

October 21, 2010



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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, is the petitioner requesting the removal of the expiration date from the authorized use of oxytetracycline for the control of fire blight in apples and pears.

For the last 106 years WSHA has represented Washington state deciduous tree fruit growers and shippers concerning state legislative and regulatory issues and has focused on education of its members about emerging technologies affecting the tree fruit industry. We have considerable concern for the proposed expiration of tetracycline.

Although this petition has originated in the Pacific Northwest, the loss of tetracycline to control fire blight in apples and pears will have broad negative implications throughout the national organic tree fruit industry as indicated by those growers, grower groups and scientists who have voiced their concern and support for this petition during the busiest season (harvest) for this industry. 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).<sup>i</sup>

We urgently request that the National Organic Standards Board examine how the decision to expire tetracycline, without a viable alternative available, will adversely affect so many organic growers and acres of pome fruit and rescind its decision to expire tetracycline, currently the only product that can control fire blight consistently.

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

Sincerely,

A handwritten signature in black ink that reads "Bruce Grim". The signature is written in a cursive, flowing style.

Bruce Grim  
Executive Director  
Washington State Horticultural Association

<sup>i</sup> 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**

**Petitioner:** 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., August 16, 2006. See attachment.

**Item B-12. “Petition Justification Statement”**

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

*“... we note the NOSB’s recommendation to only allow the continued use of tetracycline for fire blight control until October 21, 2012. 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 from the authorized use tetracycline for control of fire blight in apples and pears.

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### **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.<sup>1</sup> 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 preempts a second sunset review and instead removes 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 is no longer permitted in accordance with NOP rules after October 21, 2012.

The removal of tetracycline as an exempted substance from the National List via expiration on October 21, 2012 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 Washington State, Oregon and Idaho (the Pacific Northwest or “PNW”). Tetracycline is the only substance with a proven and reliable record of fire blight control in regions where alternative control measures have lost effectiveness and/or where biological options to tetracycline have yet to attain a comparable level of disease control.

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<sup>1</sup>See at:[http://farmlandinfo.org/documents/38361/Federal\\_Organic\\_Food\\_Production\\_Act.pdf](http://farmlandinfo.org/documents/38361/Federal_Organic_Food_Production_Act.pdf)

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Petitioner contends the expiration of tetracycline from the National List on October 21, 2012:

1. will likely result in a significant net decrease 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 unwarranted and unwise since biological alternatives to tetracycline currently available to growers of organic apples and pears are unreliable and/or ineffective under severe fire blight disease pressure and;
3. 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 a major segment of university and state extension researchers professionally involved with fire blight field studies and the exploration of alternatives to tetracycline 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, petitioner seeks removal of the expiration date and re-instatement of the sunset date of October 21, 2012 for tetracycline under §205.601(i)(11) of the National List.

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

Petitioner submits three points to support removal of the expiration date for tetracycline and re-instatement of its sunset date (October 21, 2012) under §205.601(i)(11).

#### Point Number One:

**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 PNW. 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 – 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%<sup>2</sup>. 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 should an epidemic of fire blight occur, they 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 a survey of approximately 50 organic apple/pear growers conducted in early 2010 by Washington State University, Sustainable Agriculture Specialist David Granatstein<sup>3</sup>. 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:

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<sup>2</sup> 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.

<sup>3</sup> Summarized from 2010 survey 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.

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

- 13% stated the loss would reduce their organic pear acreage
- 35% stated it would reduce their acres of susceptible apple varieties,
- 28% stated they would exit organic apple and/or pear production altogether

In other words, fully 76% of organic apple and pear growers surveyed indicated that without the ability to control fire blight using tetracycline<sup>4</sup>, they would either reduce or eliminate completely their organic apple and/or pear production.

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”.

