UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PROGRESS ON

MODERNIZING THE REGULATORY SYSTEM FOR

BIOTECHNOLOGY PRODUCTS

-- SECOND PUBLIC MEETING --

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I N D E X

P R O C E E D I N G S

MR. McNALLY: Good morning. Welcome to this morning's webinar and public meeting.

To kick things off, I'd like to introduce our regional administrator here in Region 6, Ron Curry. Ron has spent over three decades working at the federal, state and local levels. Ron is from New Mexico, and in addition to working for Governor Bill Richardson, I understand he's an avid hot air balloonist. So with that, I'm going to introduce Regional Administrator Curry.

MR. CURRY: Thank you, Bob.

Well, welcome you all to Dallas. It's very nice to have you here, and I really appreciate the fact that you're having this meeting and kind of updating what's been going on since the 1986 Coordinated Framework on the regulation for biotechnology.

Region 6 is made up of five states and 66 tribes, and we often talk about the fact that on any given day we have between 62 to 68 percent

of all the oil and gas production in the United States, but more importantly, we have about 2.58 million farmers working more than 230 million total agricultural acres within the region. And so we like to say that because we're not all oil and gas all the time, and sometimes the two come together in one form or another depending on that particular day.

But I just wanted to tell you that I appreciate the work that you're doing, because as you've heard the administrator talk about recently, everything that we do eventually ends up defining us in the terms of public health, and there's nothing more important in the biotechnology work that you all are doing that really says public health.

And one of the more interesting experiences that I had since I've been regional administrator here was that I was touring some agricultural communities in Louisiana and during the course of that tour, we were going out to see a large cotton farmer in northern Louisiana, and

one of the reasons we were out there to talk with him was about the Waters of the U.S. Rule and we were having a meeting in Monroe, Louisiana.

But what I found most interesting is when I got out there and met the guy he was an old high school classmate of mine from Sandia High School in Albuquerque, New Mexico, and he'd gone to the University of New Mexico and gotten his master's degree in classical art, and now he's a cotton farmer in northern Louisiana, and he had actually risen at one point or another to be president of the National Cotton Farmers Association.

And he told me that one of the reasons he was able to do that was talking about biotechnology and how it affected his crop and how successful he had been in going through and using the technologies that were available to them and trying to figure out how best to use the regulations to go forward with it. So for me, that was a real life experience coming from an old friend in high school that taught me the

importance of the work that you all do and how we go forward in looking at the framework of regulation.

So I just want to welcome you here to Dallas. I appreciate you being here, and I really appreciate the work that you do. So good luck to you and thanks for being here.

(Applause.)

MR. McNALLY: Thank you, Ron.

As many of you know, this is our second of three public meetings. The next one will be later this month on the West Coast. So I want to thank everyone for joining us here in Dallas, and those of you who are joining us from around the country on the Adobe Connect.

I'm going to cover the agenda and some housekeeping items here in a second, but first I want to introduce Jeff Morris, who is the deputy director of the Office of Pollution Prevention and Toxics, to give some welcoming remarks on behalf of EPA headquarters. So Jeff Morris.

MR. MORRIS: Thanks, Bob.

And like Regional Administrator Curry, I'd like to thank you for coming, both here and online. But also a career public servant, I'd like to thank you for your attendance.

It's clear now, as we're well into the 21st century, more than ever that the implications of the work we do are just too important to not ask for, receive and incorporate in our work the insights of people like you. And indeed, ensuring the continued safety of biotechnology is a great big thing, and it's clear to us that responsible development can't be taken as a given, it's something that has to be watched over, evaluated and updated from time to time, and that's why we're here, to give the Coordinated Framework for biotechnology the good government attention that it deserves.

We're going to have a really good meeting today and we're going to have a good meeting because of you and your insights. So again, welcome, and thank you very much.

MR. McNALLY: All right. Thank you,

Jeff.

Let me cover the agenda here relatively quickly. So really there are three parts of this agenda I want to call your attention to. First is going to be a background and progress report to date that Robbie Barbero is going to do to highlight where we are in the process, and that's the first part.

The second part, and really the main part of the agenda, is a discussion of case studies. Now, as Jeff alluded to, we're looking for feedback and we're looking for clarifying questions from the public, so as part of the case studies we're going to present each case study and then at the end of each case study we're going to have about ten minutes for questions and answers. And if you have a question that comes to mind when you listen to one of the case studies there are index cards, so if you didn't pick any up out front, EPA staff can get you some cards. Just jot down the question that you have, signal to one of the EPA staffers, and at the conclusion of the

case study we'll come up and read those questions here from the podium. And put your name on it so we know who to refer to. And if for some reason we don't get the question right, don't hesitate to clarify, but hopefully in the question you write we can get the gist of what you'd like to hear.

Now, for those of you at home, I understand there's a little Q&A chat box you can do the same thing. Feel free to make use of that, send them, put your name on it as well, and then we'll read those here from the podium. And we hope to have about ten minutes of questions after each of the case studies.

So that's the second area for public engagement, but related to that, at the end I think we have a list of about a dozen people who've signed up to make public comment, and so each public commenter will have three minutes to make their comments at the end of the agenda this morning. And what we'd like you to do, because of the Adobe Connect, is come up to the podium here to make those comments so the people who are

tuning in around the country can see and hear you better.

So those are sort of the two opportunities, as Jeff alluded to, get some public input, public engagement.

And at the end we're going to talk a little bit about next steps moving forward in terms of our next meeting.

Now, a few housekeeping items. If you want to get a cup of coffee or something to eat, I'm told on the 5th floor here there is a food court, feel free to make use of that.

We have a break at around 11:15 and the good news is there are bathrooms on this floor, the bad news is you're going to need an EPA employee to use one of these badges to let you in the door to get to the restrooms. So the staff will be out there and the bathrooms are on the other side of the building, and again, at 11:15 we'll make sure that flows back and forth pretty smoothly, but if in the interim you need to use the restroom, just let one of the EPA staff know

and they can let you in.

So that's an overview of the agenda. So with that, let me now introduce Dr. Robbie Barbero. He's going to give you sort of a summary of our progress to date, when we started last July, what we've accomplished thus far, what we're hoping to do today, and later in the morning's agenda we'll talk a little bit about the next step and our next meeting.

So with that, let me introduce Dr. Barbero.

DR. BARBERO: Thank you very much.

So my name is Robbie Barbero. I live in Washington, D.C. now, I work in the White House in the Office of Science and Technology Policy, although I'm originally from Grand Junction, Colorado, this isn't Grand Junction but it's closer to Grand Junction than Washington, D.C. is for sure.

So what I will walk through here today is what we are doing and why we are doing it and where we are in the process on this. I'll give

you a little bit of background and then talk you through the next steps.

So the background in this policy area is that in 1986 the White House Office of Science and Technology Policy issued a policy document called the Coordinated Framework for the Regulation of Biotechnology, and that was a document that described how the federal agencies would help to ensure the safety of the products of biotechnology using their existing authorities and especially how they would coordinate together in order to do so.

In 1992 that document was updated and then in the ensuing years after that, each of the agencies continued to issue guidance and to update their processes and also to work together to ensure the safety of the products of biotechnology.

In 2011 this administration issued an executive order that was broadly about how to improve regulation and regulatory review. And then just last summer, in July of 2015, the

Executive Office of the President issued a memorandum directing the primary agencies that have oversight responsibility for the products of biotechnology--the EPA, the FDA, and the USDA--to do three things, and I'll walk slowly through these so you can understand how they're related to each other and why we hope to accomplish these three things.

The first task is to update the Coordinated Framework for the Regulation of Biotechnology by clarifying the current roles and responsibilities. So much like in 1986, the current roles and responsibilities were articulated in the Coordinated Framework, the update we are working on will clarify the current roles and responsibilities. And in the materials that were handed out at the door when you came in, and, for those of you watching the webcast, the materials can be accessed through the docket, there is a table of oversight authority. That is just a draft version, for discussion purposes only, but in there you can get a sense of the current roles and

responsibilities of each of these agencies, vis-a-vis the products of biotechnology. So that's the first document that we are working on.

The second task then was that we were tasked with commissioning an expert independent analysis of the future landscape of biotechnology products. And so I'll have a little bit more information on that for you later, but we have asked the National Academies of Sciences to perform this analysis.

The third task then is to develop a strategic plan or a long-term strategy to ensure that the federal biotechnology regulatory system is prepared for these future products of biotechnology. So this is the document that will tie how the current system functions into what the future of biotechnology products looks like.

Let me give you a few more details on the memorandum that was issued in July of last year. So the goals and guidance were that the federal agencies that regulate biotechnology products should continually strive to improve predictability, increase efficiency and reduce

uncertainty in the regulatory process and requirements. This is consistent with the executive order from 2011 that I mentioned. And it is critical these improvements maintain high standards that are based on the best available science and deliver appropriate health and environmental protection, also, that they establish transparent, coordinated, predictable and efficient regulatory practices across agencies with overlapping jurisdictions, and promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.

Now, the principles that guide the regulation of biotechnology products -- and these are drawn largely for the 1986 Coordinated Framework and the 1992 update -- are listed on this slide here, and I'll walk through them because I think that these are important. These are the guiding principles that our forebears laid out for us and that continue to help guide the federal government as it works to help ensure the

safety of the products of biotechnology.

The first is that the process used to make a product does not determine the safety of or risk posed by the product. Rather, it's the characteristics of the organism, the environment into which it will be introduced, and the application or intended use of that organization that determine the risk or lack thereof. This risk-based approach to regulation should distinguish between those organisms that require a certain level of federal action and those that do not. And also, a real critical advantage of this risk-based approach is that it properly protects public health and the environment against risks without hindering safe innovations.

Each agency was given a principle that it should use its existing statutory authorities and regulatory programs to help ensure the safety of biotechnology products, and these federal statutes and implementing regulations regulate products based on the specific uses which has the advantage of allowing for similar products,

whether made through biotechnology or other ways, to be treated similarly by regulatory agencies.

This is where the coordinated part of the framework comes from: the agency should seek to operate their programs in an integrated and coordinated fashion. And although there is some inconsistency in the statutory nomenclature, so in other words the laws that are underlying each of the agencies authorities -- the reviews conducted by each agency should be of comparable rigor. And also, a recognition that future scientific developments would lead to further refinements of federal policies.

The update to the Coordinated Framework -- and I will not walk through all of these steps but I put them up here because this is language that's drawn directly out of the July 2015 memorandum, so I encourage you to look at it because these are the actual instructions that we were given -- is focused on clarifying which biotechnology product areas are within the authority and responsibility of each agency

clarifying the roles that each agency plays for those different product areas, and also, when appropriate, clarifying how the agencies communicate and coordinate among each other, as well as clarifying a mechanism and timeline for regularly reviewing and updating the Coordinated Framework.

So the long-term strategy had several components to it. The group is working on implementing the tasks they were charged with considering. This includes identifying timetables and mechanisms to work with stakeholders, to identify impediments to innovation, proactively engaging with the public to discuss how the federal government uses a risk-based scientifically sound approach, recognizing that the complexity of the current regulatory system makes it very difficult for small and mid size companies to navigate.

We're coordinating to develop the tools and mechanisms for assisting small businesses. And then initiating the development of a modernized,

user-friendly set of tools for presenting the regulatory agencies' authorities and practices and bases for decision-making. Recognizing that the science that underscores the regulatory system is critical, we are tasked to work with other federal agencies, as appropriate, to develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities. And then looking to the predictability and efficiency of the system, we have been tasked to conduct horizon scanning assessments of new biotechnology products and if any, identifying changes to authorities, regulations and policies that could improve agencies' ability to assess the impacts of future products of biotechnology.

And then finally, continuing to ensure the product evaluations are risk-based and grounded in the best science available, and when possible, regularly adjust regulatory activities based on experience with specific products.

So where are we so far? Well, as I've mentioned several times, in July of last year the

memorandum was issued. Shortly thereafter, the Executive Office of the President, USDA, FDA and EPA formed an interagency working group. This was established under an existing Emerging Technologies Interagency Policy Coordination Committee, and that group now has been meeting on a regular basis with a very high level of buy-in and support across all three of those agencies and the Executive Office of the President.

Last fall the working group issued a request for information which was really focused on helping the working group figure out how to address the tasks in that memorandum. There were over 900 comments that were submitted.

And then in October of last year, the first of the public meetings that were committed to was held at FDA's White Oak campus. And in that one we spent a lot of time talking about what the memorandum was describing and the goals of it, and also had some presentations from each of the agencies about what they did in their purview in order to ensure the safety of products of biotechnology.

