
From: Mattox, Brent S
Sent: Tuesday, April 13, 2004 8:26 AM
To: Buckley, Michael
Subject: RE: Re: Lab accident

I have to call CDC this morning about another import/export question (not any of our regular contacts), otherwise the reply looked OK. I suspect we answered too broadly in some cases, as CDC seemed to be keying off of singular observances, but they were issues that needed dealt with anyway. Wonder when CDC will respond? NOTE: We will be officially transferred out of Business Services on the 15th (Thursday). We will be reporting (as far as I can tell) to Charlie Clark. As far as I can tell, our functions will not change. I will let you know what CDC has to say.

Brent

-----Original Message-----

From: Buckley, Michael
Sent: Tuesday, April 13, 2004 6:40 AM
To: Mattox, Brent S
Subject: RE: Re: Lab accident

Brent,

Sounds good, how is everything else going? How did the CDC response look to you?

Mike

Michael W. Buckley, Ph.D.
Director, Research Compliance
Texas A&M University
MS 1112
Office of the Vice President for Research
College Station, Texas 77843-1112
979.847.9362

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 4/12/2004 1:20:01 PM >>>
We were informed. All accidents are investigated, but there is no requirement with the exception that needle sticks must be reported to TDH under the bloodborne pathogens rule.

Brent

-----Original Message-----

From: Buckley, Michael
Sent: Monday, April 12, 2004 9:00 AM
To: Mattox, Brent S
Cc: Meyer, Chris; Wei Zhao
Subject: Fwd: Re: Lab accident

Brent,

Not sure if you have been informed about this accidental exposure.

I have looked thru the CFRs and can't find anything which requires us report this incident - are you familiar with any requirements? Also, does EHS usually investigate this events and file an internal report on them? I was just curious if we should cross reference the procedure this tech was using with what is described in the protocol as a QA

issues to see if there were procedure problems, or just an mistake.
If
you need any information out of the file here just let me know and
we'll
have it sent over to you.

What are your thoughts?

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>>> Michael Buckley 4/12/2004 8:53:17 AM >>>
Betsy,

Thanks for passing this along. I will brief Wei at our meeting this
afternoon - not sure what else would be required. I have looked over
the federal regulations on SBATs and did not find any reporting
requirements for accidental exposures.

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>>> "Betsy Browder" <ejb@tam.u.edu> 4/9/2004 4:59:02 PM >>>
Melanie and Mike,

EHS and HR are informed through the First Report of Injury but I
wanted
to let you both know about this to avert surprises.
If there is a need for further documentation that either of you might
be aware of please let John Quarles know.
Thanks,
bb

>>> John M. Quarles<QUARLES@medicine.tamu.edu> 4/9/2004 4:10:45 PM >>>
Thanks Betsy. We've already done that and the "sharps" report also.

>>> "Betsy Browder" <ejb@tam.u.edu> 04/09/04 04:10PM >>>
Hi John,
Nothing specific regarding the animals but the "First Report of
Injury"
form needs to get to the Campus Environmental Health and Safety
Office.

Their fax number is 5-1348.
bb

>>> John M. Quarles 4/9/2004 10:01:07 AM >>>
Betsy-
One of our graduate students injected her hand with Brucella yesterday

afternoon. She saw a doc at S&W, is on antibiotics, and has a
appointment with occupational health. Is there any reporting we need
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Thanks,
John

From: Mattox, Brent S
Sent: Wednesday, April 14, 2004 9:14 AM
To: Buckley, Michael
Subject: RE: Re: Lab accident

Send money!

Brent

-----Original Message-----

From: Buckley, Michael
Sent: Wednesday, April 14, 2004 9:03 AM
To: Mattox, Brent S
Subject: RE: Re: Lab accident

Brent,

I'm sure the administrative move will have little impact on EHS operation. I have worked with C. Clarke for a number of years, and believe you will find him honest and fair and concerned that compliance issues are handled in the best interest of the university.

I know that the change will be stressful for some, if there is anything I can do let me know!

