

TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
CONSUMERS UNION)

Pages: 1 through 50
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UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
CONSUMERS UNION)

Training Room 1
4700 River Road
Riverdale, Maryland

Thursday,
March 11, 2004

The parties met, pursuant to the notice, at
1:03 p.m.

ATTENDEES:

For the USDA, Animal & Plant Health Inspection
Service (APHIS) and Biotechnology Regulatory
Services (BRS)

- REBECCA BECH, Associate Deputy Administrator
- CINDY SMITH, Deputy Administrator
- JOHN TURNER, Director of Policy Coordination
- LAURA BARTLEY
- DAVID BENNETT
- JOHN CORDTS
- TERRI DUNAHAY
- JUDY GARRISON
- SUBHASH GUPTA
- LEE HANDLEY
- NEIL HOFFMAN
- SUSAN KOEHLER
- SALLY MCCAMMON
- VIRGIL MEIER
- HALLIE PICKHARDT
- BOB ROSE
- ROBIN ROSE
- CRAIG ROSELAND
- MICHAEL WACH
- MICHAEL WATSON
- CHRIS ZAKARKA

APPEARANCES: (cont'd.)

For Consumers Union:

MICHAEL HANSEN, Ph.D., Research Associate,
Consumer Policy Institute

P R O C E E D I N G S

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(1:03 p.m.)

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MR. TURNER: Welcome to our stakeholder

discussion series on our upcoming environmental impact

statement and revised biotech regulations. We want to

thank you for taking time out of your busy schedule to

come share your thoughts with us.

The purpose of these briefings is to share

information regarding our plans to develop an EIS and

amend our plant biotech regulations and gather diverse

informative input which will support thoughtful and

effective decision making on our part in the

development of our new regulations.

We have here at BRS most of our management

team, or they will be coming, I think, as well as

numerous members of our staff, and when available,

other key agency personnel involved in supporting BRS

in this effort. I should also mention two key

individuals who are going to be dedicated to full time

management of our work to complete the EIS process on

the revised regulations. One is myself. I'm John

Turner, director of policy coordination, but a lot of

those responsibilities have been shifted elsewhere so

I can work full time on the environmental impact

statement and the new regulations.

1 The other member is Michael Wach, seated
2 here to my left. He's a recent BRS hire, and his
3 title within our group is environmental protection
4 specialist. He's in the environmental and ecological
5 analysis unit. In addition to possessing a Ph.D. and
6 an environmental law J.D., Michael brings research
7 expertise in plant pathology and weed science, as well
8 as legal experience, working on cases involving NEPA,
9 the Clean Water Act, the Clean Air Act, and other
10 environmental laws.

11 As you may know, we recently participated in
12 interagency discussions with EPA, FDA and the White
13 House. While concluding that the coordinated
14 framework has provided an appropriate science and risk
15 based regulatory approach for biotechnology to date,
16 the Plant Protection Act, passed in 2000, provides a
17 unique opportunity for APHIS to revise its regulations
18 and potentially expand its authority, while still
19 leveraging the experience we've gained through our
20 history of regulation, and particularly, this act will
21 position us well for future advancements of the
22 technology.

23 So we concluded those discussions with some
24 general agreement on the biotech regulatory approach.
25 Still, there is much opportunity for public and

1 stakeholder input as we move forward to develop the
2 specifics of our regulatory enhancements.

3 Given this, what we would like to do in
4 these meetings is have an opportunity to hear your
5 thoughts, as well as an informal give and take of
6 ideas. It's a unique opportunity to do this, because
7 we haven't yet entered the formal rule making process,
8 so we're allowed to speak freely and openly and
9 exchange ideas with stakeholders and the public.

10 Our discussions are being transcribed for
11 two reasons. First is we want an accurate record of
12 our discussions to facilitate our ability to capture
13 and refer to these discussions in the future.
14 Secondly, in the interest of transparency and fairness
15 to all stakeholders, we're planning on possibly making
16 them available on the web, certainly making them a
17 part of the public record so that the public and the
18 other stakeholders can each have the opportunity to
19 see what we've discussed with the other stakeholders.

20 I wanted to emphasize that while we're happy
21 to share information about the process, it's going to
22 be an evolving process. So in addition to information
23 from the public and stakeholders such as yourself,
24 others such as our administrator, the undersecretary,
25 our office of general counsel and, of course, the

1 secretary, will provide insightful direction to us as
2 well.

3 So while we value all the input, it's
4 important for us to recognize that we may have
5 enthusiastic discussions today about something, but
6 it's going to be an evolving process. Finally, since
7 it is hard to predict exactly what the final
8 regulation will look like, what we can do is talk
9 about us, some BRS priority areas of emphasis that
10 will certainly set the direction.

11 The first of these is rigorous regulation,
12 which thoroughly and appropriately evaluates safety
13 and is supported by strong compliance and enforcement.
14 The second is transparency of the regulatory process
15 and regulatory decision making to stakeholders and the
16 public. This is critical for public confidence. The
17 third is we need a science-based system, ensuring the
18 best science is used to support regulatory decision
19 making to assure safety. The fourth, communication,
20 coordination and collaboration with the full range of
21 stakeholders.

22 Finally, international leadership. We have
23 to ensure that international biotech standards are
24 science-based. We need to support international
25 regulatory capacity building, and we have to consider

1 the international implications of policy and
2 regulatory decisions that we make.

3 As we prepare for our discussions, I would
4 ask you simply the first time you speak to state your
5 name for the transcriber. After that, it's usually
6 not necessary. I mentioned earlier that members of
7 the BRS management team were here. In particular,
8 Cindy Smith, our deputy administrator, is tied up in
9 traffic. She plans to be here, and she's fairly close
10 to the building, so I think she'll be arriving at any
11 time. But we're not going to wait on her to start the
12 discussions.

13 With that, think I can go ahead and turn it
14 over to you, Michael, for your opening statement.

15 MR. HANSEN: Yes. What I'd like to first
16 say, my name is Dr. Michael Hansen. I'm a senior
17 research associate at Consumers Union. They're the
18 people that publish *Consumer Reports* magazine. For
19 those of you that haven't met me before, I have a
20 Ph.D. in ecology and evolutionary biology from the
21 University of Michigan and I've done field work in the
22 tropics on agricultural ecology, looking at corn, bean
23 and squash.

