

**Professor Vidaver's Warnings ; Microorganisms & BioControl - Regulatory Related**

Why do we have this topic for this workshop?	
00:01:38.0	
<ul style="list-style-type: none"> <li>I should also say that a couple of the references that I've provided with my abstract are missing</li> </ul>	
CROSS-INFECTIVE MICROORGANISMS FROM PLANTS TO HUMANS & MICROORGANISMS USED FOR BIO-CONTROL	REGULATORY ISSUES & CHALLENGES
<p style="text-align: right;">00:01:05.9</p> <p>1. ✓... there are some organisms that are used as microbial pesticides; or prospective microbial pesticides</p> <hr style="border: 0.5px dashed gray;"/> <p style="text-align: right;">00:01:50.7</p> <p>2. ✓ I'm going to talk about some illustrations of plants; of plant/human cross-infections and use those as example's</p> <p style="text-align: right;">00:02:47.6</p> <p>3. ✓ The terms are not yet agreed upon. What this means; you can talk about organisms that are cross-infected; mainly go from plants to humans; you can call them cross-over pathogens, and you can also call them cross, (or inter)-kingdom pathogens.</p> <p style="text-align: right;">00:04:48.0</p> <p>4. There are fewer bacteria that are cross-infective than fungi</p> <p style="text-align: right;">00:05:59.5</p> <p>5. ✓ Now, the majority of the diseases that I'm going to talk about in humans are rare; but there will be a few that are not so rare</p> <p style="text-align: right;">00:16:09.4</p> <ul style="list-style-type: none"> <li>This is why, I think, even if people are interested in disease; we'd would rather work with plants, rather than some of the other stuff</li> </ul> <p style="text-align: right;">00:06:36.3</p> <p>6. ✓ <u>Agrobacterium tumefaciens</u></p> <p style="text-align: right;">00:07:17.5</p> <ul style="list-style-type: none"> <li>this has been linked with <b>oral muscosal inflammation</b></li> </ul>	<p style="text-align: right;">00:01:05.9</p> <p>1. ✓ in my experience, <u>plant pathologist don't know about some of these microbes and the medical community conversely does not</u></p> <p style="text-align: right;">00:01:23.0</p> <ul style="list-style-type: none"> <li>it's unfortunate that with all the controlled regulatory agencies; we're missing a few, that could actually, hopefully learn from what I plan to say; namely the Food and Drug Administration and the National Institute of Health.</li> </ul> <p style="text-align: right;">00:02:00.0</p> <p>2. ✓ Then I'll talk about what this actually could mean; both to the scientific community and to the regulated community; and challenges for regulators as well.</p> <p style="text-align: right;">00:03:04.0</p> <p>3. ✓ Doctor Tauxe from the CDC invented the term; as far as I know, Phytoses</p> <p style="text-align: right;">00:03:17.5</p> <ul style="list-style-type: none"> <li>...they're not overlapping pathogens in the select agents list; the USDA and the NIH</li> </ul> <p style="text-align: right;">00:06:12.6</p> <p>5. ✓ And obviously, for anybody in the regulatory arena; this causes at least a plausible thought, but I'll indicate what some of the challenges are with this.</p> <p style="text-align: right;">00:06:36.3</p> <p>6. ✓ <u>Agrobacterium tumefaciens</u></p> <ul style="list-style-type: none"> <li>is, and I think most people know, has been extremely critical to the biotech industry</li> </ul>