Mike

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Thanks,
John

From: Mattox, Brent S
Sent: Monday, April 26, 2004 10:23 AM
To: Buckley, Michael; Kretzschmar, Bert
Subject: RE: unsecured door

I think it would only be a reportable incident if something was taken, which we don't know yet. The internal labs are secured, and the freezers are locked. If no tampering is evident and all the animals are still there, then it would appear to be a procedural error, not an incident. My opinion only. What do you think Bert?

-----Original Message-----

From: Buckley, Michael
Sent: Monday, April 26, 2004 10:17 AM
To: bertvk@tamu.edu; Mattox, Brent S
Cc: tficht@cvm.tamu.edu; Dianne Cornett; Wei Zhao
Subject: unsecured door

Bert and Brent,

I have reviewed 73.11 and 73.15 for reporting requirements for this unsecured door, the only applicable section is 73.11(c) which states 'the security plan must be reviewed by the RO at least annually and after any incident'.

In your opinions, would this be a 'reportable' incident? My thought would be NO because there was no evidence of intrusion into the facility itself - to me the procedure worked as it should. Unless of course Dr. Ficht's checking turns up something.

Sounds like just a sticking door. My thoughts would be to contact the PP about the door as well as the LARR staff to inform the lab techs to ensure the doors are secured when they leave until the door can be repaired.

What are your thoughts?

Mike

Michael W. Buckley, Ph.D.
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>>> Tom Ficht <tficht@cvm.tamu.edu> 4/25/2004 11:42:32 AM >>>
Bert

I am not sure what the course of action is for such an event. The person from my lab who found the door wasn't secured says that the interior labs appeared to be secure. Of course the animal room lacks any internal security. We will inventory our animals tomorrow morning,

as well as freezers, etc.

taf

Begin forwarded message:

> When I went into the BL3 this morning, the door to the women's
> changing room was not shut all the way. I was able to pull it open
> without swiping my card and without using my key. The air alarm
> wasn't going off either. I went in at 10:30 and checked the log.
The
> last person in there was : . She left at 10:05. I tried to call
> Carol but no one answered and didn't know if I was supposed to call
> Dr. Ficht. Everything appeared normal in the BL3.
>
> Kristen
>

From: Mattox, Brent S
Sent: Tuesday, September 09, 2003 8:54 AM
To: Buckley, Michael
Cc: Meyer, Chris
Subject: RE: USDA

If you think I can be of assistance, I am more than willing to participate in the meeting.

Brent

-----Original Message-----

From: Buckley, Michael
Sent: Tuesday, September 09, 2003 8:47 AM
To: Wei Zhao
Cc: Mattox, Brent S; chris-m-meyer@tamu.edu; Ewing, Richard
Subject: Fwd: USDA

Wei,

Just got a note from Tom Ficht stating that a Morris Smith, an inspector with USDA has scheduled a meeting with him on Wednesday 9/10 at 9:30 to discuss the transfer of *B. melitensis* between LSU and A&M.

I have let Tom know that if he would like one of us there, that we would be.

Will let you know if more information is passed on to me.

Mike

Michael W. Buckley, Ph.D.
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From: Mattox, Brent S
Sent: Monday, November 08, 2004 2:24 PM
To: 'Frank Stein'
Cc: Truss, Jeff C
Subject: RE: URGENT: Plan to meet past CDC Inspection Requests
Follow Up Flag: Follow up
Flag Status: Red

The self-closure issue may have only been on one door to one of the bldgs, but we will check them out tomorrow (with Bubba). I think the gauge problem is another issue. There are two solutions, the one being to add magnahelic gauges to compare pressure outside the containment (outside air) and the first room on the decontamination side. (CDC wants one on the outside) The other is to relocate the current gauge measuring differential between the first room and the containment stall to the outside. We'll resolve that issue tomorrow as well. I will have Jeff get in touch with Bubba. Installation is no big deal, drilling one hole and mounting the gauge, but availability of gauges may be a separate issue.

I will let you know what is determined and the fix.