So one of the other things that I mentioned was that we had asked the National Academies of Sciences to conduct this landscape analysis of future products of biotechnology, so in January of this year, just two months ago, the Academies officially announced their study. They're calling it "Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System."

I think one thing that's really important to note about the way that the National Academies operate is that once they have initiated a study, it is very much a hands-off approach for the organizations that are funding that study. So while the federal agencies that you'll hear from today are paying for this study and they work with the Academies to have the Academies understand what their goals of it are, the study is now in the hands of the National Academies of Sciences and they will deliver a product that the working group here can use in order to understand what the future landscape of biotechnology products will

look like.

And I've put in here some key points that the

Academies have written in their statement of tasks. All of this information is available on their website. You can see there's a URL near the bottom end of that slide there: www.nas.edu/biotech. You can find the full statement of tasks there, and my understanding is that they will be announcing the study committee that will be performing this study in the coming days, and so when that is announced, you'll be able to learn from the National Academies about that committee, as well as when their meetings will be held. And I encourage all of you to engage with the Academies and help this body of experts understand what the future landscape of biotechnology products will look like.

So since the last public meeting, each of the agencies and the Executive Office of the President have reviewed all 900 of the responses to the RFI that were received. A little bit

later in this presentation I will give you a very high level summary of what those comments were so that if you have not taken the time to read all 900 of them, you will at least be able to get a high level summary of them. And we are deeply involved in the actual process of working on this update to the Coordinated Framework and in developing a long-term strategy.

So we are now on March 9 which is our second public meeting here in Dallas, and what you'll hear from us today, after I've finished talking, I hope will be a much more interesting session where we will walk through case studies of a handful of hypothetical products and describe those products and then describe who would have oversight authority and why and what the various responsibilities of the developers and the regulatory agencies would be for those products. I think it should be very helpful because once you start talking about the details of products, you can get an understanding of what the current roles and responsibilities are.

And then there will be a third public meeting which has already been announced that will happen on March 30 in Davis, California. And more details about that will be posted on the USDA website and also placed in the docket.

And then per the mandate that we were given from the July 2015 memorandum, the update to the Coordinated Framework will be made available this spring/summer, and it will undergo a comment period before it is finalized. And so the materials that you received when you walked in today --the table of oversight and the case studies -- are available on the docket to those who are not here in person, the information that's presented in those documents will be incorporated into the update to the Coordinated Framework, and you will have an opportunity to comment on that before it's finalized.

So you can think of today as us presenting this to you verbally and having some

discussion about them, but to the extent that you have a strong interest in publicly commenting on them, you will be able to do so when the draft document is placed into the Federal Register.

Okay. So I'd like to briefly walk through the summary of the RFI comments. So written and oral comments were submitted by a wide variety of organizations, including industry, academia, trade associations, consumer groups, environmental advocacy groups, individual consumers, foreign governments and other organizations. The agencies received and reviewed slightly more than 900 written comments, and the agencies also received and reviewed the oral comments that were made at the October 30 public meeting, and what follows is a brief summary of those responses.

So in the first category of responses are what I'll call general responses, and there were comments that favored the use of risk-based, science-based regulatory systems and a Coordinated Framework that facilitates or at least does not stifle innovation and also reduces burden to

industry, especially to small businesses. There were requests for a balance between the level of regulation and the degree of risk posed by a new trait or an existing trait in its introduction into an environment. There were commenters that noted that the complexities of the current regulatory system made it difficult for small companies and academics to navigate. There were also comments that sought uniform regulation across products rather than regulation based on the process of production. There were calls for funding agencies to support more risk assessment research for biotechnology products.

There were discussions on expanding exemptions and fast tracking product reviews for familiar or well known products. There were recommendations for regulating based on process using genetic engineering, in and of itself, as the trigger for mandatory pre-market review of products with independent testing of ecological and health risks. Recommendations that agencies harmonize their regulatory approaches with CODEX

guidelines and coordinate with international regulatory partners.

Some commenters noted that the range of traits in GE products on the market is very small, and therefore, past safety evaluations may not or cannot apply to the more diverse technologies and types of products that are being developed right now. And there were comments suggesting that manufacturers publish safety data very early in the development process so that the public and others can review the data.

In the RFI comments related to public education awareness and outreach, there were comments that supported agencies taking action regarding public education awareness and training on genetic engineering very generally, as well as on specific applications. Suggestions for facilitated coordinated public outreach sessions with the agencies. Suggestions to develop simple and easy to understand information about how agencies regulate products and coordinate their respective roles and responsibilities and provide

information on a single U.S. Government website.

Commenters suggested that sharing scientific evidence and information underlying regulatory decisions with the public should happen more often. Suggestions to develop security training programs for researchers and hobbyists in biotechnology products. Suggestions to establish standards for information sharing and harmonizing protocols across the agencies. One comment suggested that by filling regulatory gaps, clarifying agency roles and responsibilities and conducting risk assessments for novel products the Federal Government would build public confidence in biotechnology products.

In the category that I will call recommendations related to coordination among regulatory agencies, there were a handful of comments. There were suggestions that coordination among regulatory agencies, including on risk assessments and data collection on unintended consequences should happen. There was

a specific suggestion to create a review board consisting of representatives from all three regulatory agencies to review all new genetically engineered and non-genetically engineered crops. There was a suggestion to establish a group of experts under or at the National Academies of Sciences, with representation from each regulatory agency, to determine whether a product is exempt from review and creating and publishing decision trees for developers to determine whether products are exempt.

There were suggestions to streamline regulatory process and procedures to expedite reviews or approvals. Suggestions to coordinate among relevant agencies such that the burden on industry with respect to obtaining multiple permits for conducting trials could be reduced. There were several comments that suggested that the establishment of a central coordinating office or a single window for entry for service of regulatory submissions for biotechnology products would be a good idea. There were suggestions about

grouping similar products into categories and appointing a primary agency in charge of oversight for each product area.

And then finally, the final bucket here is one that I'll just call other recommendations, and some of these are very specific and some are a little bit more general. There were comments around identifying and establishing appropriate restrictions related to genetically engineered crop plants, restrictions on where and how genetically engineered crops are grown so as to minimize the potential for cross-contamination and/or restrictions on privately owned genetically engineered seed stock.

There was a suggestion to adopt a U.S. federal regulatory policy for low leave presence of genetically engineered sources in food, feed and seed. Suggestion to clarify how products of genome editing techniques are regulated or will be regulated. Suggestions to fund risk assessment research to support creation of regulatory exemptions. There were several comments

indicating that confidential information business status should be granted less freely. Comments to exempt DNA from the Toxic Substances Chemical Act review process. Suggestions to impose more post-market requirements and lighten pre-market requirements.

Suggestions to assess the risk of products evolving beyond designed capacity and to identify the possible interactions between those products and the environments into which they will be released or in which they'll be kept. Suggestions around clarifying agency rules on field trials and dual use products, as well as on clarifying the regulation of genetically engineered insects. And then suggestions related to implementing post-market surveillance programs to ensure the traceability of genetically engineered ingredients or components of products.

So now that we've walked through the summary of where we are and why we are doing this, we will transition into our discussion of the case studies of hypothetical products. And what we

will do is we'll have someone from each of the agencies come up and talk through this table here. So this is a table of what we can sort of loosely call agency protection goals for the regulation of biotechnology products and these are the primary statutory authorities that the USDA, EPA and FDA use to help ensure the safety of the products of biotechnology. And there is much more detail available on each of these from the agencies and I encourage you, to the extent that you're interested, to really dig in on those. But these protection goals and statutes should give you a high level of understanding of the tools that the agencies have available. And once we have walked through these, then we'll start to do each of the case studies and walk through them.

Neil, are you ready to go first?

MR. HOFFMAN: Sure. Thank you, Robbie.

I'm Neil Hoffman, I'm with the USDA, the Animal Plant Health Inspection Service in the program Biotechnology Regulatory Services.

The USDA typically regulates under two

statutes, one is the Animal Health Protection Act. We have a program in APHIS called Veterinary Services whose mission is to protect livestock from animal pest and disease risks. And then the second statute is the Plant Protection Act, and the program that I'm in, Biotechnology Regulatory Services, regulates organisms that are plant pests and our protection goal is to protect agricultural plants and agriculturally important natural resources from damage caused by organisms that pose plant pest or noxious weed risks.

And next I'll turn it over to my colleague, Mike Mendelsohn from the EPA.

MR. MENDELSOHN: Good morning. I'm Mike Mendelsohn from the EPA's Office of Pesticide Programs. I'm in the Biopesticide and Pollution Prevention Division. I'm going to briefly talk about protection goals that we have for pesticides.

There are primarily two statutes that we work under, the Federal Insecticide, Fungicide and Rodenticide Act, and our protection goals there

are to eliminate unreasonable adverse effects upon man and the environment. For environmental and occupational risks, this involves comparing economic, social and environmental risks and benefits associated with pesticide use, and for dietary or residential human health effects the sole standard is the safety of exposure.

In addition to FIFRA, or the licensing of pesticides law EPA administers the Food, Drug and Cosmetic Act provision for pesticide residues in food or feed. The protection goal there is to ensure dietary exposure to pesticide chemical residues in or on food are safe.

Next I'll turn it over to Dr. Mark Segal for the Toxic Substances Control Act.

DR. SEGAL: So I'm Mark Segal from the Office of Chemical Safety and Pollution Prevention. This office also implements the Toxic Substances Control Act, and that act is a bit of a catchall act. It excludes from regulation those substances that are used for food or drugs or cosmetics or pesticide uses.

Other substances including microorganisms are subject to oversight under that act, and within that act we intend to ensure the manufacture, processing, distribution and commerce, use or disposal of chemical substances -- again, microorganisms are included in that -- or any combination of such activities with such substances does not present an unreasonable risk of injury to health or to the environment.

And I guess I will now turn it over to Ritu.

DR. NALUBOLA: Thank you, Mark.

So I am Ritu Nalubola. I'm a senior policy advisor in the Office of Policy in the Commissioner's Office at FDA.

FDA regulates a number of different products and we derive our authorities primarily from two different statutes, the Federal Food, Drug and Cosmetic Act and the Public Health Service Act. Our mission includes ensuring that food is safe, sanitary and properly labeled, food meaning both food for humans as well as for

animals, ensuring that human and veterinary drugs are safe and effective, ensuring there is a reasonable assurance of safety and effectiveness of devices intended for human use, ensuring cosmetics are safe and properly labeled, ensuring public health and safety are protected from electronic product radiation, and we also regulate tobacco products.

DR. BARBERO: Okay, great. Thank you.

So before we start into the first case study, let me give you a little bit of an understanding of what these case studies are and why they were chosen, and then we'll start to walk through them. As a reminder, as we walk through these case studies if you have any questions, and I think those questions should be this or that is unclear, please write them down on a note card and please put your name on it so that we know who asked that question, and then we will respond to those questions at the back end of the case study. And for those of you who are online, please do the same, please write your name and the

question that you have around that specific case.

So these case studies are intended to provide general information to developers who believe they may have or are uncertain as to whether they do have a biotechnology product that is subject to regulation under one or more of the laws that we just walked through and that are described in the Coordinated Framework for Regulation of Biotechnology. And we will walk through these case studies as a means of demonstrating how a developer might navigate the regulatory framework starting from research activities in the lab through to full commercialization of the product. Certain products may also have post-market and monitoring and reporting requirements that are not described in this document, and more information on these requirements and other requirements is available in the relevant agency's regulations and guidance.

I'd also like to note once more that the contents of the document provided,

as well as what we will be discussing today, are still in draft form and under review at the various agencies, and when they are finalized, they'll be placed in the update to the Coordinated Framework and will undergo a formal comment period.

So these case studies were selected because they cover multiple biotechnology product areas with different characteristics and intended uses and because they illustrate how the agencies coordinate with each other under the Coordinated Framework. There are other nuances such as exemptions for certain products within the regulatory system that could affect the path a product takes, and these will be touched on in the case studies as appropriate.

The case studies presented here cover typical relevant milestones from the identification of a potentially commercializable biotechnology product to research and development activities in the laboratory and field and to commercialization. Recognizing that

intricacies do exist in any regulatory system, FDA, EPA and USDA welcome and encourage developers of potential biotechnology products to contact them at the earliest stages so that any questions about regulatory status, safety and/or effectiveness, when appropriate, can be identified and addressed.

And finally, the materials and facts and scenarios that we will be discussing here are purely hypothetical and presented for discussion purposes only, so these should not be taken -- this is the part the lawyers make me read -- these should not be taken to reflect the views or policies of the federal agencies or any official position on these products.