**VIDAVER WARNING LINKS BELOW**

<http://www.biotechawareness.com/images/Professor.Vidaver.Warnings.copy.pdf>

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CROSS-INFECTIVE MICROORGANISMS FROM PLANTS TO HUMANS & MICROORGANISMS USED FOR BIO-CONTROL	REGULATORY ISSUES & CHALLENGES
<p>7. ✓ <u>Burkholderia cepacia</u> 00:08:38.5 00:09:02.9</p> <ul style="list-style-type: none"> <li>• is a <b>disease</b> partially known for being a <b>problem in lung tissue</b> and particularly in patients with <b>Cystic Fibrosis</b>. However, <b>there're other diseases</b> that it can be involved with 00:09:38.7</li> <li>• This is one of the two cases I know of where you actually do <b>have evidence; as apposed to conjecture, that the genes for plants that cause disease, and genes that can cause disease in humans, are on the same strain</b> 00:09:58.1</li> <li>• That is not true for all strains of <u>Burkholderia cepacia</u>, but it is true for at least a few that have been so characterized.</li> </ul>	<p>7. ✓ <u>Burkholderia cepacia</u> 00:09:17.4 00:09:30.3</p> <ul style="list-style-type: none"> <li>• At one time there was a biocontrol agent; actually it was going to be applied for soil-borne fungi I believe, 00:09:30.3</li> <li>• It had to be taken off the market because of objections through the <u>American Medical Association</u>. 00:10:07.4</li> <li>• Very unusual and very challenging, of course if you're ready to talk about a biocontrol agent</li> </ul>
<p>8. ✓ <u>Enterobacter cloacae</u> 00:11:18.6 00:11:48.9</p> <ul style="list-style-type: none"> <li>• And for those of you not familiar with bacteria; this is in the <b>same family as e-coli</b>, some of the <b>notorious e-coli</b>. 00:11:58.8</li> <li>• Can cause <b>generalized infections; respiratory tract infections and gas gangrene</b></li> </ul>	<p>8. ✓ <u>Enterobacter cloacae</u> 00:11:18.6 00:11:18.6</p> <ul style="list-style-type: none"> <li>• can also; at least in the literature, be known as a biocontrol agent 00:11:18.6</li> <li>• I don't believe that any have been turned over to the EPA, or anyone else yet, for actual potential commercialization.</li> </ul>
<p>9. ✓ <u>Pantoea agglomerans</u> 00:12:06.2 00:12:40.3</p> <ul style="list-style-type: none"> <li>• is <u>known by a number of different names</u>, 00:12:40.3</li> <li>• You've already heard about the <b>possibility of acquired infections</b>; this is one of the organisms that has been reported of possible acquired infections and can also be reported in <b>arthritis</b>.</li> </ul>	<p>9. ✓ <u>Pantoea agglomerans</u> 00:12:06.2 00:12:06.2</p> <ul style="list-style-type: none"> <li>• in the literature, the plant pathology literature, there are a number of strains that have been proposed for biological control, usually by competitive exclusion.</li> </ul>
<p>10. <b>More and more bacteria by the way are being reported to cause some chronic disease</b> 00:12:53.6</p>	
<p>11. ✓ <u>Serratia marcescens</u> 00:14:11.2 00:14:27.9</p> <ul style="list-style-type: none"> <li>• It can be a <b>nasty organism</b>; in terms of a number of <b>infections in the respiratory tract, urinary tract</b>, in the <b>eyes</b>, in the <b>heart</b> and so on.</li> </ul>	<p>11. ✓ <u>Serratia marcescens</u> 00:14:11.2 00:14:11.2</p> <ul style="list-style-type: none"> <li>• a [bio?] synthetic</li> </ul>

