage from infection increases during the later days of the primary bloom period, and during petal fall, while blossoms are plentiful. Infection is common, but more scattered when late blossoms are wetted during high risk periods. The potential severity of infection increases if a series of high risk days occur.

Extreme or Exceptional: Some of the most damaging fire blight epidemics have occurred under these optimum temperature conditions, followed by blossom wetting. These infections often lead to severe orchard damage, especially during primary bloom or when numerous secondary blossoms are present. As the season progresses, secondary blossoms tend to form less frequently, and hot summer temperatures of 35ºC and above greatly reduce the frequency of new blossom infections.

2. Flower life / colony growth: The four day accumulation of temperature values in earlier versions of Cougarblight were derived empirically by comparing the relationship of two day, four day, and six day temperature accumulation preceding specific fire blight outbreaks. When comparing one fire blight outbreak to another, the four day accumulation was more consistent. Studies by Thomson and Gouk (2003), and Pusey and Curry (2004) indicated that flowers could remain viable for six or even eight days, however, within the temperature range where fire blight is more likely to occur, four days of optimum flower condition seemed most likely. Pear growers are given the option of using five day heat value accumulation during primary bloom and 21 days after full bloom.

3. Bacterial growth rate:

Contamination of flowers by *E. amylovora* does not necessarily lead to infection. After infesting the flower, populations of the pathogen have only a few days to grow to at least 100,000 or 1 million CFU prior to the potential infection event. This pathogen multiplies on the flower stigmas, slowly at temperatures below 21ºC, moderately at temperatures between 21 and 24ºC, and rapidly at temperatures between 24 and 33ºC. Optimum population size growth rate occurs between 28 and 32ºC (82 and 90ºF). At temperatures over 35ºC, growth rapidly decreases to zero and populations decline in size at any

temperature over about 37ºC (99ºF). The temperature measurements used in the CougarBlight model were previously described as degree days above 15.5ºC. This has never been an accurate description, particularly when describing the 2010 version. The "temperature risk value" units were developed from unpublished data for population growth of E.a. on stigmas. Crab apple flowers were inoculated with *E. amylovora* using a suspension of 10^7 CFU/ml, resulting in a starting population of about 300 CFU per flower, and held at 15 different temperatures between 4 and 39ºC for 24 hours (see Table 1). Materials and methods were similar to those described in previous work (Pusey 1997; Pusey and Curry, 2004). The resulting population size was divided by 24 to estimate the increase in population per hour. That number was then divided by 1,000 to make the temperature value numbers smaller and more practical to manage. These numbers were used to develop a population growth curve, and fill in missing values for each half degree of temperature Celsius between 4ºC and 35ºC. Then, to simplify forecasting blight risk, a table of average daily temperature risk values related to the daily high temperature was developed (Table 3). More than 2500 days in April, May and June at numerous sites and years in central Washington State, USA, were assigned a value for every actual hourly temperature. These values were summed for every 24-hour period, and sorted into groups relating to daily high temperature. While the temperature risk values tend to fall very close to the average, there can be significant variation away from this average for any specific actual day. Due to this inevitable variation, average risk values taken from the table and thresholds should be considered as estimates and guidelines. These average daily risk values may be used to run the simple form of the model, and will be used in the forecasting mode of any automated CougarBlight model system, (see http://das.wsu.edu/index.php for spring, 2011). To accurately determine the actual daily temperature risk values, hourly temperatures must be monitored and assigned an individual corresponding risk value, which is summed with others for the day. Computer automation is almost required for this task. The hourly specific values are in Table 2. For further information and updates of this model, go to the following web site:
http://www.ncw.wsu.edu/treefruit/

Table 1. Population size of *Erwinia amylovora* on stigmas of detached crab apple flowers held at various temperatures for 24 hours, and the corresponding hourly average.

Temperatures ºC	3.48	**7.89**	**12.22**	**15.27**	**18.21**
24 hour CFU	502	397	435	10775	30637
1 hour average	20.9	16.5	18.1	449	1277
Temperatures ºC	**20.16**	**22.5**	**24.27**	**26.06**	**27.17**
24 hour CFU	65680	285230	357733	555333	907333
1 hour average	2737	11885	14906	23139	37806
Temperatures ºC	**29.87**	**32.17**	**34.01**	**35.87**	**39.05**
24 hour CFU	1153000	1259133	853667	210	0
1 hour average	48042	52464	35569	8.75	0

Table 2. Temperature risk values per hour during a specific day relative to its average temperature. Values were derived from one hour averages in table 1, adjusted to fit a smoothed curve, and divided by 1000.

Temperatures	**≤10**	**10.5**	**11**	**11.5**	**12**	**12.5**	**13**	**13.5**	**14**
Hour risk values	0	0.05	0.10	0.15	0.20	0.22	0.25	0.3	0.35
Temperatures	**14.5**	**15**	**15.5**	**16**	**16.5**	**17**	**17.5**	**18**	**18.5**
Hour risk values	0.4	0.45	0.5	0.6	0.7	0.9	1.0	1.12	1.25
Temperatures	**19**	**19.5**	**20**	**20.5**	**21**	**21.5**	**22**	**22.5**	**23**
Hour risk values	1.6	2.1	2.7	3.2	3.9	4.75	5.6	7	8.9
Temperatures	**23.5**	**24**	**24.5**	**25**	**25.5**	**26**	**26.5**	**27**	**27.5**
Hour risk values	11.5	14.7	17.1	20.3	23	26	29	32	34.5
Temperatures	**28**	**28.5**	**29**	**29.5**	**30**	**30.5**	**31**	**31.5**	**32**
Hour risk values	37.5	40.5	44	46.5	48.2	50	51	52	52
Temperatures	**32.5**	**33**	**33.5**	**34**	**34.5**	**35**	**35.5**	**36**	**36.5+**
Hour risk values	51	50	45	35	20	10	0	0	0

Table 3. Average sum of all hourly risk values relative to daily high temperature.

