

USDA-APHIS-BRS

Moderator: Richard George

June 6, 2017

9:09 am CT

Dick George: Thank you so much. And I want to thank (Don) and all the colleagues, the APHIS colleagues here for letting us use the facility. Let's see here, so we'll start our official part of our meeting.

Good morning. Welcome to our public comment meeting on proposed revisions to USDA biotechnology regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. I'm Dick George, Communications Branch Chief at Biotechnology Regulatory Services which is a part of APHIS Animal and Plant Health Inspection Service which in turn is part of the U.S. Department of Agriculture. Joining me today is BRS Assistant Deputy Administrator Sid Abel.

Sid Abel: Good morning everybody, welcome to our first public meeting of three of our proposed regulations for biotechnology. As many of you may recall back in February 2015 APHIS announced the withdrawal of its 2008 proposed rule after receiving more than 88,000 comment submissions.

Based on those comments, advancements in biotechnology in recent years and more than 28 new years of experience regulating GE organisms, we wanted to get a fresh stakeholder engagement aimed at alternative policies approaches for our new regulations.

Following those stakeholder engagements on January 19 we proposed the first comprehensive revisions to USDA's biotechnology regulations since 1987 and opened the comment period. We will be accepting comments on the proposed revisions through June 19 for a total 150 days of open comment.

Our goals in reproposing these new regulations are consistent with our statutory authority, and that is to protect plant health. We also want to improve processes to be more transparent to both stakeholders and the public. And we wanted to regulate at a level more commensurate with risk for those products that we do decide to regulate.

We wanted also to eliminate unnecessary burdens of the regulations of new products for biotechnology. And then finally, we wanted to enhance development opportunities for small companies and universities who would like to bring new products to market but cannot afford to go through our current regulatory process.

So in summary, we think the proposed rule if finalized will result from less regulation of GE organisms that pose little or no risk to plant health and more regulation for those that do pose a plant test or noxious weed risk.

Today we are here to listen what you think. We will carefully consider your comments along with the comments we receive in other public comment meetings and at regulations.gov as we decide how and whether to finalize the proposed revisions to our regulations. We want and need input from our

stakeholders and the public during the comment period which will remain open again through June 19.

Dick George: There is a wealth of information about our proposed rule on our website. The easiest way to get there to get to our site is to search Biotechnology Regulatory Services, click on the entry for us to get to our home page which is shown here. Then in the left navigation shown here with an arrow you will see a link called Engagement on APHIS Biotechnology Regulations.

Click on it and you will go to a page explaining what we are doing with a list of documents including Federal Register Notice with the proposal itself, questions and answers about the proposed rule, the regulatory impact statement that looks at the economic impact of the proposed rule, a draft environmental impact statement, and other helpful information.

Sid Abel: You can comment here today both on the proposed revisions and the draft environmental impact statement or you can comment anytime through June 19 at regulations.gov. You can get there again by clicking on the link on our website or simply going to regulations.gov and entering the docket ID number which is A-P-H-I-S-2015-0057.

We will carefully review public comments on the proposed revision, draft EIS, and other supporting documents including those we receive today and in our other two public meetings to be held next week and those received again at regulations.gov. We will decide on how and whether to finalize the proposed revisions based on our evaluations of those public comments.

Dick George: This meeting is being recorded and that recording along with the transcription of it will be posted to our website. We will hear first today from those who are in attendance and have preregistered to speak and then we will open the

mike to others in the room who would like to speak but perhaps may have not yet preregistered. Then we will open the phone lines for comments from those attending via the web.

We're going to limit it to five minutes or so. However, we only have a handful of people that desire to speak this morning so we're going to go over a little bit. And if they are finished and all the speakers who have registered to speak have already spoken, if someone would like to come up and elaborate on their comments. So with that we will begin to take comments. And the first comment from those in the room with us today is Dan Fjell. Dan? Come on up. Dale, I'm sorry Dale.

Dale Fjell: That's okay.

Dick George: So if you would please and all our speakers when you begin please say your name and spell your name.

Operator: This conference is now in question and answer mode. To alert the speaker that you have a question press 1 then 0.