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<p style="text-align: right;">00:16:02.1</p> <p>12. <b>Now, switch to fungi; and there are more of them</b>, but even though it may sound like I'm going to talk about a lot of them, I'm not going to talk about all of them <b><i>that are in the paper that I had that I was going to use as references.</i></b></p> <p style="text-align: right;">[see 00:01:38.0]</p> <ul style="list-style-type: none"> <li>• <b><i>"I should also say that a couple of the references that I've provided with my abstract are missing."</i></b></li> </ul> <p style="text-align: right;">00:16:19.8</p> <p>13. The prospective virtue of <b>fungi</b></p> <ul style="list-style-type: none"> <li>• <b>they are more desirable as microbial control agents</b></li> </ul> <p style="text-align: right;">00:18:09.4</p> <ul style="list-style-type: none"> <li>• This is why, I think, even if people are interested in disease; we'd would rather work with plants, rather than some of the other stuff</li> </ul> <p style="text-align: right;">00:18:18.8</p> <p>14. ✓ <b><u>Aspergillus flavus</u></b></p> <p style="text-align: right;">00:18:44.7</p> <ul style="list-style-type: none"> <li>• has been reported to have <b>generalized infection</b> in people, and can be a <b>problem in heart disease</b> as well.</li> </ul> <p style="text-align: right;">00:24:10.7</p> <p>15. For those of you who are not a plant pathologist, I trust that you're finding, or at least hearing that there are pathogens on almost anything you can think of, and that is true.</p> <p style="text-align: right;">00:26:59.5</p> <p>18. ✓ <b><u>People are asking questions</u></b></p> <ul style="list-style-type: none"> <li>• <i>"what do genomic islands actually mean in terms of the basic organisms since these can be differentiated genomically from the rest of the organism?"</i></li> </ul>	<p style="text-align: right;">00:18:18.8</p> <p>14. ✓ <b><u>Aspergillus flavus</u></b></p> <p style="text-align: right;">00:18:34.1</p> <ul style="list-style-type: none"> <li>• There is a strain for control of <b>A. flavus</b> on cotton, and I believe it works essentially on the principle of competitive exclusion</li> </ul> <p style="text-align: right;">00:26:25.7</p> <p>16. When we're talking about getting a potential organism, <b><u>we can't generalize about the whole main effects</u></b></p> <ul style="list-style-type: none"> <li>• we have to look at strain variation and</li> <li>• the stability of the organism.</li> </ul> <p style="text-align: right;">00:26:39.7</p> <p>17. <b>For any [ BioControl ] agent We have to look at</b></p> <ul style="list-style-type: none"> <li>• what are the virulence factors</li> <li>• how might they be transmittable;</li> <li>• transmitted to other organisms or not; particularly for bacteria, but not necessarily exclusively</li> </ul> <p style="text-align: right;">00:27:19.9</p> <p>18. ✓ <b><u>People are asking questions</u></b></p> <ul style="list-style-type: none"> <li>• In many cases they carry antibiotic resistance genes or other genes not otherwise seen in that taxon.</li> </ul>

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	<p style="text-align: right;">00:27:19.9</p> <p>19. In bacteria particularly;</p> <ul style="list-style-type: none"> <li>• pathogenicity islands have been known to have for a number of years; and these carry a number of virulence factors and may include antimicrobial resistance factors as well.</li> </ul> <p style="text-align: right;">00:27:37.7</p> <p>20. And then; notorious for bacteria is antibiotic resistance;</p> <ul style="list-style-type: none"> <li>• it may be intrinsic, that is strains that are already known to carry antibiotic resistance without any exposure to antibiotics.</li> </ul> <p style="text-align: right;">00:27:52.4</p> <ul style="list-style-type: none"> <li>• This is particularly true of those from natural systems, but certainly from artificially produced antibiotics as well.</li> </ul>
<p style="text-align: right;">00:28:02.1</p> <p>21. ✓ And then there's the question of ... for fungi</p>	<p style="text-align: right;">00:28:02.1</p> <p>21. ✓ we have the emergence of, or concern about, mycocide or fungicide resistance.</p>
<p style="text-align: right;">00:28:15.7</p> <p>22. There's no shortage of challenges. But, let's talk, refresh just a moment in terms of definitions, of what ... at least what I'm talking about.</p> <p style="text-align: right;">00:28:27.3</p>	
<p>23. The systematic question is to really look at the diversity and the relationships among organisms. Now, I think that's really what we've been talking about a lot already and we'll be doing it more throughout this workshop,</p>	
<p style="text-align: right;">00:28:41.6</p> <p>24. ✓ <b>One of the important questions for people in ... the more we know in the way - the less we know</b></p>	<p style="text-align: right;">00:28:41.6</p> <p>24. ✓ <b>how do we classify organisms?</b></p> <ul style="list-style-type: none"> <li>• <b>this is a human endeavor, but we have to do this in order to communicate</b></li> <li>• <b>it's a very challenging area then for anyone who is in the regulatory arena</b></li> </ul> <p style="text-align: right;">00:29:11.5</p> <ul style="list-style-type: none"> <li>• This is also then true in terms of Nomenclature</li> </ul> <p style="text-align: right;">00:29:14.3</p>
	<p>25. <b>What are you going to name an organism?</b>                  26. <b>How are you going to identify it?</b>                  27. <b>how are you going to characterize any group of individuals then by rank?</b></p>
<p style="text-align: right;">00:29:24.0</p> <p>28. ✓ <b>then for species; at least for the present time for bacteria</b></p>	<p style="text-align: right;">00:29:24.0</p> <p>28. ✓ <b>you have a species being defined with at least 70% relatedness by the DNA homology</b></p> <p style="text-align: right;">00:29:35.8</p> <p><b>Well, some microbial geneticists believe that this is; then again, inappropriate given what we know; but no one has yet come up with something that is actually being received ... received well as an alternative. So, this is still a challenge</b></p>