Temperatures	**10**	**10.5**	**11**	**11.5**	**12**	**12.5**	**13**	**13.5**	**14**
Daily risk value	0.1	0.15	0.2	0.3	0.5	0.7	1.1	1.4	1.7
Temperatures	**14.5**	**15**	**15.5**	**16**	**16.5**	**17**	**17.5**	**18**	**18.5**
Daily risk value	2.0	2.3	2.8	3.4	4.0	4.7	5.7	6.8	8
Temperatures	**19**	**19.5**	**20**	**20.5**	**21**	**21.5**	**22**	**22.5**	**23**
Daily risk value	10	11.1	12.4	15.6	19.7	24.2	28.5	36.5	42
Temperatures	**23.5**	**24**	**24.5**	**25**	**25.5**	**26**	**26.5**	**27**	**27.7**
Daily risk value	50	61	78	95	114	133	155	186	212
Temperatures	**28**	**28.5**	**29**	**29.5**	**30**	**30.5**	**31**	**31.5**	**32**
Daily risk value	240	270	295	325	350	380	412	440	467
Temperatures	**32.5**	**33**	**33.5**	**34**	**34.5**	**35**	**35.5**	**36**	**36.5**
Daily risk value	490	508	525	535	540	535	450	310	120
Temperatures	**37**	**37.5**	**38**	**38.5**	**39+**				
Daily risk value	60	30	15	5	0				

ACKNOWLEGEMENTS

This model is based on the research and personal guidance of Dr. Sherman V. Thomson, Utah State University, and the research and collaboration of Dr. P.L. Pusey, USDA-ARS. It could not have been developed without their innovative research and cooperation.

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WASHINGTON STATE HORTICULTURAL ASSOCIATION
1904 100 YEARS 2004
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April 8, 2011

Ms. Patricia Adkins
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2646-So, Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-11-0014
Re: Re-listing Tetracycline

Dear Ms. Adkins:

This document is a rebuttal of the Crop Committee's recommendation to the NOSB on tetracycline. It is submitted to the NOSB for review and consideration prior the Board's scheduled vote on whether to accept or reject the Crops Committee recommendation regarding tetracycline.

On October 27, 2010, the Washington State Horticulture Association (WSHA) submitted a petition to the National Organic Standards Board (NOSB, or Board) requesting removal of the expiration date of tetracycline and the re-instatement of its sunset date of October 21, 2012. The WSHA petition was reviewed by the NOSB Crops Committee. It then posted its recommendations to the NOSB on the United States Department of Agriculture National Organic Program (USDA-NOP) website on March 8, 2011. With respect to the WSHA petition submitted to the NOSB, the Crops Committee Recommended Committee Action & Vote stated: *"The majority of the Crops Committee recommends against the adoption of the petition to amend the listing for tetracycline by removing the expiration date on tetracycline so that the listing would state 'tetracycline, for fire blight control only,' thus allowing tetracycline's use to expire on October 21, 2012."*

The framework used for this rebuttal is the EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST submitted to the NOSB by the Crops Committee in March 2011 after its review of the WSHA petition requesting removal of the expiration date for tetracycline. WSHA asserts that arguments made in the Crops Committee report on tetracycline are scientifically debatable and do not constitute a thoroughly objective analysis of the matter. WSHA contends therefore that the Crops Committee's recommendation to the NOSB to deny the WSHA petition is ill-advised. WSHA further contends the adverse consequences likely to fall upon organic apple and pear growers, should tetracycline (oxytetracyline) be eliminated from the

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National List under § 205.601, have not been given adequate consideration by the Crops Committee in its review of the WSHA petition on tetracycline. Such consequences, should the Board accept the Committee's recommendation and vote to deny the petition, will likely result in a net reduction in the number of organic apple and pear acres in the United States – a result seemingly inconsistent with the goals of USDA-NOP.

What follows is a recitation of the Crops Committee's report to the NOSB on the WSHA petition for the removal of the expiration date of tetracycline from the National List and its re-instatement of the sunset date and a rebuttal to those points/references by the WSHA. Assistance and support in the creation of this document has been provided by AgroSource, Inc. and by Nufarm Americas, Inc., manufacturers and Registrants of oxytetracycline marketed as FireLine™ 17 WP and Mycoshield®, respectively. The Category/Question series along with the Crops Committee Comment/Documentation is quoted from the Committee's report template: EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST.

Category 1, Question 2. Is there environmental contamination during manufacture, use, misuse, or disposal?