If more than four-fifths 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 survey 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 is transferred overseas<sup>5</sup> – presumably to locations where fire blight has not yet been identified. Yet with fire blight now present in 43 countries<sup>6</sup>, organic apple and pear growers deprived of at least having the option to use tetracycline are forced to play “Russian Roulette” with their crop because 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 State and Oregon

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<sup>4</sup> 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.

<sup>5</sup> Personal communication, David Granatstein, 2010.

<sup>6</sup> Fire Blight, *Erwinia amylovora*, by Virginia Barlow, May 7<sup>th</sup>, 2009, Northern Woodlands, see at: [http://northernwoodlands.org/articles/article/fire\\_blight\\_erwinia\\_amylovora/](http://northernwoodlands.org/articles/article/fire_blight_erwinia_amylovora/)

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caused an estimated \$68 million loss; in 2000 a fire blight epidemic in Michigan killed over a quarter million trees generating a \$42 million loss to growers.



*Michigan apple orchard (var. 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).<sup>7</sup>

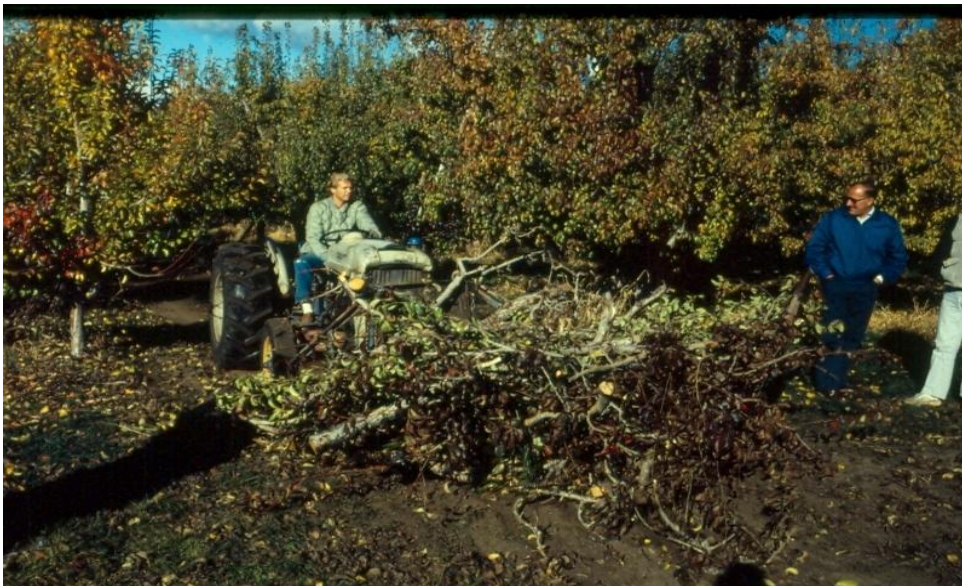
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<sup>7</sup>Fire blight of apple and pear, on-line review article by Ken Johnson, Oregon State University. See at: <http://www.apsnet.org/edcenter/intropp/lessons/prokaryotes/Pages/FireBlight.aspx>

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*Portion of 200-acre apple orchard (var. Pink Lady) in Washington State devastated 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*



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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."<sup>8</sup> Germany, Austria and Switzerland have recognized the impracticality of these approaches and, along with recognition of the lack of effective products to control fire blight, have allowed the use of antibiotics when a severe outbreak of fire blight is present. France and Greece have registered a quinolone-based antibiotic (Firestop) for fire blight control – recognizing that allowing growers of the decision to use antibiotics for the control fire blight is the best option currently available.

In short, the European "model" provides clear evidence that production of organic apples and pears cannot be maintained indefinitely (let alone expanded) without the judicious use of antibiotics<sup>9</sup>. 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.

### Point One 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 but suitable host plants, e.g., apple and pear trees, and environmental conditions favoring the pathogen's growth – mean temperatures above 60F 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

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<sup>8</sup>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>

<sup>9</sup>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.