24 I also have done postdoctoral work at the
25 University of Kentucky in a rural sociology

1 department, looking at the social impact of genetic
2 engineering, particularly on plant breeding, and I
3 focused on tomatoes and wheat. I've taught genetics
4 and other courses and have been very actively involved
5 in biotech regulations in the U.S., both the USDA and
6 FDA. We at Consumers Union have actually been very
7 active at the international level, at CODEX, and not
8 so much its biosafety protocol, although that may
9 change.

10 What I'd like to do is I have some
11 questions, and we have comments, so I'm just going to
12 go through these questions one by one. There's some
13 things that we'd like to know. Also, Jean Alloran,
14 who is the director of the Institute, was supposed to
15 be here today, but she can't make it because both of
16 us have to be in San Francisco tomorrow, and if she
17 would have come down here, she would have had to get
18 on the 9:00 flight like me. She's traveling with her
19 son, so he wouldn't put up with that, but I have
20 talked with her.

21 I guess in the opening statement I should
22 say that we very much agree with the five points that
23 you laid out about this process, that it should be
24 rigorous regulation, transparency, a science based
25 system, the communication, coordination and

1 international leadership, but we might come to
2 different conclusions as to where those lead.

3 For the first question, we do agree that
4 APHIS does need to broaden its regulatory scope, or I
5 actually should say, back up before that, we support
6 the agency revising the regulations for introduction
7 of genetically engineered organisms, so we don't think
8 you should do the "take no action." So we support
9 taking action, and for each of these questions, for
10 the first question, we do think that you should expand
11 your scope.

12 Now, the question that I have here is you
13 say you want to expand it beyond engineered plants,
14 beyond engineered organisms that pose a plant pest
15 risk, to include engineered plants that may pose a
16 noxious weed risk and those that may be used as
17 biological control agents. We're concerned. We think
18 that all genetically engineered insects and arthropods
19 that are going to be released absolutely need to be
20 regulated. So the question I have is, your definition
21 of biological control agent, how wide is that, and
22 would that capture all planned releases of engineered
23 insects and arthropods?

24 MR. TURNER: No. Biological control agents
25 would be an end use, so that in and of itself wouldn't

1 capture them all. Now, the vast majority, as I
2 understand it -- and Bob Rose might comment on this --
3 are either biological control agents plant pest or
4 animal pest, which are likely to be covered very soon
5 under different regulations, but the biological
6 control part of it goes to end use as a biological
7 control organism.

8 This is Bob Rose. He's one of our
9 entomologists and has also been thinking about what an
10 APHIS role should be in regulation of insects and
11 transgenic animals.

12 MR. ROSE: This is Bob Rose, yes. We have
13 been regulating genetically modified insects that are
14 plant pests and to some degree also biological control
15 agents, because there is no real line separating these
16 two, because the plant pests -- the bollworm, as you
17 know, is being developed, hopefully as a biological
18 control agent. So with the inclusion of biological
19 control agents, that would just give us a little
20 further stronger grip over all those insects that
21 would be plant pests and come into that category.

22 That still leaves the gap of livestock pests
23 under the Animal Health Protection Act, so you'd have
24 a large number of insects that are livestock pests.
25 Actually, there's been a great amount of concern

1 expressed about transgenic insects that are human
2 pests, but do keep in mind that almost all of these,
3 except for a very, very few, like head lice, are
4 livestock pests as well. Mosquitoes, for example, are
5 a livestock pests.

6 We are in the process of working out right
7 now, in cooperation with FDA and other governmental
8 agencies, on how to address the implementation of
9 regulations for transgenic animals in general, which
10 will, of course, include the insects. We do have the
11 authority under the Animal Health Protection Act to
12 implement regulations for livestock pests. We'll
13 cover most of the universe of insects, with a few
14 possible exceptions that may not really fit into those
15 categories.

16 MR. HANSEN: Yes. That's why I would
17 suggest -- I think it's good. We have been
18 particularly concerned about arthropods and insects
19 that vector both human and animal diseases, but if
20 it's the end use that's important, I do still think
21 it's important that if it takes getting further
22 regulation, you need to close those gaps, because
23 theoretically, somebody could engineer a mosquito not
24 for a biocontrol purpose but a performance art
25 purpose, because we've seen that with rabbits. They

1 could do it for some purpose that's not a biocontrol
2 end purpose.

3 If that insect got out, it could have
4 environmental impacts. It could potentially disrupt
5 the ecology of mosquito populations, so we would urge
6 the agency to make sure that everything gets covered.
7 If that requires new regulations, we would support
8 that, but we are concerned that all insects and
9 arthropods that are going to be released that are
10 engineered are covered. We do agree that, I think,
11 most of them, the vast bulk of them, would probably be
12 captured under the biological control agents, but I
13 can see, since it's an intentionality --

14 MR. TURNER: The biological control agent
15 part goes to end use, whether it's a plant pest or an
16 animal pest isn't end use. That's more the nature
17 occurring, and that's a pretty broad net. But your
18 comments or capture, you think it should be all?
19 Certainly, if you come up with good examples of things
20 that you think would be in a gap, we would be
21 interested to hear.

22 MR. HANSEN: Okay. Well, I'll think about
23 that. Then this question of whether environmental
24 consideration should influence the change in
25 regulatory scope. The concern that we have there is

1 we think it's good that you're working with FDA and
2 others to come up with regulations for transgenic
3 animals, although lumping insects in with transgenic
4 animals I think is a bit broad, because the potential
5 environmental considerations for escape are going to
6 be far broader with insects than they're going to be
7 with cows and other vertebrates.

8 Special consideration, I think, really needs
9 to be given to insects and arthropods. Okay. For the
10 second question about the regulation of regulations
11 based on risk based categories, our basic
12 consideration here is if there's going to be a
13 separation, the only one we would support is one
14 looking at pharmaceutical and industrial crops not
15 intended for food or feed. The others ones, at
16 present, we don't think there should be a category
17 that you call low risk pest and environmental risk, so
18 therefore, they go through a less stringent review
19 process.

20 The only reason we think this is because
21 we're particularly concerned about unexpected effects
22 that could change characteristics of the organism.
23 One potential example I could use of that is work
24 that's been done with Arabidopsis, which was
25 engineered in an experiment to look at the difference

1 between conventional breeding and genetic engineering,
2 engineering it with chlorsulfuron tolerance and
3 finding out that if you insert chlorsulfuron
4 tolerance, you have a mutation breeding versus genetic
5 engineering.

