U.S. FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING

MODERNIZING THE REGULATORY SYSTEM

FOR BIOTECHNOLOGY PRODUCTS

Friday, October 30, 2015

9:30 a.m.

A G E N D A

P R O C E E D I N G S

9:30 a.m.

Welcome

DR. NALUBOLA: Good morning everyone. We do have a full agenda today so let's get started without delay. Thank you for joining us at this public meeting on Modernizing the Regulatory System for Biotechnology Products. Welcome to the FDA White Oak Campus.

My name is Ritu Nalubola. I am a senior advisor for Policy in the Office of Policy in the Commissioner's Office here at FDA. We have a number of speakers today representing the White House Office of Science and Technology Policy, the Environmental Protection Agency, the U.S. Food and Drug Administration and the U.S. Department of Agriculture.

On behalf of all of my colleagues from all of our organizations, I want to thank you for coming to this meeting.

Our thanks also to everyone who's joining us through broadcasting. Participants on broadcast and

here in the room together, we have more than 350 participants today, and we appreciate your interest in this topic. So again, welcome to everyone.

As you will hear from our speakers this morning, in July of this year, the Executive Office of the President issued a memorandum directing EPA, FDA and USDA to undertake certain actions, including to update the coordinated framework for the regulation of biotechnology.

As part of this effort, FDA in conjunction with the White House Office of Science and Technology Policy, EPA and USDA is holding this first public meeting, which is being convened under the auspices of the National Science and Technology Council.

The purpose of this meeting is to inform you about the activities that are described in the memorandum, and to invite your comments relevant to those activities. Each of the regulatory agencies will also give you an overview of how they regulate products derived from biotechnology.

Before we get started, I want to go over a few housekeeping items. I hope you picked up the

agenda from the registration desk. We do have a full agenda with two short breaks and at 10:40 and at 11:50 a.m. We also provided you with a one-pager that shows the specific questions on which we are seeking comment. The handout also gives you information about the docket number and website for submitting written comments.

We have a number of people giving public comment this morning, as you will see in the meeting materials. We do appreciate and value your input, so thank you.

For your reference, a transcript of today's meeting will be posted on our website, as will the PowerPoint presentations that you will see today. The transcript does take a little bit of time, but we'll have that up as soon as we can, and we'll also submit it to the docket.

We do need comments in the record for them to be officially considered, so please do get your written comments into the docket. One other thing I would like to mention. If you are with the media or the press, please be sure to check in at the

registration table. We do have FDA media staff here available, so if you have any questions, you can direct it to them.

A couple of other basic items. Restrooms are at the front of the building past the registration table. Also just a quick reminder to please silence your cell phone or two, if you have not already done so. If you have any questions during the meeting, please stop at the registration table and FDA staff will be happy to help you.

So with that, let's get the program started. I will now turn the podium over to Dr. Roberto Barbero, who's the Assistant Director for Biological Innovation in the White House Office of Science and Technology Policy.

DR. BARBERO: Thank you Ritu, and thank you all for being here. I am just up here for one second, because I am going to introduce our first speaker.

Our first speaker today is Dr. John Holdren. He is the Assistant to the President for Science and Technology, and also the Director of the Office of Science and Technology Policy in the White House.

Opening Remarks

DR. HOLDREN: Well thank you Robbie, and let me thank all of you for being here, those who are in the room, those who are watching online and let me also thank the Food and Drug Administration for hosting this meeting. Today we're going to be discussing a very important topic, how the federal government ensures the safety of the products of biotechnology.

You're going to hear from some of the leading experts on that topic, from FDA, EPA, USDA, and you're going to hear from some of the members of the public who are here, who have ideas about how the federal government can clarify the roles and responsibilities of the agencies that regulate the products of biotechnology.

But before we get to that, I want to start by telling you why the White House Office of Science and Technology Policy is engaged with this issue and why we're here today. Historically, the OSTP has played a critical role in advancing responsible innovation, by helping to create a policy environment

that is welcoming to scientific and technological innovation, while also appropriately protecting public health and safety and the environment.

Innovation is crucial for meeting key national challenges, national challenges in job creation and sustainable economic growth, in biomedicine and health care delivery, in clean, safe, reliable and affordable energy, in climate change mitigation and adaptation, in stewardship of land and water and the health and productivity of the oceans, and of course in national and homeland security.

And scientific discovery and technological innovation, which are increasingly intertwined, are in fact societal values in their own right. They lift the human spirit; they're part of what makes us human.

For all those reasons of societal value of public good, it's appropriate for the government to invest in the health and progress of the national science and technology enterprise, not only by funding basic research and applied research and development where public interest dictates, but also by fostering an economic and regulatory environment that is

supportive of private sector R&D and high tech innovation, while of course also attending to the government's proper role of protecting public health and safety and the environment.

In the White House, the work of coordinating and overseeing the activities of the executive branch to these ends is shared among the Office of Science and Technology Policy, the National Economic Council, the Domestic Policy Council, the National Security Council, the Council on Environmental Quality, the Office of the U.S. Trade Representative and the Office of Management and Budget, in the latter case particularly its Office of Information and Regulatory Affairs.

OSTP plays a lead role in this partnership understandably, as we're the home of most of the White House's expertise on science, engineering and high tech innovation and entrepreneurship. It was in that role that the OSTP, after consultation with its White House partners and the relevant cabinet departments and agencies, issued in 1986 the coordinated framework for regulation of biotechnology.

That outlined a comprehensive federal regulatory policy for ensuring the safety of biotechnology products. It's important to recognize, I think, that the coordinated framework did not create new authorities in the regulatory agencies. It did describe how the agencies would use their existing authorities in a coordinated way.

That coordinated framework was updated in 1992, but it has not been updated since then. While the current regulatory system for the products of biotechnology under that framework does effectively protect public health and safety and the environment, there is much reason to believe that advances in biosciences and biotechnology, and changes in the innovation landscape require a new look at some of the aspects of our approach to regulation in this domain.

Advances in the science and technology in the nearly quarter of a century since 1992 have simply revolutionized what can be done, enabling the development of whole classes of valuable biotechnology products that were not previously possible.

Some of these may carry new risks as well as

new benefits, and the current complexity of the array of regulations and guidance documents developed under the 1986-1991 framework over the years by the three primary federal agencies with jurisdiction, the EPA, the FDA and the USDA, can make it unduly difficult for firms with new products to navigate the process, while also making it difficult for the public to understand how that process works, and to have confidence in the results.

The task of navigating the regulatory process for these products can be especially challenging for small companies, where much of the innovation is going on. For these reasons, in July of this year the Executive Office of the President, EOP, issued a memorandum to the EPA, the FDA and the USDA, directing those agencies to take a number of actions to improve the transparency, predictability, coordination and ultimately the efficiency of the biotechnology regulatory system, and improving at the same time the confidence of the public that it's working.

One action called for in the memo is to

update the coordinated framework and clarify the current roles and responsibilities of the agencies that regulate the products of biotechnology. Another is to develop a long-term strategy to ensure that the federal regulatory system is well-equipped to assess efficiently whatever risks may be associated with the future products of biotechnology.

And a third action is to commission and expert analysis of the likely future shape of the biotechnology product landscape. Since that EOP memorandum was issued, we've been working with EPA, the FDA and the USDA on all of those indicated actions.

Among other things, we have already asked the National Academies of Science, Engineering and Medicine to conduct that landscape analysis. The administration of course recognizes the importance of public engagement throughout this process. Accordingly, when the memo was released, we announced that there would be three public engagement sessions over the year in different regions of the country.

Today is the first of those sessions. We

look forward to hearing from you today, and in the coming days through the open request for information on the update to the coordinated framework and the long-term strategy, as well as through the other public engagement sessions to come.

So thank you again for joining or tuning in today and for your interest in this process.

Modernizing the Regulatory System for Biotech Products

DR. BARBERO: All right. Thank you very much, Dr. Holdren. We appreciate your remarks. So now we're going to get a little bit more into the meat of the presentations here, and as you can see on your agenda, we will have presentations from each of the agencies, describing their current roles and responsibilities under the coordinated framework.