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severe fire blight pressure, consistently reliable alternatives to tetracycline for fire blight control are not yet available.

### Point Number Two

**Current biological alternatives for controlling fire blight in apples and pears do not provide an acceptable level of control under severe fire blight pressure to give growers of organic apples and pears enough confidence to maintain current levels of organic production without tetracycline.**

A number of agents, including (i) SAR (specific acquired resistance) inducing agents, Actigard<sup>®</sup> (acibenzolar-s-methyl), and Messenger<sup>®</sup> (harpin protein), (ii) antagonistic microbial agents (based on a microbial displacement strategy), such as BlightBan<sup>®</sup> A-506 (*Pseudomonas fluorescens* A506) and BlightBan<sup>®</sup> C9-1 (*Pantoea agglomerans*), (iii) bio-control secondary metabolites such as Serenade<sup>®</sup> (*Bacillus subtilis* strain QST 713) and (iv) phosphite materials, e.g., Phostrol<sup>®</sup>, K-Phite) have all been shown to provide inconsistent control when tested against fire blight.

Copper (examples: Champ<sup>®</sup> WG [copper hydroxide], and Kocide<sup>®</sup> [copper hydroxide]) will also provide good control of fire blight, but is not a replacement for tetracycline and can only be used early in the growing season to suppress overwintering canker expression – meaning it cannot be safely used past the “green tip” stage. If copper products are used during the bloom stage, they can result in phytotoxicity to the tree resulting in moderate to severe fruit russetting.

### Review of control recommendations (references attached)

A review of the university literature and Cooperative Extension recommendations finds the following regarding the use of tetracycline. In the situations where streptomycin resistance is a problem, the findings demonstrate how essential tetracycline is to apple and pear production and how compatible it is in an integrated pest control program. It is also important to note here that the critical time for fire blight control with tetracycline is during bloom.

Aldwinckle et al. (2001) of Department of Plant Pathology of Cornell University reported that the SAR product Messenger<sup>®</sup> does not provide disease control while Serenade<sup>®</sup> WP resulted in about 60% control. Cuprofix<sup>®</sup> (copper) provided excellent control but also resulted in heavy fruit russetting.

The Oregon State University (OSU) Extension Service (J.W. Pscheidt, 2009) reviewed alternatives for fire blight control on pears and reported the following. OSU found that tetracycline is an important tool in combating fire blight in Oregon due to the high incidence of

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pathogen streptomycin resistance. For BlightBan<sup>®</sup> A506 (*Pseudomonas fluorescens*), OSU reported, “This product alone will not control fire blight and must be integrated into a regular antibiotic schedule. BlightBan<sup>®</sup> A506 reduces strikes by only by 40 to 50% but may be useful anytime antibiotics are applied within 48 hours of an infection period.” Regarding Bloomtime Biological FD (*Pantoea agglomerans*, strain E325), OSU reports, “This product alone will not control fire blight and must be integrated into a regular antibiotic schedule.” And for Serenade<sup>®</sup> MAX (*Bacillus subtilis* Strain QST 713), OSU reported, “It does not work if used like biologicals early in the bloom season.”

Timothy Smith of Washington State University (WSU) in April, 2001 reported that biological control agents provide only partial reduction of fire blight infections of from 50 to 80% in field tests and that the more effective and agronomically viable degree of control occurred only when bactericides were used. Smith’s work showed no evidence of tetracycline resistance while its field efficacy was rated at 85-95%. Several SAR products were also tested and the control of these products varied from 0 to 20%. Smith also noted that streptomycin sulfate is no longer effective in most of the PNW. His findings demonstrate the need to maintain tetracycline as a viable option for organic orchard disease maintenance.

Cooley et al. (2009) of the University of Massachusetts Extension service reported on fire blight on apples. Cooley found that Serenade<sup>®</sup> (*Bacillus subtilis*) performance was erratic in the field when it was the only material applied. Cooley also noted that phosphite materials have shown some reduction of the disease when compared to treated controls but that this reduction was not on the same level as a an antibiotic such as tetracycline.

