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September 10, 2012

National Organic Standards Board
Fall 2012 Meeting
Providence, RI

Re. Antibiotics (Streptomycin and Tetracycline) on Apples and Pears (Crops)

Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

In April of 2011, the NOSB voted to put an expiration date of October 21, 2014 on the §205.601 listings allowing tetracycline and streptomycin to be used to control fire blight on apples and pears. This should have put an end to a long history of the NOSB's reluctant affirmation of the listings of these two antibiotics. As we stated in our comments to the NOP publication of the proposed rule placing the October 2014 expiration date on the tetracycline listing, "We oppose any further extension of the expiration date."

A Brief History

There was a Technical Advisory Panel (TAP) review from 1995 for antibiotics, Technical Reviews (TRs) in 2006 and, more recently, in March 2011 for both streptomycin and tetracycline.

The antibiotic streptomycin was first approved in November 1995. Streptomycin and another antibiotic, tetracycline, were each listed with a split vote. The issue of engendering antibiotic resistance in human pathogens and in workers was raised in the 1995 TAP review. The annotation that permitted use for "fire blight control in apples and pears only" was adopted. Streptomycin antibiotics were to be reviewed again in two years, and there was to be a task force to further explore antibiotic use in fruit production.

The 1998 proposed rule would have allowed "antibiotics as pesticides." There was public opposition to the use of antibiotics as pesticides. When USDA published the next draft rule in early 2000, it removed the NOSB recommendations allowing streptomycin and tetracycline in order to be consistent with the prohibition of antibiotics in livestock. The two antibiotics were reinstated in the December 2000 final rule in response to comments from growers.

Thus, from the very beginning, there has been controversy over allowing these chemicals to be used in organic agriculture. The board discussion regarding the 2006 sunset included concerns about:

- Promotion of resistance in human pathogens
- Natural substitutes
- Inconsistency with the prohibition of antibiotics in livestock
- Inconsistency with organic principles
- Disagreement with the prophylactic use of antibiotics
- The Centers for Disease Control and Prevention (CDC) opposition to the use of streptomycin and tetracycline in crop production
- Failing to give an incentive for alternatives
- Reaction against organic fruit by consumers
- Possibility that antibiotics might be taken up by fruit trees
- Need for more research
- Restrictions on sales of fruit in Europe
- Disruption of the organic system.

And on the other hand,

- Lack of data showing impact on resistance in human pathogens
- Dependency of growers on the materials.[1]

After expressing concern and the hope that a petition might be submitted to remove streptomycin and tetracycline from the National List sooner than the next sunset, the NOSB voted 7 yes, 4 no, 1 abstention, and 2 absent to renew both antibiotics --which, we must note, was not a decisive vote, as required by law to renew a National List material.

At its November 2008 meeting, the Board considered a petition to add a second form of tetracycline —oxytetracycline hydrochloride, by removing the tetracycline annotation that limited its use to the "oxytetracycline calcium complex." This would have reset the clock on the tetracycline sunset. The Board voted down the proposal with a vote of 1 yes, 13 no, and 1 absent. However, after that vote, a motion to reconsider resulted in hydrochloride being added ("to level the playing field"), as well as an annotation that turned the sunset date into an expiration date —October 21, 2012— which would prevent any additional extensions of the sunset period.

In April 2011, the NOSB considered the 2012 sunset of streptomycin and a petition to relist tetracycline. The Crops Committee recommended on a vote of 5-0 with two absent to let streptomycin sunset and to maintain the 2012 expiration date for tetracycline.

[1] The above portion of the history is taken from the Crops Committee recommendation on streptomycin dated March 3, 2011.

Based on the testimony of growers and researchers that more time was needed to implement alternative practices, the Board voted 13-1 to relist both antibiotics with an expiration date of October 21, 2014. The recommendations stated,

> The Board expects that members of the industry will collaborate and coordinate efforts in preparing for the eventual removal of this material from the National List, specifically optimizing the use of resistant rootstocks and cultivars, preventive management methods, and the use of alternative, allowed biological and chemical controls whenever warranted.

The streptomycin recommendation also stated,

> Based on the recommendation of the Crops Committee and testimony submitted to the Board, the Board recommends delisting streptomycin as soon as is reasonable. Testimony indicated that some time is needed for the transition. The Board also asks that the National Organic Program supports the transition to managing fire blight without antibiotics to the extent possible.