Before that, what I thought I would give you a little bit of perspective on what we are doing and how we are doing it, so that you can understand in greater detail the tasks that we have at hand. My name, as Ritu said before, is Robbie Barbero, and I'm the Assistant Director for Biological Innovation in the White House Office of Science and Technology

Policy.

All right. Maybe I can use this. Yeah, there we go. Okay. So today, what I would like to cover, I will give you a little bit of an indication, as John -- as Dr. Holdren stated, what the federal policies are that guide our work in this space, and they stretch all the way back to 1986.

We will review some of the principles that were articulated in the policies from the 1980's and 1990's, and then talk about the current effort to modernize the regulatory system for products of biotechnology and go through those three tasks at hand that Dr. Holdren outlined for us, and then give you some more detail on the opportunities for public engagement, and provide some links to additional information.

Since this presentation will be made available afterwards, you will be able to follow those links in order to find additional information.

So first, in 1986, the White House Office of Science and Technology Policy, with the interagency, issued the coordinated framework for the regulation of

biotechnology, and this was developed after a very inclusive interagency process, where input from the public was taken into account.

The key goal that that coordinated framework sought to achieve was a balance between regulation adequate to ensure health and environmental safety, while also maintaining sufficient regulatory flexibility to avoid impeding what at the time was an infant industry.

In 1992, that coordinated framework was updated, and then 2015, just this summer, the Executive Office of the President announced the start of an interagency process to modernize the biotechnology regulatory system, taking the cues from the same sort of process that was undertaken in order to write the coordinated framework and update it in 1992.

So what are some of the principles that were articulated in the 1986 coordinated framework and in the 1992 update? Well, in the 1986 policy, they stated that each agency would use their existing authorities and programs to ensure the safety of

products and biotechnology.

They stated that those agencies should cover the full range of plants, animals and microorganisms derived by the new genetic engineering techniques. To the extent possible, responsibility for a product was to lie with a single agency. But where regulatory oversight or review for a particular product was to be performed by more than one agency, then coordinated review should occur.

They acknowledged that because of the comprehensive regulatory framework that used a mosaic of existing federal laws, some of the statutory nomenclature for certain actions that the agencies undertook may have seemed to be inconsistent. But they endeavored to ensure that each of the reviews conducted by the agencies would be of comparable rigor.

They also articulated that the 1986 policy was established in order to follow the traditional risk-based approach to regulation that each of the agencies already followed, and they sought to distinguish between those organisms that required a

certain level of federal review and those that did not.

I've copied a bit of a wordy quote here from the policy, but I think it's worth putting in here, and I've underlined something that identifies why we are here today.

"The regulatory framework anticipates that future scientific developments will lead to further refinements. So they knew even at the time that it would be necessary to revisit the coordinated framework.

Experience with earlier basic scientific research has shown that as science progressed and became better understood by the public, regulatory regimes could be modified to reflect more complete understanding of the potential risks involved.

Similar evolution is anticipated in the regulation of commercial products, as scientists and regulators learn to predict more precisely particular product use, the required greater or lesser controls, or even exemption from any federal review."

So in 1992, there was an update to the

original coordinated framework, and in the 1992 update, they identified that there are -- because there are applications of biotechnology product areas in many areas, that would potentially include products in medicine or pharmaceuticals, agriculture, energy, manufacturing and environment protection.

Then again here, I've taken a quote from the 1992 policy that I think is especially relevant. "The process of modification is thus independent of the safety of the organism. Although the new biotechnology processes can be used to produce risk organisms, so can traditional techniques.

It is the characteristics of the organism, the environment and the application that determine risk or lack thereof, of the introduction not the technique used to produce the organism." I've also put some language in there that came from that 1992 update, that gave some examples of the types of.

It was not intended to be comprehensive, but it was intended to give examples of the types of criteria or risk factors that they thought might be considered.

Okay. So what are we doing now and how would we like your help? So in July of this year, the Executive Office of the President issued a memorandum on modernizing the regulatory system for biotechnology products, and the goals and guidance are stated here.

The goals are that the federal agency that regulate biotechnology products should continually strive to improve predictability, increase efficiency, and introduce uncertainty in the regulatory processes and requirements. It's critical that these improvements are based on the best science available, that the agencies established transparent, coordinated, predictable and efficient regulatory practices, and that all of this is done through clear and transparent public engagement.

Since the release of the memo, we have established an interagency working group that is established under the Emerging Technologies Interagency Policy Coordination Committee, and includes representatives from the Executive Office of the President, which includes OSTP, from EPA, FDA and USDA, and there are three tasks at hand.

One is to update the coordinated framework to clarify the current roles and responsibilities of the agencies that regulate the products of biotechnology. The second is to develop a long-term strategy to ensure that the federal regulatory system is well prepared for the future products of biotechnology, and the third then is to commission an external analysis of the future landscape of biotechnology products.

So I won't read all of the words on this slide, but I do put them up here so that you can see all of this language is taken directly from that memorandum, and I share it with you so that you can understand the scope of what we are trying to accomplish in our update to the coordinated framework, and in the development of the long-term strategy.

There are four key components to the update to the coordinated framework that we will be addressing, the first of which is to clarify which product areas are within the authority and responsibility of each agency.

Then for those products where the

responsibility falls under multiple agencies, to clarify the roles that each agency plays for those different product areas, and then to clarify a standard mechanism for communication and, when appropriate, coordination among the agencies as they undertake their reviews, and finally to clarify a mechanism and time line for regularly reviewing and updating as appropriate the coordinated framework.

So you'll notice on here that this exercise is intended to be a clarification of the current roles and responsibilities. So this coordinated framework update will be about how does the system work now and what are those current roles and responsibilities. Much like the original coordinated framework did not endow additional authorities upon the agencies, I don't anticipate that this work will.

The long-term strategy is the sort of future-looking part of this activity. It will be a separate policy document, and it will have several components to it. I've kind of binned them here into the, you know, how they fall into the goals of what we are trying to accomplish.

So in order to improve transparency, there are several things that we will be doing. First is to establish a time table and mechanisms to work with stakeholders, to identify impediments to innovation and to ensure the protection of health and the environment. Second is to coordinate the development of tools and mechanisms for assisting small businesses, in order to navigate the regulatory system.

The third is to initiate the development of modernized user friendly tools for presenting the regulatory authorities, practices and bases for decision-making. The fourth is to proactively engage with the public to discuss how the federal government uses a risk-based scientifically sound approach.

The other four pieces of the long-term strategy are to develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities; to develop a plan for periodic formal horizon scanning assessments of what new biotechnologies are or may look like.

If necessary, if the interagency decides

that it's necessary to identify changes to authorities, regulations and policies that could improve the agency's ability to assess the potential impacts and risks, if any, from future products of biotechnology, and then to regularly adjust regulatory activities based on experience with specific products.

Finally, the third component of this is an activity that will be undertaken not by the federal government, but it's an external analysis of the future landscape of biotechnology products. As Dr. Holdren mentioned, we have already asked the National Academy of Sciences, Engineering and Medicine to undertake this analysis.

The two parts or, you know, the two goals that are identified in the memo for this analysis were one to identify potential new risks and frameworks for risk assessments for future products, and then also to identify areas in which the risks or lack of risks relating to the products of biotechnology or the future products of biotechnology are well understood.

Okay. So how can you get involved? Well, you already are, because you're here today or you're

watching online. So congratulations. But a little more specificity, we currently have an open interagency request for information, and all of that is available on the docket. Responses must be received by November 13 at 5:00 p.m. Eastern Time.

The interagency request for information is asking for relevant data and information, including case studies, that can assist in the development of either or both the proposed update to the coordinated framework, to clarify the roles and responsibilities of the EPA, FDA and USDA, or the development of the long-term strategy, consistent with the objectives described in the July 2nd, 2015 memorandum.

There will be two more public meetings, and when there is a draft of the coordinated framework, it will undergo public comment before it is finalized. I will not force you all to listen to me read these questions to you, because you can read them on your own, and they're provided in the handout that we gave you when you came in.

They're also available into the request for information. But these questions are the ones that we

would ask you to consider as you offer public comment, either in your oral comment today or when you offer written comment in the docket.

It would also be very helpful if you would help us think about whether you think this is more pertinent to the update to the coordinated framework, or to the development of the long-term strategy when you are answering the questions.