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	<p style="text-align: right;">00:29:57.7</p> <p>29. What is the species?  <ul style="list-style-type: none"> <li>I'm not sure, even for the fungi, ... there is agreement amongst the species</li> </ul> <p style="text-align: right;">00:30:09.5</p> <p>30. And then for defining a strain that you would actually use; and</p> <p>31. that you would worry about stability,  <ul style="list-style-type: none"> <li>we're talking about the decedents of a single isolation in your culture</li> </ul> <p style="text-align: right;">00:30:23.9</p> <p>32. if you actually don't use the microorganism itself, but the attribute of it that would be used in a plant; that a volitarious organism,  <ul style="list-style-type: none"> <li>then you could have what the EPA has; namely plant incorporated protectants.</li> </ul> <p style="text-align: right;">00:30:49.8</p> <ul style="list-style-type: none"> <li>this is the case for example in the papaya; where you have a <b>gene from a virus</b> that is protecting a papaya <b>from the virus attack</b>.</li> </ul> <p style="text-align: right;">00:31:18.8</p> <p>33. there's the question of what do you do about the host responses?  <p style="text-align: right;">00:31:18.8</p> <p>34. How do you measure the population; even of plants or of people, or animals as the case may be?  <ul style="list-style-type: none"> <li>because we are not in a static population in any of those categories</li> </ul> <p style="text-align: right;">00:31:36.2</p> <p>35. We need ... need to know a lot more about inducing the innate immunity;  <ul style="list-style-type: none"> <li>simply to be able to combat all these challenging organisms that are multiplying and changing at a faster rate than we are.</li> </ul> <p style="text-align: right;">00:31:50.</p> <p>36. Area that is of particular concern to many people; and I think is a real challenge in the regulatory agency, is the emerging area of <b>synthetic biology</b></p> </p></p></p></p></p></p>
<p style="text-align: right;">00:32:02.8</p> <p>37. ✓ We've already seen the emergence of <b>store boughten goods being able to produce a virus that has really upset many, many people</b>.  <ul style="list-style-type: none"> <li>this is probably just the beginning of <b>synthetic biology</b> and certain people couldn't believe that it will not be very long before we can actually <b>produce in vitro the first synthetic, small scale microorganism</b>.</li> </ul> </p>	<p style="text-align: right;">00:32:32.6</p> <p>37. ✓ Mycoplasmas for example,  <ul style="list-style-type: none"> <li>in about less than 600 genes that are necessary for life, and this may be down the road.</li> <li>Again a challenge for regulators.</li> </ul> </p>