Dick George: Please tell us your name right.

Dale Fjell: All right well thank you for the opportunity to speak on the coordinated framework of regulation of biotechnology. I am Dale Fjell, I am a director of research and stewardship for the Kansas Corn Growers Association. Before joining the Corn Growers staff I was a professor of agronomy for 34 years in state university research and extension.

We would prefer to have a corn farmer present this. But they're very busy this time of year for our growers who are trying to finish spring planting and

Kansas at last report was 90% completed on planning. So we're getting there. But it is a very busy time. And in some cases they're getting close to harvesting wheat and you may hear about that here in just a little bit. So I'm making these remarks on behalf of our Kansas corn members who can't be here today.

In Kansas where weeds and pests are prevalent, biotechnology has made it possible for our farmers to produce a higher quality crop with more consistent yields. Ninety five percent and probably closer to 100% of the corn seed we plant in Kansas are biotech hybrids.

Biotechnology has helped Kansas family farmers produce healthier, more bountiful corn crops and to do it more sustainably. Anyone who disputes this probably has not been on any one of our farms.

The coordinated framework was created from 30 years ago before we knew about the lack, and I'll emphasize the lack of risks presented by the use of biotechnology. With more than three decades of experience and research under our belts we have this opportunity to take another look at the way we regulate the development of biotech products.

This is an opportunity to open the door for more innovation. When the Obama administration began this process to look at the coordinated framework one of the stated goals was to reduce regulatory burdens and avoid inhibiting innovation or stigmatizing new technologies or creating trade barriers.

Our farmers are interested and involved in regulatory issues in agriculture. Regulations directly impact their farming operations and their profitability.

We are hopeful this new framework will provide regulatory efficiency, transparency, and certainty.

The future of biotechnology and other forms of advanced crop breeding is exciting and promising. This framework should reduce regulatory burdens to allow for innovations and the opportunity for innovators to bring their products to market and it should ensure certainty to the crop growers who are using the technology in their fields.

We are calling for rational approaches to determine those regulated products. These determinations should be based on the product, not the process. And processes and technologies like gene editing should not be regulated like conventional biotechnology products.

When coordinated framework was first created biotechnology was a new science and there were many unknowns. After 20 years of biotech crops being grown on our fields, a published report from the National Academy of Sciences Engineering and Medicine found no evidence of harm to human health or the environment.

As you take a fresh look at the coordinated framework we encourage you to use scientific evidence and common sense. Although a cumbersome, time consuming, and sometimes expensive system, it has provided an incredible pathway for approval to many excellent biotech products that have brought innovation and sustainability to our farms.

Let's use this opportunity to allow for more innovation and more technologies that can continue to revolutionize agriculture to provide feed, food, and fuel to a growing world population.

Our organization as well as the National Corn Growers Association are continuing to study the draft coordinated framework document and we look forward to submitting more detailed written comments before the deadline. Thank you for your time today.

Dick George: Okay.

Dick George: Thank you Dale. I think we could - thank you. Our next speaker is Daniel Heady.

Daniel Heady: Good morning. My name is Daniel Heady. Do you need me to spell that?

Dick George: Please.

Daniel Heady: Good morning. D-a-n-i-e-l and my last name is H-E-A-D-Y. I appreciate the opportunity to come here. We also would love to have a Kansas wheat farmer deliver these comments but anyone who's familiar with Kansas wheat we're at about three days from harvest so everyone is a little busy right now. So they sent me instead and so I would just like to offer our commentary as well.

So the Kansas Association of Wheat Growers appreciates the opportunity to offer comments on this issue. KAWG is a member governed organization representing wheat growers on matters affecting wheat and providing leadership in the wheat industry. Based in Manhattan Kansas KAWG is funded by our over 800 members and works in areas of farm policy, trade, environmental regulations, agricultural research, and sustainability.

After consulting with research by Kansas State and very many industry stakeholders about potential impact of these changes KAWG would like to

offer the following comments. First we will have some general commentary and then some more specific commentary towards the end.

KAWG believes that increasing regulatory burden causes inefficiencies and drives up costs that prohibit an ag advancement. Researchers have been making significant advancements in discovering genetic components in beef that have marketable benefits in nutrition, energy, and even (shelter).