Crops Committee Comment/Documentation: Daniels, 1982 (MJ Daniels, 1982, Editorial: Possible effects of antibiotic therapy in plants. Reviews of Infectious Diseases 4 (Supp): 167-170. / Manufacture results in discharges of solvents, detergents, disinfectants / Treated plants exude tetracycline

WSHA Rebuttal: The manufacturing, use, potential misuse, and disposal of pesticides in the United States are regulated by the U.S. Environmental Protection Agency (EPA). This includes oxytetracycline (in the tetracycline chemical class). The EPA registration process used in the regulation of pesticides includes manufacturing controls to prevent the discharge of the pesticide and pesticide manufacturing by-products. This is also addressed by the National Primary Drinking Water Regulations as stated in the Code of Federal Regulations. In addition, the field uses for oxytetracycline are clearly listed on the products' labels; these labels are legal documents clearly defining how the product may be applied and used. The misuse of any pesticide – meaning any use not specifically recommended in the language on the label – is a violation of U.S. Federal statutes. Penalties for any such violation(s) would be enforced to the fullest extent of the law by appropriate federal enforcement agencies. Similarly, disposal of pesticides is strictly regulated and directions for disposal are clearly listed on the product label. The standard wording used on the commercial labels for oxytetracycline in the Under Environmental Hazards section reads as follows:

- Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the high water mark.
- Do not contaminate water when disposing of equipment wash water.
- Pesticide washes are acutely hazardous, improper disposal of excess pesticides, spray mixtures, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative of the nearest EPA Regional Office.

Clearly, the EPA and other federal agencies have established (and actively enforce) extensive safeguards designed to prevent environmental contamination during manufacture, use and disposal of tetracycline.

Regarding the reference to treated plants exuding tetracycline, WSHA is aware of no data showing apple and/or pear trees treated with tetracycline will exude either tetracycline or oxytetracycline through foliage or any other treated area. Scientific evidence supports the understanding that tetracycline does not freely translocate within apple and/or pear trees. Yet, if apple and/or pear trees *did* exude tetracycline/oxytetracycline from their roots into the soil, these exudates would typically and rapidly form a highly insoluble and immobile complex with di- and tri-valent cations such as calcium or aluminum present in the soil solution. Such complexes in the soil profile would not be expected to pose a significant threat to plants, animals or microbial populations due to their high level of insolubility and immobility. This same physico-chemical process would also likely occur for any by-products associated with the manufacture of oxytetracycline. The Crops Committee's comments in this matter disregard the existence and enforcement of federal standards and regulations governing the manufacture and use of oxytetracycline to apple and pear orchards. The Crops Committee generalization that tetracycline-treated "plants exude tetracycline" does not establish nor confirm that foliar applications of oxytetracycline to apple and/or pear orchards results in these crops "exuding" tetracycline after treatment.

Category 1, Question 3. Is the substance harmful to the environment and biodiversity?

Crops Committee Comment/Documentation: Thiele-Bruhn and Beck, 2005. Effects of sulfonamide and tetracycline antibiotics on soil microbial activity and microbial biomass. Chemosphere 59:457-465

WSHA Rebuttal: The EPA Oxytetracycline Reregistration Eligibility Document (RED) dated March 1993 and the Oxytetracycline Tolerance Reregistration Eligibility Decision (TRED) dated June 2006 did not find oxytetracycline to be harmful to the environment or to biodiversity.

Thiele-Bruhn and Beck (2005) found when oxytetracycline (at rates as high as 1,000 $\mu g\ g^{-1}$) was applied to two soil groups representative of European soils (a Luvisol and a Cambisol) along with milled corn straw and glucose as organic amendments, there was an effect on soil microbial respiration rates and dehydrogenase activity, albeit a transitory one. The authors reported that *"To stimulate microbial activity and growth, the addition of a nutrient substrate to soil is required. Additionally, the application of antibiotics together with a nutrient substrate is more environmentally relevant because antibiotics mostly reach the soil via manure, sludge or excreta from grazing livestock."* Thiele-Bruhn and Beck's research was conducted in Europe where oxytetracycline is typically added to soil via manure amendments from animals (usually swine) that have received veterinary treatments of tetracycline. Thiele-Bruhn and Beck demonstrated relatively large oxytetracycline inputs are required to produce environmental effects and only when microbial activity is stimulated by organic amendments.

According to data from Blackwell et al.[1] (2007) a typical swine slurry application introduces approximately 0.5 lbs. of oxytetracycline for every 50 lbs. of nitrogen per acre (assuming oxytetracycline is used as a veterinary product on swine and the application is made with 2,000 gallons of liquid swine manure slurry per acre). Such treatment introduces to the soil approximately three (3) times more tetracycline than a typical single application to an apple orchard. If the manure application requires 100 lbs. of nitrogen per acre (not an unrealistically high number) approximately six (6) times more tetracycline is introduced to the soil per acre from a typical swine manure slurry application than is applied to apple or pear trees from a single foliar spray of oxytetracycline.

Results reported by Thiele-Bruhn and Beck (2005) are not applicable to comparable soils in the U.S. unless those soils are similarly treated with the same organic amendments in equivalent quantities. Furthermore, tetracycline added to soils through a manure application is a direct input to the soil. By definition, a foliar application of oxytetracycline to apple and pear orchards is not applied directly to the soil. The work of Thiele-Bruhn and Beck, while important, was not designed to consider oxytetracycline input to the soil via foliar application to apple and/or pear trees and therefore did not demonstrate potential harmful effects of oxytetracycline to the environment or to biodiversity for orchard soils if treated by a typical foliar application as listed on the product's label.