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<p>00:33:18.9 40. ✓ And then for everyone all of this affects</p> <p>00:33:33.3 41. ✓ One place I think that there is something missing; and it is not perhaps premature to talk about</p> <p>00:33:44.9 42. ✓ There's certainly interagency programs already in many areas</p> <p>00:34:29.4 45. ✓ In terms of looking at this issue; it could explain, perhaps in some cases, <b>the origin of human diseases as being from sick or even asymptomatic plants.</b></p>	<p>00:32:48.9 38. <b>DNA shuffling is going on</b> • actually seem like regulatory agency is not clear, at least it may ... that may come out in this workshop.</p> <p>00:33:02.6 39. Are Model system analyses appropriate? • In all the complexity that we are looking at in many people; that are on both sides of the fence • in any case this is a challenge; both for the regulated community and for the regulators</p> <p>00:33:18.9 40. ✓ what we do in terms of facilities design • in terms of cost • in maintenance • which are not trivial</p> <p>00:33:33.3 41. ✓ we could have interdisciplinary programs across agencies</p> <p>00:33:44.9 42. ✓ we do not have any, as far as I know, that incorporate USDA and NIH especially; certainly in this area of cross-infective microorganisms</p> <p>00:34:02.1 43. I dare say the medical community has no idea that some of these are problems in plants and the plant community has no idea that these are problems in medicine.</p> <p>00:34:13.6 44. the question really for the medical community; and even for the plant community is, Are we talking about the same organism? In many cases that's still very much the question.</p> <p>00:34:46.0 45. ✓ A colleague that [Europe? ]... has coined the term; <b>Virulome</b>, to talk about just a set of traits that would allow an organism to be pathogenic in particular circumstances. Whether or not it's inside a plant or human, and simply that it acquires this information and carries it around, and may be dispersed throughout the genome but, it's useful on occasions. • And that may be something that will explain some things and makes things readily understood, I mean connect.</p>

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<p style="text-align: right;">00:35:40.9</p> <p>46. ✓ And we're concerned about microbial survival, spread and gene transfer, and you already heard some of that as well.</p>	<p style="text-align: right;">00:35:52.7</p> <p>46. ✓ We have contrast here in terms of limitation and how we even look at organisms in the medical community.</p>
<p style="text-align: right;">00:36:00.6</p> <p>47. ✓ We talk about risk groups in agriculture as far as the community is concerned and the outside world.</p>	<p style="text-align: right;">00:36:00.6</p> <p>47. ✓ There are no risk groups, they're all people in a vat.</p> <ul style="list-style-type: none"> <li>• This is just not good in science and I think that this is something that we can all work on. <span style="float: right;">00:36:14.2</span></li> <li>• Permits for the medical community is selective; not everything requires a permit. <span style="float: right;">00:36:19.2</span></li> <li>• In agriculture; it is essentially a pathogen, everything does in one form or another, although it could be ... that is improving in terms of how it is being dealt with.</li> </ul>
<p style="text-align: right;">00:36:37.4</p> <p>48. ✓ For antimicrobials: we have differences among agencies</p>	<p style="text-align: right;">00:36:37.4</p> <p>48. ✓ some of which are required and some of which I understand are not.</p> <ul style="list-style-type: none"> <li>• <b>But, in the FDA, there is more emphasis given on the guidance documents</b>, which are easily ... then modified, <b>as opposed to regulations in agriculture.</b></li> </ul>
<p style="text-align: right;">00:37:09.1</p> <p>49. <b>USDA</b> has <b>IR-4</b>; which almost nobody outside of the <b>USDA</b> has any idea what that means,</p> <ul style="list-style-type: none"> <li>• and I suggested that be reexamine, if nothing else rename, so other people can understand it.</li> <li>• And perhaps have the <b>EPA</b> follow with that as well.</li> </ul>	<p style="text-align: right;">00:37:09.1</p> <p>49. <b>USDA</b> has <b>IR-4</b>; which almost nobody outside of the <b>USDA</b> has any idea what that means,</p> <ul style="list-style-type: none"> <li>• and I suggested that be reexamine, if nothing else rename, so other people can understand it.</li> <li>• And perhaps have the <b>EPA</b> follow with that as well. <span style="float: right;">00:37:23.9</span></li> <li>• And to take a look at other agencies efforts to have an examination account; small markets can be helped along... <span style="float: right;">00:37:36.5</span></li> <li>• ... and the <b>FDA</b> does have an <b>Orphan Drug Act</b> that could act as a model.</li> </ul>
<p style="text-align: right;">00:37:42.3</p> <p>50. ✓ And the take home message are several</p>	<p style="text-align: right;">00:37:46.4</p> <p>50. ✓ <b>First, that we actually recognize we have these cross-infective agents.</b></p> <ul style="list-style-type: none"> <li>• And a big, BIG question mark; Is <b>what is the accuracy of the medical diagnosis?</b> <span style="float: right;">00:37:56.6</span></li> <li>• This is where we need systematics.</li> <li>• <b>we need research in the regulatory agencies</b> to promptly research 'agencies' to work in this area because</li> <li>• <b>a lot hinges on whether or not; in fact in some cases that I've illustrated, whether we can actually have microbial pesticides.</b></li> </ul>