Increasing the cost of discovering these advancements would be detrimental to the long term success of wheat and wheat research. Due to the ever increasing price of equipment, lab space, education, and experts, the cost of agricultural research is already high.

This increasing - this increased cost effectively shuts out many researchers and makes research economically feasible for only those with the deepest pockets. Finally, regulatory measures should be made absent of politics and should be based on sound science, to echo what the Kansas corn growers association set forth today.

It's clear, biotech products are safe and they are leading the way to creating a more secure and sustainable global food supply. The World Health Organization, American Medical Association, the National Academy of Sciences, American Association for the Advancement of Science have all declared that there is no sound or scientifically accurate evidence that biotech crops are unsafe. These costs of regulatory requirements need to be based on a scientific necessity, not political motivation. Now I'll for some specific commentary.

The proposed revisions seem to echo our call for a regulatory structure that encourages innovation by minimizing useless oversight. The oversight that

does exist should be proportional to the assessment of proposed risk to a potential new variety. However, some parts of the proposed revision do not follow that framework and as a result the USDA should re-propose a rule to adequately address these issues.

First the proposed system shifts the regulatory burden and focus from the commercialization stage to the research and development stages of the product innovation. This shift in the burden places too much focus on the processes that are used for scientific advancement rather than focusing on the end products. If the ultimate goal is truly to protect against pest plants and noxious weed they should focus on the result in product rather than processes used to create that product.

Under this proposal each new plant variety would have to undergo a complex risk assessment and public comment before a single plant could ever be planted in a small scale field trial. The system also creates an ambiguous double standard about what the agency considers to be a noxious weed.

We cannot envision any scenario that we would be supportive of any commercialized U.S. crop especially wheat to be considered a noxious weed even at the developmental or research stage. This sends the wrong message to our consumers both here and abroad.

Finally on a positive note KAWG does favor the implementation of an exemption list protecting the products that have been deemed safe by the Department. This would undoubtedly be beneficial for all parties because it would get rid of the risk and give us oversight in areas for opportunities that are free of deregulation.

Additionally, USDA should engage EPA, FDA, and others to ensure domestic quality and regulatory treatment of genetic modifications of biotech products derived from other decision tools like gene editing for future use in agriculture for regulatory consistency.

USDA has an opportunity to engage with the public about modern agricultural production and the role of innovative new technologies and what they play in assuring a safe and affordable food supply. Thank you for the opportunity to comment on the issue and we look forward to looking or working with you in the future (unintelligible).

Dick George: Daniel thanks very much. So with that I would ask if anyone else in the room would care to make a comment. Anybody else whether you preregistered or not, anyone else would like to make a comment? Seeing none, I will look to the phones. So I would ask if (Cynthia Allen) is on the call and if you are would you please press 1 then 0 on your touchtone phone to make a comment. (Cynthia Allen). We will pause while we're trying to get connected. (Cynthia) are you there?

(Cynthia Allen): Yes this is (Cynthia).

Dick George: Yes, would you go ahead with your comment please.

(Cynthia Allen): Okay well actually I had a question. I'm with Bayer Crop Science and in my role with Bayer I'm responsible for biological materials that are moving throughout North America. So I have a question in particular as it regards the import of materials. And I did not see anything in reviewing your rule that really addressed this and this is why I would like to propose the question.

But anyway, I would like to know how you propose to handle imports of genetically engineered articles that are regulated as GMOs or GMMOs in exporting countries but are not regulated as a GMO or GMMO in the United States.

Because most of the time for shipments such as this that are coming across the borders there is international labeling that is required, certain UN labeling that is required, and so when this labeling come across of course the officials at the border are going to be looking for permits. And because it's not regulated on the U.S. side I'm wondering how could you help in facilitating the import of these types of articles into the U.S.

Dick George: Cynthia thank you for your question.

Sid Abel: Hi Cynthia this is Sid Abel.

(Cynthia Allen): Hi Sid.

