

PUBLIC MEETING ON VIRAL HEMORRHAGIC SEPTICEMIA

January 9th, 2007, 8:30 a.m.

U.S. Fish and Wildlife Services Office
134 Union Boulevard, First Floor Conference Room
Lakewood, Colorado

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P R O C E E D I N G S

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2 MICHAEL TUCK, USDA, APHIS: I would like to welcome
3 everyone to Lakewood, Colorado for this public meet to discuss
4 viral hemorrhagic septicemia or VHS. This is one of four
5 sessions being held around the country to allow interested
6 parties the opportunity to comment on the national response plan
7 for the disease. The other meetings are today in Memphis, and
8 tomorrow in Detroit or Romulus, and Pittsburgh.

9 My name is Mike Tuck, and I work with the USDA Animal
10 and Plant Health Inspection Service, or APHIS, and I will be
11 moderating the session today to ensure everyone has the
12 opportunity to provide input.

13 If you have not done so, please register using the
14 sign-in sheet here. I'll use those sheets to call the speakers
15 up to give comments.

16 We will begin the session with opening remarks from
17 APHIS staff and then provide time for comments from the public.
18 We'll allow each speaker a certain amount of time, depending on
19 how many speakers we have that have signed the list.

20 When all the speakers are finished and the APHIS
21 representatives respond to comments, we'll then provide some
22 closing comments.

23 The meeting is scheduled to go to noon, but we may
24 finish early if the discussion permits.

25 A couple of meeting guidelines. Please keep your

1 conversations at a minimum so everyone will be able to hear the
2 speakers. Be courteous to the speakers even if they differ in
3 opinion from what you have. And please turn off your cell
4 phones or turn them to vibrate. If you need to take a call,
5 please take it outside the room.

6 At this time, I'd like to introduce a couple of people.
7 We have with us from USDA VS Roger Perkins, who's the area
8 veterinarian in charge.

9 Roger?

10 ROGER PERKINS, AREA VETERINARIAN: Good morning, folks.

11 MR. TUCK: Also, we have Dr. Peter Merrill, who is the
12 senior staff veterinarian and aquacultural specialist for APHIS,
13 VS, National Center of Import and Export. And Dr. Paul or
14 Gary Egrie, Veterinarian Service Medical Officer and
15 Aquacultural Specialist for APHIS, VS, National Center of Animal
16 Health Programs.

17 At this time, I would like to turn it over to
18 Dr. Merrill, who will provide the opening comments and the
19 purpose of the meeting.

20 Dr. Merrill?

21 DR. PETER MERRILL, APHIS, VS, NATIONAL CENTER OF ANIMAL
22 HEALTH PROGRAMS: Can everybody here me okay?

23 Thank you, Mike.

24 And welcome, everybody, to Lakewood. And we certainly
25 would like to express our thanks to Fish and Wildlife for the

1 use of their building and facilities for this public meeting.

2 Again, I'm Dr. Peter Merrill from APHIS, and I work in
3 close conjunction with my colleague, Dr. Gary Egrie and
4 Dr. Jill Roland, who's not present. We have different staffs,
5 but we work very closely together. We have the same concerns,
6 almost the same issues -- they, on the interstate and national
7 program level, and my staff deals with import and export issues.

8 So our first slide is called, "What is VHS?" And I'm
9 including this as a general and brief background and a little
10 bit of chronology for everybody's benefit. I realize I'm
11 preaching a little bit to the choir here, but what I'm going to
12 say sets the stage for what's going to be going forward from
13 this point.

14 VHS is a viral disease that affects a number of fin
15 fish species in a variety of environments, both fresh water and
16 salt water. And I think nobody would disagree that VHS
17 worldwide has to be considered one of the primary diseases of
18 fish and one of the most serious that's caused a lot of problems
19 historically in a lot of different places. It's definitely a
20 disease that we want to avoid to the extent that we can avoid
21 it.

22 It's listed by the OIE as a notifiable disease, and
23 they have a certain list of criteria for which diseases are
24 notifiable. This is certainly one.

25 The virus itself has been around for some 40 years in

1 identifiable form. There are a number of strains, but we can
2 infer from the genetic sequencing that the virus has been around
3 for a much longer time than 40 years. It's just that that was
4 when it was first isolated in Europe. And up until a couple of
5 years ago, there were, basically, four known strains.

6 And now, even though there isn't a lot of scientific
7 information to support it, we almost all agree in the fish
8 health community that there is now a fifth strain of the virus,
9 and pretty much that's why we're here today to discuss the
10 implications of that emergence.

11 These strains differ in the ways in which disease might
12 be expressed, the species that are affected, and even the
13 environments in which fish may become infected or diseased.

14 Okay, Gary.

15 Now, the top bullet says, "VHS infection causes disease
16 in susceptible fish," and that statement bears quite a bit of
17 discussion. I'm not going to go into all the scientific
18 implications there, because we probably don't know the true
19 extent of all the susceptible species for VHS with all the
20 strains and the environments, temperature regimes, and other
21 factors involved.

22 We know already that there are some 65 species of fish
23 that can be infected by this virus in one form or another. Some
24 of them develop disease and die. Others don't show any signs of
25 disease but die. Others don't show any signs of disease but can

1 carry the virus, perhaps shed and spread it. And we can detect
2 that virus by exquisitely sensitive tests, but simply finding it
3 in a fish species doesn't automatically mean that that is a
4 susceptible species. So we have to be very careful in the way
5 that we define these terms.

6 We understand some of the mechanisms by which VHS virus
7 spread. We presume that because it's present in various types
8 of secretions -- urine and feces and mucous -- it's probably
9 spread through close contact, but there might be some other
10 mechanisms, maybe intermediate hosts. We're not sure. The
11 virus can survive for some time in water by itself.

12 Critical signs in the fish that do develop disease
13 include sluggishness, darkening, pale gills, hemorrhage. These
14 are all very nonspecific kinds of signs that could pertain to
15 any of a number of bacterial or viral infections as well, and
16 they're quite variable. Some species develop very consistent
17 types of clinical signs, others don't.

18 Now, before -- basically, last year, 2005, the
19 outbreaks of VHS in the U.S. were mainly due to what was called
20 the North American or Type 4 strain. And that was found mostly
21 in a small number, relatively small number of marine fish
22 species on both coasts of North America. We used to call that
23 Type 4. We now call that Type 4-A. And most of those
24 epizootics or die-offs probably went undetected, unreported, so
25 we don't really know the true extent of VHS, but there were a

1 few outbreaks before 2005.

2 Now, these slides demonstrate a couple of these
3 nonspecific types of signs where fish will get extended abdomens
4 that's mostly from fluid that's accumulating as their organs
5 stop functioning properly, darkening. I think you can see from
6 the right picture there are some hemorrhages showing up there in
7 the fat and on various internal organs.

8 Next slide. And courtesy of one of our researchers in
9 Michigan State, these fish were also found to have this new
10 strain of the HS virus. And this is kind of a typical
11 presentation of fish that have been involved in die-offs.
12 You'll get petechial or widespread types of hemorrhages on the
13 skin and various organs, especially on ventral surfaces,
14 sometimes even in the eye. But, once again, this doesn't
15 differentiate VHS from anything else. It's just that we know
16 these fish actually did have VHS.

17 Now, in the Great Lakes, in 2005, we had a report of
18 VHS virus that have been isolated from round gobies in the
19 St. Lawrence River on the Canadian side. This represented a
20 shift in susceptibility. We had not seen this virus before in
21 fresh water in this fashion or in the species. And probably a
22 number of people would think, round gobies, great. They're an
23 invasive or nuisance species to begin with, and if it kills
24 them, so much the better.

25 But it was the first indication of the report, anyway,

1 that something was changing. And then that was followed by
2 publication of results that had come from a muskellunge that had
3 actually died a couple of years before and had just not been
4 tested. The samples had been archived.

5 It was later discovered that this same variant of the
6 virus was found in a muskellunge that had been collected in
7 2003. So back dating, we now knew in 2006 that this virus had
8 been around for some two or three years. But that was just the
9 tip of the ice berg.