Brent

-----Original Message-----

From: Frank Stein [mailto:FSTEIN@cvm.tamu.edu]
Sent: Monday, November 08, 2004 12:48 PM
To: Garry Adams; Mattox, Brent S
Cc: Bubba Skrivanek; Charles Vrooman; Thomas Ficht; Buckley, Michael
Subject: Re: URGENT: Plan to meet past CDC Inspection Requests

Brent,

I know that you and your people have been working on these buildings from time to time. I know that we were written up for not having door closures on the doors but I believe all of the doors have closures. I also believe that your people and Bubba Skrivanek have addressed the flow gage problems. Please let me know ASAP what, I need to do to facilitate getting this resolved.

Frank Stein

>>> "L. Garry Adams" <gadams@cvm.tamu.edu> 11/8/2004 12:27:16 PM >>>
Dear Brent & Frank:

I am asking that you work together to quickly resolve CDC's issues in regard to our buildings, namely installing automatic door closures, repairing/replacing magnahelic gauges etc to meet the CDC inspection-related compliance requirements. I would also request that you work to resolve any other issues with regard to animal facilities & security/safety along these lines.

Garry Adams

Begin forwarded message:

> From: "Michael Buckley" <mwibuckley@tamu.edu>
> Date: November 05, 2004 07:57:20 PM CST
> To: <gadams@cvm.tamu.edu>, <bsmattox@tamu.edu>, <w-zhao@tamu.edu>,
> "Dianne Cornett" <DCornett@vprmail.tamu.edu>
> Cc: <c-m-meyer@tamu.edu>, <Clark@vpfn.tamu.edu>
> Subject: CDC Request
>
> All,
>
> We are making quick progress with the CDC registration.
>> Brent, Bryan Satterfield called after 5pm today to ask me about the
> flow gages and the automatic door closures in the " " facilities
> -
> they are trying to get Dr. Adams' DOD grant moving or at least minimize
> the registrations impact on it. Bryan stated that the door closures
> and
> the flow gages repairs MUST be completed BEFORE the registration can be
> approved. I talked to Garry a few minutes ago by phone and he stated
> that he would work with you to get those completed ASAP.
>
> As soon as those are done, CDC will send an inspection team here to
> look at those repairs as well as all the items that we responded to in
> the Inspection report. Bryan stated CDC will check to ensure that all
> the items that we stated would be done - are in fact completed. These
> would include all the paperwork items etc... listed on the color copy
> that we handed out today at the PATF meeting. So Dianne can work with
> the PIs et al to ensure that all those are completed and that we have
> documentation of their completion.
>
> Just to let everyone know - Bryan did say that this inspection would
> NOT take the place of the January 18-21 inspection - that inspection
> will still take place. I know that sounds strange - but I did not want
> to question him too much on that issue. Perhaps the 1/18 inspection
> will
> be to review the request they have yet to send us (attachment 2)
> regarding the Bison pens.
>
> Please remember that I will be out most of next week, but you should be
> able to get me by cell phone.
>
> Thanks,
>
> Mike
>
>
>
> Michael W. Buckley, Ph.D.
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> Texas A&M University
> MS 1112
> Office of the Vice President for Research
> College Station, Texas ! ; 77843-1112
> 979.847.9362

From: Mattox, Brent S
Sent: Wednesday, April 13, 2005 4:35 PM
To: Raines, Angelia; 'tficht@cvm.tamu.edu'
Cc: Meyer, Chris; 'Dianne Cornett'; 'Gary Adams (E-mail)'
Subject: RE: IBC: 2005002-Bowden

Follow Up Flag: Follow up
Flag Status: Red

I have already sent an email to a person in the Director's Office at USDA/APHIS and would prefer we wait until we get a response on this first. We really need to keep the two issues being discussed separate. I believe what Dr. Ficht is talking about involves USDA holding up a permit while waiting on the CDC inspection (correct me if I am wrong, Dr. Ficht) and the forwarding of the inspection report to USDA.

By the way, I have copied Dr. Adams on this one because he knows the players (in this case Karen James) I am dealing with at USDA. If everyone can, lets wait a day or two and see what responses my inquiries generate.