Sid Abel: Thanks for your question. You know, I think that's an excellent question. Obviously it did not come out clear in either the preamble or the text of our regulation on how we might handle an issue as you describe.

What we would like for you to do is submit that question to the record in regulations.gov so we can appropriately review that question in detail and then prepare a response to it as we move toward the finalization of this rule if that is the decision we ultimately make.

We're not here today actually to try to answer all the questions that the public might have about those regulations but to receive those comments such that we can address them for the entire public who may not be here today

obviously to listen to this conversation and so they have the opportunity to read and understand everyone's questions concerning those regulations. So we appreciate you (Cynthia) sending that comment to regulations.gov so we can address that for you.

(Cynthia Allen): Okay thank you.

Dick George: Thank you (Cynthia). Is there any other comment you care to make? So I would ask if Chris Anderson is on the line. Chris if you're there would you just press 1 then 0 on your touchtone phone and we will open the mike to make your preregistered comment. Chris Anderson?

Chris Anderson: Yes I'm here.

Dick George: Great Chris, go ahead.

Chris Anderson: I didn't have a question specifically. I don't know how that got out there but I will come up with one. What is the proposed timeline for reviewing and making amendments to 7 CFR 340?

Sid Abel: Thank you Chris for that question. You know, we do not have a proposed timeline past the June 19 closing of the comment period. Obviously a great deal of the work is yet to be done depending on the number of comments that we receive before we close on the 19th.

So we will probably be proposing a schedule sometime later on this summer but our hopes are is to if we decide to move forward with the regulations as they are now or modified slightly based on public comment, it's going to take us a little while to get that done. But we'd like to get it done as quickly as possible.

Chris Anderson: Thank you.

Dick George: Thanks Chris. Any other comments Chris?

Chris Anderson: No.

Dick George: Okay. Thanks for calling, thanks for your question.

Chris Anderson: Yes.

Dick George: So I will now open it up to anyone else in the room who would care to make a comment or on the phone. If you're on the phone and would like to comment the way to do it is to press 1 then 0 on your telephone keypad. We will see that and we'll open your mike and take your comment. Any commenters on the phone? Okay we're going to pause for a few seconds here to give people a chance. There is one.

Lee Van Wychen: Yes hi, this is Lee Van Wychen.

Dick George: Lee would you please spell your name? Spell your name for us so the transcriber can catch it right?

Lee Van Wychen: Sure, L-e-e, last name is V as in Victor, a-n W-y-c-h-e-n.

Dick George: Thank you, please go ahead with your comment.

Lee Van Wychen: So I was wondering about the weed risk assessment model and the current version that is up there 4.1.2. Has that been validated with field data? And if so is that data publicly available?

Sid Abel: Good morning Lee this is Sid, appreciate the question. No we have not what we call validate this model as of this time. We will appreciate if you have any information that would help us in the process of doing a thorough review of the model going forward we would appreciate that being sent in as a comment. And also just, you know, if you would send your comment in directly as well to regulation.gov that would be helpful.

Dick George: Thank you Lee.

Lee Van Wychen: Thanks.

Dick George: Sure. Anyone else on the phone would like to make a comment, please press 1 then 0 on your telephone keypad. Going once, going twice. We'll pause for a few seconds, 1 then 0 on your phone keypad to make a comment on the proposed revisions to biotechnology regulations. No?

Okay so what we'll do is we'll take a little pause. We're going to be here until noon so if anyone would like to make a comment we'll be coming back on here every few minutes. At any time anyone in the room can make a comment or if you're online and would like to make a comment hit 1 and 0 and we will see that. We will open up the mike and activate and take your comment.

So we're going to take a pause. We'll be coming back every few minutes just to remind you that we're here and to take comments perhaps from any latecomers or folks who would like to comment. So having said that, we're going to take a pause. We'll be back.

Okay this is Dick George, I'm here with Sid Abel, we're at a public comment meeting for the proposed revisions to biotechnology regulations. I would invite anyone who is listening in on this webinar to hit 1 then 0 on your telephone keypad, let us know you'd like to make a comment. We'd be happy to take your comment at this time.