6 You get dramatic impacts on per plant
7 outcrossing rates, and Arabidopsis is primarily a self
8 pollinator. So in this process is work by Joy
9 Bergelson and colleagues at the University of Chicago
10 that clearly shows an unexpected fact where an
11 inbreeding plant that normally has inbreeding rates
12 that are way less than one percent, you are finding
13 twentyfold and sometimes higher differences in
14 outcrossing rates based on that. So that can be an
15 insertional effect and insertional mutagenesis effect.

16 The FDA has actually proposed in their
17 regulation from 2001 that they want separate data on
18 each transformation event, even if you're using the
19 same gene and the same genetic background, because
20 they've said that particularly because of the
21 phenomenon of insertional mutagenesis they want data
22 on separate transformation events.

23 So therefore, we don't think you can a
24 priori say certain things are low pest or low
25 environment risk. They may appear to be in terms of

1 the gene you're engineering, but given the unexpected
2 effects, you can have other changes in the organisms
3 that were not a priori predictable.

4 This third question about providing
5 regulatory flexibility by allowing for
6 commercialization of certain engineered organisms
7 while continuing in some cases to regulate the
8 organism based on minor unresolved risks, the question
9 I have on this is we're not quite sure what you're
10 referring to there.

11 MR. TURNER: Right now, we have a
12 deregulation process. That's the end point and if it
13 gets by, there's no regulatory oversight whatsoever.
14 Are there cases where it might be appropriate for us
15 to conclude that it's safe enough to go out there, but
16 maybe with some conditions or restrictions on how or
17 where it's cultivated or that they supply us
18 additional data, or should it just be the yes or no
19 situation?

20 MR. HANSEN: Okay. Now that I understand
21 that, that that's what the intent is, yes, I think it
22 actually would be good to have some regulation after
23 you do the deregulatory process. The main reason for
24 that is we actually argue against the deregulatory
25 process, because as ecologists point out, there's

1 certain effects that you cannot see in small field
2 tests. Once you get to large acreages, there can be
3 large scale effects that are not detectable at smaller
4 scales.

5 In the late eighties, I believe both the
6 Ecological Society of America and the British
7 Ecological Society came out and said -- actually
8 before these regulations were in effect, then said you
9 should be regulating at the field test and that there
10 should be an intermediate stage, maybe a
11 semicommercialization stage, so when it goes into much
12 broader areas and much broader acreage, they should
13 still be monitoring for environmental effects, which
14 could not be detected at the smaller scale.

15 We absolutely agree with that, so if there's
16 any mechanism whereby once these things get
17 deregulated and go to larger acreages, there does need
18 to still be some monitoring for environmental effects.

19 We think there should be a distinction made and the
20 environmental factors should be considered. I guess
21 you would need to look at the genes that you're
22 putting in and the organisms involved, but in general,
23 there are large scale effects that you're not going to
24 be able to detect in these tiny field trials.

25 So some way to try to monitor, to look at

1 not just any ecological effect, but given what the
2 gene and the organism is, by looking in the ecological
3 literature, there can be some intelligent guesses as
4 to what kind of issues should be looked at at the
5 medium and large scale.

6 Now, four, which has to do with
7 pharmaceutical and industrial compounds, we think
8 there should be changes, but it's our belief that the
9 way these changes should happen is first that they
10 should say -- for your question, should the review
11 process permit conditions and other requirements for
12 nonfood crops used for production of pharmaceutical
13 and industrial compounds different from those for food
14 crops?

15 The answer to that is we believe absolutely
16 yes, because it's our position that you should not
17 permit open air field tests for food or feed plants
18 that are engineered to produce pharmaceutical or
19 industrial compounds. I would just point out you're
20 well aware of the National Academy report that
21 recently came out on biological confinement. It
22 basically said with the present methodologies we have
23 that biological containment, which is 100 percent, is
24 not feasible at this point.

25 Given that we argue that there absolutely

1 would have to be zero tolerance for any pollen flow or
2 any release, that's why we don't think these products
3 should be permitted to be grown outdoors. We would
4 also argue that for food and feed crops, they should
5 not be permitted to be grown indoors either. There
6 could be environmental effects. Those would probably
7 be very small, but we have to take into account the
8 fact that there can be human error involved and
9 inadvertent mixing of bags.

10 There's a visible phenotype corn that's
11 engineered with the plastic or some other compound
12 that might accidentally get mixed up, unless, of course,
13 you had a tagging agent. For example, I know there
14 was some talk of putting genes in that would make your
15 flesh turn orange or colored in some way. But we
16 think that because of the fact that containment is not
17 possible, and given also that a Union of Concerned
18 Scientists report which has found a low level of
19 inadvertent contamination in traditional crops, we'd
20 be very concerned if any pharmaceutical or industrial
21 compounds were to show up in any food crop.

22 There could be safety concerns, but even if
23 there's not a safety concern, people just don't expect
24 that those kind of compounds are found in a food item.
25 So it isn't just a food safety issue, because I think

1 for most consumers they would have the zero tolerance.
2 It's sort of like that regulation is for roaches and
3 rodent fragments. That's often not a food safety
4 risk, but that makes foods adulterated.

5 So we do think that you could allow for
6 nonfood and feed crops to be engineered. Those we
7 think should be done in greenhouse conditions or in
8 confined conditions, but that you do need to do a full
9 environmental assessment for those.

10 Now, for question 5, that's this notion of
11 whether it's appropriate to regulate nonviable
12 material. We would reserve commenting on this. The
13 question that we have is, what do you mean by that?
14 Do you mean, for example, cut flowers or leaves?
15 What's the thinking behind?

16 MR. TURNER: It's a fairly open-ended
17 question, actually. There's just an opportunity there
18 under the noxious weed clause of the Plant Protection
19 Act. That's a plant or a plant product that can do a
20 series of harmful things, whereas under our old
21 authority, like plant pest is an organism --

22 MR. HANSEN: Right.

23 MR. TURNER: -- which also is defined as
24 being alive. Are there instances of material that
25 might be derived from genetically engineered where we

1 should retain --

2 MR. HANSEN: We have to think of that, which
3 is nonviable. Thinking about that, there could be. I
4 could see environmental impact if you were importing
5 huge quantities of some forage material, for example,
6 that was engineered. It was going to be used as food,
7 or since it's nonviable, you could be using it as a
8 green manure. Well, if it's engineered, there could
9 be release of the transgenes and other things into the
10 soil and potential takeup by soil microorganisms.