The difference between the environmental effects noted by Thiele-Bruhn should not be used to support a rejection for foliar application of oxytetracycline to apple and pear trees to control fire blight. Typical use patterns associated with oxytetracycline on apples and pears for fire blight control and direct manure inputs to the soil plus differences in quantities of tetracycline used in the two application systems are widely divergent.

To conclude that a substance may be harmful to the environment or biodiversity and base this conclusion upon a single study not specifically designed to simulate the same mode of entry and quantity of the substance to the soil does not follow proper investigation and analysis. In short, data from scientific literature demonstrating oxytetracycline is either harmful to the environment or has lasting biodiversity issues are inconsistent and inconclusive. Data from the scientific literature demonstrating that oxytetracycline applied to apple and pear trees for control of fire blight is either harmful to the environment or has lasting biodiversity issues are non-existent.

Category 1, Question 5. Is there the potential for detrimental chemical interaction with other materials used?

<u>Crops Committee Comment/Documentation:</u> Burgos, et al, 2005. Presence of multidrug-resistant enteric bacterial in dairy farm topsoil. J Dairy Sci. 88:1391-1398. Bacteria with multiple resistance

<u>WSHA Rebuttal:</u> Burgos, Ellington, and Varela (2005) evaluated multidrug resistant bacteria from soils that had been treated with high levels of dairy cattle manure amendments (see the above descriptions for manure treatments). This research was not designed to show if similar

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[1] Blackwell, P.A., Kay P. and A.B. Boxall, The dissipation and transport of veterinary antibiotics in a sandy loam soil, 2007, Chemosphere, 67(2):292-299.

effects could be achieved with agricultural soils not amended with high quantities of dairy cattle manure, or soils characteristic of apple and pear orchards. It is acknowledged that heavy input of veterinarian medicines and growth promoting antibiotics will pass through the gut of the treated animals, in this case dairy cattle, and will accumulate in the manure and that once such manure is applied to a field, and that under these conditions, there is the strong chance that multiple antibiotic resistant bacteria can arise. However, as demonstrated in the work by Thiele-Bruhn and Beck (2005), the amounts of organic substrate added to the soil must be at high enough levels before significant biological activity is evident. The work by Burgos, Ellington, and Varela, while important, is therefore not particularly relevant to what occurs in typical apple and pear orchards when treated with oxytetracycline as foliar applications according labeled rates for the control of fire blight.

Category 1, Question 6. Are there adverse biological and chemical interactions in agro-ecosystem?

Crops Committee Comment/Documentation: Thiele-Bruhn and Beck, 2005. Effects of sulfonamide and tetracycline antibiotics on soil microbial activity and microbial biomass. Chemosphere 59:457-465. Shifts fungal-bacterial balance at environmentally relevant concentrations.

WSHA Rebuttal: Thiele-Bruhn and Beck (2005) demonstrated that soils treated with heavy organic amendments as manure (see the above descriptions for manure treatments) containing oxytetracycline will elicit a temporary selective pressure on soil microorganisms. This response should not be surprising nor is it necessarily deleterious to soil microorganism. It should be recalled that soil microflora is a complex and dynamic medium comprised of true bacteria, actinomycetes, fungi, algae, protozoa and viruses. While one of these segments of the soil microbial community might be impacted by an amendment (such as manure) or by a chemical such as an antibiotic, a pesticide or an industrial chemical, other community members will increase either because of reduced competition or because they possess the ability to degrade or even use the chemical as a source of carbon and energy. Pseudomonads are a good example of this. In addition, bacterial and fungal populations will normally fluctuate significantly throughout the year due to changes in temperature and moisture. Thus, the composition of the soil microbial community is always in flux, due to seasonality, moisture, chemical inputs as well as other factors.

As was noted by Thiele-Bruhn and Beck themselves in their 2005 work cited above, reports from the literature describing the effects of antibiotics on soil microorganisms are comparatively scarce and often inconsistent. For instance, Liu et al.[2] (2009) reported tetracycline antibiotics showed little effects on soil respiration. Patten et al.[3] (1980) showed a significant increase in glucose utilization from feces-amended soil containing either oxytetracycline or

[2] Liu, F., Ying, G., Tao, R. Zhao, J., Yang, J., and L. Zhao, Effects of six selected antibiotics on plant growth and soil microbial and enzymatic activities, 2009, Environmental Pollution, 157, 1636-1642
[3] Patten, D.K., Wolf, D.C., Kunkle, W.E. and L.W. Douglass, Effect of Antibiotics in Beef Cattle Feces on Nitrogen and Carbon Mineralization in Soil and on Plant Growth and Composition, 1980, J. Environ. Qual., vol. 9, no. 1, 167-172

chlortetracycline. Finally, Schmitt[4] (2005) showed that while oxytetracycline changed the overall microbial community structure of a manure-amended soil, it only had a slight effect on the soil's physiological fingerprint. Therefore, to conclude that oxytetracycline input to soils via comparatively high rates of manure "shifts fungal-bacterial balance at environmentally relevant concentrations" is to ignore the dynamics of soil microfauna where such "shifting" takes place as a natural course of events. Such a conclusion also ignores the fact that work by Thiele-Bruhn and Beck was not designed to simulate – and therefore did not address – input of oxytetracycline to soils via foliar application to apple and/or pear orchards.