Thanks,

Brent

-----Original Message-----

From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Wednesday, April 13, 2005 4:00 PM
To: tficht@cvm.tamu.edu; Mattox, Brent S
Cc: Meyer, Chris; Dianne Cornett
Subject: Re: IBC: 2005002-Bowden

Our office will contact the USDA and get clarification. Please email me with a few details about your experience along with the name(s) of anyone from the USDA you spoke with. Also, please summarize what you believe to be the similarities and differences between your project and Dr. Bowden's.

Thanks,
Angie

>>> Tom Ficht <tficht@cvm.tamu.edu> 4/13/2005 3:20:43 PM >>>
Since no shipping is involved here, I do not have any problem signing off.

But I would still like some help with the USDA. I can call again to get some clarification and remind them that they themselves inspected and approved my labs.

taf

On Apr 13, 2005, at 8:54 AM, Mattox, Brent S wrote:

> The agents were shipped by hospitals under a permit issued by CDC for
> comparison studies in humans. As to whether or not a VS 16-7
> (supplement to a VS 16-3) was required at the time shipment was made
I
> cannot comment on at this time, only noting it is not a select agent

> and is not known to be spread by aerosol. I am not even sure these
> strains would survive in animals. I can attempt to get a more
> definitive answer from USDA, but that will take time.
>
> -----Original Message-----
> From: Dianne Cornett [mailto:DCornett@vprmail.tamu.edu]
> Sent: Wednesday, April 13, 2005 8:41 AM
> To: tficht@cvm.tamu.edu; Mattox, Brent S
> Cc: Meyer, Chris; Angelia Raines
> Subject: Re: IBC: 2005002-Bowden
>
>
> Brent -
>
> Can you respond to Dr. Ficht's request regarding follow up with CDC?
>
> Thanks,
> Dianne
>
>>>> Tom Ficht <tficht@cvm.tamu.edu> 4/12/2005 5:55:27 PM >>>
> The original question was, are these strains considered to be a risk
> to
>
> live stock. If they are then a USDA permit for receipt is required.
>
> Furthermore, it sounds like they want to review all such transfers.
>
> However, I guess if the bacteria are already here than the point is
> moot, but it seems to me that I was fined for doing just that last
> year with Brucella and these regulations do not pertain to select
> agents alone. However, I think if they were to penalize everyone
who
>
> had shipped bacteria on the list without a permit most of the
> microbiology research in the US would be shut down.
>
> But this does raise another issue with me. Can you have CDC send a
> copy of the report to USDA/APHIS so they will approve my current
> request for which I was charged back in November.
>
> taf
>
>
>
> On Apr 12, 2005, at 3:22 PM, Dianne Cornett wrote:
>
>> Brent -
>>
>> I will forward your comments below to Drs. Ficht and Wilson and if
>> there are no other issues outstanding, we should be able to move
>> forward
>> with the approval of this application.
>>
>> Thanks,
>> Dianne
>>
>>>> "Mattox, Brent S" <bsmattox@tamu.edu> 4/12/2005 3:05:36 PM >>>
>> That would have to go through USDA, but I am unsure as to why the
>> question is being asked. The purpose of the research is to set up
>> animal
>> models in a controlled research setting. This would appear to be an
> NIH
>> issue as the funding agency. If some type of USDA certification for
> the
>> lab is actually being sought, they may try contacting our local