Paul Steiner of the University of Maryland presented a report in 1998 on fire blight on apples. Steiner reported on copper materials and that these materials can be used up to “green tip” and pointed out that applications made after the half-inch green stage can produce unacceptable levels of fruit and foliar damage. He reported that the bacterial antagonists *Pseudomonas fluorescens*, Pf-A506 (BlightBan<sup>®</sup>) and C9-1 showed good activity in protecting against fire blight. However, he also stated that these antagonists did not provide the level of nor the dependability of disease control as found with an antibiotic such as tetracycline.

Lindlow et al. (1996) tested the interaction of bactericides on *Pseudomonas fluorescens* strain A506 in the control of fire blight to pear in California in a long term study. They found that combinational use of A506 and streptomycin sulfate or tetracycline acted additively in controlling the disease and reported that “while the incidence of fire blight infection was reduced by strain A506 by about 50% when applied alone, combination treatments including single applications of strain A506 and weekly applications of either streptomycin or tetracycline

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reduced disease incidence by about 70% compared with that on untreated trees.” These results clearly indicate that a viable treatment option for organic orchard growers would be early applications of A506 as a preventative followed by tetracycline at or near bloom time on orchards experiencing streptomycin resistance.

Stockwell et al. (2008) evaluated the integrated control of fire blight by using microbial antagonists and tetracycline in Oregon on pears and apples. The group evaluated A506 (*Pseudomonas fluorescens*) and C9-1 (*Pantoea agglomerans*) along with tetracycline on Bartlett pears and Golden Delicious and Rome Beauty apples over a three year period using small test orchards. These microbial antagonists were applied prior to a bloom application of tetracycline in order to allow the microbes the opportunity to out-compete with the fire blight pathogen, *Erwinia amylovora*. This sequential application method improved the performance of tetracycline from 42 to 57% as compared to the control. They concluded, “we evaluated Mycoshield<sup>®</sup> [equivalent product: FireLine<sup>™</sup>, also known as FlameOut<sup>™</sup> (oxytetracycline)], which is a moderately effective antibiotic for fire blight management, as the chemical component of the integrated control strategy. The improved control with biocontrols over sprayed with Mycoshield<sup>®</sup> is likely due to several factors. Generally, we found that treatment of flowers with biological control agents and Mycoshield<sup>®</sup> did not kill the fire blight pathogen, but this two-pronged approach hampered the growth or establishment of the pathogen on flowers. We speculate that the reduction in growth rate or establishment of the pathogen may allow flowers to progress through their natural development stages from highly susceptible to less susceptible to infection before the pathogen attains high population sizes.”

Peracetic acid (PAA, also known as peroxyacetic acid, a mixture of acetic acid and hydrogen peroxide) has been suggested as an organic control treatment against fire blight in apples and pears. PAA is commonly used in food processing facilities, hospitals, restaurants, etc. as a sanitizing agent (biocide) because it is a strong oxidizer capable of killing bacteria on inert (non-biological) surfaces such as stainless steel and concrete. Although PAA has been registered as an antimicrobial pesticide by the Environmental Protection Agency (EPA) since 1985, its registration is for indoor use only on hard, non-porous surfaces.<sup>10</sup> Nevertheless, the reasoning by some seems to be that if PAA kills bacteria in a food processing facility, it should be able to kill the bacteria responsible for causing fire blight in an apple or pear orchard.