Antibiotics Must Not Be Used in Organic Production

In view of the petition that has been received to remove the expiration date for tetracycline, and, we assume, another for streptomycin will be received by the NOSB, we think it is important to take this opportunity to reinforce our opposition, as organic consumers and advocates for environmental protection and public health, to any attempt to extend the use of these two antibiotics in organic agriculture. Use of antibiotics for fire blight fails the three criteria for materials used in organic production—environmental and health impacts, compatibility with organic principles, and essentiality.

1. **The hazards of using antibiotics in agriculture are too great because the use of antibiotics in agriculture —in both animal and plant production— increases the spread of antibiotic resistance in human pathogens. There are other hazards associated with the use of antibiotics in fruit production, and these have been documented in technical reviews, but given the importance of the antibiotics resistance issue in medicine, all others pale in comparison.**

Although there is evidence that antibiotics are taken up by fruit trees and expressed in the fruit tissues,[2] that fact is not essential to the spread of antibiotic resistance in human pathogens. Although it has been shown that workers exposed to antibiotics on the farm carry antibiotic-resistant bacteria in their gut,[3] that fact is also not essential to the spread of antibiotic resistance in

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[2] G. Mayerhofer, I. Schwaiger-Nemirova, T. Kuhn, L. Girsch, and F. Allerberger, 2009. Detecting streptomycin in apples from orchards treated for fire blight. Journal of Antimicrobial Chemotherapy. Advance Access publication 24 February 2009: 1076-1077. "Our results clearly show that the use of streptomycin as a pesticide can lead to detectable concentrations of streptomycin in apples. Subsequent studies comparing fruit flesh, core and skin revealed concentrations in the apple core two to three times higher than those in the flesh and concentrations in the skin three to four times higher than those in the flesh."

[3] S.B. Levy, G.B. FitzGerald, and A.B. Macone, 1976. Changes in Intestinal Flora of Farm Personnel after Introduction of a Tetracycline-Supplemented Feed on a Farm, N Engl J Med 1976; 295:583-588.

human pathogens. The crucial fact is that the use of antibiotics *anywhere* increases the frequency of antibiotic-resistant bacteria *everywhere* through well-known mechanisms of horizontal gene transfer in bacteria.[4] This is not controversial and has been explained to the NOSB several times.[5] It is a fact well-known to all microbiologists and has been crucial to the development of strategies to reduce antibiotic resistance in bacteria that produce human disease.[6]

The World Health Organization (WHO) considers tetracyclines, including oxytetracycline, and streptomycin to be "critically important antibacterials."[7] WHO's criteria for these categories are:

1. Sole therapy or one of few alternatives to treat serious human disease;
2. Antibacterial used to treat diseases caused by organisms that may be transmitted via non-human sources or diseases causes by organisms that may acquire resistance genes from non-human sources.

Critically important antimicrobials are those which meet criteria 1 and 2. *Highly important* antimicrobials are those which meet criteria 1 or 2. *Important* antimicrobials are those which meet neither criteria 1 nor 2. Streptomycin and tetracycline both meet both criteria. The WHO recommends that the list of critically important antibacterials be used to help formulate strategies "for containing antimicrobial resistance due to non-human antimicrobial use."

As stated by WHO in another document,[8] "Any kind of antibiotic use in people, animals or plants can promote the development and spread of antibiotic resistance." And later, "Antibiotic resistance is a global human and animal health concern that is influenced by both human and non-human antibiotic usage. The human, animal and plant sectors therefore have a shared responsibility

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[4] T.F. O'Brien, 2002. Emergence, Spread, and Environmental Effect of Antimicrobial Resistance: How Use of an Antimicrobial Anywhere Can Increase Resistance to Any Antimicrobial Anywhere Else, Clin Infect Dis. 34 Suppl 3:S78-84 K.M. Shea, 2003. Antibiotic Resistance: What is the Impact of Agricultural Uses of Antibiotics on Children's Health? Pediatrics 112: 253-258. http://pediatrics.aappublications.org/content/112/Supplement_1/253.full.html

[5] One time was in the 2008 testimony of former NOSB member Rebecca Goldburg, writing on behalf of Keep Antibiotics Working. She said, "A first concern is that the use of antibiotics on fruit trees likely makes at least a small contribution to the growing crisis of antibiotic resistance in human medicine. Modern molecular tools for tracking the movement of genes make clear that antibiotic resistance is an ecological and not just a medical problem. The use of antibiotics selects for resistant bacteria, whether in orchards or hospitals. Even if these resistant bacteria are not human pathogens, gene transfer mechanisms special to bacteria allow these microbes to spread their resistance genes to other, unrelated bacteria, including pathogens. Although the odds are very low that resistance genes from any particular orchard bacterium will end up in bacteria harmful to humans, such highly unlikely individual events become probable given the vast numbers of bacteria present in soil, water, and living organisms. In short, the use of antibiotics in orchards increases the load of antibiotic resistance genes in the environment, and thus likely contributes at least modestly to medical problems from resistant bacteria."