>> representative, Dr. Parton, but I do not believe this will be
> necessary
>> unless USDA funding, select agents, or shipping is involved. Also,
> USDA
>> primarily is concerned with livestock and plant pathogens.
Resistant
>> staph is not a plant pathogen, I am not sure about livestock but
> since
>> no livestock exposure is to occur and there are no animal models, I
>> doubt this is an issue either.
>>
>> -----Original Message-----
>> From: Dianne Cornett [mailto:DCornett@vprmail.tamu.edu]
>> Sent: Tuesday, April 12, 2005 2:46 PM
>> To: Mattox, Brent S; IBC VPR
>> Cc: gbowden@ibt.tamhsc.edu; Meyer, Chris; Angelia Raines
>> Subject: RE: THIRD REMINDER: IBC: 2005002-Bowden
>>
>>
>> Brent -
>>
>> Well this answers the shipping question. What about the question
> "are
>> these organisms considered to be of no risk to livestock and/or
>> poultry?". Is this an answer you can provide or does it have to go
>> through USDA?
>>
>> Dianne
>>
>>>> "Mattox, Brent S" <bsmattox@tamu.edu> 4/12/2005 1:54:37 PM >>>
>> All:
>>
>> After re-reading the proposal again, I was under the impression the
>> organisms are already here. If no one is going to ship them
anywhere
>> else, then no permit would be required. rather than wait for
> feedback,
>> I
>> contacted Dr. Bowden directly and got an answer. The agents are
>> already
>> at IBT, and no agents will be shipped in the future by IBT. Thus,
no
>> permit is needed. This is important, based on a conversation with
>> USDA/APHIS today, which I listed below. In summary, I see no reason
>> not
>> to approve this research.
>>
>> USDA/APHIS Response:
>>
>> There are too many organisms to list that are regulated, so they
>> advise
>> that a permit be applied for and if not applicabale, they will send
> a
>> letter to that effect (shouldn't take more than a month or so). By
> the
>> way, the person who was supposed to call me back no longer works at
>> USDA. I guess that explains why I wasn't called back!
>>
>> -----Original Message-----
>> From: IBC VPR [mailto:ibc@tamu.edu]
>> Sent: Friday, April 01, 2005 12:21 PM
>> To: Mattox, Brent S
>> Cc: Dianne Cornett
>> Subject: THIRD REMINDER: IBC: 2005002-Bowden
>> Importance: High
>>
>>

>> ** High Priority **
>>
>> Brent-
>>
>> Below is the comments that were made by the IBC chairs on the latest
>> revision of 2005002-Bowden and attached is the application
> submitted.
>> Please let me know your comments on this protocol.
>>
>>
>

>
>> -----
>> 2005002-Bowden
>> Are these organisms considered to be of no risk to livestock and/or
>> poultry. If they are then USDA import permits should be obtained
>> and
>> they are not to my knowledge replaceable by CDC permits. If they
>> are
>> not
>> then the investigator should state such.
>>
>> Posted by: Thomas Ficht
>>
>

>
>> -----
>>
>>
>>
>> Thank you,
>>
>> Amanda Pietsch
>> VPR Compliance Office
>> Institutional Biosafety Committee
>> 979-458-3624

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Follow Up Flag: Follow up
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>>> Tom Ficht <tficht@cvm.tamu.edu> 4/12/2005 5:55:27 PM >>>
The original question was, are these strains considered to be a risk to live stock. If they are then a USDA permit for receipt is required. Furthermore, it sounds like they want to review all such transfers.

However, I guess if the bacteria are already here than the point is moot, but it seems to me that I was fined for doing just that last year with Brucella and these regulations do not pertain to select agents alone. However, I think if they were to penalize everyone who

had shipped bacteria on the list without a permit most of the microbiology research in the US would be shut down.

But this does raise another issue with me. Can you have CDC send a copy of the report to USDA/APHIS so they will approve my current request for which I was charged back in November.

taf

On Apr 12, 2005, at 3:22 PM, Dianne Cornett wrote:

> Brent -
>
> I will forward your comments below to Drs. Ficht and Wilson and if
> there are no other issues outstanding, we should be able to move
> forward