With that, let's start with our first case study which is a hypothetical genetically engineered corn with pesticidal properties. So the way that we'll do this is I will describe the product and then introduce which agencies have oversight authority and why, and then we'll have someone from each of those agencies come up and

walk you through the details of their oversight.

So in this case study, a field crop which is used for food for humans and animals is genetically engineered with a plant pest component to have pesticidal activity against certain insects. The corn produces a protein with pesticidal activity. The gene encoding the protein is isolated from the bacterium Bacillus thuringiensis and is controlled by the cauliflower mosaic virus derived 35S promoter. The genetic construct is actually integrated into a binary vector and is introduced into the corn genome using Agrobacterium- mediated transformation. Also encoded on that vector, and stably incorporated in the corn genome, is a gene that enables selection of transformants during the R&D process.

So which agencies have oversight and why? Well, the GE corn is engineered with a plant pest component, so the USDA will have oversight authority. The DNA codes for a pesticidal trait, so EPA will have oversight. And the GE corn is

going to be used for food for humans and/or animals, so FDA will also have oversight. So our first one will be Neil.

MR. HOFFMAN: So I'll walk you through how USDA would regulate through the stages of R&D, field trials and commercialization.

So the USDA does not have the authority to regulate gene organisms in contained facilities, so pretty much the only involvement the USDA would have during the R&D phase would be in case genetically engineered organisms are moved from state to state or imported into the U.S., and for those sorts of movements, an authorization would be needed, either a notification or a permit. In this case a corn qualifies for notification so the GE corn could be moved under notification.

For the small or large scale field trials, an authorization would be needed in addition now for environmental release. The USDA complies with NEPA and NEPA is an environmental statute to inform decision- making. It does not

give us any additional authority. Typically when we do a permit activity, permits under our NEPA implementing regulations are categorically excluded from NEPA. If there are new species or novel modifications that raise new issues, then that's an exception to the categorical exclusion and typically we do an EA.

Prior to commercialization, the companies can collect information and submit what we call a petition for non-regulated status. If we grant non-regulated status, then the developer no longer needs to get authorization for the import, interstate movement or environmental release. And typically when we grant non-regulated status, we would do either an environmental assessment or an environmental impact statement to comply with our NEPA obligations.

And I'll turn it over to Mike.

MR. MENDELSOHN: Okay. I'll talk shortly here about how EPA oversees a GE corn

trait with pesticidal properties. So during the R&D phase, EPA is largely not involved, small scale testing the same. Now, prior to large scale trials, which would be over ten acres, typically developers submit an experimental use permit application and that experimental use permit oversees the field trial.

In this case, the case study involves food or feed, so in order for that food or feed to get into the food supply, for that pesticide residue, there has to be a temporary tolerance or tolerance exemption for the residues of the pesticidal traits. And what we call these traits in plants, we call it a plant-incorporated protectant, and that's a two component item, so it would be both the genetic material that's necessary for the production of the trait, as well as the pesticidal trait itself.

Prior to commercialization, that would require a pesticide registration for the PIP, or the plant- incorporated protectant, as well as a tolerance or tolerance exemption for the pesticide

residue in food.

Now I'll turn it over to Ritu for FDA.

DR. NALUBOLA: So where FDA would come into this case study is because our oversight is actually on the finished food and its intended use, and in this case it would be the corn that is going into the food supply either as a food for humans or for animals. And under the Food, Drug and Cosmetic Act, the developer has the responsibility and legal duty to ensure that the food they market is safe and lawful, and to help industry to comply with their responsibility, what FDA has set up is a voluntary consultation process whereby a developer may provide relevant scientific and technical information to FDA for our consideration and begin the voluntary consultation process.

So in this case, at a point during either small scale trials or prior to starting the large scale field trials, we would encourage the developer to come in and begin the voluntary consultation process. However, prior to

commercialization we do strongly recommend that the developer complete the voluntary consultation process with FDA, and we can talk about the voluntary consultation process either during the Q&A or a couple more case studies that will also touch on this.

But essentially, during this consultation process, FDA would review all of the information that is submitted by the developer. We use a multi-disciplinary comparative approach to assess the safety of the food from the GE plants. The approach involves comparing key aspects of the new food to one that has been historically safely consumed.

And under this consultation process, the FDA evaluates all of the data and the information. Once we have addressed all of the safety and regulatory issues and those are resolved and the data and information support the conclusion that the food from this new variety is safe or is as safe as food from the conventional varieties, we would then conclude the

consultation. And once we complete the consultation, a letter would be sent to the developer indicating that FDA has no further questions, and also reminding the developer that it is their responsibility and a legal obligation is still upon them to ensure the safety of the food.

At the end of this consultation process, FDA also makes information available to the public by posting on the internet our response letter and a note to the file which provides a summary of the relevant information.

DR. BARBERO: Thank you very much. We will do the second case study that's in this category of food for humans and animals, and then do Q&A if anybody has questions.

So the second product is a hypothetical genetically engineered herbicide-tolerant canola. This is a field crop used as food for humans and/or animals and it is genetically engineered with a plant pest component to tolerate an already registered herbicide. This particular herbicide

has not previously been used on plants for food for humans and/or animals.

If you're following along in the case study handbook, we are on case study #3. Sorry about the confusion. That's why I was also flipping pages. So we're on case study #3. We're not going to do case study #2 today.

So this hypothetical genetically engineered herbicide-tolerant canola is a field crop used as food for humans and/or animals. It's genetically engineered with a plant pest component to tolerate an already registered herbicide, but this particular herbicide has not previously been used on plants used for food for animals. The product is a domesticated canola, genetically engineered to tolerate an herbicide by increasing the expression of a gene found in the canola genome using a constitutive 35S cauliflower mosaic promoter. Extracted canola oils will be used for biodiesel production and the remaining biomass will be processed into meal for food for animals and the animal or products of the animal

may subsequently be consumed by humans. The 35S cauliflower mosaic virus promoter and the canola gene are both introduced into the plant using a biolistic approach.

Because the canola gene confers resistance to an herbicide, no additional selectable marker is required. This particular herbicide, which we will call Herbicide X, is already registered by the EPA but is not yet approved for use on animal food crops. In this scenario, a single developer produces both the herbicide resistant canola and the herbicide.

So which agencies have oversight and why? The herbicide-tolerant plant is genetically engineered with plant pest components, therefore, USDA will have oversight. EPA regulates the new use of the herbicide itself, because remember that the herbicide had not previously been used on plants used for food for animals, but not the genetic material used to engineer the plant. And FDA will have oversight because the GE canola will be used for food for humans and/or animals.

MR. HOFFMAN: So our oversight is very similar to the previous example that we discussed. During the R&D phase notifications would be needed for interstate movement or import. We would not be regulating in the greenhouse. For environmental release, a notification would be required. This herbicide-tolerant canola is not a new species or a novel modification that raises new issues, so the notification for the release into the environment would be categorically excluded from NEPA. If we recieved a petition for non-regulated status, then we would most likely do an EA associated with that petition analysis.

MR. MENDELSOHN: I'm going to talk about for the herbicide-tolerant canola; the part EPA plays, and as was mentioned earlier, this is not a PIP or a plant- incorporated protectant, we focus on the actual herbicide itself. So at small scale field testing, it's not applicable unless the Herbicide X treated canola enters the food supply. Regarding large scale field trials,

if the company was going to go ahead and test it on greater than ten acres, this is an herbicide, they would have to get an experimental use permit for, and if the canola was going to enter the food or feed supply, there would have to be a temporary tolerance exemption. In practice this doesn't happen very often at all. Usually the developers test the herbicide-tolerant crops at small scale and don't come into EPA until they are seeking a registration or amendment.

So before they can commercialize the herbicide for that use, it allows it to be used on the herbicide- resistant crop. And you might ask yourself why would they need to do this. Because the use rates and the timing are often different for the herbicide for use on the herbicide-tolerant crop, that would require either an amendment to a registration, or more likely what happens is the company comes in with a new product to amend the use of that particular herbicide, and as well, they come in with a petition to amend the tolerance to allow for that residue to be in the

food or feed.

So primarily where EPA focuses for the herbicide-tolerant crops is on the herbicide itself and that would be for amending the use of that herbicide for use on the crop for the timing and rate, and then also to amend the tolerance to allow for residues of that herbicide on the crop.

DR. NALUBOLA: So even in this case, as in the previous one, our oversight would be on the finished food that's intended for humans or for animals, and as I mentioned in the previous case, we do have a voluntary consultation process that is intended for industry to come in and consult with us so any food safety or other regulatory issues can be resolved. And as an example, one of the questions that the food safety or other regulatory issues that may come up may include the presence of an unapproved food additive in the resulting food product, in which case that would trigger a pre- market approval process.

An important point that I should also note in this case, as I did in the past, is that

although the consultation with FDA is voluntary, compliance with the relevant statutory provisions is not. The compliance with law is mandatory, the consultation process is voluntary and intended to help industry to meet their legal obligations.

Just to elaborate a little bit on the consultation process, we do have guidance that talks about these procedures, and during the initial consultation phase, the GE developers may meet with FDA and explain their product to us, we may provide feedback about the kinds of data and information and testing that may be needed for a complete safety assessment. And during these initial consultations is also where FDA would provide feedback to the firm on the specific plant variety, the types of safety testing, legal questions that need to be addressed.

The final consultation process begins once the GE plant developer completes its safety assessment and submits a summary of the assessment to FDA, and this is where, as I mentioned in the previous case study, we would do a multi-

disciplinary comparative approach to look at the safety of the product.

Some of the questions that we may consider and that may be evaluated by FDA include, for example, uses of the food, including in humans and in animals, the purpose or intended technical effect of the modification, as well as the expected effect on composition and characteristics, and then a comparison of this composition and characteristics with other commonly consumed varieties or the parental variety with a specific focus, for example, on nutrients or anti- nutrients or toxicants that may be naturally present in the plant and food, as well as whether the genetic modification altered in any way at all the potential for the food to induce an allergic response. These are just examples of some of the things that we would consider.

And as I mentioned in the previous case, once all of the safety and regulatory issues are resolved and the data and information logically

support the conclusion that the food from the GE plant is as safe as from a conventionally bred variety, we would then conclude the consultation and information about the completed consultation and our no questions letter to the developer are also provided on our website.

So let me stop there.

DR. BARBERO: Have we gotten any questions from this group? So both of these questions are from Judith McGeary. Did I get that right? Okay, great.

So the first question is do any of the agencies have specific standards that the developer's data must meet such as one, sample sizes or statistical power, or two, scope of effects studied and what results are measured. Did I get that question right?

Anybody want to take a stab at answering that first?

DR. HOFFMAN: So yes, the USDA provides some guidance about the number of field trials that need to be done. I'm sorry, it's been a while so

I don't actually remember, but for example, there needs to be field trials done in different geographies where that crop will be used, it needs to be replicated a certain number of times.

DR. BARBERO: Sample sizes, statistical power, scope of effects studied, what results are measured.

DR. HOFFMAN: So statistical power, that's really not -- that would probably be more for the EPA. I'll let them discuss that. The scope of effects, there's a list of about 20 or 30 parameters that are typically encouraged to be looked at for these field trials. We're interested in plant pest effects, so often disease susceptibility is an important characteristic for us but then there are other agronomic phenotypes that are looked at, as well as the vigor of the plant and its predilection to become weedier, that sort of thing. We do have a list of things.

So I'll pass the microphone over to Ritu.

DR. NALUBOLA: For FDA I was only going to say that we do have guidance on our website.

The 1992 policy document, as well as in 1996, we provided guidance on our voluntary consultation procedures.

I think some of these questions about the scope of effects and what results are measured, they're so dependent on the specific case, the plant, the food and really its intended use, that I think this is why the initial consultations are so helpful from our perspective because depending on the specific case, we can then look at the circumstances and the unique situation and then provide more information to the developer on the specific testing and safety assessment data that need to be collected.

MS. McGEARY: If I could, if you could maybe use the two case studies that you have put forward this morning as an example of what sort parameters and what you'd be expecting them to provide data on.

DR. BARBERO: So Ritu, there was a followup question on that. Let's have Mike do this, but I think it's worth thinking about for

either or both of those case studies, what some of those additional details would be.

MR. MENDELSOHN: From the EPA side, to answer Judith's question, we have a number of data requirements for microbial pesticides. Right now we do not have the data requirements in place for the plant-incorporated protectants, but much of the plant-incorporated protectants that have been developed, such as a BT protein, are microbially based. We utilize a number of pesticide assessment guidelines that are in place that address many of the points that you raise as far as statistical power, how the studies are to be run, et cetera.