I'll pause for a second, anyone who is listening who would like to make a public comment press 1 then 0 on your keypad. We'll pause a moment or two here, give people a chance to do that if you care to, 1 then 0. Okay seeing none we'll take another pause. So we'll be checking in every five or ten minutes and we'll take comments as you indicate you have them. So we'll be back in just a minute or two. Okay so Dale Fjell, is that the right way to say it?

Dale Fjell: Yes it's one reason I wanted to come back. I forgot to follow the rules the first time and spell my last name. It's F-j-e-l-l and it's of Scandinavian descent, the name is Fjell.

Dick George: Fjell, okay.

Dale Fjell: And again I represent the Kansas Corn Growers Association. And I just - I guess I'm just - there are a couple of things I probably wanted to reemphasize or emphasize based on what the testimony of the Kansas Association of Wheat Growers. And I had that in my notes too and I did not bring it up.

But this - bringing in the noxious weed into this whole process I think is kind of concerning to us. I feel it is concerning. And I think Kansas Association of Wheat Growers brought it up with the idea that it could slow down the process of discovery - in the discovery at the universities, at the - with the private companies where - and again I don't know all the forms that it would take.

But it seems like anytime you open up another organization and they have rules, they have authority that you bring up that - the noxious weed, they may have in their rules maybe a little bit different type of - well again regulations pertaining to GMOs. Where we have protection I would say currently by bringing in the noxious weed, their authority and their regulations might open that up to some other things.

Now I'm not saying that would be a complete barrier but it could slow it down, slow the process down. And I think that's - because we're trying or we feel that we want to be able to speed up the process where we can.

And I understand that yes we have to be concerned about noxious weeds but I would think that it could be something a very yes, no type of thing very quickly at the beginning that within certain events, some of the trials or certain things that you would have to go through. So I think that is something that I know our Kansas corn growers would sure like to have you take a look at.

And the other thing would be just anytime as you're going through the current policy and looking to change the regs to be mindful of that timeline, that time process that it takes. Because we really don't want to be able to stifle people, small organizations that could - that probably have limited funding and with that a limited amount of time with the process of getting something brought forward. And so hopefully as you look at making changes you'll be mindful then of how that affects the timeline. That's all I have to add.

Dick George: Okay great, thank you.

Dale Fjell: Thank you.

Dick George: Any other comments from folks in the room? No? Folks on the phone? Anybody would like to make a comment press 1 then 0 on your telephone keypad. Going once, okay we'll take another pause. We'll be checking back in every few minutes to give people the opportunity to comment. Thank you. Hold on.

Chris Anderson: Yes this is Chris Anderson again from Ames, Iowa from Biogemma. And to add to Dale's comment, one thing - I think the 7 CFR part 340 is fairly sound, maybe it needs a little bit of revision. But what has spiraled out of control, Dale mentioned it, the timeframe, temporal aspect of getting products to market. But the deregulation cost is huge.

And I think from my standpoint that's why a lot of the large private companies are merging together and getting larger because for some of these trades that have insect properties too where both the APHIS and EPA need to get involved, you might be talking more than \$100 million to \$200 million to get a product deregulated. It seems like over time - I realize we have to factor in inflation but that has spiraled out of control. That's all I had to say.

Dick George: Great, thank you Chris. Anybody else on the phone would like to make a comment please, press 1 then 0 on your telephone keypad. We'll pause here for a second to give you a chance to do that. No commenters at the moment. So we'll take a pause and we'll be checking back in every few minutes or so. So we'll take a pause right now.

Okay we're back. I'm Dick George with Sid Abel, we're here to take comments on the proposed revisions for biotechnology regulations. Perhaps you may have joined us late.

If you'd like to make a comment we would love to hear it. Please press 1 then 0 on your telephone keypad and we'll see that and we'll know that you want to make a comment. We'd be happy to take that comment. So we'll pause for just a few seconds here and give you a chance to do that.

Also if anybody in the room would like to comment just raise your hand. Seeing none. There is no one indicating that they would like to comment so we'll take another pause and we'll come back every five minutes or so and give people a chance to comment. In the meantime there is a slide up that indicates so we're monitoring that constantly. So we'll take another pause. Thanks.