[6] American Academy of Microbiology, 2009. Antibiotic Resistance: An Ecological Perspective on an Old Problem. http://academy.asm.org/images/stories/documents/antibioticresistance.pdf "Horizontal gene transfer—the movement of genetic material from one organism to another—is the primary mechanism by which bacteria acquire antibiotic resistance."

[7] World Health Organization, 2009. Critically important antibacterial agents for human medicine for risk management strategies of non-human use, 2nd Revision. http://www.who.int/foodsafety/foodborne_disease/CIA_2nd_rev_2009.pdf

[8] WHO, 2011. Tackling antibiotic resistance from a food safety perspective in Europe. Pages xv, 54. http://www.euro.who.int/__data/assets/pdf_file/0005/136454/e94889.pdf

to prevent or minimize antibiotic resistance selection pressures on both human and nonhuman pathogens."

2. The use of antibiotics in organic production is incompatible with organic principles.[9]

Rather than relying on practices central to organic production —such as the choice of resistant cultivars and rootstocks— the antibiotic-dependent system relies on synthetic off-farm inputs. The use of antibiotics to control fire blight is not sustainable and does not promote the long-term viability of organic farm operations because resistance to antibiotics will ultimately develop. The use of antibiotics in organic fruit production is inconsistent with the prohibition against antibiotics in organic livestock production. It is inconsistent with organic standards in the European Union and Canada. The use of antibiotics in organic fruit production does not satisfy consumer expectations regarding the authenticity and integrity of organic products.

3. The use of antibiotics in organic fruit production is not essential.

As of March 10, 2011, there were 96 businesses certified as EU-compliant organic producers of apples and/or pears in the state of Washington alone, representing about one third of the state's organic apple and one fourth of the state's organic pear production.[10] EU-compliant organic apple and pear growers cannot use antibiotics. Instead, these growers rely on a number of other practices, allowing them to avoid fire blight damage to susceptible varieties:

- Balancing nutrients and avoiding over-application of nitrogen fertilizers, especially on susceptible varieties of apples or pears;
- Avoidance of over-pruning in the dormant season;
- Use of pre-bloom foliar nutrient sprays even though there is no foliage;
- Use of copper materials on the trees between delayed dormant and tight cluster sages as preventative measures against overwintering FB.
- Use of lime sulfur during bloom to thin apples.
- Use of Serenade MAX (in the future, perhaps Blossom Protect) post-bloom and at petal-fall, with good spray coverage.

With some differences for pears:

- For the Bosc, use of low levels of copper only sprayed foliar during bloom and infection periods.
- For pear varieties Bartlett and Anjou which are subject to skin russeting, use of antagonistic bacterial products during bloom, followed by Serenade MAX or Blossom Protect at petal-fall;
- Copper and Lime Sulfur with oil.

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[9] See NOSB, 2008. "Principles of Organic Production and Handling," adopted by the NOSB October 17, 2001, and NOSB Guidance Document on Compatibility with a System of Sustainable Agriculture and "Consistency with Organic Farming and Handling," adopted by the NOSB October 24, 2003, revised April 29, 2004.

[10] Washington State Department of Agriculture printout, "International Organic Program—EU Compliant Operations, March 10, 2011.

In addition, growers could take heed of Steiner's observations of how changes in the orchard environment have contributed to epidemics of fire blight.[11] If they did so, they might:

- Increase species diversity;
- Decrease tree density;
- Use resistant cultivars and rootstocks;
- Plant a variety of cultivars on a variety of rootstocks.

In conclusion, we ask that you take seriously the urgency of the problem of antibiotic resistance in bacteria that cause human disease. We ask you to remember the criteria that you are to apply in considering whether a synthetic material may be allowed in organic production. One of those criteria is "the effect of the substance on human health." That criterion does not ask you to weigh the impact of the material's limited use in organic production against widespread use in nonorganic agriculture –for such impacts are always less,it asks you to evaluate whether the material adds in any way to the many threats to human health and to ensure that organic agriculture does not add to those threats.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors

[11] Paul W. Steiner, 2000. A Philosophy For Effective Fire Blight Management, Presented at the State Horticultural Association of Pennsylvania Annual Meeting, January 2000.
http://www.caf.wvu.edu/kearneysville/articles/PHILOSOPHY2000.html