10 Next slide, Gary.

11 During 2006, there were a number of reports of die-offs
12 of fish, and once again, it can be very difficult to collect
13 timely samples or usable samples, and occasionally, the results
14 would vary. But we did discover that this new variant of the
15 virus was occurring in a number of species that, presumably --
16 that previously had not been known to be susceptible -- new
17 locations, brackish water, fresh water, and in temperature
18 conditions that we believe would inhibit replication of the
19 virus before these events started.

20 And some of those locations included Lake Ontario, Lake
21 St. Clair, Lake Erie. And there's a certain epidemiology
22 involved in the Great Lakes in terms of the way the watersheds
23 interact with each other, and there's certainly connections
24 among the Great Lakes.

25 But, interestingly, there was another isolation of this

1 virus from several species in Conesus Lake, New York, one of the
2 finger lakes. There's no direct connection to the Great Lakes,
3 a number of barriers in between. And that in itself pointed out
4 to regulatory agencies that something was involved that didn't
5 necessarily involve the transmission of this virus just by
6 water. There were probably other factors involved -- human
7 actions and so on.

8 Next slide. I put about 25 species up here of fish
9 that are susceptible to VHS virus in the sense that we have
10 detected virus from these fish. In almost every case here, we
11 have isolated virus from these fish. This means that the virus
12 itself is replicating in these fish.

13 And if you look at this list, it's immediately apparent
14 that there are recreational fish, there are food fish, there are
15 bait fish, there are stocking enhancement, and conservation
16 fish. There's a lot of different fish involved. And this is
17 very unusual behavior for a virus to affect so many new types of
18 fish so quickly and in a new environment as well.

19 Next slide. So all too often, this is the kind of
20 thing that would be reported, and by the time people could
21 actually get out, investigate these die-offs, occasionally, we
22 would get reliable samples, sometimes we wouldn't. The range of
23 die-offs would go from anywhere from a few fish to hundreds of
24 thousands of fish; probably many die-offs went entirely
25 unreported or untested.

1 So up till about the middle of 2006 or the end of 2006,
2 this kind of summarized what had happened as far as VHS
3 outbreaks.

4 Next slide. So why is it important now? Well, it's
5 safe to say that something happened with this virus between 2003
6 and 2006. It, essentially, has mutated into a new strain that
7 affects new hosts and it affects them in new environments.

8 And if you think about the factors that are involved in
9 disease expression, this represents a kind of perfect storm of
10 virus development in that respect.

11 There are no effective treatments for VHS. People have
12 been working on vaccines and continue to work on vaccines.
13 Nothing has been proven to be effective in any sense. Research
14 will continue in that regard.

15 But I think the central statement on this slide and the
16 central statement that we're here to discuss today is that when
17 we reviewed the factors involved in this phenomenon, in
18 conjunction with inputs that we had from the public, from a
19 number of state regulatory agencies, and from a number of other
20 federal partners as well, that we came to the conclusion that
21 the unregulated movement of VHS-susceptible species would
22 certainly put the health of U.S. farm fish at risk. And there
23 is a lot behind that statement, and we're going to be
24 entertaining comments from you today to either support or to
25 debate that particular statement, but it's up there for your

1 perusal.

2 The regulations that different states have right now
3 and are developing are highly variable and range from very
4 restrictive, even exclusive, to nonexistent. This is part of
5 the problem to date, because unless there's a consistency of
6 fish health regulations that govern the way that fish move and
7 approach to try to keep VHS out of areas where it doesn't exist
8 now is almost doomed to be ineffective. And there are definite
9 areas where this virus and where this disease are known to
10 exist.

11 Now, we don't know where the virus is not. We have not
12 investigated that. We're certainly in the process of setting up
13 a surveillance system by which we hope to determine the
14 prevalence of the virus, the distribution of this virus. It
15 could be everywhere, it could be nowhere. It could be just in a
16 few places. We're presuming right now that it's in very limited
17 distribution, mainly in that Great Lakes watershed, and we
18 certainly want to keep it there. And by "we," I mean everybody
19 involved in fish health. We do not want this disease to spread
20 to farm fish. That's almost a non sequitur. If it gets into
21 farm fish, it will be very difficult to get it out of farm fish
22 without eradicating those fish.

23 Next slide. Well, APHIS -- I'm shifting gears a little
24 bit and talking about how our agency became involved. We have
25 had historical involvement with fish through our ISA program,

1 which stands for infectious salmon anemia. The agency has dealt
2 with infectious salmon anemia now for five years plus in a
3 demonstrably successful program in Maine, for the most part.

4 And more recently, we developed regulations for spring
5 viremia of carp whereby we regulate the eight susceptible
6 species coming into this country, including koi and goldfish
7 from anywhere in the world. We don't have very many interstate
8 requirements for either of these two diseases. We can limit the
9 movement of diseased fish if either of these diseases were known
10 to occur in farm fish.

11 But under the Animal Health Protection Act of 2002, we
12 have very broad authority as a U.S. competent authority for
13 aquatic animals and for farm animals to detect and control or
14 eradicate diseases of livestock, and we have since defined fish
15 as animals and livestock, essential farm fish.

16 Now, we do this in conjunction with at least two other
17 federal agencies, namely, U.S. Fish and Wildlife and the
18 National Oceanic Atmospheric Administration, and National Green
19 Fisheries Service. They are our co-competent authorities for
20 aquatic animals as well. We won't go into all the nuances of
21 those relationships, but we have very strong interdependent
22 relationships for farmed and wild aquatic animals of many types,
23 particularly for fin fish.

24 Next slide. The regulations that exist today for VHS
25 were developed under what's called a federal order, and that's a

1 mechanism that was picked by our administrators to put together
2 some requirements that represent emergency actions. We take
3 those to limit the spread of a disease such as VHS, but they've
4 been -- other diseases have been dealt with by federal orders
5 before. They're temporary, administrative measures when there
6 really isn't time to write a thorough and comprehensive
7 risk-based kind of an approach. And we do need to follow up a
8 federal order by formal rule making, and we're in the process of
9 starting that right now.

10 The federal order that is in effect today was
11 originally issued on October 24th, amended a few weeks later to
12 be a little bit clearer and a little bit more facilitative.

13 Next slide. And currently, that order says that
14 susceptible species of fish -- and we have a list of 37 that are
15 on the Internet right now -- are prohibited from moving out of
16 the eight states that border the Great Lakes and from entering
17 the U.S. from the two Canadian provinces of Ontario and Quebec,
18 unless those fish meet those conditions that I have listed there
19 in white. So they can move to slaughter under certain form as
20 long as the disinfection of any effluent is being taken care of.
21 They can be sent to a research or diagnostic facility as long,
22 again, as adequate biosecurity is being met. And very
23 importantly, fish can be moved live if they test negative for
24 the virus by laboratory assays.

25 Now, we have delegated the appropriateness of those

1 assays and labs and people who do the collection and various
2 other components to the states and to tribes and even to other
3 federal agencies in terms of approving what is an appropriate
4 kind of a test. So we have tried to facilitate movement to the
5 extent that we can without compromising what our federal order
6 is about in terms of limiting the distribution of VHS.

7 And fish can come in from the two provinces in Canada
8 if they're salmonid species and they meet the U.S. Fish and
9 Wildlife's Title 50 requirements. Basically, 150 fish would be
10 tested out of that group, and if they test negative for VHS
11 virus, they can be imported into the U.S.

12 Next slide. So our next step is to develop a rule or
13 regulation that will replace our existing federal order. And
14 what we're here today to talk about is really the scope of what
15 that regulation could include.