11 So I think that it probably is a good idea
12 to regulate nonviable plant material, because even if
13 the plant is not viable, depending on how much of a
14 quantity you're talking about, there is theoretical
15 possibilities, because I do know there's been work
16 done under your risk assessment grant process that has
17 found transgenes and other things in soils, months
18 after the end of the season found gene fragments.

19 So you could see that if you're bringing in
20 plant material that's nonviable, there could be an
21 environmental impact, because if it's put out, it
22 could be released that way, or if it's consumed by
23 other organisms, there could be an effect that way,
24 even though the plant material itself is nonviable.

25 For six, about APHIS is considering a new

1 mechanism involving APHIS, the states and the
2 producers for commercial production of plants not
3 intended for food or feed in cases where the producer
4 would prefer to develop and extract pharmaceutical and
5 industrial compounds under confinement conditions with
6 government oversight, rather than use the approval
7 process for unconfined releases. For the
8 characteristics of this mechanism, we think it should
9 only be available to nonfood and feed plants.

10 We agree that APHIS and the states and the
11 producers all need to be involved. We believe that
12 the state permits need to be affirmative, and we
13 believe that the state must disclose information to
14 the public on the crop, the location, the genus that's
15 engineered, because the public has an absolute right
16 to know these things, because if there's something
17 that goes wrong, particularly with pharmaceutical or
18 industrial compounds being engineered into plants,
19 people in the local communities do need to know that.

20 We think that the increasing amount of
21 secrecy is untenable in this area. If you look for
22 the pharmaceutical crops, so many of these things,
23 they're all confidential, the organisms that they come
24 from, the gene itself. We think that raises serious
25 questions. That secrecy is untenable. We'd also

1 point out that a couple years ago, the National
2 Academy, in a report about the USDA, did also raise
3 this question of excessive secrecy, so we think action
4 needs to be taken there.

5 Current regulations have no provision for
6 adventitious presence. The one question that I have
7 here is, does that mean under the current regulations,
8 would that make adventitious presence not legal? When
9 you say there's no provision for it, does that mean if
10 it's present it's not legal?

11 MR. TURNER: Right. It's not supposed to be
12 there if it's an unapproved event. This is not
13 talking about approved events and commodities such as
14 --

15 MR. HANSEN: Okay. So for unapproved
16 events, it's not proper language, but there's
17 functionally a zero tolerance? I've dealt with it,
18 because our concern is we don't think there should be
19 an allowance for adventitious presence of unapproved
20 events. The only thing that should be allowed is
21 things that have gone through complete regulatory
22 scrutiny for human and environmental effects.

23 MR. TURNER: You support a zero tolerance?

24 MR. HANSEN: Yes. We support a zero
25 tolerance for the adventitious presence, particularly

1 of unexpected or of nonapproved events. I would point
2 out that this is also of great concern
3 internationally. The U.S. I know has raised this a
4 number of times at CODEX, and from our discussions
5 with Europeans in other countries, they might allow
6 some adventitious presence for things that are
7 approved, but they have told us that their position
8 probably would be they do not want -- if it's
9 unapproved, they would probably have a zero tolerance.

10 So, there are international ramifications.
11 There are, I think, countries that would say that
12 should be zero. So that's why we don't think there
13 should be any exemption from low level occurrence.

14 MR. TURNER: Your B is noted. Remember when
15 we talk about exemption here, we talking about from
16 APHIS regulations, so not that it wouldn't have been
17 reviewed necessarily by FDA, so there's another
18 characterization we could make.

19 MR. HANSEN: Right, but FDA would look at
20 the food safety, and the environmental impacts have to
21 be looked at. In an ideal world, we'd like to see the
22 EPA do that, but if it's between the USDA and the FDA,
23 with all the issues we have at the USDA, I think they
24 understand environmental issues better than the FDA
25 and have better expertise.

1 Now, for this question No. 8 about expedited
2 review or exemption of certain low level genetically
3 engineered organism commodities intended for
4 importation that have received all necessary
5 regulatory approvals in their country of origin and
6 are not intended for propagation in the U.S., we'd
7 point out with this it's unclear what you mean by low
8 risk genetically engineered organisms, but we would
9 point out that there are quite a number of countries
10 throughout the world that have no regulations in
11 place.

12 The regulatory approvals are functionally
13 nonexistent. So therefore, just because something has
14 gone through some other country does not necessarily
15 mean from our viewpoint that it's gone through any
16 kind of strict or rigorous environmental or human
17 health review. The question we have here is that it
18 was our understanding that from our examination of the
19 law, we didn't know whether the USDA has jurisdiction,
20 because we know there's nothing in FDA policy, for
21 example, that would require safety review of things
22 coming in from other countries, because the stuff we
23 have here, the process in place at FDA is voluntary.

24 They haven't dealt with the foreign import.
25 We would point out that just in the press in the last

1 couple of days, there was an article about Chile is
2 working on engineered grapes and fruits. There aren't
3 any strict regulations in Chile right now, so what
4 kind of review is going to happen there, and what will
5 the agency do when these foods show up? So the
6 question we have is, what jurisdiction do you have
7 over these commodities? What's your thinking for what
8 authority you have to look at commodities?

9 MR. TURNER: Well, we have authority right
10 now under present law over anything coming in, if it's
11 an organism genetically engineered and it might be a
12 plant pest. Maybe a better example, regardless of
13 whether we think FDA would have the authority to make
14 it mandatory, there are examples of things that have
15 been through FDA that maybe have not been reviewed by
16 APHIS for the environmental effects, but the intention
17 of the imports to go straight into food processing.
18 Can that be considered an exceptional case, or are the
19 environmental issues --

20 MR. HANSEN: It seems to me that those lines
21 get fine, because I could see for products that are
22 coming in straight for food, but if it's a commodity,
23 you could be shipping in wheat or corn that was
24 designed to go straight into animal feed or into
25 processing, but in the process of moving, seeds fall

1 out. It happens. They get into the field, and there
2 could be environmental impact.