Category 1, Question 7. Are there detrimental physiological effects on soil, organisms, crops, or livestock?

<u>Crops Committee Comment/Documentation:</u> Xiujie Xie et al, 2010. Genotoxicity of tetracycline as an emerging pollutant on root meristem cells of wheat (*Triticum aestivum* L.) *Environmental Toxicology* doi: 10.1002/tox 20567 Tetracycline may be genotoxic to plant cells.

<u>WSHA Rebuttal:</u> Due to its antibacterial nature, when applied to *in vitro* cell cultures at high concentrations, oxytetracycline may elicit a genotoxic effect. However, to infer that such potential genotoxic effects either occur or may occur when oxytetracycline is applied *in vivo* under EPA-approved label rates to apple and pear trees is unsubstantiated and does not follow experimental scientific methodology. WSHA is aware of no scientific field studies conducted or proposed which demonstrate a genotoxic effect by the application of oxytetracycline to apple and pear trees for the control of fire blight.

Regarding the potential for genotoxicity among animals, EPA determined that oxytetracycline is a Group D carcinogen and is therefore "Not classifiable as to Human Carcinogenicity" (Oxytetracycline HED Chapter of the TRED and Proposed New Uses on Apples, June 19, 2006). Based on the lack of genotoxicity to animal cells and tissues, it is therefore highly unlikely that genotoxicity would occur on a whole plant level due to oxytetracycline treatment from normal applications. The Crops Committee comment that "tetracycline may be genotoxic to plant cells" is a vague assertion derived from a study not designed to establish and quantify the matter by duplicating or even simulating the foliar application of oxytetracycline to plant tissue and is, therefore, an inference unsubstantiated by the evidence presented.

Category 1, Questions 8 and 10 (these have been combined). Is there a toxic or other adverse action of the material or its breakdown products? And, is there any harmful effect on human health?

<u>Crops Committee Comment/Documentation:</u> TRI 163-171, 279-293 / Lugo-Melchor et al, 2010. Characterization of tetracycline resistance in Salmonella enterica strains recovered from irrigation water in the Culican Valley, Mexico, Microbial Drug Resistance 6:185-190/Levy et al, 1976. Changes in intestinal flora of farm personnel after introduction of a tetracycline-

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[4] Schmitt, Heike,, The effects of veterinary antibiotics on soil bacteria: community structure, physiological profile, and induced tolerance, Chapter 5, *In* The effects of veterinary antibiotics on microbial communities, University Utrecht, 2005, see at: http://igitur-archive.library.uu.nl/dissertations/2005-0616-200013/index.htm

supplemented feed on a farm. N Engl J Med 295:583-588 / Wikipedia.org tetracycline antibiotics "prop 65 list" /

Workers are at risk for contracting tetracycline-resistant disease and suffering allergic reactions. As a consequence of the widespread use of tetracyclines, the emergence and spread of tetracycline-resistant bacterial pathogens, among them the food borne pathogen Salmonella enterica, has become a serious health hazard worldwide.

Workers who handle feed with tetracycline have tetracycline-resistant flora in their intestines.

Tetracyclines remain the treatment of choice for infections caused by chlamydia (trachoma, psittacosis, salpingitis, urethritis, and L. venereum infection), Rickettsia (typhus, Rocky Mountain spotted fever), brucellosis, and spirochetal infections (borreliosis, syphilis, and Lyme disease). In addition, they may be used to treat anthrax, plague, tularemia, and Legionnaires' disease.

They may have a role in reducing the duration and severity of cholera, although drug-resistance is occurring, and their effects on overall mortality is questioned.

Developmental toxin listed by the state of California.

<u>WSHA Rebuttal:</u> As with any antibiotic, there is always the potential risk for antibiotic resistance to oxytetracycline. Resistance to tetracyclines has been known for at least the past five decades since this class of antibiotics was first used for the control of infectious diseases in humans and livestock. The U.S. Food and Drug Administration (FDA) permits the pharmaceutical use of tetracyclines for both disease control and growth promotions of livestock. The EPA has registered oxytetracycline for use as a pesticide for the control of fire blight on apples and pears. Both FDA and the EPA have stringent procedures for insuring that these materials are used in a manner in accordance with the regulations that cover both the safety of the product and the minimization of the product's potential risk to humans; this includes individuals who handle the product in the field and end use consumers of treated food products, including apples and pears.

EPA has been and is currently evaluating the human safety of oxytetracycline as is required under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) and, more recently, under FQPA (Food Quality Protection Act). In its most recent assessments, EPA has informed the public that it is further investigating the potential risks to the public concerning antibiotic resistance and potential cross-resistance. Currently with regards to antibiotic resistance, EPA has determined a medium risk factor to the general public and specific age groups, such as children with regards for oxytetracycline (U.S. EPA Memorandum, June 19, 2006), and given this, there are no restrictions (except as established by approved label recommendations) for the use of oxytetracycline on apple and pear trees for the control of fire blight. EPA has also determined that the dietary risk exposure for oxytetracycline is expected to be low due to the long post-harvest intervals for treated apples and pears. EPA has also stated that drinking water exposure may occur due to run-off from agricultural uses of oxytetracycline in orchards, but again this would be a limited exposure and is not considered a risk in the exposure assessment. Finally, the

EPA is currently in the process of requiring data (Data Call-In) from the Registrants of oxytetracycline covering environmental fate, including run-off and soil dissipation.