In an email dated May 3<sup>rd</sup>, 2010, the Northwest Horticultural Council, a trade association representing tree fruit producers in Idaho, Oregon and Washington, asked Dr. Ken Johnson,

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<sup>10</sup> Pesticides: Topical & Chemical Fact Sheets, Anthrax spore decontamination using hydrogen peroxide and peroxyacetic acid, Environmental Protection Agency, July 2007. See at: [http://www.epa.gov/pesticides/factsheets/chemicals/hydrogenperoxide\\_peroxyaceticacid\\_factsheet.htm](http://www.epa.gov/pesticides/factsheets/chemicals/hydrogenperoxide_peroxyaceticacid_factsheet.htm)

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Professor, Department of Botany and Plant Pathology at Oregon State University and Tim Smith, Washington State University extension agent to comment on the possibility of using PAA as a treatment for fire blight. Johnson and Smith are two widely-respected tree fruit researchers and extension workers in the Pacific Northwest with a combined professional experience in fire blight field studies exceeding 40 years. Their comments are reproduced below verbatim.

Ken Johnson: *“... there's a general interest in these products for plant disease control, but demonstrated efficacy by the scientific community is virtually nil. The various oxidizing sanitizers do a good job on concrete surfaces (e.g., potato storage), equipment, and perhaps as a treatment for irrigation water, but their punch dissipates nearly instantly on an organic surface (no residual). Epiphytic Erwinia amylovora associate intimately on surfaces of pear and apple flowers (more so than non-pathogens), and thus are not sufficiently exposed to fast acting oxidizers. A peracetic acid application might hit a few cells of E.a., but it would be only be a relatively small proportion of what's there. If conditions were right, these would be quickly replaced (a few hours).”*

Tim Smith: *“I'm not aware that this product has been tested and shown to be effective for the control of fire blight. In all my years of attending the ISHS World Workshop on Fire Blight (since 1986), I have no recollection of any reputable scientist claiming efficacy for this substance, though similar products may have been tested and found ineffective. In general, those products that are otherwise good bacterial sanitizers (such as hydrogen peroxide, sodium hypochlorite and quaternary ammonias) are effective on inert substrates such as kitchen countertops, but are rapidly tied up by the organic matter on trees.”*

Although the EPA has registered PAA as a pesticide, it has done so for use only as a disinfectant and sanitizer on hard non-porous (non-biological) surfaces; PAA is not currently labeled for use on apples and/or pears for the control of fire blight. Petitioner knows of no PAA registrant pursuing a label for use of this substance on apples and/or pears to control fire blight.

### Point Two Summary

Literature, university extension service publications, and method development findings demonstrate the following: (i) Tetracycline is the only consistently viable solution left for effective disease control where streptomycin resistance is present; in geographical areas that do not currently experience streptomycin resistance, a rotational use of these two important bactericides should be considered as a means to avoid resistance development; (ii) Registered copper products, if used just prior to or during the bloom stage, can result in significant losses from either blossom phytotoxicity or severe fruit russetting; (iii) Phosphite materials will not

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effectively control fire blight; (iv) SAR materials, such as Actiguard and Messenger<sup>®</sup>, are also not effective in controlling fire blight; (v) Antagonist bacterial products using *Erwinia herbicola*, *Pantoea agglomerans* (C9-1), *Pseudomonas fluorescens* A506 (Blight Ban), and bio-control agents such as *Bacillus subtilis* (Serenade<sup>®</sup>) are not effective when used alone or in combination with one another and, at times, the control has been referred to as erratic. This periodic lack of control may be due to the fact that in order to be successful, these microorganisms must be established on the plants' surfaces and in the flowers in order to out compete (via population displacement) or control (via secondary metabolites) the pathogen (*Erwinia amylovora*); if the pathogen is not completely displaced or controlled by the antagonist bacteria, then the flowers will be infected; (vi) Tetracycline is known to provide excellent control of fire blight and there are cases in which that control can be improved by the use of microbial antagonists when the antagonists are used first as preventatives followed by tetracycline prior to and during flowering (vii) Research has shown (Stockwell *et al*, 2008) that a two-pronged approach of using microbial antagonists prior to using tetracycline will hinder either the growth rate and/or the establishment of *Erwinia amylovora* in the apple and pear flowers, thus reducing or eliminating fruit loss; (viii) The antagonist microorganisms, *Pantoea agglomerans* (C9-1) (*Erwinia herbicola*), *Pseudomonas fluorescens*, and *Bacillus subtilis* are capable of producing a number of antibiotics that are similar and/or dissimilar to tetracycline and (ix) use of peracetic acid (PAA) as an alternatives to tetracycline is not a viable option because, among other factors, biocidal mode of action cannot be successfully adapted to work in a biological environment such as an apple or pear orchard.