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<p>50. ✓ <i>And the take home message are several, continued</i></p>	<p>50. ✓ <i>And the take home message are several, continued</i></p> <p style="text-align: right;">00:38:14.5</p> <ul style="list-style-type: none"> <li>• We're not going to have them, if in fact any of those agents really are a problem, a real problem in the medical arena. <span style="float: right;">00:38:22.1</span></li> <li>• So, we need risk assessment comparability between medical and agricultural fields. <span style="float: right;">00:38:26.8</span></li> <li>• And we've already heard we need to have vigilant monitoring and surveillance with all these organisms that are <b>cross-infective</b>. <span style="float: right;">00:38:35.3</span></li> <li>• And then we need to look at interagency research opportunities and regulatory challenges.</li> </ul>
<p><b>QUESTIONS:</b></p>	<p><b>RESPONSES FROM PROFESSOR ANNE K VIDAVER:</b></p>
<p style="text-align: right;">00:39:09.7</p> <p>51. ✓ <b>Yes, Chris Wozniak, CSREES.</b></p> <ul style="list-style-type: none"> <li>• The question I have is basically; when you look at these various species that are implicated in the literature as <b>infective agents</b>, whether transfer or otherwise plant pathogens ... <span style="float: right;">00:39:21.8</span></li> <li>• ... And then you look at the regulatory process; where you're really focussing on <b>strains</b> and the genotype of the [inaudible] strain ... <span style="float: right;">00:39:28.8</span></li> <li>• It's kind of interesting; that there's sorta the history of these species as it exists in the literature, whether that's accurate or not, and that it is suspect of that strain that's going through probable registration or whatever. <span style="float: right;">00:39:42.6</span></li> <li>• I guess I'm kinda wondering is; with the varieties that you've showed, if we're getting to this point where any report of some <b>organism</b>, and some instance which is considered a <b>pathogen of livestock or on humans</b>, is gonna basically negate this potential use of that <b>organism</b> and that it [inaudible] probable disease it posed.</li> </ul>	<p style="text-align: right;">00:40:05.8</p> <p>51. ✓ I don't think so. <span style="float: right;">00:40:08.9</span></p> <ul style="list-style-type: none"> <li>• As I think I indicated; the majority of these in human literature are still extremely rare. So I think basically you have one or two reports in a population of a billion or so. I don't think that's likely. <span style="float: right;">00:40:27.0</span></li> <li>• But it does still require that we need to do a better job on systematics I think.</li> </ul>