Right now we've also had numerous what we call scientific advisory panels to get outside expertise providing input on how to run the studies. In 2001, EPA did a reassessment for the plant-incorporated protectants and looked at the types of data we were requiring. I think right now the best way to look at how we evaluate these are through our BRADs, or Biopesticide

Registration Action Documents. These are available on the same website which listed this meeting. There's a site for plant-incorporated protectants, it lists through there. For each of the registered plant-incorporated protectants it provides the details as far as how we assess all those data points. And essentially, just briefly, we look at human health, and then non-target effects and environmental fate.

DR. BARBERO: And Mike, while you're up there, there's another question specific to EPA for this.

MR. MENDELSOHN: Okay. The question here is: In addressing the herbicide impacts, do you consider the actual field formulations used or just a declared active ingredient?

So for the herbicide risk assessment, that's the chemical herbicide risk assessment, EPA considers the active ingredient portion for the tolerance and for the uses as far as the generic data, but there's also product-specific data that's required for the end use product as well.

So there's generic data on the active ingredient and there's a subset of product-specific data that's required on the actual formulation.

MS. McGEARY: And how is that data used?

DR. BARBERO: Can you repeat the question?

MR. MENDELSOHN: Yes. How is the data used for the formulation for the herbicide? It would basically be for the end use product primarily the acute toxicology and the precautionary labeling for that product.

DR. BARBERO: Thank you for those questions. We have another question here from someone else.

How might regulatory oversight differ if the herbicide tolerance in the canola resulted from targeted nucleotide changes in an endogenous canola gene without incorporation of exogenously provided DNA? And this is from John Salmeron -- did I get that correct? -- from Precision Biosciences. Did I pronounce your name correctly? John Salmeron. Okay

Who would like to take this question?

MR. HOFFMAN: I'll go first. So our regulation is triggered based on these plant pest sequences, and so one way of doing what you're suggesting is to often use a plant pest sequence to add a type of endonuclease and then to make directed change, and then to remove the plant pest sequences in a subsequent generation. And so there have been cases where just a deletion has been made, and we have not regulated those. They have no plant pest sequences and it's just a simple deletion. Chances are you wouldn't make an herbicide tolerant phenotype that way. If you made modifications this way, we probably would regulate.

DR. BARBERO: I saw you nodding your head, so it seems like you got an answer to your question. Okay.

I have three questions here and we have just about five minutes left so we'll do these three questions and then move on to the next case study. These are from Mary Tedei Edens -- did I

say that right?

MS. TEDEI: Marie Tedei

DR. BARBERO: Marie Tedei. And the Eden's is?

MS. TEDEI: Eden's Garden CSA Farm.

DR. BARBERO: From Eden's Garden CSA Farm. Great.

So I will read all of your questions and then we'll see if we can field them appropriately for you. So the first question is: How are economic benefits weighed against risks to environment, health and the public?

MS. TEDEI: Those were the criteria that were up there, health risks to the environment and to the public health.

DR. BARBERO: Yes, that's right. Environment and public health.

MS. TEDEI: Versus the economic benefit. I'm curious as to how that's weighed.

DR. BARBERO: Okay. The second question is: What is considered an unreasonable or adverse risk of injury, for example, or unreasonable or

adverse effect?

And then the third one is: Under what circumstances would a petition be granted non-regulatory status or exemptions?

MS. TEDEI: During the R&D process.

DR. BARBERO: During the R&D process.

MS. TEDEI: So before we know that it's okay. While we're experimenting with it, under what circumstances do we just waive that.

DR. BARBERO: Under what circumstances would that be granted during the R&D process.

Okay. So it's probably best if everybody takes a turn at answering all three of these. Neil, do you want to go first? And I'll give you these three questions.

And thank you for your questions.

MR. HOFFMAN: I'm not sure I remembered everything, so work with me here. Okay. So how are economic benefits weighed against the risks? So one of the reasons we put the protection goals in the very first slide was that that is where our authority comes from, and we do not regulate based

on economic risks that are unrelated to plant pest and noxious weed risks. So our agency would consider whether or not there are risks that are to plant health, and if there weren't risks to plant health or animal health, then we would not even consider those risks. So that's the first one.

What is considered an unreasonable adverse risk? I've sort of alluded to that. We're looking for what is going to affect the herd of livestock, what is going to affect American agriculture. We're looking for weed risks and risks such as disease. We're looking at effects that might impact beneficials that impact agriculture, such as pollinators and that sort of thing.

And the third one was: Under what circumstances would a petition -- gee.

DR. BARBERO: During the R&D process would you grant exemption?

MS. TEDEI: I don't remember which of the three of you had the different -- because it

went kind of quickly.

MR. HOFFMAN: Now I understand the question. During the R&D process the strategy is to impose conditions that keep the GE organism confined so there is no exposure.

Risk is exposure times a harm, or if the exposure is zero, there is essentially zero risk. So that's the paradigm we're working under. If it's truly confined, there should be no risk, and so we don't grant any non-regulated status under R&D conditions, it's the permit or the authorization requires that conditions to keep that organism confined to a specific area.

MS. TEDEI: But then that's not clear in what we have. So to a lay person I'm going: Oh, my, we're just issuing waivers for this stuff that we don't know what it's going to do.

MR. HOFFMAN: There's no waiver in that case.

Who wants to go next?

MR. MENDELSOHN: I'll go.

I think, Marie, you first two questions

related to the EPA slide, so the first question had to do with how we use economic analysis with respect to the unreasonable adverse effects, and so that's a statutory issue with EPA under the Federal Insecticide, Fungicide and Rodenticide Act. So when we make a licensing decision for a registration, we take into consideration both risks and benefits and so the economic benefit is part of that, but in the cases we've seen thus far, where the economic benefit or the public interest has come in mostly is when we have a registration for a new plant- incorporated protectant where we have to ask for new data that we had not anticipated. So there's a provision in the law that when you conditionally register a new active ingredient, or in this case a new plant-incorporated protectant, and you're conditionally -- you're asking for data, so you register it and the applicant will be sending in the data after it's registered, that decision has to be in the public interest, and that's where we primarily look at the economic benefit. So that's the one

question.

SPEAKER FROM AUDIENCE: Hey, Mike. Do you want to clarify food different from FIFRA finding?

MR. MENDELSOHN: Yes. Excellent. Thank you. So that's for the licensing of the pesticide. For the setting the tolerance of the amount of residue of the pesticide in the food, or in this case for a plant- incorporated protectant in food, we do not -- it's based upon there's a reasonable certainty of no harm, so that the economic part doesn't play for the food aspect, but it's for the licensing of the pesticide, so that's where we look at the economics.

It says: What is considered an unreasonable adverse risk? And we would say unreasonable adverse effect. Again, that weighs both risk and benefit part of it. To date we haven't had to invoke the benefit part because all of the PIPs that we've registered have been determined to be safe.

MS. McGEARY: But going to the case

studies, what would an unreasonable adverse effect be or what would an unreasonable risk potentially be?

MR. MENDELSOHN: Well, it depends, but certainly if it's something that caused grave harm to humans or to non-targets. That would then be balanced with the benefits.

MS. McGEARY: The economic benefits.

MR. MENDELSOHN: Correct.

MS. McGEARY: The economic benefits to the public you're saying.

MR. MENDELSOHN: Yes, to the public.

DR. BARBERO: So I think we may have covered those. We are running up against our time limit and we've got two questions that are relevant to this case study. I'm going to bring Mike back up because they're both about pesticides. But one of them is from Martin Levin: Who is responsible for monitoring compliance with the pesticide tolerance, how is it done, and how frequently is it done?

And then this one doesn't have a name.

What is your name, sir? Jeffery Campbell asked: Is there any testing or are the guidelines on tank mixes of pesticides used on crops?

So I'm going to just give you these pesticide questions and then we'll move on to the next case study after this.

MR. MENDELSOHN: Okay. As far as the pesticide tolerance, just generically for pesticide residues in food, we work together with our colleagues at the Food & Drug Administration, and largely they're involved with monitoring, also USDA has a program in place where they look at pesticide residues in food.

As far as is there any testing or guidelines on tank mixes of pesticides used on crops, there's guidelines on tank mixes used on crops, and this is not really a biotech question per se, but typically what's required is that the companies do a compatibility assessment and that is often put on the label, so whether that particular product is compatible for certain tank mixes. That data is often not submitted to the

agency but the companies are required to make sure that it's compatible with what's listed on the label for tank mixing.

DR. BARBERO: Okay. Are we ready for the next case study?

Thank you for your questions, really appreciate it. And for those of you who submitted online but we didn't get to those, we'll follow up with you and capture all those questions. So thank you very much.

So the next case study, if you are following along in the booklet that we have is actually case study #8, and this is a product for biomedical applications.

So this is a hypothetical genetically engineered rabbit. It's an animal that is genetically engineered to make a therapeutic protein insulin, recombinant insulin for treatment of humans that lack the ability to make this protein or have an inactive form of it. The rabbit genome is genetically engineered to express recombinant human insulin for use as a therapeutic

protein in the treatment of human patients that lack adequate functional insulin. The human insulin coding sequence is controlled by a 5' bovine alpha S(1) casein promoter sequence to allow expression of recombinant insulin protein in the rabbit's milk.

The genetic construct is micro injected into fertilized oocytes and the issuing embryos are transferred to the oviduct of a recipient animal. Also encoded in the vector and stably incorporated into the rabbit genome are upstream and downstream regulatory sequences that enable expression of the included codon- optimized human insulin coding sequence and insulator sequences to minimize the position effects at the locus of genome integration. Once a germ-line transgenic animal is identified (a potential founder animal). it is bred to establish a lineage of rabbits used in insulin expression in milk.

So which agencies have oversight and why? Well, the FDA will have oversight because the

recombinant DNA construct encoding the recombinant human insulin is integrated into the genome of the genetically engineered rabbit. Therefore, it is regulated as a new animal drug by the FDA Center for Veterinary Medicine. And also the recombinant insulin that is purified from the rabbit's milk is regulated as a human drug by the FDA Center for Drug Evaluation and Research.

MS. NALUBOLA: So this case study is really intended to illustrate the coordination that would occur within FDA between the two centers that Robbie just indicated. This would be between FDA Center for Veterinary Medicine and the Center for Drug Evaluation and Research, CDER.

So the developer's responsibilities during GE rabbit and insulin development, example, at the lab, the farm or the clinic, responsibilities of the developer really with respect to interactions with FDA would begin very early in the product development process. Under the Act -- here I'm referring to the Food, Drug and Cosmetic Act -- in general, a new animal drug

is deemed unsafe unless FDA has approved an application for that particular use or unless, among other things, it is for investigational use and is subject to an exemption.

So the developer must initiate discussions with FDA's CVM once the founder animal has been developed and the lineage is actively being characterized. The center would at this point open an investigation new animal drug file, INAD, into which the developer could submit data and information pertaining to this GE rabbit lineage. The developer also must obtain what is referred to as an INAD exemption, investigational new animal drug exemption. This would be from the FDA's CDER center, and that would need to be obtained prior to clinical trial activities associated with the recombinant insulin product derived from this line of GE rabbits.

The development of the GE animals constitutes clinical investigation because it involves studying the effectiveness of the drug in the target species and the effects of the rDNA

construct, including those of its expression products on the animal containing it. In general, the INAD regulations specify requirements related to shipping, labeling, recordkeeping, animal disposition and environmental considerations.

We also recommend that the developer schedule a meeting with us soon after the INAD file has been established. And then developers of human medical products involving GE animals should come in to discuss with FDA much earlier than for medical products not involving GE animals because the use of GE animals raises additional questions.

With respect to prior to commercialization, there are additional processes. The Act requires that a new animal drug be the subject of an approved new animal drug application based on a demonstration that it is safe and effective for its intended use. The developer must submit to FDA what is referred to as a new animal drug application for the rDNA construct in the rabbit, and the developer, among other things, must demonstrate containment measures to make sure

that the animal does not enter the food supply. This includes byproducts and derivatives, including appropriate disposal mechanisms. As is the case for all NADAs, after completion the agency will then post a summary of the information of the NADA file, including information used to assess the safety.

In addition, the developer must submit also a new drug application, and this would be for the insulin, for the recombinant insulin product. In order to receive FDA approval of the drug, the developer must demonstrate to FDA that the GE rabbit meets the FD&C Act's safety and effective standards pertaining to the animal and human drugs.

One other point, the developer must also submit to FDA under NEPA an EA, environmental assessment, or a claim of categorical exclusion as part of its NADA or NDA submission. For the GE animal, we would recommend that the EA focus on environmental issues, potential impacts related to the use and disposal of the GE animal and its

final product. The appropriate scope and content of the EA may vary widely depending on the GE animal product, the claim and conditions of these, and therefore, we recommend that the developer contact and work closely with us on all of these issues.