Finally, here are the links to all of the relevant documents that I discussed today and some other relevant policy documents. So the coordinated framework in the 1992 update, as well as the 2015 memorandum from the Executive Office of the President, and then finally there are several policy documents that this administration has put out in the last several years that we provide links to as well. Okay. Thank you.

DR. NALUBOLA: Thank you, Robbie. Our next two speakers will be from the U.S. Department of Agriculture. I am pleased to introduce Dr. John Turner and Lisa Ferguson from the U.S. Department of Agriculture APHIS. They will discuss the regulation

of products of biotechnology within their jurisdictions.

Dr. Turner is the Director for Biotechnology Risk Analysis Program within APHIS, Animal and Plant Health Inspection Service at USDA. Ms. Ferguson is the National Director of Policy Permitting and Regulatory Services within the National Import-Export Services of Veterinary Services wing of APHIS at USDA.

USDA-APHIS Role in Regulation of Biotech Products

DR. TURNER: Thank you and good morning. As you've just heard, our presentation will be in two parts. So I'll be talking about our regulations at 7 C.F.R. 340, perhaps the ones most of you are familiar with, for regulating certain genetically engineered plants and for regulating plant pests.

Then Lisa Ferguson will speak on regulations and a different enabling authority for protecting animal health.

So a little of the history first, since we're talking about the coordinate framework. You just heard from Robbie that the coordinated framework policy was issued in 1986. So in 1987, we at USDA

promulgated our regulations at 7 C.F.R. 340, under authorities of the Federal Plant Pest Act and the Plant Quarantine Act.

These regulations were then revised in 1994 to include a petition process to remove organisms from regulation. So prior to that, if something was regulated, it was always regulated. But this new petition process gave a mechanism by which you could demonstrate that if something wasn't a plant pest, it could be no longer regulated by APHIS under 7 C.F.R. 340.

We also added a notification process to allow for a more streamlined review of field test requests, and I would add also it also applies to importation and interstate movement. So this notification process is a more streamlined version of a permit, and in 1994it was introduced for just six common crops for which we had a lot of experience.

In 1997, the regulations were revised to extend this notification process to include any species of crops, as long as it met the eligibility criteria. In the year 2000, Congress passed the Plant

Protection Act. This consolidated several previous enabling authorities, including the Federal Plant Pest Act and the Plant Quarantine Act, which were the acts under which we were regulating. So the Plant Protection Act is our current authority. In 2008, we proposed to revise 7 C.F.R. 340 and this proposed regulation actually received a lot of comments, tens of thousands of comments and it was never finalized, and earlier this year, we withdrew that proposed rule. Since withdrawing, we've begun engaging the public and stakeholders for input into possible future revisions.

So, here are the very basics here in summary. Our law is the Plant Protection Act. Our regulations, 7 C.F.R. 340, and our protection goal is around protecting plant health, specifically to protect plants and plant products from plant pests. At the bottom of the slide, you'll see a link to our web page.

So here you can read the regulations, guidance documents and see the many products and we've deregulated over the years.

I want to talk a little bit about how our regulations work, what our regulatory trigger is. Organisms are subject to our regulations if (1) the organism has been altered or produced using genetic engineering, and that is defined in our regulations as using recombinant DNA techniques, and also the organism is produced using plant pests; that is, the donor, recipient or vector is a plant pest, or there is some otherwise reason to believe that the GE organism is a plant pest.

Under these regulations, we regulate a variety of organisms, and any organism which is engineered using plant pests is regulated. The largest group of organisms we regulate and maybe the most important is plants, because they're often engineered using plant pests.

Either they use an organism called agrobacterium to shuttle the genes in, or they use other plant pest components to regulate the expression of genes. Plants are our largest class, but we also regulate genetically engineered plant pests such as bacteria, fungi, viruses and invertebrate animals such

as in insects, arachnids and nematodes.

Not all GE plants are regulated at APHIS. There has to be a plant pest component, as I mentioned earlier, and the list of organisms that we consider to be plant pests is found right there in our regulations at 7 C.F.R. 340.2.

I also want to mention that we have a formal process by which a developer can inquire and receive an answer as to whether a GE organism is within the scope of our regulations at 7 C.F.R. 340, and I'll talk a little bit more about this near the end of my presentation.

So if an organism is genetically engineered and there's a plant pest component, then it's regulated. If it's regulated, that means you need a permit or notification for any of the following activities: importation into the United States, interstate movement or a field test, also sometime called a confined release. You would need either the permit or the more streamlined application method of notification.

A little about confined field tests.

Applicants often apply for these early in the development process. So you don't know everything about the organism; you know a little about the trait and about the genetics and what the intended phenotype is. So at this point there's a presumption that there may be a plant pest risk and the focus is on keeping it confined.

So to do that, we rely on familiarity with the plant, the trait and the environment, and characteristics of the plant are often the key here, things such as is it out-crossing or self-pollinating; is it weedy, is it invasive in any way.

Then you think about whether there are wild relatives with which it could cross-pollinate, and are they weedy or invasive. Can the plant or offspring persist after the test is over? Then of course you have to think about the trait also, and whether it could have changed the plant with respect to any of these important considerations.

So field testing for many products which are out there on the market today may take place for several years or a few years, and after safety has

been established through these field tests, a developer may petition APHIS to grant non-regulated status.

So if a GE organism receives non-regulated status, then it's no longer considered a regulated article, and it can be moved and planted without permits or any further APHIS oversight, at least under the regulations at 7 C.F.R. 340.

And the petition process, this is really our most comprehensive review. This is when you get a very full data package, very large dossier. We have a team of scientists that will be assigned to this and review this, and they'll look at everything that's known about the crop biology. They'll look at any genotype differences, which involves descriptions of all the genes, the molecular characterization, to make sure that the genes that were intended to be inserted are what are there.

We also look at intactness of the insert, so it’s really a thorough genetic molecular characterization. We also look at phenotypic differences, both those which are intended based on

the trait and observations from field and greenhouse to show the phenotype. We receive the field test reports for all the testing that took place under permit or notification, and of course we consider all the relevant experimental data, including published literature and any other information which is available that we need to make our determination.

As we're considering all of this data in a petition request, we really do two types of evaluations, and this is very important. First there is the plant pest risk assessment. This is done under our enabling authority. This is to determine if the GE organism poses a plant pest risk.

Ultimately, the determination to deregulate will always be made on this plant pest risk consideration. But this is a major federal action, which is also subject to NEPA, the National Environmental Policy Act. So we also prepare either an environmental assessment or an environmental impact statement. We have a large and very capable staff, I think, which is produces very high quality documents presently, and it needs to be very thorough work to

look at all the environmental impacts.

But again, my point is after that's done, whether it's an environmental assessment or a full environmental impact statement, the decision will be made based on the plant pest risk assessment.

If you look at one our plant pest risk assessments, these are the parts you'll see. We look at whether this new GE plant could cause pest or disease problems for agriculture. We consider whether the plant could become a weed. We think about whether it could increase the weediness of sexually compatible plants should the gene introgress.

We consider harm to non-target organisms. This is of course something EPA does for plant incorporated protectants. But our assessment here is really limited to those which are beneficial to agriculture, because that's our mission. It's protecting plant health and protecting agriculture.

We consider whether it could affect agriculture practices in a way which could create disease or pest problems, sort of a more indirect way to create disease or pest problems, and finally we

look at whether it could transmit genes to organisms with which it does not normally interbreed. This is horizontal gene transfer and is part of the data requirements under petition, maybe not a major concern these days. But you'll see that described in each of our plant pest risk assessments.

To date, we've made determinations of non-regulated status in response to 117 petitions representing 17 plant species. The determination of non-regulated status extends to the GE plant and its offspring.

Maybe a way to describe the phrase "and its offspring" is to say that once we've made a determination of non-regulated status, that plant can go into a breeding program and be used in conventional breeding to moved into to other varieties with which it can interbreed, and that typically happens.

And some people think we approve things for commercialization, and we don't actually do that. Our determination, in the practical sense, is often needed before a developer could commercialize. But commercialization is determined by market demand, not

an APHIS decision, and it's really out of our hands after we've determined that it's not a plant pest.

So these are the types of crops that we've deregulated. The code out to the right of each plant represents what we call the phenotype category. So for instance with alfalfa, you'll see herbicide tolerance, and you'll see product quality. With some of the others, you'll see agronomic properties and insect resistance.