3 We also think that there should always be an
4 environmental assessment that is done of things that
5 come into the U.S., because the notion of equivalency
6 is not going to work in this area, because the U.S.
7 environment and environmental conditions are going to
8 be unique. Some environmental review that's being
9 done in Chile or China or other environments don't
10 have the same environment as the U.S. So we don't
11 think that equivalency, which works in many other
12 areas, that it doesn't particularly work in the
13 environmental review area, so we would want the agency
14 to review anything that comes in.

15 Again, the concern is -- I guess there would
16 be less concern if you're bringing in -- would a
17 commodity also be grapes, fruits or fruit puree to go
18 into drinks? If you consider those commodities, I
19 could see how the environmental review there could be
20 far less, because there's no sort of possibility of
21 things going wrong.

22 But with what people consider bulk
23 commodities, even though they might be intended to go
24 straight into human food or animal feed, if they're
25 seeds or anything else that could be viable, there

1 could be, through human error or some other problem,
2 there could be --

3 MS. MCCAMMON: Could I ask for a point of
4 clarification?

5 MR. HANSEN: Sure.

6 MS. MCCAMMON: Sally McCammon. How about
7 just a clarification of anything coming in? Would you
8 consider categories of things? You know, like we
9 counted grapes from Chile, rather than case-by-case do
10 a category.

11 MR. HANSEN: I'd have to think actually
12 there might be categories where, yes, you could have a
13 much lower level of regulation. For example, if you
14 want to use grapes from Chile, if they're seedless, or
15 say they want to import fruits, mangoes or something
16 else that are going to be pureed, if they want to
17 bring the puree in and it's engineered, there doesn't
18 need to be a safety review, but the environmental
19 review would probably only be minimal. I mean, there
20 might be some theoretical ways you could think of
21 something, but yes, there would be certain categories.

22 Obviously, bulk commodities that are seeds
23 and that are potentially viable should require far
24 more in environmental review than seedless grapes or
25 pulp. We have to think about whether they should be

1 totally exempted. We would agree that their level of
2 review should be much lower. We'd have to think
3 whether that should be zero.

4 I just want to go back to the pharmaceutical
5 crop issue again. We said about disclosing the
6 information to the public. You might think, well,
7 what's the environmental risk if these things, since
8 we think nonfood and feed crops can be used for
9 pharmaceutical and industrial production, but only
10 under confinement, that is, only in greenhouses. But
11 what happens if there's tornadoes or acts of nature?

12 There was a case in Kentucky. I think it
13 was Large Scale Biology that had engineered tobacco.
14 It was engineered with a virus, and a tornado came
15 through, and goodbye facility. Now, some of us, when
16 we were told about this, they said there's going to be
17 no viable parts of that tobacco plant left over after
18 the tornado, but you could point out that if
19 particularly one had been engineered with the tobacco
20 mosaic virus or something like that, all you'd need is
21 a little bit of the tobacco plant.

22 Not even anything that's viable could
23 potentially, if it rained down on tomatoes, transmit a
24 disease. So there can be, I think, acts of nature,
25 that even in confined facilities can lead to releases

1 that can have an environmental impact, and that can
2 also affect the surrounding community. That's another
3 reason why we think that all this information needs to
4 be disclosed to the public.

5 Now, let's see 8. We've done 8. Nine. The
6 engineered Arabidopsis are exempt. Should the
7 regulation of other similar or genetically engineered
8 plants be consistent? No. The reason we think not is
9 because -- I've already mentioned the example of the
10 Arabidopsis where when it was engineered just for
11 herbicide tolerance, and it was just looking at the
12 effect of conventional breeding via genetic
13 engineering. They found this large increase in per
14 plant outcrossing rates.

15 So to say that you understand, I think that
16 was a case where nobody could have predicted that, and
17 they still don't quite understand what the mechanism
18 was behind that, so I think that shows that even with
19 the Drosophila of the plant world, which is what
20 Arabidopsis is, we can still be surprised, so I can't
21 see that other things should be as lax as with
22 Arabidopsis. I would say for things that are going to
23 be studied within academia, that are going to be grown
24 indoors, perhaps their restrictions could be less,
25 because I know you can do field tests.

1 So the concern that we have there for the
2 risk based criteria is again, that unexpected effects
3 can happen, and we've even seen them with a plant
4 that's as well understood as Arabidopsis.

5 MR. TURNER: A point of clarification. You
6 probably know this, but this is talking about
7 exempting just from interstate movement restrictions,
8 not for releases. To a large extent, it was the
9 academic community lab, that lab that we were thinking
10 about.

11 MR. HANSEN: So what are the restrictions?
12 Is it that they have to fill out all sorts of forms to
13 do any kind of --

14 MR. TURNER: Yeah. They have to do a permit
15 or a notification now, just as if it were a release.

16 MR. HANSEN: Even if they're doing -- okay.

17 MR. TURNER: For interstate movement, even
18 if it's lab to lab.

19 MR. HANSEN: Yeah, then we would reserve
20 judgment on that. I would have to talk to others at
21 Consumers Union, but my personal opinion is yes, for
22 stuff in academia, if it's going to be done in labs,
23 some of the paperwork could probably be reduced,
24 because I've talked to some scientists that have
25 complained about --

1 MALE VOICE: We have to.

2 MR. HANSEN: I'll skip over 10. With 11, we
3 actually think that they should keep it at the
4 prescriptive container requirements and not move to
5 performance based, because we think the prescriptive
6 is stronger.

7 So I think that about does it for our
8 comments. I would like to again thank you. We really
9 had, since we do a lot of international work, this
10 question of jurisdiction over anything coming in from
11 overseas. It's good to hear that the USDA believes
12 they have authority over any commodity coming in.

13 We really think you should look at potential
14 environmental effects of things coming in, and you
15 should do environmental reviews of anything coming in
16 from other countries. Unless the FDA changes their
17 policy to where they're going to require safety
18 assessments, part of that can be under, I guess,
19 USDA's purview as well, potentially, or would the FDA
20 have to do that? Because we're concerned about --

21 MR. TURNER: We're looking. I mean, we
22 would not duplicate their effort, but whether there's
23 a coordination process of whether we could consider
24 this review status at FDA possibly and our actions.