Another point to make is that in this case study, graphics as well as the narrative, while we don't cover the post-market monitoring and recordkeeping requirements, that may also come into play. And throughout the process, the developer should keep FDA's CVM and CDER apprised of activities related to their NADA and NDA applications, and adequate communication is important because we do have two different centers, one with the GE animal and the other the insulin.

We have, as I mentioned for the foods case, we do have several guidances that we have issued for industry. GFI-187 in particular is relevant for the GE animal piece of it, and then the new drug application requirements, we have

several guidances on our website for that as well.

So I will stop here.

DR. BARBERO: Thank you, Ritu.

Any questions from the audience on this one or from online?

SPEAKER: I was just going to ask one simple question. What is CDER that you mentioned in that last slide?

DR. BARBERO: So the question was about some of the acronyms that were used. The FDA has multiple centers that have responsibilities for different types of products, and there are two different components of FDA that would have oversight responsibilities for the genetically engineered animal that is used to produce a therapeutic drug for humans. One is the Center for Veterinary Medicine, CVM, and that is the center that would look at the animal itself. And the other one is the Center for Drug Evaluation and Research, and that is the center that would look at the actual human drug that was being produced by the animal. And they would work

together to make sure that both the animal and the drug have proper oversight.

SPEAKER: That would have been my question: Who oversees the safety and effect of the animals, the CVM?

DR. BARBERO: That's right. So the question was: Who oversees the safety of the animal? And that would be the Center for Veterinary Medicine which is a center in FDA. So FDA is wholly responsible, but there are two parts of FDA with oversight authority: one that is the Center for Veterinary Medicine, so they are the experts on the animal; and the other one is the Center for Drug Evaluation, and they would look at the drug that was being produced by the animal. And they would work together to make sure that all of the right information was there.

MS. NALUBOLA: Sorry if I went too quickly, but one of the things that we would look

at as part of this case study, what you mentioned about containment, and in containment measures multiple levels of containment would be part of the evaluation and to make sure and demonstrate that those containment measures are in place and are being implemented properly to ensure that to the extent these are animals are also food producing animals that they do not enter the food supply. We don't know about rabbits, but we have, like for example, chickens or goats that have been previously looked at.

DR. BARBERO: Can you speak to FDA's ability to engage experts from other agencies?

MS. NALUBOLA: I mean, I don't know if in this particular case whether and how USDA would fit in, but as part of the evaluation, to the extent there is a role for other agencies or expertise that we could tap into from other agencies, we definitely do look at that, especially for environmental considerations.

DR. BARBERO: Right. Actually, I think that your point was that as a farmer you saw

rabbits as a farm animal, and so the question was why would USDA not be involved. But I think this is a lot of information that we're sharing with you all, but if you go back to one of those principles that guide the oversight of the products of biotechnology, it was that it's the characteristics of the product but also the intended application of the product that matters. Right? And not the way that it was made. And so in this case the FDA looks at it and says the application here is the production of a drug and we have a Center for Veterinary Medicine that knows how to assess the safety of changes made to animals and a Center for Drug Evaluation and they can do this.

This question is from Dan Nuckols: Please describe post-commercialization policing framework, i.e., longitudinal studies to identify intended and unintended consequences. So that's for this rabbit?

MR. NUCKOLS: It would be helpful if we had an actual case study, maybe, one that you had

some data on post-commercialization instead of emphasizing all these prior to commercialization.

MS. NALUBOLA: So I mentioned that there would be some post-market reporting and recordkeeping and several requirements that would apply here. I'm not quite sure about specific longitudinal studies but there would be as part of the NDA, the new drug application, as well as NADA, the new animal drug application, there would be certain post-approval records and surveillance that would have to met. I don't know if that gives you the description that you're looking for, but I'm not quite sure about your example about the longitudinal studies.

MR. NUCKOLS: Well, how do you ascertain that you've reached the goal that completes the mechanisms that you set out to do five years post? What's that framework that you can circle back and do an evaluative study?

DR. BARBERO: One way to break this quiestion up is to consider the animal and the drug separately. You looked at the safety of the animal,

how would you ensure the conclusions were still valid? And for the drug as well. I think you could use this specific example to talk about that a little bit.

MS. NALUBOLA: I actually don't have more details to share. I mean, I can definitely get you in touch with people in the two centers who will be able to better answer that question.

MR. MENDELSOHN: I would be able to answer on EPA's side, not for this case study but he mentioned more broadly.

DR. BARBERO: Okay. So if you want to backtrack to one of the other ones.

MR. MENDELSOHN: Just to address your issue for post-commercialization, how do we look at the effects later on, and I think particularly EPA has a process of reassessing pesticide risk every 15 years. In the biotech area we've been more aggressive in that area. The first plant-incorporated protectants were registered in '95, in 2000 we did a complete reassessment, for BT corn we did a complete reassessment in 2010. And

often what we do at that point we look at the current science.

In the case of BT corn, what happened was there had been a number of meta studies that had been done and so it essentially pointed to the fact that it was -- at least for some of the non-target insect scenarios in that area, environmental fate, we kind of backed off from some of the requirements that had been more onerous based on the scientific advisory panel advice around the time of registration. So there had been a lot of work in the academic community, a lot of data had been generated, and we evaluated that and used that to kind of recalibrate for those particular products.

But we're continually reassessing pesticides at EPA and there's a 15-year cycle, but in the biotech area we've been a little bit more aggressive than that.

MR. HOFFMAN: So there was a question that pertained to the USDA involvement in some of this animal research. If the animal had been a

cow, would USDA APHIS or FSIS have had any responsibility for the animal entering the market supply?

APHIS Veterinary Services has relatively limited role in the regulating of GE animals, and to kind of give you an idea of what they would be involved in, sometimes animals are being made to be disease-resistant and there's the possibility of somehow those animals, particularly if they were imported into the United States, maybe now they're a carrier for a disease that's not in the United States. In that situation, APHIS VS would be very interested in regulating that. But let's suppose that animal was made resistant to a disease that's already very widespread in the U.S., they probably would just defer to the FDA.

And as far as FSIS, FSIS is really blind to whether it's a GE organism or not. They have responsibility to inspect whatever they do, meat and eggs, I'm not even sure, but whatever it is they would do it independent of whether it was

genetically engineered.

I don't know if that answered the question.

DR. BARBERO: It was an online question.

So we are up against our time limit for a break. We will take a break now. We are only five minutes behind schedule, of which I am very proud because I like to stay on time. And we will reconvene in 20 minutes and go through the rest of the case studies. Thank you.

(Whereupon, at 11:21 a.m., a brief recess was taken.)

DR. BARBERO: Thank you, everybody. We will start now. Thank you so far for the great questions. For those of you who are online, I apologize that we're not able to ask and answer all of your questions. We are able to print those out and so we will be keeping a record of those questions and we'll try to find a way to consider those moving forward. I would like to request that if you are submitting questions online that you put your name and organization in there so that we know

who's asking those questions.

Now it's time to move on to the case studies around microbial products for pesticide or industrial applications. So the first case study will be, if you are following along in the book, case study #6. It's a hypothetical genetically engineered microbial pesticide. So this is a phytopathogenic bacterium that is genetically engineered to express a pesticidal substance that protects against insects. The genetically engineered living bacterium will be used to inoculate crops to increase their defense against insects.

The product is a bacterium Clavibacter xyli, that is genetically engineered to express a delta- endotoxin protein used for controlling a pest originally isolated from the bacterium Bacillus thuringiensis, so the protein was isolated from that other bacterium. The gene is controlled by a promoter that is derived from a bacterium. The gene, the promoter and the selection marker that is used to select

transformed bacteria during R&D are part of a vector that is transformed into the C. xyli via electroporation. It is an endophytic bacterium and the genetically engineered bacterium will be used to inoculate corn to induce insect resistance in the plant.

Now, which agencies have oversight and why? The USDA because the C. xyli is a plant pest, and the EPA because the product is a genetically engineered microbial pesticide.

MR. HOFFMAN: So the USDA would regulate this organism similar to some of the cases that I've mentioned before, but there are some differences because this is a plant pest, we're not just talking about engineering a crop with a plant pest sequence, this is a plant pest. And so some of the differences are that it could not qualify for notification authorization, so it would only be done under permit. And in terms of commercialization, they could petition for non-regulated status but chances are because it's a plant pest, we may not grant it non- regulated

status, and this might be the sort of situation where we would only consider it under permit. This is a hypothetical, we haven't encountered this situation before, so it's not really clear what we would do.

MR. MENDELSOHN: So this is a microbial pesticide which is genetically engineered, and I want to point out little differences between this and the plant- incorporated protectants which, for instance, we mentioned a BT crop earlier. In the case of a plant- incorporated protectant, EPA regulates the genetic material and the pesticidal substance in the plant, in the case of a microbial pesticide, we're regulating the entire microorganism, so that's kind of a little nuance there.

So for small scale testing, also for a genetically engineered microbial pesticide there's a provision in our regulations that those that want to test these in the field have to notify EPA about the nature of the organism and what they've done, the field test, et cetera, to see whether an

EUP is necessary. So normally for most pesticides, an experimental use permit is not required under ten acres, but for a genetically engineered microbial pesticide, we require the developers to notify us and to essentially ask the question is an EUP necessary. So if we make that decision, then they have to come in for an experimental use permit; if they test over ten acres of land, they have to come in for an experimental use permit.

And at that stage also, of course, if any of this is going to get into the food supply, they have to get a temporary tolerance exemption. And the tolerance exemption essentially is a legal limit to allow for that residue in food or feed. Prior to commercialization, before they wanted to sell this, they would have to get a registration for the microbial pesticide and they would have to get a tolerance or tolerance exemption for residues of the pesticide in food or feed.

So again, one of the primary differences between the GE microbial pesticide and the PIPs is

they have to come in under ten acres and ask the question as to whether an EUP is necessary, and we regulate the entire microorganism as a pesticide product.

DR. BARBERO: We will do the next case study and then we can do Q&A on both of these case studies.

So the next case study is case study #7, if you're following along in the book. It's a hypothetical genetically engineered algae used for biofuel production. So this is a unicellular algae that is genetically engineered with a plant pest component to produce industrial oils for conversion into biofuels. The eukaryotic microalgae Chlamydomonas reinhardtii are genetically engineered to produce an enzyme that increases lipid biosynthesis. The extracted oils are later converted into biodiesel.

The enzyme that increases lipid production was originally isolated from the soybean, Glycine max. The soybean gene is controlled by the cauliflower mosaic virus 35S

promoter that we've heard about before. The plasmid encoding the enzyme promoter and selection marker is introduced into the algae through electroporation. The algae will be cultivated in an open pond system and the remnants of the microalgae are intended for use as fish food.

Which agencies have oversight and why? USDA has oversight because the microalgae are engineered with a plant pest component which is the cauliflower mosaic virus 35S promoter. The EPA has oversight because the microalgae are engineered for industrial use with genes from outside the genus of Chlamydomonas, and as such, they fall under the rules implementing the Toxic Substances Control Act. And the FDA has oversight because the microalgae will be used for animal food.

MR. HOFFMAN: So again, just trying to focus on how this would be different than in the previous examples. The main difference here is this is something that is very new to our organization, and so they need authorization for

movements under R&D, when they go outside, they'll need authorization. Because we've never seen it, this would probably trigger our exception to the categorical exclusion under NEPA. This is a new species. There may also be a novel modification that raises new issues. So chances are we would do some sort of environmental assessment prior to field testing.

And I think the rest would be the same, it's possible that they could petition for non-regulated status. This is not a plant pest, it's just engineered with a plant pest sequence, so we may be in a position where we could grant it non-regulated status depending on the circumstances of this situation.

DR. SEGAL: Okay. So we have a new microorganism because it has genes from more than one genus. We call it intergeneric. It is being used for a purpose that's not excluded under TSCA. So in the first phase of the development of this microorganism if the initial development, the initial research and development occurs in a

contained system, there's no reporting requirement under TSCA, and contained can be anything from a lab, a contained greenhouse, or even something like a contained photobioreactor. In our regulations we have specified certain good laboratory practices that should be followed, but again, no reporting that's required at that stage.

The next stage or the next two stages, under TSCA, or under our regulations we don't differentiate in terms of scale of release. If something is released, if it occurs in an 800 liter mini pond or if it occurs in a one-acre raceway pond, it's a release, and therefore, the vehicle that's used is the TSCA experimental release application.

Now, obviously, the review of these applications will vary based on the complexity and the scope of the intended release, but the actual manner of reporting to EPA will be the same. Not only do we have 60 days to review the case, if there are complications that occur, of course, during the course of our review, that timeframe may be

extended. There may be some needs to, for example, modify the intended research program.