On the right-hand side, you'll see potato. We very recently deregulated the first plant with fungal resistance. So I guess one of the things I would remark here is while you often hear that, you know, it's all herbicide tolerance and insect resistance with corn and soybean and cotton, and while there's a certain amount of truth to that with respect to the first generation crops, we're really seeing a wider variety of traits coming through in our petitions.

And certainly we see a greater diversity in field tests. There's a number of new traits and it's certainly broader than what you would think of with

those first generation.

So I mentioned earlier that not everything is regulated, and developers can inquire with us whether their organism is regulated. So we call these "Am I Regulated" letters and there are instructions on how to do this on our website. So this is because our scope is actually limited in our regulations, and GE organisms, if they're outside our scope, then you don't need permits or notifications and the petition process doesn't apply.

And since we established a formal process for making these inquiries in 2010, we've responded to 32 inquiries with respect to their regulated status. So those letters of inquiry and our responses are available on our website. This process is case by case. Typically, we have a lot of people ask us hypothetical questions, and we usually say send us a letter. We want to see the particulars and the specifics, and it's different than our determination of non-regulated status in response to petitions.

So there's no plant pest risk assessment. It's not so much a full-blown risk assessment. It's an

examination to see whether it's in the limits of what we regulate, as defined in our regulations.

Okay. So that's the end of my part, and now we have Lisa Ferguson to talk about insects and animals.

MS. FERGUSON: Thank you and good morning everybody. Glad to be here to hopefully share some information with folks this morning. So our authority for animals and insects is actually very similar to what Dr. Turner has described related to plants. Our authority is based in the law. Our statute is the Animal Health Protection Act, and this Act grants the Secretary very broad authority for regulating animals, including insects that would present a risk to livestock or poultry health.

So our protection goal is to protect the health of the U.S. livestock and poultry population. Now you'll note I'm referencing livestock there. Our regs do apply to those animals traditionally thought of as livestock. So cattle, sheep, goats, horses, poultry. We do include farmed fish in that regulation, but we don't regulate absolutely all

animals, just those that would present a risk to the livestock population.

So one way to think of that, if you think of like zoological ruminants, those are not livestock. But they could carry certain viruses that could present a risk to the livestock of the U.S. So they would also fall under our regulations on import to protect the U.S. livestock from those types of diseases.

Our regs are contained really, I'll talk very briefly about three parts of our regs. So 9 C.F.R. Part 93 and 71 relate to animals and Part 93 is the import of animals. Part 71 is our interstate movement requirements, and that regulates animals infected with certain diseases.

Then 9 C.F.R. Part 122, what we call our organisms and vectors section, that one then would regulate insects which could be considered vectors of animal diseases. This top button. Okay, sorry. Technology often is not my friend.

So our regulation of GE insects. As noted, Part 122 is related to vectors. We do consider

vectors to be any type of an animal or an insect that is treated or inoculated with organisms, or which are diseased or infected with a contagious or communicable or infectious disease, that would present a risk to livestock or poultry.

So under this section, GE insects are regulated similar to non-GE insects. So our basic point that we're looking at is their ability to contain any contagious, infectious or communicable disease of livestock or poultry. So for the import or interstate movement of a GE insect, a permit application should be submitted and what we will do with that is then evaluate the animal health risk of that vector.

So if that doesn't have an animal health risk, then we're essentially done. We do collaborate with the other agencies such as FDA, EPA and CDC, to ensure that where our regulations overlap, we're using appropriate authority and oversight.

So our regulation of GE animals. Again, our focus here is protecting the animal health status of the livestock and poultry population. For GE animals,

FDA actually takes the lead, and then we collaborate closely with FDA when we have overlapping authority.

As I noted previously, our regs are limited to those animals that are considered livestock, but that does also include farmed fish. For GE animals, we apply the same standard of review for GE animals as non-GE animals.

Again, we are looking at the animal health risk. So if an animal, regardless of their GE status, poses some type of an animal health risk to the livestock and poultry population of the U.S., then those risks would be mitigated through our regulations regardless of their GE status. And that's our animal health authority in a nutshell. Thank you.

DR. NALUBOLA: Okay. Looks like we are running a little ahead of schedule, but we are scheduled for a very short ten minute break. It's about 10:20 now. So if we can comeback by 10:30, we will resume then.

(Whereupon, a short break was taken.)

DR. NALUBOLA: Our next two speakers will be from the Environmental Protection Agency. First I

would like to introduce Mike Mendelsohn, who will discuss EPA's role in biotechnology pesticide oversight. Mr. Mendelsohn is a senior regulatory specialist within the Office of Pesticide Programs at EPA.

EPA Role - Biotechnology Pesticide Oversight

MR. MENDELSOHN: Well good morning. As was mentioned, we're going to break the EPA presentation into two parts. I'm going to talk about biotech pesticides and Dr. Mark Segal will talk about genetically engineered microorganisms regulated under the Toxic Substances Control Act.

Okay. I'd like to talk about EPA's biotechnology program and some of the cornerstone thoughts that we have there, that the program is protective, uses sound science. We use independent scientific experts in pesticides, with the FIFRA Scientific Advisory Panel. We involve collaboration with regulatory partners, and we strive to be fair, consistent and transparent.

The laws that are -- that we work with pesticides are the Federal Insecticide, Fungicide and

Rodenticide Act, FIFRA. This is not the right presentation. Yeah. Is Megan here? I have it on a flash drive.

(Pause.)

DR. NALUBOLA: Okay. We have IT help, so sorry about that.

(Pause.)

MR. MENDELSOHN: Okay. I think we're ready to go. Thank you for your patience. All right. So briefly today, what I'd like to talk about, again focusing on biotechnology pesticides, what's EPA's mission, EPA biotechnology program goals, the laws that we administer with pesticides, pesticide registration, the different types of biotechnology pesticides that we oversee, genetically modified microbial pesticides and plant-incorporated protectants or PIPs, how we look at herbicide resistant plants, considerations that we have in decision-making, how we coordinate with our federal partners, and at the end we'll have some resources for you from our website.

So here to focus on EPA's mission, the

mission of EPA is to protect human health and the environment. EPA's purpose is to ensure that all Americans are protected from significant risk to human health and the environment, where they live, learn and work. National efforts to reduce environmental risk are based on the best available scientific information.

Federal laws protecting human health and the environment are enforced fairly and effectively. Environmental protection is an integral consideration in U.S. policies concerning natural resources, human health, economic growth, energy, transportation, agriculture, industry and international trade, and these factors are similarly considered in establishing environmental policy.

All parts of society, communities, individuals, businesses and state and local tribal governments have access to accurate information, sufficient to effectively participate in managing human health and environmental risks.

Environmental protection contributes to making our communities and ecosystems diverse,

sustainable and economically productive, and the United States plays a leadership role in working with other nations to protect the global environment. So again, EPA's mission to protect human health and the environment.

Again, looking at some of the biotechnology program decisions, what we want to base those on, that they're protective, that they use sound science, that they use independent scientific experts, that they involve collaboration with our regulatory partners, and that these decisions are fair, transparent and consistent.

The laws that we look at relative to pesticides, the Federal Insecticide, Fungicide and Rodenticide Act or FIFRA, the Federal Food, Drug and Cosmetic Act or FD&C, and how those were amended by the Food Quality Protection Act, and also the Pesticide Registration Improvement Act. We also work with the Endangered Species Act, the Migratory Bird Treaty Act and the Clean Water Act. I'll be talking primarily about FIFRA and FD&C.

So what is -- how does FIFRA work for us?

What does that entail? The Federal Insecticide, Fungicide and Rodenticide Act gives guidance and oversight with regard to the distribution and the use and sale of pesticides. This involves registration, emergency exemption and state registration for local need. It also involves the reevaluation of older pesticides. So once something has been commercially approved, there's a time table for that to be reevaluated. It also oversees the field testing and distribution of experimental pesticides.

The FD&C oversees the establishment of tolerances or the maximum residue levels for pesticides on food and feed. These tolerances apply both to domestic and imported foods. For most of the biotechnology based pesticides, what we see are tolerance exemptions or exemptions from the requirement of a tolerance.