Regarding the potential risk to workers who handle tetracycline (oxytetracycline) for applications in orchards, the risk is already mitigated by the requirement in the labels for use of Personal Protective Equipment (PPE). This requirement is enforced by EPA and violators are subject to severe penalties; the label warning for this reads as follows: "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling". The labels are very specific and in the case of the oxytetracycline labels, the following wording is required:

Applicators and other handlers must wear:

- long-sleeved shirt
- long pants
- chemical-resistant gloves made of any waterproof material
- shoes plus socks
- NIOSH approved respirator with any N, R, P or HE filter

The EPA approved labels for the two oxytetracycline formulations currently available also contain instructions on how to clean PPE or to discard it, if necessary, along with the proper sanitation procedures to follow when using the product. The vast majority of registered product labels state that "Prolonged or frequently repeated skin contact can cause allergic reactions in some individuals"[5]. This situation can be avoided by the use of appropriate PPE, which is clearly stated on oxytetracycline labels. It is also important to note that the majority of pesticides as applied in the major apple and/or pear growing regions of the U.S. are made either by or under the direction of a certified pesticide applicator and these applicators have responsibility to insure the product label directions are followed.

Lugo-Melchor et al. (2010) reported tetracycline resistant *Salmonella enterica* collected from irrigation water used in growing fresh fruits and vegetables in the Culiacan Valley, Mexico. While these findings are cause for concern, they do not fairly characterize typical chemical use and agricultural practices the U.S. The *Salmonella* resistant strains could have been introduced into the water systems by a number of different agricultural or cultural practices illegal in the U.S., such as use of irrigation water systems as dumping grounds for human sewage – a situation that would harbor resistant bacteria as a result of local human pharmaceutical uses. Resistant strains of *Salmonella enterica* could also have arisen from the misuse of tetracyclines by direct contact with the water or careless over spraying of the crop near a body of water – both actions specifically prohibited on the EPA approved labels for oxytetracycline.

Furthermore, EPA has not found oxytetracycline to be a potential developmental toxin nor is there any reference to this in the Oxytetracycline TRED, dated June 2006, or in any other document as produced by the EPA Health Effects Division. In fact, within the TRED for

[5] Even the labels of many organically certified, e.g. OMRI certified, products used in agriculture or horticulture state that the product may cause irritation or injury if brought into contact with sensitive areas such as eyes or skin.

oxytetracycline, the EPA notes the differential between typical therapeutic doses of oxytetracycline and exposure estimated from pesticidal application and states the following:

> *EPA estimates that the pharmaceutical oxytetracycline exposure a user is expected to receive from a typical therapeutic dose (25 mg/kg/day for children) is 50,000 to 200,000 times greater than the estimated dietary exposure from the pesticidal sources of oxytetracycline (0.000121 mg/kg/day to 0.000473 mg/kg/day). Therefore, because the pesticide exposure has no more than a minimal impact on the total dose to a pharmaceutical user, EPA believes that there is a reasonable certainty that the potential dietary pesticide exposure will result in no harm to a user being treated therapeutically with oxytetracycline.*

In other words according to EPA's own estimates the potential human exposure to oxytetracycline from doctor-prescribe antibiotic treatment is between four and five orders of magnitude <u>greater</u> than that of any estimated potential exposure to oxytetracycline from application to crops by EPA-approved application techniques. Clearly the EPA does not consider oxytetracycline to be a developmental toxin and this should over-ride any such positions as were taken by California, either through its Proposition 65 process or through that state's pesticide regulatory agency, the Department of Pesticide Regulation.

Category 1, Question 9. Is there undesirable persistence or concentration of the material or breakdown products in the environment?

<u>Crops Committee Comment/Documentation:</u> Daniels, 1982. Editorial: possible effects of antibiotic therapy in plants. Reviews of Infectious Diseases 4 (Supp): 167-170 / Chander et al, 2005. Antibacterial activity of soil-bound antibiotics. J Environ Qual 34:1952-1957 / Halling-Sorensen et al, 2002. Toxicity of tetracyclines and tetracycline degradation products to environmentally relevant bacteria, including selected tetracycline-resistant bacteria. Archives of Environmental Contamination and Toxicology 42:263-271.

Tetracycline is taken up by plants and appears in all tissues and in exudates.

Soil-bound tetracycline maintains biological activity.

<u>WSHA Rebuttal:</u> Published research has shown that oxytetracycline and its by-products 4-epi-oxytetracycline, α-apo-oxytetracycline, and β-apo-oxytetracycline will persist in treated soils although the three by-products are typically at much lower levels than the parent compound. They also retain much lower antibacterial potencies relative to the parent compound. However, most of this research has focused on European soils that were treated with animal manures rich in oxytetracycline (see the above descriptions for manure treatments). These soils had levels of oxytetracycline much higher than would be found in typical orchards soils following standard treatments of oxytetracycline for fire blight control. In addition the high enrichment of organic molecules resulting from these manure treatments would stimulate the growth of bacteria and as such would make such bacteria more susceptible to developing resistance. Such shifts from non-

resistant to resistant bacterial colonies have not been observed for stable soil systems as would be the case with orchards.