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<p><b>QUESTIONS</b>, <i>continued</i></p> <p style="text-align: right;">00:40:35.2</p> <p>52. ✓ <b>Daniel Jones, USDA - CSREES.</b></p> <ul style="list-style-type: none"> <li>Anne, do you have a rough estimate of the proportion of the kind of pathogens that are <b>cross-over pathogens</b>?</li> </ul>	<p><b>RESPONSES FROM PROFESSOR ANNE K VIDAVER</b>, <i>continued</i></p> <p style="text-align: right;">00:40:45.8</p> <p>52. ✓ Very small ... very small. <span style="float: right;">00:40:48.9</span></p> <ul style="list-style-type: none"> <li>Let me see.</li> </ul> <p><i>Professor Vidaver turned to direct her continued answer to the attendees of the conference</i></p> <p style="text-align: right;">00:40:50.0</p> <ul style="list-style-type: none"> <li>If I remember; we have perhaps anywhere from hundred (600) to several thousand pathogens that have been described as plant pathogens and here <b>we're talking about less than a hundred, selectively of bacteria and fungi.</b></li> </ul> <p><i>Professor Vidaver then turned to DANIEL JONES, USDA, CSRES</i></p> <p style="text-align: right;">00:41:09.2</p> <p>It ... it is not a large problem, <b>but it's not a problem that we can ignore.</b></p> <p style="text-align: right;">00:41:14.9</p> <p>And I should indicate to you one more thing. <span style="float: right;">00:41:18.2</span></p> <p><b>The fungi seem to be increasing in terms of most severity and incidence; and I have seen where the medical community is puzzled by this because it is not only in terms of immunocompromised patients; maybe those with transplants and those with AIDS, but also with even otherwise healthy people. And so, the incidence is going up.</b></p>
<p><b>STATEMENT BY UNIDENTIFIED MALE:</b></p> <p style="text-align: right;">00:41:49.7</p> <p>53. What is the significance of the fact that <b>bacteria</b> may ... the soil is an environment, and us, and bugs is [an] extension of this environment?</p> <p style="text-align: right;">00:42:07.5</p> <ul style="list-style-type: none"> <li>The ... at least one of the underlying things is; in <b>opportunistic infections</b>, without an immune system shock of the Embryobiota appear .... appearances; almost anything I gave a disease ... in some, can infect humans.</li> </ul> <p style="text-align: right;">00:42:29.3</p> <ul style="list-style-type: none"> <li>And what regulatory conclusion can be drawn from that; in the use of <b>bio regulatory agents</b>?</li> </ul>	

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<p>53. <b>STATEMENT BY UNIDENTIFIED MALE,</b> <i>continued</i></p> <p style="text-align: right;">00:42:40.2</p> <ul style="list-style-type: none"> <li>As you've pointed out; it's rather rare and under certain circumstances we're just culture idiots. And yes; that occurs, occurs very rarely.</li> </ul> <p style="text-align: right;">00:42:54.1</p> <ul style="list-style-type: none"> <li>I think the significance is; in each incidence has to be evaluated. And not just say; well it's occurred in the literature. But, I think it's these six cases I remember.</li> </ul> <p style="text-align: right;">00:43:08.3</p> <ul style="list-style-type: none"> <li>You know; if you go far enough into the realm of realization of a normal human being; and look at all your <b>organisms</b> and see, you're going to find a large number, especially among farm mycologists.</li> </ul> <p style="text-align: center;"><i>[Laughter in room]</i></p> <p style="text-align: right;">00:43:23.9</p> <ul style="list-style-type: none"> <li>Now, it's ah ... If you're going to ... we all carry these things; and I think we need to think very carefully about what that means [inaudible], I would think ... seeing the situation that I saw in <b>cepacia</b>, where the representatives; very rightly in a way, of the <b>Cystic Fibrosis Society</b> objected to the use of <b>cepacia</b> as an <b>insecticide</b>.</li> </ul> <p style="text-align: right;">00:43:57.7</p> <ul style="list-style-type: none"> <li>Of a ... the reason was that they had shown that there were occasional cases of <b>cystic fibrosis</b> that hadn't carried this organism. But here's the important thing, not as the major organisms. All <b>cystic fibrosis</b> tends to be infected with <b>pseudomonas aeronosa</b> and carry a secondary infection as well.</li> </ul> <p style="text-align: right;">00:44:29.6</p> <ul style="list-style-type: none"> <li>So, the objection that it was found; was taken as a means for not using one of these [inaudible]</li> </ul> <p style="text-align: right;">00:44:40.6</p> <ul style="list-style-type: none"> <li>I think one ought to look very carefully at these microorganisms, that for one reason only, that one overlooks therapeutic possibilities that occur in <b>secondary infections</b>.</li> </ul>	