16 For instance, would we want to take in a
17 watershed-based approach to determining the spread of VHS and
18 possible control of VHS? Do we want to not look at watersheds
19 but really limit ourselves to more jurisdictional geographic
20 degrees such as states or regions? Do we want to include the
21 eight states that border the Great Lakes in one way or another
22 or just the four states that have reported outbreaks, namely,
23 New York, Pennsylvania, Ohio, and Michigan? Do we include all
24 50 states, all countries and the rest of the world, all the
25 strains and virus? Because even though this new strain Type 4B

1 is the most problematic for those 25 species of fish that we had
2 before, there are marine strains of this virus, and there is no
3 guarantee that any of those marine strains could not continue to
4 mutate. We think that's how this new strain developed. It
5 mutated probably out of the Type 4 marine-based virus strain.
6 It could happen again.

7 The strain that we have now, the new Type 4B, could
8 continue to mutate as well. That becomes very difficult if you
9 use a very specific strain-based regulation in case that strain
10 continues to change.

11 And, we also have to provide in our regulation for the
12 specifics of how we're going to be doing testing and how we're
13 going to be certifying fish to allow movement and for trade
14 commerce to continue to take place.

15 Inherent in all of that is really sort of defining and
16 refining what we are calling susceptible species. And I think
17 that is a subject that we can discuss at greater length in a few
18 minutes.

19 Next slide. So we need, as I said before, with
20 Dr. Egrie's staff and my staff, we need to harmonize the
21 regulatory approach so that our import and our interstate
22 regulations parallel each other and complement each other. In
23 fact, we are obligated to do this because of OIE and world trade
24 organization considerations. But it also makes good, logical
25 sense as well. You don't want to have weaker regulations on

1 import compared to interstate or vice versa.

2 So we need to define what those import or entry
3 criteria would be in terms of kinds of permits that people might
4 need, where they would bring these fish in from, the types of
5 health certificates and assurances that we would want to see.

6 And we need to do the exact same thing on the
7 interstate level as well, and we need to do this, taking into
8 account all of the state involvements and recognizing industries
9 concerns, and acknowledging the amount of information that is
10 known and is not known as well.

11 Next slide. So the purpose of these meetings, as Mike
12 indicated before, is really to receive comments from you, the
13 public, on how you might suggest our regulatory approach proceed
14 from here.

15 We are in the process of commissioning risk assessments
16 for VHS. They're underway. And that will inform our
17 rule-making efforts as we go down the road. It will tell us
18 what we do know, what we don't know, and what we need to know in
19 order to make a good regulation and an effective regulation.
20 But we can also get comments from you as well that might help us
21 in that respect.

22 So your inputs will be recorded. We have a
23 stenographer here today. And if possible, we'll try to arrange
24 for comments to be put onto the Web for review at some point in
25 the future. And then we will consider everything that we hear

1 during these next few months, because we want to develop these
2 regulations as soon as possible.

3 It's still an emergency situation as far as APHIS is
4 concerned. Nothing has changed to make us think that this is
5 still not an emergency situation. It's been developing for a
6 few years, but with the spring coming and temperatures changing,
7 the risks of unregulated movements of fish into and through the
8 United States is just as great today as it was a couple of
9 months ago or last year.

10 The federal order will help in that respect. It will
11 not solve all of our problems. We hope to improve on the
12 federal order through the development of the next part of the
13 rule-making process.

14 We're proceeding as though we're doing this as an
15 interim rule. That's the most effective way for us to get this
16 done in a timely manner. But that could change also.

17 We'll take comments through the close of business
18 tomorrow, essentially, that you might want to give in written
19 form, or anything that you say today will be accepted as
20 comments as well.

21 Next slide. If you want to e-mail any of the four of
22 us who are directly involved in these rule-making inputs, our
23 addresses are here. We can provide those to you later.

24 And there's an Internet link at the bottom of the slide
25 that, I think, also, you can get in one of our handouts up here

1 if you wish, that will summarize almost everything that I have
2 said today here that we know about VHS and the VHS virus.

3 At the point that a rule is published, you, the public,
4 will also have an opportunity to make additional comments for a
5 specified period of time, but that will be down the road, so
6 this is your opportunity today.

7 We will be happy to answer questions given the size of
8 the number of people in the room. We don't want to get into a
9 debate, really, about what has been done so far and what our
10 thinking was or why we did it, why we're putting people out of
11 business. That's in the past. We're going forward from here.

12 We want to make the best rule that we can to address
13 all of these very complex issues for a very serious disease.

14 So, please -- I think I'll pass it back to Mike for the
15 order of people who wish to speak today. And we'll be happy to
16 take your comments. And to the extent that we can respond,
17 Dr. Egrie and I will do so. And then we can open the floor to a
18 more informal question and answer session if we have time as
19 well. So that's really all I have to say.

20 Thank you, Mike.

21 MR. TUCK: Thank you, Dr. Merrill.

22 I'd like to describe the process we'll use for this
23 public input of this portion of the meeting. First off, I'd
24 like to introduce Karen Michelsen, who is our transcriber. As
25 Dr. Merrill said, she's transcribing everything that's said in

1 this meeting, and hopefully, we'll be able to put the transcript
2 of this meeting up on the Web.

3 This is the part of the listening session where the VS
4 staff is going to hear your comments so you can provide input
5 into the process.

6 I'll call each speaker up in the order they've signed
7 up to speak. If you haven't done so, please sign up if you wish
8 to speak. When you begin, please provide your name and the
9 affiliation that you're representing so that we can capture
10 that.

11 And with that, I'd like to call Doug Burton, who is our
12 first and only speaker who has signed up as of right now.

13 DOUG BURTON, FISHERY PATHOLOGIST, IDAHO DEPARTMENT OF
14 FISH AND GAME: My name is Doug Burton. I'm a fishery
15 pathologist with the Idaho Department of Fish and Game. And as
16 such, I'm speaking as a representative of our state department.

17 I brought a written letter that I have submitted. I
18 can say that we ran this letter by a number of other groups
19 within our state -- the university, some private commercial
20 people -- and we got no objections to what we're going to say.
21 So while I'm strictly a representative of Fish and Game, we do
22 feel that we're -- this letter is a pretty good representation
23 of the opinion of the aquaculture industry and conservation
24 agencies within the state of Idaho.

25 So, to APHIS and the presiding officers, the Idaho

1 Department of Fish and Game appreciates this opportunity to
2 provide comments supporting the USDA-APHIS efforts to restrict
3 the dissemination of viral hemorrhagic septicemia beyond the
4 current endemic area in the Great Lakes basin.

5 Our department considers VHS a significant risk to
6 private and public aquaculture in Idaho as well as to the public
7 fishery resources of the state.

8 The Idaho Department of Fish and Game supports efforts
9 taken to date by USDA-APHIS and acknowledges that these
10 restrictions of live fish movements are going to adversely
11 affect some conservation programs and some private individuals.

12 These restrictions on movements are necessary interim
13 measures to contain the virus and to prevent rapid dissemination
14 until further research may demonstrate that the risk of this
15 virus is lower than we currently perceive.

16 The fishery resources of Idaho include the nation's
17 largest commercial trout production industry, an extensive
18 federal, state, and tribal conservation aquaculture program,
19 several aquaculture research programs or academic institutions,
20 and sport fishing industry on a free-ranging fisheries that has
21 an estimated annual value of \$450 million.

22 These various forms of aquaculture and natural
23 resources would be adversely impacted if VHSV were introduced
24 and established in our state.

25 To date, Idaho Department of Fish and Game has taken

1 the following measures to illustrate the department's view of
2 the serious nature of this threat:

3 We have imposed an embargo on all live fish, viable
4 eggs, and gametes from the Great Lake basin endemic area as of
5 July 2006.

6 Our state drafted and endorsed a resolution which was
7 passed in October 2006 by the Pacific Northwest Fish Health
8 Protection Committee, a group which encompasses both state,
9 federal, tribal, and commercial entities within the northwest.

10 This resolution passed an embargo on all fish movement
11 from the VHS endemic area into the PNFHPC area of concern and
12 also targets unprocessed, frozen whole fish, while encouraging
13 funding for research and improved diagnostic tests.