### Point Number Three

**Removal of the Sunset Date for tetracycline and its replacement with an expiration date does not have widespread support among those groups most directly affected by this action, namely –**

- **growers, packers and shippers of both organic and conventional apples and/or pears,**
- **various university and state extension scientists involved with fire blight field studies and the exploration of alternatives to tetracycline 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.**

Petitioner canvassed representatives from among the apple and pear growing industry and asked the following question –

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*“How will the loss of tetracycline in 2012 affect your commitments to organic 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.

### “Small” organic apple/pear growers (1 – 100 acres)

- **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™, aka FlameOut™ (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.”*

### “Medium” organic apple/pear growers (101 – 250 acres)

- **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.”*

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**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

**Certified Organic Acres**

*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, also Board Director, Washington State Department of Agriculture Organic Advisory Board

**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, 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 ineffective 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.”*



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**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.”*

Petitioner 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](mailto:johnsonk@science.oregonstate.edu)  
**Affiliation:** Oregon State University, Corvallis, Oregon  
**Position:** Professor  
**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](mailto: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*

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*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](mailto: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.”*

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**Name:** Jim. E. Adaskaveg, Ph.D.

**Contact Information:** 951-288-9312, [jim.adaskaveg@ucr.edu](mailto: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](mailto: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 are 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](mailto: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](mailto:dang@gslong.com)

**Affiliation:** G.S. Long Company, Union Gap, Washington

**Position:** Crop Advisor

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**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.”*

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 received a copy of 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 public institution 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, aka FlameOut™
Nufarm Americas, Inc. USA	Mycoshield®

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### Point Three Summary

A representative group of grower/packer/shippers of organically grown apples and/or pears were asked to supply a written statement for inclusion in this petition regarding the impending removal of tetracycline from the National List via expiration. In addition, written comment in this matter was also requested from a wide range of individuals within the scientific community involved with fire blight research. Based on comments received by the petitioner in this matter, a broad segment of pome fruit growers see 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 view 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 indicate agreement with action taken by the NOSB to remove tetracycline from the National List. 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. In short, the removal of tetracycline from the National List via expiration is not supported by a large segment of those directly involved with the production of organic apples and pears nor is it supported by broad range of researchers actively investigating biological alternatives to tetracycline neither is it supported by a wide range of commissions, boards and grower organizations representing thousands of apple and pear growers across the U.S.

### Petition Summary and Conclusions

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

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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 circumvents the OFPA-mandated sunset review process for tetracycline and removes it from the National List as *fait accompli*. Consequently, 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, 2012.

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 a net reduction 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 converted back to conventionally managed orchards.

By the rule change adopted on July 6, 2010 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. Petitioner requests an amendment to remove the expiration date and re-instatement of the sunset date of October 21, 2012 for tetracycline under §205.601(i)(11) of the National List. A re-instatement 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. Should the expiration date for tetracycline be allowed to stand, dramatic reductions in organic apple and pear acreages will undoubtedly lead to a reduction in research priority levels for biological alternatives to tetracycline. Therefore, maintaining tetracycline on

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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.

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

1. Reference Articles
2. NOP Tetracycline (Oxytetracycline Hydrochloride Complex) Petition, AgroSource, Inc., August 16, 2006. Redacted CBI version.
3. AgroSource Fireline™ Label and MSDS
4. NuFarm Mycoshield® Labels and MSDS
5. Letter of Support- California Apple Commission




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