The significant adsorption of tetracyclines to soils has been addressed in the open literature. Jones et al.[6] (2005) studied 30 soils differing in texture, cation-exchange capacity, iron oxide and organic carbon content and showed that oxytetracycline binds strongly to soil. MacKay and Canterbury[7] (2005) further showed that binding is enhanced in the presence of divalent cations like Ca^{++} and Cu^{++}. Although Chander et al.[8] (2005) showed soil-adsorbed tetracycline still retained antibacterial potency, their experimental procedure involved autoclaving the two test soils on three separate occasions. In fact, when soils are autoclaved their physical structure usually becomes pelletized – significantly reducing the surface area of the soil and thereby lowering its exchange capacity. Thus, results from this study may not correlate to field conditions.

The oxytetracycline molecule itself also has a strong affinity to form chelates or complexes with divalent cations e.g., Ca^{++} and Mg^{++}. This action generally reduces bioavailability of oxytetracycline as well as its antibacterial effects (see Halling-Sørensen et al.[9], 2002). Thus through natural processes within soils, oxytetracycline is effectively removed or rendered biologically inactive at a moderate rate through a combination of degradation, adsorption and chelation.

Category 2, Question 4. Is there a wholly natural substitute product?

<u>Crops Committee Comment/Documentation:</u> Stockwell and Stack, 2007. Using *Pseudomonas* spp. for integrated biological control. Phytopathology 97:244-249.

<u>WSHA Rebuttal:</u> The basic strategy behind using *Pseudomonas* spp. for controlling fire blight is that the nonpathogenic *Pseudomonas* spp. will "crowd out" the fire blight pathogen *Erwinia amylovora* on the surface area of developing apple or pear blossoms. Under "real world" use conditions, this bacterial displacement approach with *Pseudomonas* spp. has shown variable results – but neither as effective or consistent as oxytetracycline. It seems to work best only if there is complete and early coverage of *Pseudomonas* spp. on the critical flower parts <u>and</u> the *Pseudomonas* spp. populations are able to grow to adequate numbers such that they out-compete any *E. amylovora* populations. This displacement strategy does not always succeed. Under adverse weather conditions where poor inoculum distribution and/or timing and/or where *E. amylovora* have already established overwhelming populations, if temperature and moisture

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[6] Jones, A. D.,, Bruland, G. L.,, Agrawal, S. G.,, and D. Vasudevan, 2005. Factors Influencing the Sorption of Oxytetracycline to Soils, Environmental Toxicology and Chemistry, Vol. 24, No. 4, pp. 761–770.
[7] MacKay A. A., and B. Canterbury, Oxytetracycline Sorption to Organic Matter by Metal-Bridging, 2005. J. Environ. Qual. 34:1964–1971.
[8] Chander Y., Kumar K.,, Goyal S. M., and Satish C. Gupta, 2005. Antibacterial Activity of Soil-Bound Antibiotics, J. Environ. Qual. 34:1952–1957.
[9] Halling-Sørensen, B., Sengeløv, G., and J. Tjørnelund, , 2002. Toxicity of tetracyclines and tetracycline degradation products to environmentally relevant bacteria including selected tetracycline resistant bacteria. Arch. Environ. Contam. Toxicol. 42, 263–271.

conditions are favorable for the growth of *E. amylovora*, fire blight will rapidly spread in the orchard with devastating results despite the actions taken to introduce competing bacteria.

It is for this and other reasons that EPA does not consider *Pseudomonas spp.* to be a replacement for tetracycline. The Oxytetracycline TRED ([page 5 of 15], June 2006) states that the biological control agent, BlightBan® (a.i. *Pseudomonas fluorescens* strain A506) is used to <u>complement</u> an antibiotic pesticide (meaning that it is used in conjunction with) and is <u>not a replacement</u> for antibiotics (including tetracyclines) and that the commercial use of BlightBan® is limited (in use) due to poor efficacy. In summary, EPA did not endorse the use of *Pseudomonas fluorescens* as a substitute for tetracycline (oxytetracycline). Although much research has been focused on discovering and developing other "biological" alternatives to oxytetracycine for fire blight control in apples and pears, the simple fact remains that no "biological" product yet discovered, tested, registered and commercialized exists that has the ability to combat fire blight as consistently effective as does oxytetracycline.

Category 2, Question 6. Are there any alternative substances?

<u>Crops Committee Comment/Documentation:</u> TRI 317-330

<u>WSHA Rebuttal:</u> The discussion regarding alternatives to tetracycline should focus on products currently registered by EPA for outdoor use on apple and pear trees and not on potential candidate materials or surface area sterilant products. For example, peracetic acid has been suggested as a potential alterative to tetracycline, even though peracetic acid is currently only registered for use on hard surfaces, much in the same way as bleach. Recently, a manufacturer of a hydrogen dioxide product has sought EPA registration as a broad spectrum bactericide/fungicide for use as a non-porous surface sanitizer and as a pre-plant dip treatment or foliar spray for certain crops. Notably however, the product is <u>not</u> recommended for application to apple or pear trees for control of fire blight. The inability of surface sanitizers to control pathogens on a delicate plant tissues such as flower blooms without causing phytoxicity, the potential product liability resulting from such conditions, the projected costs to register such products for a new outdoor use with associated residue tolerance requirements (including dietary risk assessments), the limited use such a product would receive compared to other products currently registered, all argue strongly against the likelihood of an EPA-registered label for these agents as a field treatment for fire blight control in apple and pears.