14 We have mailed letters to all the fish bait dealers
15 within Idaho informing them of this prohibition, and we have
16 sought agreements with surrounding states on what efforts we may
17 do to develop other sources of fish that we need for our
18 conservation program. One example being tiger muskies.

19 Our department encourages APHIS to continue its efforts
20 to reduce the dissemination of VHS through the regulatory
21 process, while still acknowledging a few facts.

22 First, the respective fisheries agencies have primacy
23 to preserve, protect, and perpetuate and manage the fisheries
24 resources within their individual states; that the laws of many
25 states will vary in their definition of cultured aquatic species

1 and game species, and which state agencies within each state may
2 have jurisdiction over those.

3 The individual state policies also vary concerning
4 which pathogens, including VHS, are of concern within their
5 jurisdictions.

6 Finally, we wish to point out that there already exists
7 several industry and public agency cooperative groups such as
8 the PNFHPC with expertise in fish health, and we encourage APHIS
9 to seek their assistance in a joint containment effort.

10 We encourage APHIS to include aquatic enforcement
11 provisions into their rule-making process, because without
12 enforcement, such rules are not likely to be effective. And the
13 efforts to contain this virus, if done by individual states or
14 individual groups, will probably not be successful. Thank you
15 very much.

16 MR. TUCK: Thank you, Doug.

17 Is there anybody else in the audience that would like
18 to speak?

19 With that, I'd like to open up the floor to any
20 comments or questions about the presentation Dr. Merrill gave.

21 Yes, sir.

22 STEVE HALLBERG, GREEN RIVER TROUT FARM: I notice that
23 the affected or at-risk regions included, basically, all the
24 states that border the Great Lakes. I'm wondering why the
25 states that border the Mississippi River are not on that list.

1 MR. TUCK: Please state your name.

2 MR. HALLBERG: Steve Hallberg, Green River Trout Farm.

3 DR. R. GARY EGRIE, VMD, AQUACULTURE SPECIALIST, USDA,

4 APHIS: Did everyone hear that question? Okay, so the question
5 was: Why -- basically, we listed the states where we've seen
6 the pathogen, we've seen the disease are New York, Pennsylvania,
7 Ohio, and Michigan, yet the federal order also affects the
8 states of Indiana, Illinois, Wisconsin, and Minnesota. But
9 there is a connection through the Chicago Sanitary Waterway that
10 connects Lake Michigan, the southern part of Lake Michigan,
11 where we have not seen the disease, with the Illinois River.
12 The Illinois River then connects with the Mississippi River all
13 the way down to Louisiana. So the question is: Why didn't we
14 consider the states that are also connected through that
15 waterway.

16 At the same time, there are connections through the
17 Erie Canal going out to Hudson River and going down into
18 New York Bight. And so there are connections all over the
19 place, and so when we're making these regulatory decisions, we
20 have to draw a line in the sand somewhere. And the decision was
21 made that there is an electric barrier at the entrance to the
22 Chicago Sanitary Canal that prevents the movement of fish south
23 from Lake Michigan and north from Illinois River into
24 Lake Michigan.

25 And Peter was mentioning that the transmission of VHS,

1 we believe, is most likely through the contact, fish-to-fish
2 contact, or through the excrements. It could survive in water,
3 but we still believe that the highest likely transmission is
4 going to be through fish-to-fish contact. And since there is
5 the electric barrier at the sanitary canal in Chicago, we made
6 the decision that we will include those four states where we
7 have seen disease and then the other four where we have not seen
8 disease but we know there are natural fish movements.

9 MR. HALLBERG: Thank you.

10 DR. EGRIE: Thank you.

11 DR. MERRILL: I'll add another comment to that. When
12 we looked at the ways that fish were being moved from state to
13 state, it really made sense to include those eight states
14 bordering the Great Lakes, the ones that are contiguous with the
15 states that had reported outbreaks, because that is where the
16 trade actually occurs. And we did look at trends of movements
17 among those eight states and states that are outside of those
18 eight states as well.

19 The point could be made that all 50 states are at risk,
20 because they are, including Hawaii and Alaska. And, really, it
21 also depends on how many strains of the virus we're going to be
22 concerned with in the regulation, because a number of states
23 like Maine or Alaska, Washington state, Oregon, you know, have
24 been involved in outbreaks of other types of VHS virus of former
25 Type 4 or 4A.

1 So, again, our risk assessments will, hopefully,
2 provide some better level of detail about those risks down the
3 road.

4 MR. HALLBERG: Thank you.

5 DR. EGRIE: And one more thing. May I take the
6 question and turn it around to you, since this is a public
7 meeting, and we want to hear your comments. And rather than
8 asking us the question, I would like to hear from you. What do
9 you think should be included in future regulations?

10 MR. HALLBERG: Well, considering the possible impact on
11 the industry, I think the playing field needs to be leveled.
12 Ultimately, it probably will be as -- if this disease spreads.

13 I own a trout farm in Michigan, and I live here in the
14 wintertime. And our Michigan Aquaculture Association asked me
15 to be present at this meeting. I'm not really up to speed on
16 VHS at all. We're a very small operation. But I was concerned
17 about the three trillion gallons of water that go through the
18 Chicago canal every day and, you know, how these regulations
19 will affect our industry. That's basically it.

20 MR. TUCK: Any other questions, comments?

21 CAROLYN GUNN, CDOW: I have a question.

22 MR. TUCK: State your name, please.

23 MS. GUNN: Carolyn Gunn, assistant state fish
24 pathologist for the Colorado Division of Wildlife. And I'm very
25 new so -- but do you have any thoughts on how this virus might

1 be spreading to sort of noncontiguous spots on your first map
2 there? It's spotty. Are those all connected by water, or do
3 you think there are foamites of some sort?

4 DR. EGRIE: All the spots on the map are contiguous, so
5 all the Great Lakes are contiguous. There is one mark on
6 Conesus Lake, which is the western most finger lake. There is a
7 connection. The water flows north from that lake into
8 Lake Erie. Although there is connection, there aren't many
9 barriers, waterfalls and such that it's unlikely a fish would
10 swim up.

11 So the question is: How did the pathogen get into that
12 lake? And our best guesstimate is that somebody took bait fish
13 and drove their boat and went fishing. I'm not blaming
14 fishermen. That's just a guess of what could have happened.
15 And then at the end of the day, threw fish in the water, and
16 that's how the pathogen got into that lake. A bird could have
17 taken it there, some other way possibly, but we think some type
18 of human activity could have been involved in that activity.

19 All the other sites that we've seen mortalities in are
20 connected.

21 MS. GUNN: And are you working on transmission studies,
22 or is somebody working on transmission studies to determine if
23 it is only direct fish-to-fish contact or water or --

24 DR. EGRIE: Well, I know there are a lot of groups out
25 there and universities and federal agencies who are interested

1 in those types of questions. The big question is funding. Who
2 will pay for this? And USDA is looking for that type of funding
3 to support those types of activities.

4 PETER WALKER, COLORADO DIVISION OF WILDLIFE: My name
5 is Peter Walker. I'm the senior state fish pathologist for
6 Colorado Division of Wildlife. I'm concerned about the bait
7 industry. I'm concerned about virtually all of the industries
8 that are nonsalmonid.

9 We have, for years, had regulations here in the system
10 for inspecting our own fish as well as allowing importation only
11 of inspected fish from various states. And I'm fairly confident
12 that VHS is being kept out of Colorado through the regulatory
13 process in salmonids. But we also see so much trade in bait,
14 particularly wild cod bait, and a few other species from the
15 Great Lakes area and, of course, from all other areas.

16 So if it shows up somewhere else, I'm very concerned
17 about protecting our state from those various sources, and
18 particularly, the wild cod baits, because there is so much
19 interchange of fish from so many different sources, that I see
20 that as practically an impossibility short of just banning the
21 trade of bait fish. And I don't think that's going to be very
22 palatable for those who make their living at it, of course. So
23 it looks like a big entanglement, and I do not envy the job that
24 you have in trying to figure out how to handle this from the
25 national level.