What are the standards that we look at with respect to pesticides? So with our licensing standard that oversees the commercial approval, FIFRA, EPA may register a pesticide if, when used in accordance with widespread and commonly recognized practices, it

generally will not cause unreasonable effects -- unreasonable adverse effects on human health or the environment.

For the residues and food under FD&C, EPA may establish a tolerance or tolerance exemption if there is reasonable certainty that no harm will result from residues of the pesticide in food or feed. So these are the governing statutes for our oversight of pesticides, for our oversight of biotechnology pesticides, and these are the standards that we have to see that are met before these are accepted.

Again, FIFRA it will not cause unreasonable adverse effects on human health or the environment, and under FD&C that there's a reasonable certainty no harm will result from residues. There are primarily two different types of biotechnology-based pesticides that are registered.

The first is microbial pesticides and the second are plant-incorporated protectants. Microbial pesticides include microorganisms that are used as pesticides such as bacteria, fungi, viruses, bacteriophages, both naturally occurring and

genetically engineered.

Pesticidal modes of action can include competition or inhibition, toxicity, pathogenicity to pests or the use of the pest as a growth substrate. For genetically modified microbial pesticides, there's a special provision that there's a notification requirement that's been promulgated in 40 C.F.R. Part 172, and that is when pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified, there is a requirement to notify the agency, to see whether an experimental use permit is required when the testing is under ten acres.

Normally, for traditional pesticides, conventional pesticides, an experimental use permit is required when testing is ten acres or over. In the case of genetically engineered or genetically modified microbial pesticides, under that ten acres the person who's conducting the studies or the entity needs to notify the agency about it and the nature of the organism and the trait, for us to determine whether an experimental use permit is required, even under that

small-scale testing.

So essentially it's a small-scale testing notification requirement that goes beyond the requirement for non-genetically modified microbial pesticides.

The second type of biotechnology-based pesticides that we look at are plant-incorporated protectants. So what are these? What's the plant-incorporated protectant? A plant-incorporated protectant is a pesticidal substance intended to be produced and used in a living plant, or in the produce thereof and the [genetic material] necessary for production of such pesticidal substances.

Now what does this mean? So for instance if we look at Bt corn, EPA oversees the pesticidal substance produced by plants, which is for instance a Cry1ab protein in Bt corn, and the genetic material necessary for its production, the Cry1ab gene. So we're focusing on our oversight on that trait, both the pesticide substance that's produced and the genetic material necessary for its production.

PIPs that have been evaluated and of course

we kind of use the term "PIPs" for plant-incorporated protectants, PIPs that have been evaluated for commercial use include Bt crops and plant virus protected crops. Those are what we've evaluated so far.

I'd like to mention here herbicide-resistant plants. EPA regulates the chemical herbicides used on herbicide-resistant plants. We don't regulate the plants, because the plants are not pesticides. So again just kind of a clarification there. EPA regulates the chemical herbicides used on the herbicide-resistant plants.

What about PIPs with experimental use permits. For PIPs, testing on a cumulative total over ten acres is when an experimental use permit is required. So for testing, if the test is under ten acres, then EPA does not require an experimental use permit. At that stage of testing, I just want to note that most of those field trials are under USDA oversight.

I'd like to also mention here some things, considerations that we make in decision-making. When

we're looking at, for instance, the registration of a plant-incorporated protectant, we evaluate the molecular characterization and the pesticidal substance expression levels.

Looking at human health, we look at toxicity and allergenicity. For our environmental assessment, we look at non-target organism effects, environmental fate, gene flow, and also we look at resistance management for the protection of these products. Many times plant-incorporated protectants can reduce the need and the volume of chemical pesticides in the environment, and they have an environmental benefit.

Looking at, I mentioned about for the small scale testing of PIPs, many of those are under the oversight of the USDA. Looking at the federal oversight of GE crops with pesticidal traits, EPA focuses on the safe use as a pesticide. USDA focuses on being safe for agriculture and the environment, and FDA focuses on safe for use in food and feed.

With plant-incorporated protectants, all three agencies are involved. EPA focuses on the PIPs, but again if you look at it, the GE corps with

pesticidal traits, the PIP is part of that crop, but it doesn't take up the entire crop.

I'd like to talk a little bit about coordination. We feel very strongly about this and work with our colleagues. We work closely with USDA and FDA. So there's a number of ways in which we do that. There's regulatory action coordination. As things come in, we talk about it with each other. We keep each other informed on specific actions. There's a monthly interagency teleconference that we're involved with.

Also, at the end of my talk, there will be some resources on the web. There's an information-sharing memorandum of understanding that's been written between FDA, USDA and EPA to share information.

We work together on international outreach and coordination, such as with FAO and OECD. We've worked together with incident coordination, with small scale testing of biotech microorganisms. USDA and EPA inform each other each time they receive applications to test biotech microorganisms.

USDA makes use of EPA's biopesticide and EPA's chemical herbicide risk assessments performed by EPA to support their plant pest risk assessments and NEPA compliance involving herbicide and insect-resistant crops. So we share those analyses with USDA.

And another point here is that we coordinate with USDA regarding weed resistance management related to herbicide-resistant crops. These are the resources I mentioned, the websites. I want to point out that if you have if you have some of these websites saved, we just recently changed them. So they'll be available, as was mentioned, on the web and you can hopefully find everything else that you found before.

We've put a lot of effort into it and hope you like it. We should be a little bit more user friendly now. Thank you, and Dr. Mark Segal will come next.

DR. NALUBOLA: Thank you Mike, and I apologize for the snafu with the slides this morning. Our next speaker is Dr. Mark Segal, who will discuss the Toxic Substances Control Act and Genetically

Engineered Microorganisms. Dr. Segal is a senior microbiologist within the Office of Pollution Prevention and Toxics at EPA.

Toxic Substances Control Act and GE Microorganisms

DR. SEGAL: Okay. So good morning. I am Mark Segal from the Office of Pollution Prevention and Toxics. My purpose today is to describe the use of Toxic Substances Control Act and providing oversight for certain uses of biotechnology. So these are the topics that I'm going to be discussing today, provide you with an initial introduction to the Toxic Substances Control Act in general, TSCA as we call it.

We'll talk about how TSCA and the Coordinated Framework work to provide oversight for microorganisms, and then we'll go into details of how that oversight is conducted. We've already seen this slide [referencing EPA Mission statement]. I just want to bring it up to note the point that EPA is responsible for administration of many environmental laws.

You've heard about several that Mike [Mendelsohn] presented. So our focus is on the Toxic

Substances Control Act and, combined, the laws that Mike referred to and that I'm referring to are the ones that EPA uses to regulate biotechnology.

TSCA is a rather older law; not as old as FIFRA. But it went into existence in 1976 and covers all aspects of chemical substances, but not all chemical substances. There are exclusions within TSCA for those chemical substances that are subject to oversight by other laws. All of these applications [noting the display of a list of exclusions from regulatory oversight] are not subject to TSCA oversight. TSCA is regarded as a gap-filling statute, so we won't be talking about the oversight for these excluded other kinds of applications. Think of TSCA as sort of an other-than-the-above kind of statute.

So I'm going to focus today on oversight of new biotechnology products. We'll get to how TSCA addresses microorganisms in a bit, but first TSCA requires premanufacturing reporting of all new chemical substances.

The key to understanding what is new under TSCA is to understand that TSCA requires EPA to

maintain an Inventory of Chemical Substances. Any chemicals or microorganisms that were created after that inventory went into effect are considered to be 'new', and are so until those substances go into commerce and can be listed on the Inventory.

So how did TSCA become the law that provides oversight for microorganisms? Well, first of all, TSCA has defined chemical substance in a broad manner, and in terms that can cover both microorganisms and traditional chemical substances. Secondly, when that TSCA Inventory went into effect, many people proposed microorganisms as chemical substance to be listed on that original inventory, and as I mentioned, TSCA's a gap-filling statute.

So understanding of all of that, EPA is part of the Coordinated Framework in 1986, which we've already heard discussed several times, including [establishing that] microorganisms that were subject to TSCA, and that policy statement, in 1986, became the basis for the formal regulations that EPA issued in 1997 under these parts of 40 C.F.R. [noting display of 40 CFR Parts 700, 720, 721, 723 and 725]

The focus for my talk, the rest of the focus, will be on new microorganisms. We use a term for those: Intergeneric Microorganisms. As pointed out, all new chemical substances have to be -- have to undergo reporting prior to manufacturing. So EPA needed some criteria to determine what the difference would be between those that there were New Microorganisms and those that were existing.