> with the approval of this application.
>
> Thanks,
> Dianne
>
>>>> "Mattox, Brent S" <bsmattox@tamu.edu> 4/12/2005 3:05:36 PM >>>
> That would have to go through USDA, but I am unsure as to why the
> question is being asked. The purpose of the research is to set up
> animal
> models in a controlled research setting. This would appear to be an
NIH
> issue as the funding agency. If some type of USDA certification for
the
> lab is actually being sought, they may try contacting our local
> representative, Dr. Parton, but I do not believe this will be
necessary
> unless USDA funding, select agents, or shipping is involved. Also,
USDA
> primarily is concerned with livestock and plant pathogens. Resistant
> staph is not a plant pathogen, I am not sure about livestock but
since
> no livestock exposure is to occur and there are no animal models, I
> doubt this is an issue either.
>
> -----Original Message-----
> From: Dianne Cornett [mailto:DCornett@vprmail.tamu.edu]
> Sent: Tuesday, April 12, 2005 2:46 PM
> To: Mattox, Brent S; IBC VPR
> Cc: gbowden@ibt.tamhsc.edu; Meyer, Chris; Angelia Raines
> Subject: RE: THIRD REMINDER: IBC: 2005002-Bowden
>
>
> Brent -
>
> Well this answers the shipping question. What about the question
"are
> these organisms considered to be of no risk to livestock and/or
> poultry?". Is this an answer you can provide or does it have to go
> through USDA?
>
> Dianne
>
>>>> "Mattox, Brent S" <bsmattox@tamu.edu> 4/12/2005 1:54:37 PM >>>
> All:
>
> After re-reading the proposal again, I was under the impression the
> organisms are already here. If no one is going to ship them anywhere
> else, then no permit would be required. rather than wait for
feedback,
> I
> contacted Dr. Bowden directly and got an answer. The agents are
> already
> at IBT, and no agents will be shipped in the future by IBT. Thus, no
> permit is needed. This is important, based on a conversation with
> USDA/APHIS today, which I listed below. In summary, I see no reason
> not
> to approve this research.
>
> USDA/APHIS Response:
>
> There are too many organisms to list that are regulated, so they
> advise
> that a permit be applied for and if not applicabale, they will send
a
> letter to that effect (shouldn't take more than a month or so). By
the
> way, the person who was supposed to call me back no longer works at

> USDA. I guess that explains why I wasn't called back!

>

> -----Original Message-----

> From: IBC VPR [mailto:ibc@tamu.edu]

> Sent: Friday, April 01, 2005 12:21 PM

> To: Mattox, Brent S

> Cc: Dianne Cornett

> Subject: THIRD REMINDER: IBC: 2005002-Bowden

> Importance: High

>

>

> ** High Priority **

>

> Brent-

>

> Below is the comments that were made by the IBC chairs on the latest

> revision of 2005002-Bowden and attached is the application

submitted.

> Please let me know your comments on this protocol.

>

>

> -----

> 2005002-Bowden

> Are these organisms considered to be of no risk to livestock and/or

> poultry. If they are then USDA import permits should be obtained and

> they are not to my knowledge replaceable by CDC permits. If they are

> not

> then the investigator should state such.

>

> Posted by: Thomas Ficht

>

> -----

>

>

> Thank you,

>

> Amanda Pietsch

> VPR Compliance Office

> Institutional Biosafety Committee

> 979-458-3624

From: Mattox, Brent S
Sent: Monday, May 02, 2005 10:44 AM
To: 'Tom Ficht'
Cc: Raines, Angelia
Subject: RE: feral pig update

Follow Up Flag: Follow up
Flag Status: Red

Progress, so to speak. I spoke to USDA who said that CDC (not us) had to send the inspection report. I then talked to CDC who said they thought it had already been sent, but would check on the status and let me know. After that, I will either get CDC to send it or notify USDA that it is in their possession.

I will keep you informed,

Brent

-----Original Message-----

From: Tom Ficht [mailto:tficht@cvm.tamu.edu]
Sent: Sunday, May 01, 2005 12:55 PM
To: gadams@cvm.tamu.edu
Cc: Cornett Dianne; Mattox, Brent S
Subject: Re: feral pig update

Garry

In order to receive such samples from out of state I would require a VS16-3 form. Since I am within the state, perhaps this does not apply. I will ask for guidance from EHSD concerning this issue.

However, I will use this opportunity to again request that the compliance office or EHSD please forward a copy or request that CDC forward a copy of our BL3 lab report to USDA/APHIS in order to obtain approval of my VS16-3 permit for which I applied in November 2004. Based on past experience, this license will be up for renewal again in November and I will be again charged \$150.