25 MR. HANSEN: That should be looked at. The

1 issue for imports from other countries was actually
2 raised in the policy that the FDA proposed in 2001.
3 We applauded the agency for doing that, because we had
4 been concerned about a potential import into the U.S.
5 from other countries for a while. Our concern,
6 though, is that the FDA, for the first year that was
7 on their B list of priorities. This year, it has
8 dropped off, so it's not even on their radar. Dr.
9 Crawford did testify up on the hill that they thought
10 that the old policy from 1992 was sufficient. We
11 really disagree with that.

12 So yes, you can coordinate with that, but if
13 the FDA is not going to do anything, unless they're
14 going to change their mind and implement or finalize
15 the policies that they proposed in 2001, which would
16 actually look at imports. We think it is a good
17 thing. If they're not going to do that, then we think
18 somebody has got to do it. So if you want to
19 coordinate with FDA, that's fine, but if they're not
20 doing it or they do something that's voluntary or
21 weak, which we think other things they've done are,
22 then the USDA should pick up the ball, but somebody's
23 got to do it.

24 Hopefully, it should be the FDA, but unless
25 they change -- we've been told that possibly from

1 2001, which we actually supported, isn't going
2 anywhere, but maybe that will change.

3 I guess that's about it for the basic points
4 here. We'd also wait for the environmental impact
5 statement to come out, and we'll do detailed comments.

6 I'll go to the scientific literature and point out
7 more detailed examples to back up a number of points
8 we've said here, but from what I've told you, these
9 are the basic positions that Consumers Union has.

10 We look forward to being involved in the
11 rest of this process as it evolves. I note Cindy
12 Smith had said, can there be any update? Is there
13 anything for when this draft EIS would appear? Are
14 you talking 12 months, 6 months, 2 years?

15 MS. SMITH: Our intention is to try to
16 complete it this year, but we also recognize this is a
17 huge undertaking and we don't want to compromise the
18 integrity of what we're doing, so part of what we're
19 going to have to consider is what the breadth of
20 comments is that we get during the scoping period.

21 MR. HANSEN: But are you going to try --

22 MS. SMITH: It's our objective to complete
23 it this year.

24 MR. HANSEN: So within a year? That's good,
25 and then that would be followed by a round of what we

1 were told would be -- you'd make it available not only
2 for public comments, but there was talk about also
3 perhaps convening a number of public meetings?

4 MS. SMITH: What we're looking at is we want
5 to have public meetings and scientific meetings
6 associated with this whole process. What we'd
7 probably do is have those meetings in conjunction with
8 the draft rule coming out. That way, people have more
9 to actually comment on than just the EIS. That's our
10 thinking now, but we're open. As this process, our
11 thinking --

12 MR. HANSEN: I think that's a good idea.
13 That's a good point to do it at. The only thing I
14 would suggest is that you should also hold those
15 things outside the DC area, in other parts of the
16 country, so you can get a wider range of civil society
17 groups coming in, and you actually might be able to
18 get more scientists as well.

19 MS. SMITH: That's a good suggestion.

20 MR. HANSEN: Yes, I should have said that.
21 That's something we strongly support, too, going
22 forward with both having public meetings and convening
23 scientific meetings as well that are open to the
24 public, similar to the science advisory panels that
25 EPA does that we think are very good.

1 MR. TURNER: Thanks, Michael. Your comments
2 are very concrete, substantive. I know it took some
3 time to do the review, and we appreciate it.

4 MR. HANSEN: Okay. Thank you. We look
5 forward to seeing the EIS. I hope you can get it done
6 within 18 months, because it does appear to me -- I
7 hope you don't have problems, that there's problems
8 with the FDA trying to get any kind of rules out, and
9 it's actually not problems with the agency, it's
10 problems with the general counsel. Hopefully, there
11 doesn't appear to be that as much a problem here.

12 MS. SMITH: We have a very supportive
13 general counsel.

14 MR. HANSEN: You're lucky, because we've
15 been meeting -- I can tell you for veterinary
16 medicine, it's very frustrating about their engineered
17 animal regulations. So we do think that it's good
18 that the agencies are trying to coordinate. I like
19 the time line for being a year, but if you can get it
20 done in a year and a half, that would be good, because
21 I know how long these things can take.

22 MS. SMITH: We would agree.

23 MALE VOICE: A lifetime.

24 MS. SMITH: Do we have any questions?

25 MR. CORDTS: I have one question. This is

1 John Cordts from BRS. We have been struggling
2 somewhat with our definitions of pharmaceutical and
3 industrial compounds, and I was wondering if Consumers
4 Union had any recommendations for how we should define
5 these. There are your strict pharmaceuticals that
6 come under prescriptions, and then there are
7 neutraceuticals and that sort of thing.

8 MR. HANSEN: Yes. Thank you for that
9 question. We've been thinking about that issue as
10 well. Our concern is that it should be as broad as
11 possible, so it should be anything for pharmaceutical,
12 that's anything that would have some kind of
13 physiological action, so that could include your
14 neutraceuticals and other things. You have industrial
15 compounds, but things that might be considered as
16 research chemicals.

17 The example of avidin is perfect, that that
18 can actually be used -- it's got insecticidal
19 properties and other things, but its intention was to
20 be used as a research chemical, and therefore, it sort
21 of fell through the cracks with this notification
22 system, even though it could have environmental
23 impacts or health impacts. So we think that the
24 definition should be as broad as possible to sort of
25 basically get everything.

1 Perhaps the way it could be defined is
2 almost anything that's produced, it's going to be
3 produced in food plant that's not considered to be a
4 food item. We've actually in a bill in Texas that
5 Consumers Union helped to draft, which would have
6 outlawed the planting of these farmer crops, the way
7 it was defined there was basically anything that was
8 not intended to be used as a food couldn't be produced
9 in food crops. Now, that was amended so it didn't
10 include plant protection, because we didn't want to
11 get into fights over engineered BTs and that.

12 But I do think you need a broad definition.
13 Things that could be physiologically active should be
14 considered, because it is the intention that counts.
15 We don't care. Something that could have a drug
16 effect, if you're going to say it's a research
17 chemical, it still can have that effect, but it would
18 not be considered a pharmaceutical from what I
19 understand by your definition, because your definition
20 is intentional, that there has to be an intentionality
21 there, right? That the compound, you say you want to
22 use it for a pharmaceutical purpose.