What EPA has used as a criterion is that microorganisms that were formed through the deliberate combination of genetic material from organisms that were classified in different taxonomic genera are considered to be new, and that includes microorganisms constructed using genetic material that was made synthetically, and is not identical to DNA that comes from within the same genus. Both of those, we said in 1986, were construed to be Intergeneric. The inverse of that is that microorganisms that don't fit those criteria are considered to be Intrageneric and are not new.

I listed, before, examples of excluded applications of -- applications that are excluded from

TSCA. These are examples, [referring to a displayed list] -- just a small condensed set of examples -- of applications that are in fact subject to TSCA. Anyway, as you can see this is a fairly wide-ranging subset of applications. Now with the development of these applications, many of those [pointing to the displayed list] are new or are enhanced from those that were considered when the original Coordinated Framework was created. We understand that a lot of these new applications were not considered when that Coordinated Framework was issued or when our initial regulations went out.

These technologies may sometimes entail the use of microorganisms that have both excluded from TSCA and non-excluded uses, so that several of us will possibly be working on the same microorganism, even though our statutes exclude each other. We and our federal partners are working to adapt to this new landscape, and we are working right now to strengthen the coordination that currently exists.

When microorganisms are subject to TSCA oversight, there are two primary types of

notifications that the EPA must receive prior to the initiation of commercial activities. One of those is called a Microbial Commercial Activity Notice and, like its similar notification for traditional chemical substances, a submitter that's required to report to EPA must do so at least 90 days prior to initiation of manufacturer or import.

EPA has determined that it will not exempt research for microorganisms that are subject to TSCA automatically.

We have a provision for a notification to us prior to commercial research, so that before commercial research can go to the field -- this is for research that goes into the environment -- we require that researchers or those who are doing research and development report to us at least 60 days prior to the time that they go to the field, so that we can evaluate their research program.

We understand that reporting to us can be complicated. So we have provided guidance to potential submitters for either the Microbial Commercial Activity Notice or the TERA [referring to

display of 'TSCA Experimental Release Application'], and we call it our "Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms". And this guidance provides a comprehensive list of categories of information and data that we think submitters should consider as applicable to their particular situation.

Each case is going to be different, so we know that submitters will not need all of the guidance that we're going to be providing them. But we hope that the guidance will initiate a thought process, so that they're aware of the kinds of data and information that we would expect to see when we undergo our review. The guidance that we provide maps to our review process, which all of us have indicated, when we do our product reviews, is comprehensive in a wide variety of areas. We're going to look at health and environmental effects, potential exposure and release to the environment, stability of genes, things of that nature. So our 'Points to Consider' cover all of these.

Our last update of our 'Points to Consider'

unfortunately took place in 1997, and we know that technologies have undergone dramatic changes in a relatively short period of time. So we have initiated the process of updating our points to consider. A month ago we held a public meeting to solicit input, as we addressed two categories of information on algae production and new techniques of advanced genetic engineering which are going to affect our submitters, that the comment period for that meeting is still open through today.

We're providing you with the URL so that you can address it if you so choose, if you have time. It's [referring to a comment period] actually open through tomorrow, … if you choose to work tomorrow.

We at EPA would prefer not to expend resources on cases where we expect that we're not going to likely find a reason to take action. So we have established exemptions from full reporting, what we call our cured exemptions. When we developed our initial regulations, at the same time we did a set of categorical risk assessments on a set of microorganisms that we considered to be traditional

workhorse microorganisms in the biotechnology industry, some that have been used for centuries with no unreasonable effects.

So we have exempted these. We allow submitters to provide simple one-page notices; that they comply with our guidance that they're using; that these organisms are contained; that they know that they don't have any introduced genetic material that would cause problems.

I mentioned that we do have oversight for research and development, for commercial research and development, and by commercial, we interpret commercial broadly, but we use the declarations of the developer of the microorganism to determine whether or not they are commercial.

So if you're doing research and development and you identify that you're developing it for -- so it becomes the greatest thing since sliced bread, you've identified -- if that's in your research proposal, you've basically declared that you intend to do commercial research, so then you're potentially subject to our oversight.

But not all research and development is subject to reporting. In fact, most is not subject to reporting because most of the time it's done under contained conditions. We have indicated that if you follow all of these requirements [referencing text on a slide] that are listed here and it's done within a contained structure, you don't have to report to us.

If you have to report to us, and when you undergo review, there are three potential outcomes. One is that we find that your case - may not present an unreasonable risk to man and the environment. In that case, we're going to take no regulatory action. If you don't hear from us within 90 days, you're able to go ahead and initiate your commercial activities.

Conversely to that, we may find -- when they find it--, your case may present an unreasonable risk to man and the environment, as you've described, your production or use or importation of the microorganism, in which case we can take a variety of actions that can limit or even prohibit use of your microorganism. But that's not something we really would prefer to do.

In a few cases, it's simply a matter of not

providing us appropriate information. It's one of the reasons we give you Points to Consider so you can avoid that scenario. But it may be that you have not provided us all of the information, maybe not done it all [referring to needed data collection]. So there may be testing that you need to do to show that you may not present an unreasonable risk.

There are a variety of ways in which we can deal with that. You can choose for us to not complete the time frame for our risk assessment and this will stop our review clock until we receive the necessary information. Or at the end of the review process, you can agree to provide us the information that we need or to limit voluntarily your production or use so that we no longer have -- no longer can find that your case may present an unreasonable risk.

And like Michael [Mendelsohn], I'm providing resources [noting display]. You can go to our websites, and we also have changed our website . So if you've previously bookmarked it, please refer to these, and thank you very much.

DR. NALUBOLA: Thank you, Mark. So we now

turn to our last speaker before we get into the public comment session, and for that I am pleased to introduce Leslie Kux, who is our Associate Commissioner for Policy at the U.S. Food and Drug Administration, and today Leslie Kux will discuss FDA's regulation of products derived from genetic engineering.

FDA/Products Derived from Genetic Engineering

MS. KUX: Good morning everyone and welcome to FDA and to White Oak. I'm going to talk about FDA more generally and then focus on our regulation of food, feed and animal drugs. So and here are all of the -- an outline of the presentation.

FDA's mission is to protect the public health by assuring that food, and by food we mean both food for humans and animals, are safe, sanitary and properly labeled, ensuring that human and veterinary drugs and human vaccines and other biologics and medical devices are safe and effective.

We also protect the public from electronic radiation. We assure that cosmetics are safe and properly labeled. We now regulate tobacco products,

and we also have as our mission to advance the public health, by helping to speed product innovations, which is an important component of our work in the biotech space.

So our core business functions focus on three areas. We conduct pre-market review for a number of the products that we regulate. That includes new medical products, as well as the safety of new food and feed ingredients. We do product safety and compliance, which involves inspection of facilities, manufacturing facilities and products to ensure their safety, quality and compliance with other FDA regulations like labeling regulations.

Then we also do post-market surveillance and compliance activities, as well as education and outreach, to ensure the safety of the products that we regulate, both for consumers and for patients. So it's a life cycle approach that we apply when we regulate across all of our different product areas.

With respect to biotech products, we regulate human and animal drugs and biologics, as well as medical devices, and then on the food and feed

side, we regulate food for humans and food for animals, with the exclusion of the meat and poultry and egg products regulated by USDA.

I'll focus our presentation on the regulation of human and animal food from GE plants, and then also our regulation of GE animals. So under the coordinated framework like the other agencies that we work with, we base our approach on a rational and scientific evaluation of the products, and we don't assume, a priori, that certain processes have particular implications. Another way we say it is that we regulate the products, not the processes by which they are manufactured, and that framework is the way our regulatory authority is set up in our statutes.

So the review of a product produced using biotechnology is based on the intended use of the product and on a case-by-case approach, and as with USDA and EPA, we coordinate across as needed, depending on the products that we're addressing.