1 And, by the way, I do very much appreciate and applaud
2 your efforts at finally bringing us a national regulation of
3 movement of fish diseases.

4 DR. EGRIE: I would like to, at this point, take your
5 comments and turn it into a question for us. So we do have an
6 amended federal order in place, and you mentioned your concern.
7 How do you feel the amended federal order is protecting you now,
8 and how would you suggest that we change it or not change it to
9 protect you in the future?

10 MR. WALKER: Well, we immediately stopped -- our
11 regulations allow us the freedom to, in effect, enforce your
12 embargo. When you said that -- when the USDA came out with
13 their first embargo on shipment of fish from those provinces and
14 states, we immediately backed that up by taking that action.
15 And we will certainly continue to. We may even be tougher at
16 some point as far as allowing fish in from those states
17 depending upon circumstances -- when they were inspected and
18 that type of thing. I'm having a senior moment. My train of
19 thought just left me.

20 DR. EGRIE: We were talking about the amended federal
21 order, and do you think that's protecting you now.

22 MR. WALKER: Part of our problems sometimes -- this is
23 going to make Ken mad, but its process. It takes so long to
24 change regulations, whereas if you're in a position to change
25 regulations immediately on an emergency basis, I appreciate

1 having that. It puts strength in some of the moves that we're
2 forced to make also. It's nice to have uncle backing us up.

3 As far as what can you do, I don't know. We will
4 abide, certainly, by whatever you decide to do. We might go --
5 we might take a more strict stance if it turns out not to be as
6 tight as we want and as tight as our industry wants.

7 The bait fish thing is a really perplexing one for me,
8 because there is a fair amount of importation of bait fish into
9 Colorado. It would be very tough to just say, No, it can't come
10 in without a backing from your agency.

11 DR. EGRIE: Thank you.

12 MR. TUCK: Any other questions?

13 Yes, sir?

14 KEN CLINE, CLINE TROUT FARMS: My name is Ken Cline.
15 I'm an official aquaculture producer here in Colorado. The
16 current amended federal order allows for movement of fish. The
17 practicality -- I guess I'll ask a question. Are you guys aware
18 of any significant movement of fish from or between the Great
19 Lake states at the current time under this amended order? Is it
20 allowing for movement of fish, or are there still some unseen
21 hurdles that are preventing fish to be moved?

22 DR. EGRIE: Okay, well, the comment is, before we came
23 out with the amended federal order -- so when we first came out
24 with that first federal order on the 24th of October, my phone
25 and e-mail were ringing off the hook. We amended it to allow

1 for movement under certain testing regimes, OIE and blue book.

2 Since that time, my phone has stopped ringing, and my
3 e-mails have slowed down. So I believe that the people who can
4 test are testing. The people -- and we hope that we make
5 regulations that people can abide by. We don't want people to
6 feel that they cannot abide by these federal regulations and
7 need to move fish illegally. So we want to make sure that
8 whatever regulations we come out with that they are doable
9 regulations. Are things moving illegally was the question.

10 MR. CLINE: No, that wasn't the question.

11 DR. MERRILL: And Ken brings up a good point that I'll
12 add to, and that is that both on the interstate and the U.S.
13 import levels, we often don't know what is moving in live fish.
14 They're under the radar in many cases.

15 Some people and some states have very good databases
16 for what comes in and goes out; other states don't.

17 On the federal level, salmonids can be tracked to some
18 extent when they come into this country, but then once they're
19 in the country, there's no federal database by which we can
20 access salmonid movements easily or comprehensively. And for
21 nonsalmonids, it's much less reliable than that.

22 So I think, as we go forward, we need to develop a much
23 better tracking system that will allow us to answer your
24 question.

25 And I don't know if anybody else in the room wants to

1 comment on that situation, but I think that's going to be
2 critical in terms of identifying, not only what is moving, but
3 what risks are being addressed by movement.

4 MR. CLINE: Well, I'm not -- I don't know if the
5 industry would be real receptive to an extensive reporting
6 requirement to keep track of all fish movements. That could be
7 a real burden on us to try to keep up with something like that.
8 My question was, you guys have somewhat of a pulse on the
9 industry, whether anecdotally you are aware of fish being moved,
10 because I don't know if they're moving or not, and the current
11 interim -- the current amended ruling is practically allowing
12 fish to move. It seems like it should be.

13 DR. EGRIE: The answer is yes, anecdotally, fish are
14 moving.

15 MR. TUCK: Anybody else?

16 JOHN WOOD, PISCES MOLECULAR: Peter and Gary, I see
17 that you're talking about diagnostic testing, you do blue book
18 and OIE. Does the blue book or the OIE regulations address
19 viral strain types, and are they PCR-based tests? And quick
20 perusal of the literature suggests there's a whole slew of
21 different VHS PCR tests -- regular PCR, RT-PCR, heminested,
22 fully nested, strand-specific, all of these things. What are
23 your thoughts about this? What are your ideas or plans for the
24 interim rule for testing? And finally, how does a lab get
25 approved for testing?

1 In Colorado, we've had, I guess, because of the
2 Colorado experience of whirly disease, we've had lots of
3 turbulence about whirly disease positive test results that are
4 or are not to be believed.

5 DR. MERRILL: That's a very compound question. I think
6 my answers are, Yes, No, I don't know, and I'm not sure.

7 (Laughter)

8 You can find me so if I forget, but the OIE typically
9 does not deal with a strain-specific approach, and the blue book
10 doesn't either. The OIE also considers the detection of the
11 pathogen that is responsible for the disease to be the disease.
12 They don't distinguish that. And we find through PCR or any
13 acceptable assay, the presence of the pathogen, you then have
14 the disease as far as OIE is concerned. That is or can be
15 highly problematic in terms of the repercussions.

16 But, because the U.S. is an OIE signatory, and because
17 we have various legal and other obligations, we need to at least
18 recognize that the blue book is entirely different. The blue
19 book is -- both of these schemes are voluntary. There's no
20 regulatory requirements for these. They differ in detail, but
21 they agree in most principles and almost interchangeably.

22 However, when it comes down to the real nitty gritty of
23 what primers you may use and what assays, what cell lines you
24 would use, and whether tests are acceptable, they differ
25 considerably in that respect. So I think some carbonization

1 needs to occur, or, as we develop our regulatory approach, we
2 have to look very carefully at those differences and what those
3 implications are.

4 Now, for becoming approved, APHIS already has a
5 mechanism in place by which a laboratory or facility may become
6 APHIS approved on an assay-by-assay specific basis. So you
7 still make your protocols, you get a review, you have a site
8 visit, and you join the list of APHIS-approved facilities. And
9 any lab in the country, whether you're a state lab, another
10 federal lab, a private facility or research facility, whatever,
11 can qualify for that kind of an approval. And, certainly, for
12 export purposes, that's very important.

13 Now, down the road, as this -- not only as this VHS
14 regulation proceeds, but as the National Aquatic Animal Health
15 Plan, as Dr. Egrie can tell you more about, as that develops as
16 well, that approval mechanism has to be much better codified,
17 whether that's left up to the states to do the initial approval,
18 or for the types of tests and the types of facilities, types of
19 bio security involved, and types of collection involved, whether
20 a biologist collects a sample, a veterinarian collects the
21 samples, interstate health certificates signed by somebody or
22 not or whatever, all of those details get to be worked out. So
23 that's where the hard work is, and that's the kind of input that
24 we're soliciting from you all here today and in our other
25 meetings. So please speak up if you have preferences about how

1 any of these things should be done. And that's what we're here
2 to listen to.

3 TED SMITH, AQUACULTURE INSTRUCTOR, TSJC: My name is
4 Ted Smith, and I am an aquaculture instructor with Trinidad
5 State Junior College. I'm also with the Colorado Aquaculture
6 Association and the National Aquaculture Association. And I
7 have a couple of questions. I guess, first of all, your
8 opinion. How well do you think the emergency rule is working so
9 far? And then, secondly, how is APHIS integrating with fish
10 health experts in each of these individual states? We have 50
11 states, so, theoretically, we have 50 cooks in the kitchen. So
12 how is APHIS advising or counseling these various states so we
13 have some rhyme and reason here?