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<p><b>QUESTIONS, <i>continued</i></b></p> <p><b>UNIDENTIFIED MALE:</b></p> <p style="text-align: right;">00:45:12.4</p> <p>54. ✓ [ Inaudible] ,, And uh... I think your points are well taken, but you know, I saw these <b>plant pathogens</b>; some of them aren't too ... probably in the same category of the <b>human</b> [inaudible] or very little...</p> <p style="text-align: right;">00:45:22.4</p> <p>... and; OK, do you know any kind of strategy to avoid [inaudible]?</p>	<p><b>RESPONSES FROM PROFESSOR ANNE K VIDAVER, <i>continued</i></b></p> <p style="text-align: right;">00:45:22.1</p> <p>54. ✓ Right ...</p> <p style="text-align: right;">00:45:33.9</p> <ul style="list-style-type: none"> <li>• Well, that's ... that's where risk assessment comes in.</li> </ul> <p style="text-align: right;">00:45:36.7</p> <ul style="list-style-type: none"> <li>• And I would argue that while those of us that work with <b>plant pathogens</b> know that we have some so-called minor pathogens; when it comes time to explain this however to the public, you're talking about, in my view, permits for risk assessment groups; we don't have it, and I think that's long overdue.</li> </ul> <p style="text-align: right;">00:45:57.0</p> <ul style="list-style-type: none"> <li>• So that we could actually say that we have; and it's clear that we have, minor pathogens, just equivalent to.. and put that back in [inaudible]</li> </ul>
<p><b>UNIDENTIFIED MALE:</b></p> <p style="text-align: right;">00:46:10.7</p> <p>55. ✓ Yeah, I think this about ... is kinda along the same lines on Michael [Braveman?]; [inaudible] on the four or five organizations that nobody's ever heard of.</p> <p style="text-align: center;"><i>[Laughter in room]</i></p> <p style="text-align: right;">00:46:18.3</p> <ul style="list-style-type: none"> <li>• I think there... I think what has been missing in some of this discussion is really; is the <b>exposure that already exists.</b></li> </ul> <p style="text-align: right;">00:46:18.5</p> <ul style="list-style-type: none"> <li>• I think that the history of <b>exposure to these organisms</b> is really what ... what's telling you that the relative importance; not the fact that a report exists on the presence of an <b>infection in human</b>, it is the fact that there are so few reports in light of the fact that these <b>organisms</b> are so prevalent and that <b>man is so being exposed to them.</b></li> </ul>	<p><b>PROFESSOR ANNE K VIDAVER</b></p> <p style="text-align: right;">00:46:52.8</p> <p>55. ✓ I don't disagree with that at all, but having known about; for example the <b>Burkholderia cepacia</b> situation...</p> <p style="text-align: right;">00:47:03.7</p> <ul style="list-style-type: none"> <li>• ... Part of my presentation is to try to minimize having that occur again; and that means that I think people know that there are <b>these kinds of situations</b> and to put them in the appropriate content.</li> </ul> <p style="text-align: right;">00:47:16.0</p> <ul style="list-style-type: none"> <li>• If you don't even know; then you can be blind sighted and that's what I think no body wants.</li> </ul>

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<p><u>QUESTIONS</u>, <i>continued</i></p> <p>56. ✓ Yes, <b>Greg Simmons</b> with <b>APHIS</b>. 00:47:24.9</p> <p>00:47:28.1</p> <ul style="list-style-type: none"> <li>• You mentioned that there are a few cases of <b>fungi</b>; I think, that are <b>increasing in some prevalence in humans</b>. 00:47:35.1</li> <li>• And so just a kind of follow-up question is; Have any of the cases where information is known; is there any information about <b>occupational risks and people that are associated with more with these sorts of organisms</b> where you have some relationship there?</li> </ul>	<p><u>RESPONSES FROM PROFESSOR ANNE K VIDAVER</u>, <i>continued</i></p> <p>56. ✓ There probably is, but right now I couldn't give you ... I ... Right now I couldn't give you a [inaudible], 00:47:54.0</p> <p>00:48:00.9</p> <ul style="list-style-type: none"> <li>• But, I have come across a few.</li> </ul>