The best part of this is that the USDA/APHIS requested this report despite the fact that they inspected the labs themselves prior to the previous CDC inspection (with a three year renewal) and charged us \$900. At least CDC does it for "free".

taf

On Apr 30, 2005, at 7:17 AM, Garry Adams wrote:

> Tom, I have been communicating with Ken Wadrup the last several weeks
> to obtain these strains. Please provide me guidance if/how you would
> like for me to proceed? My thought was to add to the wild type library
> of Brucella from anywhere we can obtain them. Maybe consider AFLP or
> HOOFF printing a la Bricker style as a summer student project?
>

> Anyway, your thoughts please, obviously following all rules.
>

> Garry

> -----Original Message-----

> From: Ken Waldrup <kenw@tahc.state.tx.us>
> Date: Sat, 30 Apr 2005 05:49:23
> To: ddavis@cvm.tamu.edu, gadams@cvm.tamu.edu, DLWilliams@cvm.tamu.edu,

> jmusser@cvm.tamu.edu
> Cc:mcoats@tahc.state.tx.us
> Subject: feral pig update
>
> Hello All,
> We have culture results now, and, to no great surprise, we did not
> culture
> B. abortus out of any of the feral pigs. We cultured B. suis biovar 1
> out
> of two animals - one sero-reactor (#12) and one sero-negative
> (#5). Spacially both of these pigs were killed west of HW 148. Our
> infected cattle herd was also west of HW 148. None of the pigs killed
> east
> of HW 148 were sero- or culture positive.
> Dr. Adams, I am requesting B. suis cultures from these two pigs and
> from
> the infected cow for you from Rick Nabors. Is there an official
> process
> and/or paperwork to transfer these cultures to your lab now?
> Dr. Musser, Dr. Coats and I will be further analyzing the spacial
> distribution of the pigs and will be looking to present this at USAHA
> in
> Hershey. Obviously any additional data on the genetics of the B. suis
> cultures at hand would be appreciated. Thank you for your thoughts and
> consideration.
> Ken W
>
>
> L. Garry Adams, DVM, PhD, DACVP
> Associate Dean for Research & Graduate Studies
> College Station, TX 77843-4461
> gadams@cvm.tamu.edu
> 979-845-5092 office
> 979-845-5088 fax

From: Mattox, Brent S
Sent: Monday, September 15, 2003 2:09 PM
To: Meyer, Chris
Subject: FW: FW: USDA Investigation

FYI

-----Original Message-----

From: Mattox, Brent S
Sent: Monday, September 15, 2003 2:07 PM
To: Adams, Richard
Subject: RE: FW: USDA Investigation

Dr. Adams:

To help clarify the issue, I will provide a brief overview of the actions taken to this point as I know them.

On 5/16/03, LSU shipped *Brucella melitensis* cultures interstate to Dr. Ficht at our Campus. Dr. Davis actually went to LSU and transported it. Prior to the shipment, a permit to ship was issued by CDC (EA101), which the researchers at LSU and A&M and Virginia Brown of our office took to be all they needed. In fact, Dr. Ficht had contacted the USDA Lab in Ames who indicated that was all they used. Unfortunately, no one contacted APHIS at USDA, who share a different opinion.

On 6/10/03, Eddy Carter, a Senior Staff Veterinarian at APHIS requested an investigation into the 5/16/03 transfer. A Morris Smith of the USDA Investigative Enforcement Services was assigned the investigation. Mr. Smith then requested Mike Mills, a USDA investigator to interview the folks at LSU about the incident. Mr. Mills came across in a very confrontational manner according to LSU.

Legal Council was consulted concerning the affair and appeared at the Institutional Biosafety Committee to discuss the issue. Their review initial review of the regulations followed the view that even though the interim rule we were complying with seemed to be satisfied (EA 101 CDC), the older 1953 USDA rule would still apply. They then stated the opinion that the matter was between Dr. Ficht and the USDA, and he should hire a Lawyer, as the Legal Council would not defend his personal actions (my interpretation, you may want to get a second opinion from Dr. Buckley or Dr. Gary Adams). It is my understanding that the USDA treats violations as a criminal misdemeanor, punishable by a \$1000.00 fine and up to one year in jail for the perpetrator. There was then some correspondence between Dr. G. Adams and USDA, referenced in his reply to the summary of the meeting that hopefully would speed up the resolution of the incident.