14 DR. EGRIE: Okay, well, first part of the question was
15 kind of answered. Ken was asking, how is this working. And I
16 do believe that, particularly for salmonids who had been testing
17 previously, they are being able to move. Industries such as
18 nonsalmonids, who traditionally have not been testing for VHS or
19 any pathogens, don't really have relationships with
20 veterinarians or sometimes with state agencies, are having a
21 more difficult time moving fish within the federal order. So I
22 think that those relationships are starting to build out now,
23 but fish are being moved within the federal order.

24 The second question is: How are we relating with
25 different state agencies? We do have relationships with AFWA,

1 who work with -- the name just slipped my mind, but we do have
2 representatives from AFWA that we've worked with, and USAHS for
3 our contacts with different state fish and wildlife agencies and
4 state departments of agriculture. So we try to reach out as
5 much as we can. We have been reaching out much more with the
6 eight states that have been affected than we have with maybe
7 New Mexico or Florida that are further away. But we do regulate
8 and try to reach out to different states and make sure that we
9 are compatible with what we're going to be moving forward with.

10 DR. MERRILL: I think, just for the record, AFWA
11 represents the Association of Fish and Wildlife Agencies and
12 USHA is U.S. Animal Health Society.

13 DR. EGRIE: Eric Schwab is his name from AFWA. And so
14 we use him as kind of a contact or a representative for
15 different state fish wildlife agencies, because he's right.
16 It's difficult to speak to 50 people, so we have one that
17 disseminate information or bringing information from the
18 different states. So that's how we really work with a lot of
19 different state agencies.

20 Do you have any suggestions for us?

21 MR. WOOD: Oh, boy. Find a cure.

22 MR. TUCK: Any other comments, questions?

23 MR. CLINE: My name is Ken Cline again. Just to
24 comment on the follow-up to your question, Ted, the interstate
25 certificate or whatever it is, a certificate that a facility,

1 say, is being just free to set up some kind of process for that
2 I think would be very valuable from a person who moves fish
3 interstate. If we did have a certificate like that that was
4 recognized by all the states, it would probably greatly help
5 fish farmers who move fish interstate. So I would encourage the
6 development of something like that. The key to that, though, is
7 to get by all the other agencies involved.

8 MR. BURTON: I'd just like to add a comment. I'm
9 Doug Burton with Idaho Fish and Game again. I write a lot of
10 import permits for, primarily, salmonids, because, again, like
11 Colorado, our state regulation is almost exclusively salmonid.
12 We have very little in our book about nonsalmonids. But my
13 authority does not extend beyond our state borders. Basically,
14 my import is for -- my permits are for the people who are
15 bringing it in, because that's where my authority lies.

16 I see this APHIS regulation as an extended umbrella of
17 protection for my constituents in Idaho. Again, it would be a
18 cooperative thing between all the other states, between the
19 growers, the providers of the fish that may be coming, but this
20 is something that, since my authority ends at an imaginary line,
21 where the rivers and everything across that line don't really
22 recognize my authority. We don't have a border patrol. We're
23 not stopping everybody out there asking, Are you bringing fish
24 in? This is important on a pretty critical issue that we get a
25 nationwide system established to at least control an issue like

1 this. We don't want to impact anybody's livelihood. In fact,
2 we encourage the commercial people and -- we just need -- we
3 have a mandate to protect our resources, and that's what this is
4 all about.

5 DR. EGRIE: I've got one question for Doug. In the
6 letter that you read, you mentioned an embargo against the
7 affected states, but you don't actually define affected states.

8 MR. BURTON: Well, let's see. From the Great Lakes
9 basin endemic area -- it's probably put in the letter, but we're
10 going with your definition of endemic area of the Great Lake
11 states.

12 DR. EGRIE: Okay.

13 MR. TUCK: Thank you, Doug.

14 Anybody else?

15 MR. WALKER: I'm Peter Walker, again, from Colorado. I
16 don't want to beat this to death, but I do see the bait fish
17 industry, bait fish trade wild cod as being the Achilles heel of
18 this whole effort by all of us. I have worked with and against
19 sometimes the bait fish industry in terms of regulating it now
20 for about well over 30 years. And I know, without being able to
21 give you exact facts, I do know that bait fish are almost
22 certainly being moved between states and the Great Lakes and
23 finding their way to other states. It's an industry we just
24 don't have a handle on. These are people who are not organized
25 into an industry the way the trout farmers are, the way other

1 aquaculturists are. They are just common folk dealing with live
2 fish back and forth. And I hope that this isn't true, but I
3 happen to be pessimistic on the basis of experience that that,
4 almost certainly, is going to be a big problem for us is the
5 movement of these fish despite all of the regulations. It's
6 almost impossible to stop movement of them, and I know it's
7 taking place.

8 DR. MERRILL: Well, we certainly understand the reality
9 of bait fish movements. A couple of comments. First, I don't
10 think we've seen the end of the number of species of bait fish
11 that are susceptible to VHS. There's early indications that a
12 whole host of other bait fish species -- minnows, shiners,
13 sticklebacks. I mean, there's many potentially susceptible
14 species, and I think it will just be a matter of time before
15 they are also found.

16 Some of those are very economically significant
17 species. So whatever approach we take is going to have to be
18 open ended and open minded in that respect. That's one of the
19 reasons why we're electing to post the list on the Internet
20 rather than in the code of federal regulations. Much more
21 cumbersome to change it after the rule making than just through
22 the Internet.

23 There are some models, though. Even though the U.S.
24 bait fish industry is not that organized as you characterized
25 it, there are elements of the bait fish industry in the U.S.

1 that are highly organized and do a very good job, a very
2 proactive job of testing for lots of diseases and can actually
3 certify their stocks as such. And in the future, I think that
4 kind of a pressure is just going to make the industry evolve.

5 Also, in Canada, the bait fish dealers in Ontario are
6 beautifully organized by comparison and very effectively
7 organized, and they do a lot of internal pulsing, but
8 administrative oversight for their industry. And I think that
9 would be great for our industry to emulate as well. But we
10 can't predict that or shape our regulations to encourage it.
11 That just may be what happens. But we do appreciate the fact
12 that movements will happen, clandestine or otherwise. We're
13 sure that we haven't seen the end of lists of susceptible
14 species as well.

15 DR. EGRIE: Maybe I'll turn the question around to you
16 again. You mentioned the wild bait fish issue. And for
17 everyone's background, he's referring to fish that are caught in
18 the wild, usually in Great Lakes -- emerald shiners and such --
19 and traditionally have not been tested for disease. They're put
20 on a truck and driven up and down different states, bait shops,
21 dropped off in buckets, and they move them on from place to
22 place.

23 The issue is that these fish are not held for a long
24 enough period of time for testing, which could take two to four
25 weeks. So, in that particular instance, let's talk about that

1 wild bait fish industry. What do you suggest to APHIS as far as
2 regulating that type of industry?

3 MR. WALKER: That's a tough one. Along with the
4 experience of dealing with these people comes the knowledge that
5 it is so tough to regulate. Some of the western states have
6 simply banned the use of live fish as bait, and that would be
7 the simplest thing, but it depends on the history of the
8 individual state and the agency as to whether or not it has
9 become a tradition, and therefore, banned by the public in those
10 states. Unfortunately, Colorado -- unfortunately, from my
11 regulatory point of view, Colorado is the state that does allow
12 the use of live bait in the eastern half of the state. Again,
13 I've lost my any train of thought. I should not be talking
14 today.

15 DR. EGRIE: Well, let me ask you a question. If
16 someone collected wild shiners from Ohio and put them in a tank
17 long enough to test and tested that tank and that tank tested
18 negative, what would you think about that?

19 MR. WALKER: I would think that was pretty good. The
20 problem -- in fact, I would welcome that. That certainly would
21 be better than almost all importations of bait into Colorado
22 right now which are uninspected.