So we're going to assume that all has gone well with the TERA, all the reviews have been helpful and data have been gathered during the course of the TERA that are useful, both for the developer in making their product and for us when we do our subsequent reviews for commercialization. When the time comes that the developer feels they're ready for commercialization, at least 90 days prior to the time they are ready to initiate production, they are required to report to us and provide us with microbial commercial activity notes

One thing I did not stress in the research and development phase is that in order to go to the field, EPA must issue an approval of the research program. However, when commercialization takes place, EPA is not a registration statute, so we're not going to be issuing approvals for commercialization.

We will review for risk for not only the

described preferred use that the manufacturer has intended but for all plausible uses of this particular microorganism that we have been able to ascertain whether here from the submittal or from whatever sources we have available. We have to do that because if we choose not to regulate at the end of our risk assessment and we say nothing, then those other plausible uses can be established either by this submitter or by somebody else.

So we will review in detail this case and there are several potential outcomes. One is the one I've just suggested: that we find that all the details provided shows there's no potential to make a finding that there may be an unreasonable risk to human health or the environment for any plausible use, in which case EPA remains silent. At the end of 90 calendar days, if the submitter has not heard from us, they can initiate production. If they do so, they will notify us with a notice of commencement, and this particular organism can be placed on the inventory of chemical substances.

If, on the other hand, we find that there are uses or there are production methods that may present an unreasonable risk, we can either unilaterally establish limitations, or preferably, we will go into negotiation with the submitter to mitigate risks, to find ways to mitigate risks, such that we don't have that finding. We will, at the end of the period, need to come up with a significant new use regulation, but at that point, again, the submitter will then be able to go into production under those conditions and the organism can be listed on the inventory of chemical substances.

And I'll turn it over to Ritu.

MS. NALUBOLA: So again, FDA would have oversight here because the micro algae will be used as animal food, as food for animals, and so FDA has oversight on that aspect. Prior to small scale trials or large scale trials, at this point, if not earlier during the product development process, we encourage the developer to come consult with us so that any food safety and

regulatory issues can be considered. And definitely prior to commercialization, we strongly encourage that the developer come and consult with us.

One of the questions that will need to be considered is whether the use of the micro algae for animals involves the presence of an unapproved food additive which would then, as I mentioned in the previous case too, trigger pre-market food additive approval process. And there are a couple of guidances that I think would be relevant that we have issued in the past that would be relevant here. One specifically is guidance to industry GFI-221 that talks about what different factors must be considered and the different pieces of information that would need to be provided as part of the food additive submission. And the guidance GFI-53 that specifically talks about products that are diverted for food for fish. So those are two different documents that would be relevant.

DR. BARBERO: Okay. Time for questions.

This question is from Allison Exall. Did I say it right? And help me to make sure that I'm getting this correct. Does the product have to be genetically engineered to be covered by this initiative? What about a product that is not genetically engineered, such as a seaweed extract?

So let me understand. You're asking about the product that might be used for food applications?

MS. EXALL: Or like sprayed on plants, crops. All these case studies are genetically engineered products. This whole conversation only addresses that?

DR. BARBERO: So you're asking a broader level question here, and we do have an answer.

MR. McNALLY: Yes. Thanks. Bob McNally, the director of the Biopesticide Program.

I think you're talking about a substance more like a biostimulant, and we're working on a policy on whether those are regulated or not. We're going to have a policy out later in the year because we know there are issues with those where

people are uncertain whether they're regulated or not. So it's not biotech but the same program at EPA is trying to come out with a policy to describe what you have to do with those or what you don't have to day. Does that answer the seaweed extract?

DR. BARBERO: I will answer your question about today. One thing that I think is really important to keep in mind here is that the agencies don't use the fact that something is genetically engineered as the primary criterion for whether it's safe or unsafe or there are risks associated with it. It's really about what are the features of that organism and what its intended application is.

In this case, because there are a lot of questions about genetically engineered organisms, we have focused this discussion on case studies that do have some sort of genetic engineering component to them. But the agencies that are at the table here today have a lot of expertise in regulating products that are not genetically

engineered and ensuring the safety of those as well, and many of these people and their colleagues can help you get answers to those questions as well.

MS. EXALL: I guess my question is does this biotechnology initiative, are there other kinds of biotechnology besides genetically engineered organisms?

DR. BARBERO: So the question is around the definition of biotechnology. I will refer back to the memorandum released in July of last year, which for the purposes of this specific effort provides a definition in there or a scope that we can put around this activity, and it is primarily focused on those sort of modifications that come from genetic engineering. Broadly, though, the agencies that are at the table here can help you think about how products across the spectrum of applications we've been discussing would have regulatory oversight. So I think the one real advantage to the way this system functions in this country is that these

people and the agencies that they work for think about the breadth of products and have experience with them, whether they are genetically engineered or not, and can assess them side by side.

Okay. I have a question here from Keerti

Rattore: If only algal genes or promoters were used to transform the algae, would USDA get involved?

MR. HOFFMAN: As far as I know, there are only three algae that are considered plant pests, and so under our current regulations, if it wasn't from any of those three algae that are parasitic, we would not be involved.

DR. BARBERO: Do you want to do that one?

MR. HOFFMAN: Sure. This is from Marie Tadei: During the R&D period when a study item is tested in an open field or an open pond, how are the tested items kept contained? That is, what parameters are used or measures taken to keep accidental release or contamination to the

environment or food supply at large?

Great question. What the USDA considers contained would not be in an open pond or an open field. That would be an environmental release for us. A contained facility we consider like a growth chamber or a greenhouse, there may be pressure on there to keep things inside, walls, more walls. For what we call a field trial, we use the word confined. That means that things can get out but the conditions are met to limit those GE organisms should persist in the environment.

What sort of measures are used? Isolation distances, scouting to make sure that there are no sexually compatible weeds or plants within a certain area. There are specific requirements for disposition of the materials, volunteer monitoring to make sure that the materials do not keep volunteering. Anyone grows corn, you know that it is very easy to get seeds germinating the following season, so there's restrictions on the use of that land until all of

the material that was grown has been used up. If you have a crop that you're testing that has some kind of dormancy, it could be several years of restrictions on the use of that land. So those are the sort of things.

There are also what we might call bio-containment or bio-confinement measures. You may have plants that are sterile, there's some cases where the trait cannot be transmitted through the pollen. So there are a number of both biological and physical measures that are used.

Mark, did you want to answer that for EPA?

DR. SEGAL: Yes. In large part, much of what was said also applies to us, but I want to focus on the cases where we're dealing with microorganisms. In an open pond we agree that these are releases but there can be limits. We actually have experience with algae and experimental releases. We have had one expressly with an open pond release and it was monitoring the site to determine just how much was

released, how far things released, what was the survival in terms of relationship to the production of the organism. So as these kinds of experimental releases take place, we will get more experience and understand what limits are.

But such things as isolation in terms of environment, if you're growing something in the desert and you have an organism that demands a lot of water to survive, that helps limit the release. It's still a release, we're not talking about containment. We don't use the term confinement but we understand it the same way.

DR. BARBERO: Okay. Let's move on to the final case study. So our final case study is a product with other applications. If you're following along in the booklet, it is case study #4.

This is a hypothetical genetically engineered rose, an ornamental plant genetically engineered with a plant pest component to increase the production of a pigment in its petals. The product is a rose, Rosa x hybrida,

that is genetically engineered to express a pigment from a black pansy, Viola tricolor. The trans gene is controlled by the cauliflower mosaic virus- derived 35S promoter and is introduced into the rose via Agrobacterium-mediated transformation. The purpose of the genetically engineered plant is to improve the quality of the product.

Which agencies have oversight and why? The USDA because the plant is engineered with plant pest components and is for ornamental use only.

MR. HOFFMAN: So there really isn't anything new on this one in terms of what the USDA would do. During R&D you would need a notification to move it, you'll need a notification to release it during field trials, and they could petition for non-regulated status.

The reason this one was interesting is the USDA would be the only regulatory agency involved in this one, and as Robbie said, the company intends to use it for ornamental purposes.

People want to grow this rose in their garden. I don't know how many of you are aware about the quest for blue roses, there have been contests for decades to get a blue rose. Well, they succeeded in doing it with genetic engineering.

The reason we wanted to mention this one is there could be some issues here if the company is thinking their market is people's gardens, rose petals, I suppose, can be consumed and I suppose they can be used for fragrance, and a lot of companies are interested in changing the fragrance of plants. So this is one where we would need to really coordinate very closely with FDA to make sure that there would not be food uses, or if there were potentially going to be food uses, we would really recommend the consultation with the FDA.

And I think in a case like this, this was a hypothetical, but as I think about it, it probably would be a good idea, if there's a possibility that this flower would be used for anything other than ornamental, to consult with

the FDA. The onus is on them to make sure that they meet all the regulatory requirements.

DR. BARBERO: By them you mean the developer?

MR. HOFFMAN: The developer.

DR. BARBERO: Any questions?

Well, if we don't have any questions, it looks like we have a little bit of time here until our next section. Why don't I do this? I will give you a little bit of an overview of what the next meeting will look like and provide some additional information.

And then we will take a short break and reconvene at about 12:40 to do the public comment. That will give us about 20 minutes and then we can do the public comment.

We do have one question. So the question is: What if the rose did not have a plant pest component, would it be regulated? And we don't have a name associated with it. I would ask that you please give us your name so that we can recognize you. Sorry, you did give us a name.

What's the name? Anna Muldoon.

MR. HOFFMAN: Yes, if the plant did not have a plant pest sequence, under the way we're regulating currently we would probably not regulate it. It's a hypothetical, there are other considerations we would need to look at, but if we talking about changing the flower color and they did that completely without using any plant pest sequences, our regulations would not be triggered.

DR. BARBERO: And just to further elaborate on that, I think it's important to go back to some of those principles as well as the protection standards that each agency operates under. Really, the system is intended to be a risk-based approach, so the agencies are on the look out for potential risks that are in their purview, and the process of making a product does not per se indicate that there is a risk associated with it. That's a very good question.

Let's go on. So our third public meeting is coming up three weeks from today. That meeting will be at the UC Davis campus in the

conference center there. We will have more information, including an agenda and how to register, available in the Federal Docket that is accompanying all of these activities, as well as on the USDA website. So we really look forward to having participation and engagement at that meeting, and please stay tuned as we will share more information about that meeting soon.

We'll come back to the public comment at 12:40. Before that, though, I just want to make sure that you have an opportunity to see some of the other background materials that we have. Well, you know what I'll do? I'll leave these up on the screen while we take a break. So let's take a break now.

We'll reconvene at 12:40 for public comment. We have a list of people who have asked to give public comment. If you have asked, please come up to the front and Mike can work with you. We'll do three minutes per person and we ask that you stick to that so that we can accommodate

everybody and get out of here on time. Thank you.

(Whereupon, at 12:21, a brief recess was taken.)

DR. BARBERO: Okay. Thank you, everybody. So we will now be hearing some public comment from people who have asked to speak. Just to give a little bit of the logistics on it here, we have a list here with Mike. Hopefully you all have checked in with him to let him know that you're ready. He will call you out when it is your turn. When you come up, please come up to the podium here, and just in case it hasn't been obvious to you -- you know where I'm going with this -- there's a little piece of tape down here and you should stand on the tape, otherwise, people will be staring at your neck and not at your face.

(General laughter.)

DR. BARBERO: And we'd ask that you let us know who you are and keep it at three minutes. We have a little time here -- it's not little, actually, it's kind of large, but it will give you

an indication of when you're getting close to and then when you've reached the three-minute point, and then we'll ask you to wrap it up at that point.

And all of the comments that are given here are going to be transcribed and they'll be inserted into the docket as part of the full transcription of this meeting.

Mike, who do we have first?

MR. MENDELSOHN: Keerti Rattore will be our first commenter.

MR. RATTORE: I guess there are some advantages to being from Texas, I'm the first one.

Good afternoon, everyone. My name is Keerti Rattore, professor of soil and crop sciences, Texas A&M University, College Station. I want to thank you for the opportunity to share my experience with the Coordinated Framework and to offer my perspective on the effects that current regulations have on the development and deployment of genetically engineered plants and plant products.

My research interests are in genetic improvement of important crop plants. I work on the cotton, sorghum, rice, tomato and potato, and my research involves enhancement of disease-resistance in plants, conferring drought tolerance to crop plants, conferring insect tolerance and resistance, as well as improving the nutritional quality of the seeds.