23 That's my understanding. If that's
24 incorrect, that's fine, but where we think the
25 intentionality is not enough. I guess the way for a

1 drug, you could look at it. Look at the definition of
2 drug, if it has a physiological effect. I mean, it
3 shouldn't be as broad. I know at the Center for
4 Veterinary Medicine that the definition for vet drug,
5 which is actually being debated internationally now
6 because it's in CODEX as well, is this very vague,
7 anything that affects the structure or function.

8 Okay. An organism, then, that can be so
9 wide, you can argue that certain nutrients have that
10 effect. Maybe a narrower definition on what a
11 pharmaceutical is, something that is physiologically
12 active. So I think you need to get away somewhat from
13 the intentionality argument, because what's important
14 is the characteristic of what you're putting in, not
15 necessarily what the person says they want to do with
16 it, because in our mind a drug is a drug.

17 Now, there are drugs that can also be used
18 as research chemicals. You can say you can use them
19 for something else, but it's still a drug and should
20 be treated as such, even if you say this, now what you
21 want to use it for vis-a-vis for the environmental
22 impact.

23 MS. KOEHLER: Susan Koehler. Just drawing
24 on your example of neutraceuticals, suppose you have
25 enhanced vitamin A content. Now, that enhanced

1 vitamin A, maybe you could extract that and say you're
2 using it as a nutraceutical, but it could also be a
3 normal component of a food crop. So how would you
4 view those kinds of nutraceuticals? Likewise, when
5 you get into things like starch, where some starches
6 may have multiple uses in industries as well as for
7 the food industry, that's where we get into this sort
8 of gray area.

9 MR. HANSEN: Yeah, that gray area. That is
10 true. Starches can be used for -- I don't know. It
11 seems to me that is a hard question, because if you're
12 talking about engineering a plant, if it has vitamin C
13 or vitamin A or one of these things, to increase it,
14 how much should it take for you to basically look at
15 it differently? We'd have to think about this, but
16 there was a regulation that we pointed out to the FDA
17 when they first wanted to regulate -- I'm sorry, I
18 just lost it. Could you repeat that question again?

19 MS. KOEHLER: About nutraceuticals --

20 MR. HANSEN: Yeah. Now I remember. We did
21 do comments to the FDA back in 1992 and pointed out
22 that there had been a proposal in the seventies to say
23 that there should be grass affirmation petitions, even
24 for conventional breeding. If there was an increase,
25 and I think the way it was talked about is if there

1 was an increase in a key nutrient, and I think they
2 would say like vitamin C, you would say for a certain
3 range of crops where we get most of our vitamin C, I
4 believe that they were proposing if there was more
5 than a 20 percent change or 40 percent change for key
6 things, that would trigger a process.

7 That was happening, because when the first
8 mechanically harvested tomatoes, the UC 82s that were
9 originally developed, there was concern, because when
10 those first ones were coming out, they did have lower
11 vitamin and other content than the conventionally bred
12 tomatoes. There was a meeting at the American
13 Agronomy Society, and the interesting thing is if you
14 go back and read about that workshop where they
15 proposed this, you had Campbell's and other companies
16 there that were supporting this move, because they
17 were seeing a change, and that concerned them for the
18 vegetables that they were using in their soups, but
19 nothing happened functionally because the plant
20 breeders said no.

21 So those regulations are still on the book,
22 but they've never gone anywhere. I would go back and
23 look at that. There might be something you could take
24 from there, because they actually did a good job
25 pointing out if it's vitamin A or these other things,

1 if there was more than a 20 or 40 percent change that
2 would trigger it. It wouldn't be in any crop. It
3 would only be in the ones where that's considered an
4 important source of the nutrient in the diet.

5 So something similar that you could probably
6 think about for the nutraceuticals, that if it's an
7 increase above a certain amount could kick in more
8 regulation, because the concern that we would have
9 there would be twofold. There is some concern that if
10 the levels get too high, they could have an effect,
11 but there's also this concern with if it does involve
12 genetic engineering because of insertional mutagenesis
13 and pleiotropy and epistasis, there's these unexpected
14 effects. But in terms of the cutoff for the
15 nutraceuticals, you might look at some of those
16 proposals 30 years ago, because I think they're
17 interesting.

18 One other question I have for Sally, that
19 is, with the International Plant Protection
20 convention, how does what you're doing here jive with
21 that, or not?

22 MS. MCCAMMON: Sally McCammon. One of our
23 top five principles is we want to have this be
24 responsive to international needs. We want to exert
25 leadership in science based international standards,

1 so I think part of our rationale -- and Cindy can
2 correct me if I'm wrong -- of taking the time to go
3 through this environmental impact statement as well as
4 having the public meetings and getting in the
5 scientific information in our proposal is to make sure
6 that we do cover as broad a base as possible and have
7 the appropriate science for whatever decisions we
8 make, because we realize that this will have an impact
9 internationally, as well as domestically.

10 APHIS does have the chief plant health
11 officer for the U.S., so we are major players in the
12 IPPC and are working on a standard in that area. The
13 information we gather here will influence future work
14 in those arenas, and I assume in other arenas, too,
15 such as CODEX and OIE.

16 MR. HANSEN: Yeah. CODEX is going to be
17 hard, because they can't look at environmental issues
18 unless they're associated with human health.

19 MS. MCCAMMON: Well, we'll take that back in
20 an absolute sense.

21 MR. HANSEN: Well, if there's a human health
22 implication of an environmental effect, then it can be
23 looked at at CODEX. I think you're right. What we'll
24 do is, I need to be up more with what's happening with
25 the International Plant Protection convention, because

1 I've done some talking. I have not been able to go to
2 the meetings, but I know that as of last year, there
3 was this sort of struggle between the U.S. and others
4 on whether things should be case-by-case.

5 I have to go back and look, but I'll go back
6 and look, not by the 23rd, but when your EIS comes
7 out, I'll make sure we look at what's happening in
8 IPPC and look to see how that's consistent with this.
9 I'm sure with the U.S. doing an IPPC would be
10 consistent with what you're putting forward here, but
11 I do need to look at the IPPC model to see where the
12 debates are, because that could help inform some of
13 our comments as well.

14 MS. MCCAMMON: Yeah. Well, definitely for
15 any environmental work, the major forum is IPPC.

16 MR. HANSEN: I know.

17 MS. MCCAMMON: I don't know what you mean,
18 what the issue of case-by-case, but we've always stood
19 by that reviews have to be done case-by-case if you
20 want to have a real true safety assessment, and I
21 think you made that statement also, that you feel that
22 way also.