23 The problem I see is that a lot of bait wholesalers
24 that are dealing with wild cod and sometimes a mixture of wild
25 cod in farm bait are pooling these. They're mixing them

1 together constantly, so you never know what the sources are in
2 those shipments. And it might be multiple sources.

3 In western Nebraska, the fathead minnow industry is
4 wild cod fathead minnows from the many, many ponds in the
5 sandhills. Those are all going together. They're coming from
6 as many as 150 different sources and all going into one big fish
7 hatchery situation and then being shipped out from there. I see
8 it as being very cumbersome to get those fish inspected and
9 inspected properly.

10 MR. TUCK: Any other questions?

11 MR. CLINE: The increase in regulation is going to
12 require an increase in -- I mean, an increase testing
13 requirement is going to require increased lab facilities. And
14 this testing isn't cheap. Someone in the salmonid industry has
15 been doing it for 30 years primarily for other viral diseases,
16 but viral testing isn't cheap.

17 My question is -- and the concern that's come up with
18 people that I've talked about is that testing being both
19 affordable and available to industry. And as we increase
20 regulatory requirement here, we're going to require a lot more
21 testing we already have, but if we expand that, say, beyond the
22 endemic area into all 48 or 50 states or worldwide or whatever
23 or for all fish, we may not have -- I question whether we have
24 the lab capabilities in this country to support that type of
25 regulations.

1 Therefore, it seems like testing of susceptible species
2 from the endemic or infected areas would be more appropriate,
3 and hopefully, that would stay ahead of and prevent the spread
4 of disease and at least allow the lab testing capabilities to
5 increase along with, say, the increase or lack of increase in
6 the endemic area. So, in effect, what industry needs is
7 something that's affordable and available.

8 MR. TUCK: Okay. Anybody else? With that, I'd like to
9 turn back to Dr. Merrill for closing comments.

10 DR. MERRILL: Okay. I didn't actually prepare any
11 concluding comments, but I think we've heard some good points
12 here today. And, again, you can submit anything in writing to
13 us through the close of business tomorrow or by e-mail up until
14 the close of business eastern time tomorrow, your western time,
15 your time, and we'll accept those.

16 And we do realize that as this regulation goes forward,
17 that we are going to be faced with some aspects that we may be
18 able to control and others that we probably can't. Some
19 information that we know, we know, and some information that we
20 don't even know that we don't know, and everything in between.

21 And we appreciate everybody's comments here today. And
22 we appreciate the support that we've gotten from state agencies,
23 other federal agencies, from our Canadian partners, and various
24 other people, and the public, too, for that matter. I'm
25 appreciative that everybody understands the difficulty of what

1 it is that we're trying to do but also the necessity.

2 Dr. Egrie?

3 DR. EGRIE: We're obligated to be here for two more
4 hours, and I hate to see people travel so far, and I know
5 there's some people who haven't spoken yet.

6 There are still a couple of major questions out there
7 that this gentleman from Michigan mentioned that, why did we --
8 why aren't the other states in the Mississippi River being
9 affected. And maybe that's some points that people that haven't
10 spoken about, I'd like to hear about that particular issue.

11 Do you think any future regulations should just be on
12 this four states where we've seen disease, the states in the
13 Great Lakes, the whole country? We have two hours, so we'll end
14 it now, but I'm going to be here until noon anyway.

15 DR. MERRILL: I'll add a comment about the use of the
16 term "endemic." We've heard that from a number of people today.
17 And it can be used in a sort of colloquial sense, and it can be
18 used in a technical sense. And I think we have to be very
19 careful how we do use that. We may not be understanding the use
20 collectively.

21 Endemic or enzootic means that a pathogen or a disease
22 has become established there and that it is there. Enzootic is
23 an area that's free of that disease. And then there is a sort
24 of interim classification that I call limited distribution. I
25 don't think it technically has a definition, but it essentially,

1 it's just as and in some places if not in other places.

2 If we're going to call VHS endemic, we have to agree on
3 the use of that word. We don't know where this virus is right
4 now. We do know where it was, and we know where it might be,
5 but we don't know for sure the prevalence of distribution. And
6 we do want to know that very much. And so we're dealing with
7 questions of surveillance, you know, how we're going to go out
8 and determine that prevalence, how endemic this virus or disease
9 is.

10 But in order for us to do that, we have to also decide
11 how we're going to do that. That's very technical, very
12 involved if we test every watershed in the country. How often
13 do we test it? How many fish do we use, what species, what
14 tests? Those are all very important considerations. So if
15 anybody has suggestions along those lines, we'll entertain them
16 as well. But we truly do not know that VHS is limited to just
17 those four states that have reported outbreaks.

18 MR. SMITH: Just to keep things going here, seeing we
19 have two hours, is there a standardized testing? Are we looking
20 at the OIE code or blue book, or are there differences here? If
21 we were going to standardize testing procedure that all states
22 would follow -- and, you know, going back to what Mr. Cline was
23 saying, having maybe a federal import certificate for
24 importation, interstate where you're going to try to standardize
25 this whole thing. What would be your suggestion? What are your

1 thoughts on that? How can we rein this thing in so that it's
2 workable and protect our environment but we don't stimy industry
3 as well?

4 DR. EGRIE: We are hoping for your suggestions.

5 MR. SMITH: We'll throw it out on the floor, I guess.

6 DR. EGRIE: Is everyone familiar with the different OIE
7 and blue book testing protocols?

8 DR. MERRILL: The OIE code and the manual diagnostic
9 tests provides a number of examples by which you can set up
10 surveillance schemes. There is no one-size-fits-all approach,
11 basically. That's the answer to your question. There's no one
12 way of establishing disease freedom. And that flexibility was
13 built in to be really as accommodating to the differing
14 circumstances of different countries.

15 Now, the U.S, as one country, has fantastically
16 differing circumstances for all 50 states, so there is not any
17 one approach, and there cannot be any one approach, and we've
18 discussed this with other agencies as well in terms of how would
19 we set up a national surveillance program. And that's very
20 developmental at this point. So I think, as Gary says, we're
21 looking for suggestions from affected stakeholders, whether
22 state or federal or private. So I'll just leave it there.
23 There is no one-size-fits-all approach.

24 The blue book is a little different. I mean, for
25 purposes of surveillance, it's not that specific.

1 MR. SMITH: Excuse my ignorance, but why cannot there
2 be one protocol?

3 DR. MERRILL: The question is: Why can't there be a
4 one-size-fits-all approach to surveillance? It really has to do
5 with epidemiology of the disease, the way that things are
6 spread. But even on the geographical and logistical basis, when
7 you have watersheds that drain north and south and east and west
8 all in the same general part of the country, how are you going
9 to determine, really, the appropriateness of sampling? Would
10 you test 150 fish from four rivers that feed into one lake, or
11 do you just test the lake? What if you have a pond with one way
12 in and no way out? The possibilities are just endless.

13 And that's why the OIE sets forth examples which you
14 can claim freedom. It's just a claim. You're not proving
15 beyond a shadow of a doubt that there is no disease. It's just
16 that you're satisfying certain criteria in order to make that
17 claim. Sort of a presumption of innocence versus a presumption
18 of guilt. And we haven't really tackled that on the national
19 level even conceptually. So we do need to make those
20 qualitative decisions first.

21 Can we assume that all areas of the country are free of
22 VHS and let's prove otherwise, or can we assume that it is
23 everywhere unless we prove the negative?

24 MR. WOOD: Peter, I guess I object slightly. Yes, I
25 agree with the difficulties in setting up a surveillance

1 program, but what Ken and Ted are talking about is farmed fish,
2 that they have given facility and would prefer, would like to
3 have a certificate of freedom from VHS so that they can export
4 or import into some other state. Does the OIE specify in the
5 PCR-based test for VHS?