Dr. Ficht was contacted by Mr. Smith that he would like to meet with him on 9/10/03 on our Campus. The meeting took place on 9/10/03 as outlined in the summary. I used the term "alleged" to describe the VS 16-3 to signify that USDA had not made a decision in this particular instance, although their view is now well established. I would also note that prior to 9/11 USDA did not enforce the interstate provisions on shipping select agents, instead concentrating on the international shipping. I think this added to the confusion for the people involved.

In conclusion, these are the events leading up to the meeting as I understand them. The Vice President for Research's Office, the IBC, and Legal Council have been involved up to this point, as has EHSD through our representation on the IBC and as Alternate Responsible Officers for select agent control. We have no way of knowing how substantial the fines or penalties will be, the Investigator implied not much would become of it and fines appear limited.

I hope this helps explains the issue and where we now stand. Let me know if I can be of further assistance.

Sincerely,

Brent S. Mattox, CIH
Manager of Industrial Hygiene
Environmental Health and Safety Department

-----Original Message-----

From: Adams, Richard
Sent: Saturday, September 13, 2003 10:21 AM
To: Mattox, Brent S
Cc: Garry Adams; Perry, Bill L; Meyer, Chris
Subject: Re: FW: USDA Investigation

I assume a university counsel was present at the meeting or was briefed about the situation and approved the interview, etc? I see the term "allegedly required by USDA", which suggests we do not know for sure if VS-3-16 is in fact actually required instead of CDC EA 101. I would think legal counsel would have required we determine whether law indicates the USDA permit is an absolute requirement. If we still think "allegedly" and we are now expecting a letter or even a fine, it will not be surprising if the letter and/or fine are very substantial penalties.

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 09/12/03 04:10PM >>>
Dr. Perry requested I forward the attached summary of a meeting between USDA and the University. If you need any additional information, let me know.

Sincerely,

Brent S. Mattox, CIH
Manager of Industrial Hygiene
Environmental Health and Safety Department

-----Original Message-----

From: Mattox, Brent S
Sent: Wednesday, September 10, 2003 8:07 PM
To: Perry, Bill L
Cc: Floyd, Rick; Meyer, Chris
Subject: USDA Investigation

A meeting was held with an investigator from the USDA concerning the Brucella melitensis transfer between A&M and LSU. Present at the meeting were Morris Smith with the USDA, Dr. Thomas Ficht, Dr. Donald Davis, Dr. Mike Buckley, and Brent Mattox. The Investigator indicated that his sole purpose was to collect information for an investigation requested by Eddy R. Carter, DVM of the National Center for Import and Export, USDA. The Investigator was very non-confrontational, and stated that no one had to answer any questions if they chose not to.

The main argument continues to be the failure to obtain a USDA VS 16-3, an import/export permit allegedly required by USDA. As stated previously, the feeling expressed to the Investigator was that Texas A&M thought it was in compliance at the time of the transfer because of the possession of an EA 101 authorization number granted by CDC. The Investigator requested and received copies of the CDC authorization and the signed shipping receipt (signed by Dr. Davis) verifying the Institution's good faith effort at transfer documentation. After a detailed discussion outlining the events surrounding the transfer, an affidavit was taken from Dr. Ficht (in private between Investigator and Dr. Ficht). I would note that Morris Smith had requested that the LSU interviews, and I assume will be compiling the final report.

In summary, the meeting took on a very non-confrontational and cooperative tone, and concluded amicably enough. The Investigator (incidentally Morris Smith turns out to be an Aggie Class of 84 grad) implied that he did not think much would come of the issue, and doubted much action would be taken (suggested a letter, possibly a fine at worst). He stressed this was only his opinion, but I view the comments as encouraging. The completed investigation will be forwarded no later than the end of next week for action.

If you have any questions or desire a more detailed description of the conversations, please let me know.

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Manager of Industrial Hygiene
Environmental Health and Safety Department
4472 TAMU

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