The regulation of food derived from GE plants, like USDA and EPA I will cover our statutory

authority, so that you all have a good understanding of the framework that supports the coordinated framework. We ensure the safety of food and food ingredients, and there are two provisions that we use when we're doing our food safety work, and again these provisions apply both to food for humans and food for animals.

We have very broad jurisdiction over the food safety aspects of food from genetically engineered plants, other than the pesticidal traits that EPA regulates. We regulate these under what we call the food additive provision and then what we also refer to as the general safety provisions of the Federal Food Drug and Cosmetic Act (FDCA).

Under all of the statutory authorities, the manufacturer of the food is always responsible for ensuring the safety of the products that they're putting into interstate commerce. It's their responsibility to determine that their products meet the general safety standards, the labeling requirements and to the extent the food additive provisions apply, to make sure that they are in

compliance with those as well.

When it comes to foods such as fruits, vegetables and grains that are derived from plant varieties developed through genetic engineering, they're subject to the same safety standards as non-GE foods. So two apples, one produced through biotechnology, the other produced through traditional breeding techniques, both meet the same safety standards.

The two sections that we rely on are the post-market authority that allows us to look at food safety more generally. We're looking to make sure that food is not injurious to health, that it's safe, that it's not going to harm the consumers that eat it. Then with respect to ingredients, we have an additional safety tool.

The first question you ask is whether something is being added to food intentionally, and if it is then there's a two-part inquiry that needs to be made, to determine how to regulate it. If it's what we call generally recognized as safe (GRAS), then you can go ahead and use it in the food supply without

coming to FDA for premarket review, although you can consult with us about whether something is GRAS.

If it's not generally recognized as safe, which is a fairly stringent standard to meet, then you have to come to FDA and get approval as a food additive.

On the human food side, the experts at FDA that do human food safety reside at the Center for Food Safety and Applied Nutrition (CFSAN), and on the animal side they reside at the Center for Veterinary Medicine (CVM). We, like the other agencies, have issued guidance to industry, both in 1992 and then a later document that talks about consultation, which I'm going to go into more detail about.

Actually let me back up a minute. When it comes to looking at food and feed additives, what we talk about in the biotech space is that the transferred genetic material and then the expression products that are what we're looking at to determine whether it's GRAS or whether it needs a food additive regulation.

So our '92 policy statement applies the

regulatory framework that I've just described to foods from genetically engineered plants. Its goal is to answer questions about how we regulate those products and to assist developers prior to marketing to meet their legal obligations to assess the safety of the food for consumers.

We expect developers of food derived from GE plants to analyze the composition of the food from their new crop varieties, to ensure that any changes compared to foods conventionally derived counterparts are appropriately considered and addressed before marketing the foods.

Under this policy, we assume that a traditional whole food like a tomato is GRAS, and that the GE version of that food would remain GRAS if it's substantially equivalent to the conventional counterpart. So if the genetic modification doesn't result in any compositional changes in the plant that would raise a safety concern, such as the addition of a novel protein, then the GE food is considered to be substantially equivalent.

Otherwise, the added substance would be

considered a food additive, and would require premarket approval. To date, we only have one substance as a food addictive for human food, and that's an enzyme produced by an antibiotic-resistant gene, kanamycin, and I think that's the flavor savor tomato, right? Yeah.

We've only used the food addictive process a couple of times, and that's largely because of the policy that I'm about to talk about now, which is our premarket consultation process. So recognizing that with this technology and to support it, there would be a great deal of interest in consulting with FDA prior to putting a product on the market, we put in place consultation procedures in 1997. The title of guidance document is up on the slide and it's available on our website.

Participation in this process is voluntary, not mandatory, but it's been our experience that everybody does consult with us prior to engaging in the commercial distribution of food from GE plants. As a practical matter, as I think USDA referred to, the marketplace insists on it.

I'll have some information on the number of consultations we've conducted in my next couple of slides. But the goal of the consultation process is to ensure that any safety issues associated with a food from a new plant variety result prior to commercial distribution.

So usually what happens is developers will come into us very early in their process, to have a conversation with us about what are the appropriate questions to answer as they're assessing safety and as we will look at it. Then that information can be developed and provided to us as they're completing their development work.

During a consultation here are the kinds of information that we expect, and the kinds of issues that we'll discuss with developers. We're looking, of course, to resolve food safety, nutritional and other issues. So the questions are making sure that we understand if there's anything that, as I've said earlier, would make the GE plant not substantially equivalent to its traditional counterpart.

So does it have a new toxin? Or is the

alteration going to add an allergen? And then we're also looking at the nutritional composition of the plant, because people, you know, usually expect two things that look-alike to generally have the same nutritional composition. So that also addresses whether there will be any labeling needed from a nutritional standpoint.

We won't complete our consultation until we're satisfied that all the questions have been answered, and then once the consultation is complete, we send what we call a no questions letter to the firm, and we post our completed consultations on the website for purposes of transparency.

We have completed over 100 consultations and evaluated over 150 plant varieties, and here's a more colorful version of the information. But you see that a lot of food crops, canola, corn, potato, soy beans, cotton and then a bunch of other foods including alfalfa, apple, cantaloupe, creeping bent grass, which I actually had to look up last night and now I know what's infesting my yard; flax, papaya, plum, radicchio, rice, squash. So a whole range across the

spectrum of plants in the food supply.

And as a little bit of additional background information, there are times when developers will withdraw their consultation, because there are questions that we won't be able to answer and they won't get a no questions letter. So we do feel like the process provides a good oversight mechanism.

As I referred to earlier, most of the substances have been presumed GRAS, due to their similarity to the traditional counterpart. But we have had a couple of food and feed additives that have had to go through the formal food additive process, but not many.

So now I'm going to switch to a completely different area, and talk about the regulation of genetically engineered animals. So this is managed completely by FDA's Center for Veterinary Medicine, and in general we're referring to an animal that's produced by the introduction of a new or altered DNA via techniques of modern biotechnology, including recombinant DNA technology, so that they exhibit new or altered traits.

These traits can be introduced for a wide variety of purposes, including enhancing food production, reducing disease in animals and producing products intended for human therapeutic use pharmaceuticals, and then also the use of animals as models for human disease. So it does have a very wide range.

We regulate these animal drugs under the Federal Food, Drug and Cosmetic Act and it's the definition of drug, the definition of new animal drug, and then we have provisions that govern the investigational use of animal drugs and the premarket approval of animal drugs.

The National Environmental Policy Act (NEPA) also comes into play in this provision, because our approvals can be agency actions that are subject to NEPA. So when it comes to determining what the products are, because the genetic material integrated into the DNA is intended to affect the structure or function of that animal, that triggers the definition of drug in our statute, and so the new animal drug process then applies.

Under NEPA, we'll then do an environmental assessment in conjunction with the approval of genetically modified animals under our approval authority. It is important to note that as with the other agencies that implement NEPA, NEPA is an analytical statute.

It's not an outcome statute, so it's information that's available, but it doesn't govern the action we take under our approval authority. There, the question is whether the product is safe and effective, and that determines our decision.

So the new animal drug provisions prohibit the introduction into interstate commerce of drugs that are intended to cure, mitigate, treat or prevent disease, or are intended to affect the structure or function of the body. So that's, as you can see, where the applicability comes in.

We have provisions set up that allow for the exemption from premarket approval for investigation use. For approval, the sponsor has to demonstrate three things if it's for a food producing animal, that the GE change is safe to the animal, that the

resulting food is safe for humans or animals, depending on where it's going to end up, mostly humans, and then is it effective? Does the GE material do what the sponsor claims it will?

We issued guidance for industry in 2009, which lays out the stepwise process that we use to work with sponsors, to answer the questions that arise when we're reviewing a new animal drug.

So as with other aspects of FDA regulation, we recommend that sponsors consult early and often, so that we can be coordinating with them and making sure that they're answering the right questions, and that we're working together as efficiently as possible.

The key concepts in the guidance is that we cover all GE animals bearing heritable rDNA constructs, including animals intended for biopharming, and it's the rNA construct in a GE animal that is intended to affect the structure of function.

So it doesn't matter what the intended use of the ultimate product is; it's the alteration which is intended to affect the structure or function of the body that triggers the definition. We do a case by

case evaluation and like others use a risk-based approach, and there is mandatory approval prior to marketing required.