6 DR. MERRILL: PCR is a confirming assay. It's not one
7 of the primary subculture virus. There's isolation by
8 subculture and then there's a bunch of confirming assays. But,
9 okay, so maybe I misunderstand. And if you are asking this
10 question or making those comments in the terms of only farm
11 fish, then, yes, oh, yeah, there are certainly schemes by which
12 you can claim, demonstrate disease freedom.

13 And the blue book typically calls for testing 60 fish
14 on per-lot basis, and so you would need to carefully define what
15 is a lot of fish. And this is not something that everybody is
16 in agreement with either, and states argued the definition of
17 lots for years before they came up with an adequate definition.
18 And it's a relative definition.

19 The OIE typically requires testing of 150 fish on a
20 per-facility basis. And so then in terms of defining lots, you
21 then have to be very careful in terms of the species
22 susceptibility to a disease or pathogen involved. But there are
23 existing ways by which you can make those claims. And the blue
24 book certainly also allows for testing 150 fish. That's using
25 different prevalence, pathogen prevalence assumptions. But both

1 have pretty well worked out assays and confirming tools.

2 MR. WOOD: And it's at least a more tractable problem
3 than the issue of surveillance.

4 DR. MERRILL: Well, then, okay, then even for farm
5 fish, we then get in -- Dr. Egrie can probably give some more
6 details, but we have many farms that are farms only in the
7 loosest sense. They may have a number of physical locations
8 over which their fish are spread, a number of ponds with
9 differing water sources, some protected, some not, differing
10 species susceptibility factors sometimes involving geographical
11 distribution over different state boundaries or even
12 international in the case of some tribes. It's a very
13 complicated case.

14 DR. EGRIE: I think Peter's comment about farm fish or
15 not farm fish, which we're saying it's so difficult is because
16 when we start trying to define what a farm fish is, it starts
17 getting on a slipper slope. If someone takes wild fish at the
18 Great Lakes, some emerald shiners, and throws them in a bucket,
19 are they farmed? I don't know. Someone could define them --
20 someone could say they're farmed and then use a play of criteria
21 we come up with. So we really need to make something all
22 encompassing for all different scenarios.

23 MR. TUCK: Maybe we should take a break for right now
24 and be back in maybe 10 or 15 minutes. As Dr. Eiger said, we
25 will be here for the next couple of hours. If you want to come

1 back and talk and ask more questions, please do. If you want to
2 leave, then please have a nice, safe trip back to where you came
3 from. And we definitely enjoyed you being here. Thank you.

4 DR. EGRIE: Feel free to call us Peter and Gary. We're
5 pretty informal here, So that's fine too.

6 (A 15-minute break was taken at 10:00 a.m.)

7 MR. TUCK: Okay, we've had some time here. Hopefully,
8 you all have some more questions. Anybody have any other
9 questions?

10 MR. WOOD: Well, all right, I guess. Again, John Wood.
11 Peter or Gary, what's the thought about timing on interim rule
12 and then the permanent rule? Interim rule will be in this next
13 year?

14 DR. EGRIE: Well, it's dangerous to give out dates and
15 times, so I won't give a day or time, but we're looking at
16 springtime. I think that's general enough for interim rule.

17 As far as a final rule, we're still looking for a risk
18 assessment. We have to do -- talk about different issues. So I
19 don't see a final rule coming for quite some time. But,
20 certainly, an interim rule would be coming out sometime in
21 spring.

22 MR. WOOD: Interim rule can last for an indefinite
23 period of time, or does it have a statutory limit?

24 DR. EGRIE: No. I think an interim rule is an interim
25 rule until it's a final rule.

1 MR. TUCK: Anybody else?

2 DR. EGRIE: What do you want to see in the interim rule
3 is the question? Anything we haven't heard yet?

4 MR. WOOD: I think it should address the testing
5 procedures. I mean, just leaving it to say blue book or OIE,
6 I'm not sure that's enough given the variety of tests that are
7 in the blue book, or I guess, the ambiguity in the OIE
8 procedures. And, certainly, the PCR, the plethora of PCR tests
9 that we talked about, mentioned earlier, I think the interim
10 rule should at least attempt to address that.

11 DR. EGRIE: Let's turn it back to you. What
12 specifically? Are there particular PCRs? Are there cell lines?
13 Are there a particular prevalence? Two percent, 5 percent, 10
14 percent?

15 MR. WOOD: I think, at least on the PCR, if you're
16 going to have anything in there at all, yeah, you should say,
17 This is the assay that we want you to use. And you can argue
18 why that one is better, or you can just say, Here. You
19 arbitrarily decide that this is the test to use, and these are
20 the conditions to use. Don't mess around with primers or buffer
21 conditions or anything else. Otherwise, it becomes a zoo.
22 There are too many variations that we face -- this whirly
23 disease and any number of other aquaculture diseases where PCR
24 testing has gotten a pretty bad name because it's not done very
25 consistently from one place or one facility to the next.

1 MR. SMITH: Ted Smith again. I think the rule also
2 needs to address probably the risk themselves, you know, what
3 situation poses the greatest risk and what situation poses the
4 least risk, and then develop regulations accordingly. So in
5 susceptible species from positive waters while caught versus
6 disease -- certified disease free in the farm-raised fish and
7 then try to sculp the regulation to really affect the greatest
8 risk and provide a leniency, I guess, for the lack of a better
9 word, than minimal risk from an industry perspective.

10 DR. EGRIE: Are there any programs out there, let's
11 say, an endangered species program, for instance, that could be
12 negatively impacted or inadvertently affected by VHS
13 regulations? Anybody aware of things like that, programs in
14 your states or things that you may have not thought about that
15 regulations come out? Unfortunately, we don't know what things
16 will be affected until we actually come out with the regulation.
17 So it would be nice to have a little heads up.

18 DR. MERRILL: Actually, the MEBA (ph) requirements for
19 the -- part of the environmental association.

20 DR. EGRIE: Are they interim rule?

21 DR. MERRILL: Yes.

22 DR. EGRIE: Okay.

23 DR. MERRILL: But it's a good question on the state
24 requirement, because there may be state issues as well as
25 federal.

1 MR. SMITH: There is a -- we do have an aquatic native
2 species restoration down in Alamosa, and they were hard pressed
3 to find genotypically pure Rio Grande suckers, I believe it was.
4 So they went into New Mexico to get that gene pool. So there is
5 an interstate movement of native species in that respect that
6 possibly you have a --

7 DR. MERRILL: Rio Grande suckers aren't
8 VHS-susceptible.

9 MR. SMITH: It's interesting how that list grew.

10 MR. CLINE: Are you sure about that?

11 DR. EGRIE: They're not on our list.

12 MR. SMITH: Are there any gadus stovers out there?

13 DR. EGRIE: Yeah.

14 DR. MERRILL: There's redhorse.

15 MR. TUCK: Any issues you need to address?

16 DR. EGRIE: I want to make sure everyone has an
17 opportunity to speak.

18 DR. MERRILL: Doug's got a finger on his mouth.

19 MR. BURTON: Well, we deal with anathermous (ph) threat
20 to endangered species. Fish that are coming from the Pacific
21 Ocean where we know that we have the Type 4A that we've been
22 monitoring that, apparently, these things are not bringing it
23 up. We haven't found it anyway.

24 In our hatchery produced programs, we don't do a
25 hundred percent viral sampling on five or six or 10,000 chinook

1 salmon that have to be coming back. If we get five anathermous
2 sockeye that are threatened and endangered, yes, every one of
3 those is tested. We have a hundred percent sampling. So I
4 really don't know that a regulation is going to apply to affect
5 that. I'm just trying to think of the implications. I was
6 trying to think out of all the different aspects of dealing with
7 anathermous fish not out of the Great Lakes area but from an
8 area where we know at least one strain of VHS is present.

9 MR. TUCK: Okay. If there aren't anymore questions or
10 comments, I'd like to thank you all for coming and taking time
11 out of your day. And, hopefully, it has been productive for you
12 all as well as it was for us. And we appreciate your comments
13 and attendance. Thank you, and have a great day.

14 (Meeting adjourned at 10:30 a.m.)
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