It's Dick George at the public comment meeting for proposed revisions to our biotechnology regulations. If you would like to make a comment on the phone perhaps you came late to the meeting, you're welcome to comment. Please press 1 then 0 on your telephone keypad. We'll see that, we'll open your mike, and go ahead and take your comment.

So we'll pause for a moment or two to give anyone out there who may want to make a comment a chance to do so. Press 1 then 0 please. Seeing none. We'll take another pause and then we'll check back in every five minutes or so. Thank you.

Hi it's Dick George, I'm at the public comment meeting for the proposed revisions to our biotechnology regulations. If you're on the phone please if you'd like to make a comment please do so by pressing 1 then 0 on your telephone keypad. So if anyone in the room would like to make a comment you still have the opportunity to do that in the room.

So we'll pause for a moment to see if anyone cares to make a comment. And hearing none, seeing none, we shall take another pause. So I'll be checking back in every five or six minutes or so and I'll be back in a little bit. Thanks.

Hello again, this is the public comment meeting for the proposed revisions to our biotechnology regulations. If you're on the phone and would like to make a public comment please let us know by pressing 1 then 0 on your telephone keypad. We'll pause a moment to give you a chance to do that. And seeing that there are none, we will take another pause and back in a short bit. Thanks.

Hi, it's Dick George back at our public comment meeting for revisions to our biotechnology regulations. If you're on the phone and would like to make a comment we'd like you to do so by pressing 1 and then 0 on your telephone keypad. We'll open your mikes and take your comments. We'll pause for a moment to see if anyone takes us up on our offer. Seeing that there are none we will take another pause. Thanks.

Okay hi, we're back at the public comment meeting for our revisions to our biotechnology regulations. We welcome your comments. If you're on the phone perhaps a latecomer, we'd love to hear from you if you have a comment you'd like to make please press 1 and then 0 on your telephone keypad and we'll see that and open your phone line and take your comment. We'll pause a moment and give you a chance to do that.

I wanted to say there are documents related to those revisions on our website, Biotechnology Regulatory Services. Google that and it will take you to our website and you can see all the documents that are related to this including Q&A that answers a lot of questions about it and some other documents

including Federal Register Notice that I described. So I see there are no takers so we shall take another pause.

In the meantime if you'd love to make a comment we will see that and we will come back on and take your comment. So seeing none at the moment we'll take another pause. Thanks so much.

Okay so we will ask once again for comments at the public comment meeting on proposed revisions to our biotechnology regulations. If you're on the line and would like to comment press 1 then 0 and we'll see them. I will mention that at noon local time, we're in Kansas City, so in about 15 minutes we will end this meeting. We welcome all comments until that time. So please press 1 then 0.

I see no comments coming in at the moment so we will take another pause and we'll be back on about just a little bit before noon to close the meeting. In the meantime if you'd love to make a comment hit 1 then 0. We'll see that, we'll open the mike and take your comment. Thanks.

Okay this is - we're getting ready to close our public comment meeting on revisions to our biotechnology regulations. If you'd like to make a comment this is the last call. You can do so by pressing 1 then 0 on your telephone keypad. So we'll pause just a little bit here, see if there's any last commenters.

Seeing none I will say that thank you for your comments today. Our next public comment meeting is a week from today, June 13 in Davis, California followed by our final meeting in Riverdale, Maryland, Friday, June 16. The public comment period closes on June 19 at midnight.

Sid Abel: And for me, thank you all for joining us today. We appreciate everybody who appeared in person and provided verbal comment and those of you that were joining us by webcast we also appreciate your attendance here today and look forward to seeing you all or hearing from you all in future meetings. You can still comment online anytime through June 19 at regulations.gov or by just putting in to the search box at regulations.gov A-P-H-I-S-2015-0057 in the search box.

As we mentioned, there is a lot of information on our website. The address is on the slide. You can also find us on the web by searching Biotechnology Regulatory Services. We will consider all comments received before deciding how or whether to finalize the proposed revisions to our biotechnology regulations. Again, thank you for your comments today. This concludes today's public comment meeting.

Operator: We're sorry, your conference is ending now. Please hang up.

END