23 MR. HANSEN: But there's something. It's
24 just I don't remember it now, but I remember when I
25 was told about it, it was similar to --

1 MS. MCCAMMON: This is for IPPC?

2 MR. HANSEN: Yeah.

3 MS. MCCAMMON: Okay.

4 MR. HANSEN: It was similar to a debate that
5 was going on in CODEX, but I'm going to have to go
6 back and look at that and figure it all out. I do
7 think that it is important to look at the implications
8 at both IPPC, and even though we haven't signed on it,
9 the provisions that have been passed by our safety
10 protocol. There was a lot of good things that came
11 out of the meeting of parties, the first one.

12 MS. MCCAMMON: Definitely, but you know
13 there is an agreement between IPPC and the secretary
14 of the CPD to work together as well.

15 MR. HANSEN: Okay. Good.

16 MS. MCCAMMON: So that these international
17 organizations are coordinating to avoid duplication
18 and confusion.

19 MR. HANSEN: That's a very good thing.

20 MR. GUPTA: I'm Subhash Gupta, Michael.

21 MR. HANSEN: Hello.

22 MR. GUPTA: Thanks for your comments. I
23 just wanted to get some clarification on your
24 recommendation about carrying out risk assessment on
25 imported commodities coming from overseas. Could you

1 clarify this a bit more?

2 MR. HANSEN: Yes. The commodities that we
3 would have the most concern about is you could have
4 commodities -- wheat, rice corn, soybeans -- that are
5 engineered coming in from other countries, and they
6 could say these are designed to be -- in the U.S.
7 they're designed to be processed into human food or
8 used as animal feed, but in the process of being
9 transferred, there can be spillage en route. There
10 could be mixups where people don't realize that this
11 was supposed to go into animal feed and it ends up
12 being planted someplace or falling off a transport.
13 So with seeds, those should be looked at.

14 MR. GUPTA: It seems that the AIA could have
15 asked them for an agreement.

16 MS. MCCAMMON: No. He's saying a commodity
17 that's made up of seeds, not something that's being
18 imported as a seed.

19 MR. GUPTA: A clone.

20 MR. HANSEN: Right. But if it's being
21 imported as a commodity and it's not intended to be
22 planted, it's intended to be sort of processed into
23 animal feed or into human food, there can still be
24 escape of those seeds. The concern would be, you need
25 to look at and do an environmental review for that

1 probability, because an environmental review that's
2 done in some other country is just -- environments are
3 unique. I mean, you can have the rough environment in
4 terms of basic climate might be the same, but a lot of
5 the species are going to be different, and the
6 microecosystems are just not the same.

7 Somebody wanting to import soybeans from
8 China is going to be -- and we're particularly
9 concerned, because there's now more of these countries
10 in Asia and elsewhere that are talking about doing
11 some genetic engineering. The levels of regulation
12 which are nonexistent in those places is concerning to
13 us. That's why we're actually trying to get a lot of
14 countries around the world to develop safety
15 regulations based on the principles that have come out
16 of CODEX alimentaris.

17 So that's basically it for the commodities.
18 I do realize that there is this hierarchy. We would,
19 of course, have much more concern on the seeds and
20 other things than on seedless grapes or fruit purees,
21 or if you're importing commodities that are ground or
22 milled, there's going to be much less concern. It's
23 just that concern that since it's technically not
24 supposed to be planted, if you just consider it a
25 commodity. If they're seeds, they can escape through

1 human and other kinds of error.

2 MR. TURNER: I know Canada, I think, has
3 made some provisions for, I think it's papayas or some
4 tropical fruits that are unlikely to grow there and be
5 the victim of escape.

6 MR. HANSEN: Yeah, but that's something
7 where --

8 MR. TURNER: But you could emphasize other
9 cases where they're not, and you've given a few.

10 MR. HANSEN: Yeah. A papaya in Canada is a
11 good example. It wouldn't be good in the U.S. It
12 would just depend on where you imported it. If you
13 bring it into Florida, it could. So I would have to
14 think that if there might be plants from some other
15 places that just couldn't grow in conditions here, but
16 unless it's something that really does require real
17 tropical conditions, I can't see -- Canada doesn't
18 have some of where we have such a range from
19 temperate, subtropical.

20 I'll think about that, whether there is any
21 environments or categories of plants that just
22 couldn't grow here because the environment is not
23 appropriate, so therefore you wouldn't have to worry
24 about the risk.

25 MR. TURNER: Anyone else?

1 MS. KOEHLER: Go ahead.

2 MR. WACH: No, I thought you were going to
3 reach for the microphone.

4 MS. KOEHLER: Well, I was just -- go ahead.

5 MR. WACH: No, go ahead.

6 MS. KOEHLER: This is Susan Koehler. I just
7 wanted to repeat our appreciation for taking the time
8 to prepare very colorful comments.

9 MR. HANSEN: Thank you.

10 MS. KOEHLER: It helps when we go through
11 and look at what the reg might start looking like to
12 have real concrete examples to wrap our hands around,
13 so thanks.

14 MR. HANSEN: Yeah, and we felt it was
15 important to come down here to do that, because there
16 are a lot of civil society organizations or NGOs
17 working on these issues, but there are not many that
18 are also active at the international level, and that's
19 always been a concern of ours, that there are. It's
20 been for decades that a lot of groups in the U.S. can
21 be very U.S. focused and not realize there's the rest
22 of the world and that there are things going on at the
23 global level that affect us, and we need to coordinate
24 that, so that's one of the reasons why we wanted to
25 come down here.

1 A number of the comments we're doing, a lot
2 of other people, I think, will make, but there's also
3 other comments. We always try to look at the
4 international aspect, because I do think that's
5 important, and there are good things happening.

6 Any other?

7 MS. SMITH: Okay. Well, thanks a lot for
8 coming in. We really appreciate your time and all
9 your comments.

10 MR. HANSEN: Thank you.

11 (Whereupon, at 2:12 p.m, the meeting was
12 concluded.)

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REPORTER'S CERTIFICATE

TITLE: Stakeholders Mtgs. (Consumers Union)
DATE: March 11, 2004
LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: March 11, 2004

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