For the last 18 years my primary focus has been on a project that involves elimination of Gossypol from cottonseed. My lab has successfully demonstrated in 2006 RNI-mediated reduction of Gossypol in the cottonseed to levels that are below what FDA and WHO consider safe for human consumption. If cotton growers around the world adopt this what we call ultra low Gossypol cottonseed, it can make enough available protein to meet the basic protein requirements of 500 million people.

Additionally, elimination of Gossypol from cottonseed enables its use for non-ruminant farm animals, such as poultry or swine, at higher

feed ratios than is currently tolerated for significantly improved protein conversion and lower feed costs for the producers. Similarly, elimination of Gossypol enables the use of cottonseed in agriculture, thereby extending the protein in current agriculture feeds derived from marine fishes, a declining and increasingly costly resource.

Importantly, elimination of Gossypol from cottonseed enhances the value of cotton production to the U.S. growers which can help stem the historical decline in the U.S. cotton acreage and the loss of production to synthetic fiber and foreign producers.

Now, we're also committed to the humanitarian use of this cottonseed technology in places where food is less secure. I have seen firsthand how agriculture technology improved the health and well-being in my country of origin that is India, and I count the late Dr. Norman Borlaug among my mentors at Texas A&M, who instilled in me a passion to complete this work for the benefit of

humanity. His interest in my research has encouraged me to persevere for nearly 20 years in pursuit of this new cottonseed variety for humanitarian use.

Today we are in the final stages of laboratory and field studies on this cottonseed for submission to the USDA and FDSA, but this regulating process has been arduous and costly, especially for people working in a university environment.

I just want to say that as a public sector researcher I understand the need to ensure the safety, both environmental and food safety, of any new plant variety introduced into the U.S. agriculture. I have no desire to see genetically engineered crops developed by public sector researchers held to any lesser standard of safety. At the same time, I submit that the current regulations impose significant opportunity costs on human and animal health, on global resources, and U.S.

agriculture production and trade. That

cost, while difficult for large private companies, severely limits public sector biotechnology from having an impact on producers and consumers.

So anyway, we face significant challenges to our global food supply and agriculture production systems. Genetic engineering and related technology for agriculture offer promising solutions that should be encouraged, not hindered by government policies and oversight. The U.S. federal agencies should seize this important opportunity to improve their long-term strategy for regulation of biotechnology products.

Thank you for the opportunity to share my perspectives.

MR. MENDELSOHN: Next we'll have Bob Hemesath, farmer, also with the National Corn Growers Association.

MR. HEMESATH: Good afternoon. Like Mike said, my name is Bob Hemesath. I am from Decorah, Iowa. I am a fourth generation farmer, I farm with my family. We raise corn and we have a

wean-to-finish hog operation. I traveled here today because the need for these products is very important to my farm and the livelihood of my family, as well as the sustainability of my farm.

The National Corn Growers Association appreciates the opportunity to provide comments to the OSTP and participating agencies. We have a longstanding position supporting science-based regulatory oversight of products eligible for review under the Coordinated Framework. From the grower's perspective, the Coordinated Framework allows the commercialization of important crop protection products in spite of increasingly non-risk based regulations that have impeded product development. Additionally, seed and technology companies have, for the most part, understood what regulatory obligations need to be met to bring value to the ag industry.

The value these products provide to growers is undeniable and maintaining access for growers is a priority for NCGA. These tools have revolutionized weed and insect management, opened

up new conservation practices, and increased the efficiency of farming operations. We use less pesticides, less fertilizer per bushel and are able to withstand the variability in weather to continually produce record crops year after year.

U.S. agriculture in the best in the world, due in large part to innovations regulated under this framework. This is what has been achieved to date, but we understand that demand for food will not be weakening any time soon and we have to be prepared to feed the growing world population in an ever-shifting climate. Adoption of biotech products is impressive. Herbicide-tolerant soybeans quickly exceeded 85 percent of the market within a few years of launching. Insect-protected corn is used by 90 percent of growers. These products are widely adopted because they add clear value to us and the rest of the food industry.

As with any crop-protected technology, making sure there is competition and options for growers makes each product more robust. For

example, when only one type of herbicide-tolerant was widely adopted without a robust alternative, that single mode of action was over- utilized. Growers want to implement a robust integrated management and can only do so with options to rotate into. The viability of current BT products depend on this continuous innovation and the framework needs to be continued to allow this development to occur.

U.S. growers also understand our place in the global market and how the world accepts biotechnology. Appropriate regulation has fostered trust and coordinated regulatory regimes for the most part. Moving forward, we want to remain resilient to global demand and avoid any changes that would create new trade barriers for our products. A predictable and science-based regulatory system allows it.

Finally, we want to look to the future. These are new and exciting methods for unlocking the genetic potential of our crops. These new techniques seek to more efficiently explore the

natural variability that is the foundation of breeding new and more robust crops. We don't wish to see these technologies hampered by onerous regulations.

NCGA recognizes that the Coordinated Framework works. The USDA, FDA and EPA have allowed safe products to become commercially available to support food security worldwide. We also recognize the recent efficiencies implemented by the USDA have gone a long way to clearing the queue and getting products to market. Let's keep this trend moving forward.

Thank you for allowing me to make comments today.

MR. MENDELSOHN: Next we'll hear from Jeffery Campbell.

MR. CAMPBELL: Hi. My name is Jeffery Campbell. I live in Fisher County. I'm here representing myself as a consumer and a producer.

My great-great grandparents moved to West Texas to the McKinney area in the 1890s and started growing cotton. My dad was about the

first generation that decided not to grow cotton and we're from cow country now. We keep a five-acre market where we raise Heritage Hogs, we raise Dwarf Nigerian Goats, mini donkeys, we try and keep about 500 pasture poultry a year, we keep chickens, turkeys, guineas, peafowl. We sell direct to customers and at a farmers market and farm stands which puts us in front of a lot of producers and a lot of consumers. I also work part-time for NASDA compiling surveys of things like that with farmers, so it puts me in front of a lot of producers also.

Cotton farmers in East Texas don't have much choice for seeds other than offerings from biotechnology companies. Roundup-ready products like Deltapine and FiberMax are basically the norm where we're at. Operators that use these products are stuck with very high seed prices and even larger chemical prices. The pests that chemicals are designed to destroy, we're seeing very bad problems everywhere with resistance to those chemicals, which we're having to use like a lot

more chemicals than we always have, more spraying than normal.

All of these aspects, they forced the closing of delinting plants because we can't delint the seeds anymore. They hurt American small farmers which are historically the backbone of America. The costs are really high and the returns are really low for us, especially with the weather conditions. We're not getting the results, we're not getting better numbers in the field.

Farmers around me are trying to grow organic and conventional cotton. Organic cotton only makes up a half a percent of the 5.2 million acres planted in Texas. We're forced to try and deal with the overspray of chemicals like Treflan, Roundup. These are all commonly sprayed on genetically engineered crop plants to prepare the seed beds and after the plants are already coming up. So we're having to stagger our plantings and work around them so that it doesn't destroy our crops. We're having to replant a lot of crops when

they are.

A lot of folks feel the small farmer shouldn't be the one that has to bear the burden of these. Vegetable farmers like myself, we face losing our whole crop because they're so sensitive to the drift of the chemicals. My neighbor, my buddy grows 150 acres of watermelons, and he plants every year with the intent that he'll lose a third of his crop to overspray. Acres of watermelons in Texas, you lose 50 acres, it's a lot of problem for a small farmer.

Time and again the biotechnology companies have made it very hard for farmers to find alternatives to their products. It's not very easy to find animal feed that doesn't have a genetically modified organism in it. It needs to be easier for us, the consumers. The farmers and consumers, we feel like there's no other option, what else we can get.

The extra production numbers are there, there aren't many alternatives. They not only hurt the people that don't choose to use the

products, but they're hurting the people that are using the products. It seems like an assault on small farmers these days because they don't meet the scale of economy for the large corporations.

Thank you for listening.

MR. MENDELSOHN: Next we'll have Jill Kauffman Johnson. Is she here?

(No response.)

MR. MENDELSOHN: Okay. Judith McGeary.

MS. McGEARY: Thank you. My name is Judith McGeary. I'm with the Farm and Ranch Freedom Alliance, which is a nonprofit that advocates for small farmers and independent farmers, many of whom are selling directly to consumers or into local markets.

Our farmers are deeply concerned about the current Coordinated Framework and believe there needs to be a fully revamped one that looks both at a comprehensive pre-release analysis and post-release monitoring and evaluation.

One of the key considerations that we think all the agencies should be taking into

consideration are human and animal health impacts. That needs to include the impacts not only for consumers who ultimately eat the food, but the health of the farmers, the farmworkers, and the rural residents, all of whom are impacted, particularly by genetically engineered crops that are herbicide-resistant and new waves of herbicide-resistant crops.

GMO foods should undergo long-term testing to ensure that they are safe for human and livestock use. The 90-day standard test is woefully inadequate when you're talking about foods that people will be consuming over their entire lifetime. And most particularly, we need this done by independent studies and data.

As I bought up during the question and answer session, one of our concerns is how the studies are designed. There seems to be a mismatch between the discussion that there is serious rigorous scientific study designed up front and what we are seeing.

And to use just two examples, in the

recent approval of AquaBounty salmon, it came out that there were several studies that had six or fewer salmon in them. This does not provide any statistical strength, and in essence, from a scientific perspective they're useless to address the concerns such as allergenicity that they were supposed to be addressing.

Also, in looking at the effect, again focusing for a moment on herbicide-resistant crops, the field applications need to be addressed and not just the active ingredients. There's a study that was just published last month in the International Journal of Environmental Public Health showing that Roundup, the full product, is up to 100,000 times more toxic than glyphosate alone. We need to be addressing the real-world conditions when agencies are looking at whether or how to approve genetically engineered crops.

We also need to be in consideration of the social and economic factors. We're looking at things such as the emergence of more and more herbicide- resistant weeds. These are plant

pests. Whether the GMO crop itself is a plant pest or not, if it leads to the creation of superweeds, that is a threat to American agriculture as a whole. We also have to address the crop contamination and loss of crops to pesticide overdrift. It almost got buried in what you said, a third of a watermelon farmer's crop he expects to lose every year. That's unacceptable for agriculture to have to suffer through that.

I see the time and I'll wrap it up quickly. It's very important that the agencies don't say that it's done with initial approval. We have seen far too many times over our history that things that we thought were benign proved not to be so.

But there isn't a mechanism for tracking these things, both agriculturally and in our food supply, post- market, post-approval, in the market. We have no way of knowing if they actually do have adverse effects. That means we have no way of knowing if our regulatory system is working.

The last point I'd like to make is that all too often there's a discussion of needing to feed the world, and there's a rhetoric that involves either we have genetically engineered crops or we sit on our hands and do nothing and millions starve.

And this is reflected all too often in the regulatory analysis where the comparison is between the genetically engineered option and a do-nothing option or a chemically intensive option. There are other alternatives, and there are studies after studies that show, particularly at the international level, that sustainable farming not involving genetic engineering is one of the best ways to feed the world, not just our community.

So when the regulatory agencies are looking at whether to approve genetically engineered crops and you are weighing social and economic and humanitarian interests, it needs to look at all the alternatives, not set up the strawman of the genetically engineered crops are

having.

Thank you very much.

MR. MENDELSOHN: Next we'll have Marie Tedei.

MS. TEDEI: Hello. My name is Marie Tedei and I own and operate an organic farm just outside of Dallas in Balch Springs, Texas. I raise vegetables and Icelandic sheep and laying hens, all of which are raised using organic methods or fed using organic feeds. I am also the regional director of the Texas Organic Farmers and Gardeners Association here in North Texas.

Although mostly raised on native pasture in a sustainable way, it is important to me to have available organically raised, non-genetically modified supplemental feed grains for my hens, and when needed, for my yew. I'm concerned with the lack of independent long-term testing of genetically modified corn and soy commonly used in animal feeds of many kinds, including dog, cat and horse feeds, all of which I use. Unfortunately, most of the feeds on the market are not organic

and most contain genetically modified grains of corn and soy.

When these crops are genetically modified to accept multiple strains of glyphosate-based herbicides, the residue would then be fed to my animals, commercial and domestic, daily, and we know it is not safe to consume this herbicide. It is also not safe for those who work on the farms that raise these crops for the feed to so often be exposed to the herbicide, frequently without proper safety gear, or to then upon harvesting handle the grains that have previously been sprayed.

I also operate a farmer's market on my farm where consumers are regularly sharing with me their concerns over whether or not they and their families are buying non-GMO foods because there is not adequate labeling in the grocery store unless the product is certified organic or that they know if they are buying it from a farmer whom they know grows using non-genetically modified feed stock. Many were surprised last summer to learn that

their common summer squash are now in the genetically modified category, along with soy and corn. Our salmon supplier is up in arms over the potential for GMO salmon to be sold side by side with her wild caught Alaskan salmon without labeling.