The Oxytetracycline TRED also listed potential viable pesticide alternatives for tetracycline for fire blight control as copper, prohexadione (Prohexadione®), BlightBan® (a.i. *Pseudomonas fluorescens* strain A506), and Fosetyl-AL (Aliette®), as well as streptomycin. Except for *Pseudomonas fluorescens* and streptomycin, none of these materials are acceptable for organic production. Given that oxytetracycline is used where streptomycin resistance is established and given that *Pseudomonas fluorescens* is not considered consistently efficacious (described above), it is evident that if oxytetracycline is not available under these conditions, then there are <u>no viable alternatives</u> for the reliable control of fire blight on apples and pears, organic or non-organic.

Category 2, Question 7. Is there another practice that would make the substance unnecessary?

Crops Committee Comment/Documentation: TRI 297-302, 335-343 / Aldwinckle et al, 1998. Fire Blight: the search for better control. IDFTA Compact Fruit Tree, Vol 31, No. 4 / "Fireblight Management in the Pacific Northwest USA"
http://www.ncw.wsu.edu/treefruit/fireblight/principles.htm

WSHA Rebuttal: The Crops Committee comment perhaps is referring to non-chemical practices that can be used to either control or alleviate the effects of fire blight on organic apple and pear orchards. Such practices would typically involve either plant husbandry and/or a combination of sanitation methods to reduce *Erwinia amylovora* populations. The Oxytetracycline TRED lists pruning and the planting of resistant cultivars as ways to reduce the potential for fire blight.

Pruning is a general plant sanitation process employed by virtually all growers, both organic and non-organic. Pruning of fire blight infected branches and tree limbs is done to reduce the source of inoculum for the next year. In some cases, but not all, pruning infected limbs can reduce the tree mortality from fire blight. However, pruning is done after the fire blight disease has taken hold in the orchard and therefore reduces the source of inoculum for the next growing cycle. Consequently, pruning has no effect on stopping fire blight once it has started or in preventing the disease from becoming established and spreading unless by pruning all sources of fire blight inoculum are completely eliminated from the orchard.

The Oxytetracycline TRED suggests planting fire blight resistant cultivars, stating: *"Resistant cultivars: Red Delicious variety of apple has some resistance against the fire blight disease."* However, the TRED also notes that *"All other commercially grown varieties are susceptible"* to this plant pathogen. This includes newer cultivars such as 'Jazz', 'Honey Crisp', 'Gala', 'Pink Lady', 'Fuji', 'Braeburn', 'Granny Smith' and others. Since these relatively new cultivars have developed popularity with consumers, apple growers – both organic and conventional – have tended to plant them in increasing numbers over the past two decades. However, these newer cultivars are all susceptible (some extremely so) to fire blight; therefore the success of their continued production by organic growers will hinge in no small measure on the availability of oxytetracycline.

It is also important to note that most commercial pear varieties are highly susceptible to fire blight. Without the ability to use oxytetracycline to combat fire blight, production of organic pears in the U.S. will, in all likelihood, come to a halt. Given the limited options of viable alternatives available to organic apple and pear growers and the high degree of risk of tree and crop loss associated with fire blight, growers of organic apples and/or pears must rely on oxytetracycline for fire blight control and pruning to remove infected branches (assuming streptomycin resistant *Erwinia amylovora* is present).

Summary and Conclusions

The WSHA disagrees and rebuts the Crops Committee review of its petition to the NOSB for the removal of the expiration date of tetracycline and the re-establishment of its sunset date effective October 21, 2012. In its review of the WSHA petition, the Crops Committee used its

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST as a template for its report to the NOSB. In so doing, the Crops Committee failed to acknowledge that tetracycline has been an exempt substance on the National List since 2000. This begs the question: if the use of tetracycline for the control of fire blight in apples and pears poses such a threat to the organic segment of agricultural production, then why has it been an exempt material on the USDA-NOP National List for over ten years?

The Crops Committee's recommendation to the NOSB that the WSHA petition be rejected cited as justification certain studies and general concerns about the presence of tetracycline in the environment. However, the studies cited do not specifically indict the use of (oxy)tetracycline when applied in organic apple and pear orchards to control fire blight under current EPA-approved label conditions. Nor is it apparent the Crops Committee report to the NOSB gave any consideration to the specific points raised in the WSHA petition, namely 1) that the removal of tetracycline from the National List will likely lead to a reduction in organic apple and pear acres in the U.S.; 2) that there are no viable biological alternatives for the control of fire blight on apples and pears having comparable abilities to control fire blight as oxytetracycline, and 3) that there is no widespread support for the removal of tetracycline from the National List current among either organic growers of apples and pears or from the many university scientists and extension agents currently involved with research on fire blight (several of whom have written in support of the WSHA petition and plan to testify at the NOSB meeting in Seattle for the retention of tetracycline on the National List).

Based on the rebuttal arguments put forward herein, the WSHA strongly urges the NOSB to vote to reject the Crops Committee report on tetracycline and instead take action to remove the expiration date and re-instate a sunset date for tetracycline of October 21, 2017.

We look forward to working with the NOSB as it reviews our comments and would gladly provide clarification of any concerns.

Sincerely,

Bruce Grim
Executive Director
Washington State Horticultural Association

cc: Miles McEvoy, Deputy Administrator, NOP
NHC Science Advisory Committee