As food producers and suppliers, we ask that oversight by the agencies be a formal assessment and regulatory process, not fast tracked, that is done prior to releasing crops to farmers growing where wind, honeybees and other pollinators carry pollen from genetically modified crops where they can harm the bees as well as contaminate other farmers' non-GMO crops and now genetically modified animals before they're released to the wild open seas where they can cross-breed with native non-genetically modified animals or other unintended consequences.

And we ask that as consumers a more in-depth and mandatory labeling process be put into effect, not blocked, before placed on the market for the general public to consume. Allergy

issues, as well as safety of consuming insufficiently tested by independent long-term studies concern us all and we respectfully ask that the process be more stringent and consumer-biased than it currently is.

Thank you.

MR. MENDELSOHN: Next we'll hear from Bill Peck. Okay, it doesn't matter. That's fine. John, go ahead. John Cumbers from SynBioBeta.

MR. CUMBERS: Good morning, everybody. My name is John Cumbers. In addition to working at NASA for the last seven years in synthetic biology, I'm the founder of SynBioBeta, a global activity hub for the synthetic biology industry. We bring together key members of industry, academia and regulatory agencies multiple times a year in various parts of the world to hold conferences, workshops and courses. This year we're running events in the United States, the United Kingdom and China, which all have a lot of support for this new fledgling industry. We maintain a company database of over 200 companies,

track investment in the field, and support entrepreneurs, investors, partners and policymakers in the field.

I'm uniquely qualified to serve as the voice of the synthetic biology industry. I wanted to speak to thank the OSTP and government for recognizing the need for the government to take an active role in the regulation of the products of biotechnology in the future. The rapidly growing industry in the last twelve months has raised over three-quarters of a billion dollars in venture financing. Venture capital has long been the mechanism by which many startups have been created, new industries born, and new economic growth and leadership in the United States has been made possible. Over the last 40 years of biotechnology, we've seen amazing new numbers of discoveries, including the structure of DNA, and also in our ability to read and now write DNA.

I represent over 10,000 people in our community and I'm excited that the government is looking forward to these new applications of

biotechnology because the community that I represent is passionate about seeing the products of their labor make it into the hands of the people that need it most, whether that's a new engineered cell line to defeat cancer, a new sustainable bio-based material, a fuel, chemical or food product. Biology is technology and has an immense amount of power to do good, and it's important that we support the community while building the future in a safe and responsible manner.

In particular, I represent a new startup community in the synthetic biology industry who are well educated, thoughtful and respectful citizens of this country and passionate about communicating the work that they do to a broader public. The current regulator system as it functions, however, is far from supportive of these passionate entrepreneurs, delaying them in decades of bureaucracy, paperwork and with sometimes irrational take on risk that does not represent the potential benefit of these

technologies and can be too one-sided towards the potential unintended consequences.

In addition, there's currently no regulation of biotechnology products and the regulation is siloed into different organizations. There needs to be more clarity and easier routes to market so that the entrepreneurs can more easily embark on a route to see their company and products succeed and investors have the confidence to back them based on known timelines.

There are a number of challenges in innovation posed by the regulatory system as it exists today. Given their experience in traversing the regulatory pathways to commercialization, small companies developing new products believe that the current regulatory framework imposes significant burdens on innovators and so reduces the economic potential of the industry. It's time to try a less burdensome regulatory approach aligned with the actual scientific consensus on the risks, and I want to applaud the government for taking on this

issue and thanking you all for being here.

Thank you.

MR. MENDELSOHN: Now we'll hear from Bill Peck, the CTO Twist Bioscience.

MR. PECK: Yes. I asked John to go first just to give some context for who we are. I'm Bill Peck. I'm the CTO of Twist Bioscience.

We're a small startup in San Francisco, California. We started three years ago and as of now we're just over a hundred people, we've raised about $130 million of venture funding, and we've got a $5 million government grant. And our mission is to provide synthetically manufactured genes to scale and accelerate the biotechnology field test design cycle. So it's very similar to the traditional engineering approach. I'm a mechanical engineer by trade, so I speak this language but with a strong accent. So typically, as in engineering, you go through a design-build-test cycle, and what the biotechnology community needs is access to genes to do that, and we're providing that.

An early and important customer is Ginkgo Bioworks from Boston, Massachusetts. They say their products are to engineer new organisms and self challenges across a range of industries from fuels to pharmaceuticals. In this capacity we are a tool provider, so we are not engineering the application so much as providing tools for the people engineering the application.

And there seems to be a natural hierarchy developing in this field: tool providers manufacturing genes and application engineers taking the genes and developing biology. So as a tool provider, we concentrate typically difficult technologies, so we bring the semiconductor world into biology, so we're using all the tools from semiconductor to scale and provide this product at unprecedented availability.

So as this becomes, as John talked about, the ability to write DNA -- so I've been involved in reading DNA for the past 15 years and now we're into a world where we're writing DNA --

so as we enter this world, it's a whole new form of engineering. And it's not limited to just biology, actually it's just information in general. So if you look to the New York Times, I think in December, there's an article where we had a collaboration with Microsoft. And I believe one of the engineers from Microsoft will be coming to UC Davis to speak to us, and they're using DNA as a data storage media. So biology can be used to store the information on this computer, the DNA can be used to store that information for long-term data storage. So it's a marvelous thing as we know as it exists today to store information.

So does the orange mean I'm out of time? Very good. Right to the end.

MR. MENDELSOHN: You have another minute.

MR. PIKE: So at Twist we especially the support the construction of a really open and frank conversation with everyone, all the stakeholders, everyone from -- I'm a farmer too, I have a small farm that raises canola -- and so all

the farmers, the people that use the products, the application engineers, the EPA, the USDA, all of them, we'd like that open conversation to really make sure that we're doing the right thing.

So I'll just read now: While policies and procedures require both time and monitoring from small companies like Twist, our company is committed to accelerating scientific research to improve lives worldwide. Synthetic biology holds great promise for improving human health and the global environment. Twist Bioscience is proud to be a part of this promise and also support the principled. use of the technology.

Finally, we also applaud the efforts of the agencies represented here today and support the efforts to refresh the Coordinated Framework to reflect the current biotechnology companies.

Thank you.

MR. MENDELSOHN: All right. Is Jeffrey Farrell here? Great.

MR. FARRELL: My name is Jeffrey Farrell, and I am a former university lecturer,

public school teacher, a teacher of literature and drama, something that is not typically heard from in these settings.

And I'm here today because I have children, I know many people who are well educated, and myself too, I have post-graduate degrees including work here at UT Dallas, Washington University at St. Louis where I studied biology and left that behind me, and pursued work in the world of literature and drama, including work at Yale University, and I've received grants from the National Endowment for the Humanities, from the French Ministry of Culture.

And these issues that we're talking about today are significant. It is not merely about marketable technology. Marketable technology is not the same thing as science, and many times we who oppose this biotech onslaught are labeled as Luddites and anti-science fear mongers. Well, that's simply not true.

What I would suggest is that the entire process so far, as I've studied -- Washington

University is in St Louis, home of Monsanto, our friends. Right? What I have observed in the 30 years of this process is that the oversight of it has not been sufficiently guided, that there are some serious problems right in the heart of the system.

Now, I'm not going to get into further details and I'm not going to change your minds, most likely, if you have your minds set, and you've said before how important with the economics and all like this, and our president has offered this biotech blueprint, of course.

Can I help you?

SPEAKER: No, I'm just making sure that's okay.

MR. FARRELL: That's okay. Thank you for interrupting me.

SPEAKER: Sorry.

MR. FARRELL: That was like 30 seconds of my time.

If we have this kind of interference this way, if we have a problem at the very heart

of the oversight process, which in many cases it can be demonstrated, there needs to be something else done.

And I'll leave you with just one thing, and I'd like for you to consider how tobacco, the process of tobacco over a hundred years, and I'll be very brief. In 1900 there were no manufactured tobacco packages or anything like that, but the technology allowed tobacco to be placed into actual cigarettes, mass produced, put into packages and then shipped off, sold. They were then approved through our federal agencies. At the time EPA didn't exist, all these agencies didn't exist, but our military did and they were provided in rations to our soldiers.

Well, if you look at the consumption of cigarettes from 1900 when the technology first arrived until 1965, the growth in consumption of tobacco spiked. In 1965 you know what happened. Right? Our surgeon general said, Cigarettes are dangerous. Consumption began to drop significantly.

We do not have 65 years to prepare observations and studies to demonstrate the hazards of the biotechnology. Mr. Peck observed earlier just a moment ago how the DNA receives information and it can be encoded with vast information.

This is true and all the more reason that we need to be particularly sensitive to these issues of development and to avoid the hubris -- and it is hubris -- that is potentially far greater damage than what we're looking at here in some of the smaller issues.

I want to thank you very much for taking the time to listen and I appreciate being here.

MR. MENDELSOHN: Next we'll hear from John Salmeron, director of plant science, Precision Biosciences. Is John Salmeron here?

(No response.)

MR. MENDELSOHN: Okay. Next is Suzie Marshall with the Texas Organic Farmers and Gardeners Association. She wasn't able to make it. Okay.

All right. Was Lisa Griffith here with the National Family Farm Coalition?

MS. McGEARY: So I'm presenting these on behalf of Lisa Griffith with the National Family Farm Coalition.

The National Family Farm Coalition, representing thousands of independent family farmers, ranchers and fishermen throughout the United States, wishes to state our support for a fully revamped Coordinated Framework to regulate biotechnology products in the U.S.

The current Coordinated Framework seems designed to advance the release of GMOs, not to ensure their safety. We hope that the FDA, EPA, USDA and other agencies take the opportunity to change the course of the regulatory review by adopting an approach that seeks to ensure, first and foremost, that GMOs and their accompanying pesticides are safe.

This new framework must be based on a comprehensive pre-release analysis of any new GMOs that addresses the concerns of and the

socioeconomic, environmental and health impacts on the farmers or fishermen, their families and the rural communities neighboring GM crops. We also believe that GM foods, including seafood, should undergo long-term testing to ensure that they are safe for livestock and human consumption.

The U.S. Government agencies responsible for testing, approving and monitoring GMOs should not rely on information provided by those who manufacture GMOs or who profit from their production to determine how to test them. Each agency has the means, authority and public responsibility to regulate GMO crops and the pesticides used with them to ensure safe planting and harvesting that does not harm farmers, their livelihoods or regional biodiversity.

For the past 20 years we have watched government agencies approve dozens of GM crops, despite concerns raised by farmers, fishermen and other members of the public. These concerns include, but are not limited to: reduced farmer choice in non-GMO crops due to the consolidated

seed industry; the loss of independent seed dealers and other rural businesses, leading to the overall demise of rural communities throughout the U.S.; crop contamination from seeds and pesticides; fence row to fence row planting of GMOs resulting in habitat loss for birds, bees, butterflies and other wildlife, along with increasing numbers of concentrated animal feeding operations where independent diverse family farms once stood; the reduced use of crop rotations and cover crops; the emergence of scores of herbicide-resistant weeds; the loss of organic and non- GMO certification for farmers, followed by lower prices and market share; diminished research and development of non-GM seeds at public universities, including land grant colleges; and the unproven but noted correlation between cancers and other diseases in rural areas where herbicide-resistant GMs are widely planted.

We reiterate our stance that in a nation built on opportunity, U.S. Government agencies should ensure that our farmers and ranchers have

the opportunity to raise non-GMO crops without worry of contamination frm one element or another, and that genetically modified crops approved by these agencies are safe for consumption. The ongoing deregulation of new herbicide- resistant GMOs based on the current uncoordinated framework is completely at odds with USDA's efforts to promote local foods, rebuild rural economies and provide healthier foods to school children.

Thank you for the opportunity to present these comments.

DR. BARBERO: All right. Is that it from everybody?

Okay. We had one question from online which was when and where will a recording of this meeting be posted. So this will be transcribed and placed into the docket, and there will also be a recording of this posted on EPA's website, the same website that you used to register for the meeting.

So with that, I thank you all for coming and thank you to everyone online for listening and

spending the morning with us, and look forward to further discussions on this. Thank you very much.

(Whereupon, at 1:25 p.m., the public meeting was concluded.)

REPORTER'S CERTIFICATE

DOCKET NUMBER: FDA-2015-N-3403

IN RE: PROGRESS ON MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS

DATE: MARCH 9, 2016

LOCATION: DALLAS, TEXAS

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 U.S. Environmental Protection Agency.

Date: 3/17/2016

Leslie Berridge

Official Reporter