Consistent with the risk-based approach that's set out in the coordinated framework, this guidance also gives a couple of examples of situations in which we intend to exercise enforcement discretion, and we consider other situations in which enforcement discretion is also appropriate.

So we would not enforce the requirement for investigational exemptions or for premarket review, and I think the most well known situation in which we've exercised enforcement discretion is the glowfish.

So as I indicated, the guidance lays out a step-wise process that's -- wow. I can't even read that. Well, if I get really close to it I can. I recommend that you look at the guidance. But it starts at the base with defining the product, and works its way up, to make sure that the questions are getting tighter and tighter, and through that step-wise process, reach an approval

decision.

We're not asking you to submit all of the -- you know, we want to work with the developers, to make sure that we're asking for the right information. So that's the need -- that's our preference for a step-wise approach.

We don't want all of the information that you think is necessary all at once, because we may be able to have conversations about what's the most appropriate information and focus everybody's resources.

With respect to the investigational use of GE animals, again this is an opportunity for developers to come speak with us early. It is a confidential process, and it authorizes both the shipments of the drug and testing that can be done to determine the safety of the construct to the animal and the resulting food, as well as any additional questions about effectiveness.

There are, under this exemption, products do not go into the food supply, and it also is the first look that everybody gets at the environmental

considerations that may exist. We have approved one animal drug under this guidance. It was a biopharm animal, a goat that produced a licensed biological called Atrin (ph), and I think what's notable about this process is it was a very well and tightly coordinated process between CVM and then the Center for Biologics Evaluation and Research, ensuring that the regulatory actions were able to proceed side by side, so that both approvals came at the same time.

So that the developer was able to have the highest degree of regulatory certainty. We also have more information on our website. For GE plants, you go to CFSAN's website and CVM's website for GE plants. For GE animals, CVM's website.

And since I'm the last official speaker before we start presentations, I just wanted to close with a few overarching remarks on behalf of everybody up here. We recognize that it has been quite a while since we took a look at the coordinated framework.

So we're looking forward to working with OSTP in support of the objectives laid out in the summer memorandum. We are looking forward also to

public comment that can help us focus both updates to the coordinated framework and our long-term action plan.

We're excited at the opportunity we have to update the framework and help support the safe and productive use of these technologies. So thank you very much, and we're looking forward to the public presentations.

DR. NALUBOLA: Thank you, Leslie. So we will now take our second break. It's 11:35. We will come back promptly at 11:45 to begin the public comment session.

Public Comments Session

DR. NALUBOLA: If people could please return to your seats. So we will now begin our public comments session for this meeting. I'll just give a very brief note about the logistics part of it, and then turn it over to Dr. Barbero. So for this session, on the overhead, you will see the list of individuals who are preregistered to speak.

We ask speakers to please limit your comments to three to four minutes. As you speak, you

will see a yellow light I am told -- where exactly is that going to flash -- here, to inform you that you have about a minute left.

We also ask that individuals who are next in line to make your way to either the podium or the microphones here in this corridor, to be ready to go as soon as the preceding speaker is done.

We leave it open whether you want to come to the podium here and make your remarks or use one of the microphones on the floor. So with that, I'll turn it over to Dr. Barbero.

DR. BARBERO: Okay. So can we please have our first public commenter come up and start your remarks, and you can come to either the microphone here or the podium, whatever you prefer. Thank you, and please introduce yourself when you start.

MS. BADEN-MEYER: I'm reading the comments of Stephen M. Druker, Executive Director of the Alliance for Biointegrity, who could not be here today. For more than 20 years, the FDA's behavior regarding genetically engineered foods has been consistently deplorable. Not only has it routinely

issued false and misleading statements, it has seriously violated explicit mandates of federal food safety law, to the extent that every genetically engineered food on U.S. supermarket shelves sits there illegally.

These allegations are not exaggerations. They are solidly backed up by documents that were pried from the FDA's own files, through a lawsuit my organization initiated. For instance, when the FDA issued its policy statement on GE food in 1992, it claimed it was not aware of any information showing that these products differ from other foods in any meaningful or uniform way, despite the fact its files contained multiple memos from its own scientists explaining how GE foods do indeed differ, why they pose greater risks, and why none should be presumed safe unless its safety has been demonstrated through rigorous testing.

The pervasiveness of the concerns within the scientific staff is attested by a memo from an FDA compliance officer who declared "The process of genetic engineering and traditional breeding are

different, and according to the technical experts in the agency, they lead to different risks."

Moreover, the FDA compounded the fraud by claiming that GE foods were generally recognized as safe amongst experts, and could be marketed without the requirement of any safety testing at all, even though its files reveal that it knew there was no expert consensus, and even though the law mandates that foods containing novel substances must be established safe through solid technical evidence.

Furthermore, to give the illusion that responsible regulation was being exercised, the agency set up a voluntary consultation process that it claimed afforded rigorous review. But the process is not a genuine scientific review, and the FDA's biotechnology strategic manager had acknowledged that fact, while admitting that the agency does not even request or receive any original test data.

Additionally, although by now the agency is well aware of much more information showing that GE foods differ significantly from others, it persists in its bogus claim it is not aware of any, and this

blatant falsehood was repeated by an FDA official just last week at the Senate Agriculture Committee hearing.

It is high time that the FDA stopped deceiving Congress and the public, and stop violating the law. It is high time that the agency starts telling the truth about GE foods and at long last obeys the law by removing them from the market and requiring that they be demonstrated safe via formal food additive petitions.

Otherwise, it will continue to serve the interests of Monsanto, while turning its back on the public interest.

DR. BARBERO: Next, we have Richard Engler.

DR. NALUBOLA: Do you want to just use this? I'll fix that in the meantime.

MR. ENGLER: My name's Richard Engler. I'm a senior chemist with Bergeson and Campbell. Bergeson and Campbell appreciates the opportunity to comment on the update of the coordinated framework for the regulation of biotechnology. Biotechnology is coming of age.

After years of dedicated research,

technologists have been successful to the point it has become routine to modify organisms to meet a commercial purpose in an economically competitive manner.

Biotechnology has already begun to supplant traditional petrochemical techniques or isolation of natural products from harvested organisms. Biotechnology, employed correctly, will be critical in reaching a sustainable economy that can support a growing global population. It is vital that the regulatory oversight continue to ensure considered risk-based review of the products of biotechnology.

The public must have confidence in the process, so that it can have confidence in the products. The oversight must be clear, predictable and reproducible. The review process needs to be transparent, even if some of the underlying data is kept confidential to protect intellectual property.

Innovators and the investors supporting them must have a clear picture of the regulatory burden that they face to make sound business decisions. Many promising technologies may die on the vine because

innovators are unwilling to take the potentially substantial financial risk, while waiting for some unknown amount of time for a review to take place.

The report that -- the legal and scientific experts at Bergeson and Campbell authored, that was recently published by the Wilson Center Synthetic Biology Project, provides a number of case studies, each of which lays out specific recommendations.

We must find the political will to make this investment in the regulatory oversight of products of biotechnology. While too much regulatory oversight will stifle promising innovations just as they are gaining momentum and market competitiveness, too little oversight will result in the public rejecting technology, due to a lack of understanding and trust.

It is critical to note that each of these recommendations from the report will require an investment of government resources.

Number one, consider embedding new technology stewards in each office of all relevant federal agencies, to monitor and coordinate topics of emerging technologies, and share information with

other agency offices. Federal experts must have the time and management support to ensure that information decisions are shared among the group.

Number two, create dedicated centers of technological excellence in appropriate federal offices to stay abreast of new developments. These centers can be the entry point for regular routine communication by innovators from industry and academia, to government agencies on trends, developments and challenges.

These centers can also be the implementers of an ongoing process to demystify biotechnology and its products, so they are more clearly and accurately understood by federal decision-makers and the public. Develop a long-range government-wide strategy to assure that the regulation of products of biotechnology support innovation while identifying and addressing risks through a science-based, timely and transparent process that encourages public confidence.

Developments in synthetic biology will not halt during the overhaul of the coordinated framework. Improvements in regulatory oversight can and should be

put in place, even while updating the coordinated framework is in progress. Thank you again for the opportunity.

DR. BARBERO: I think that microphone might be working now, if you want to try that one. All right. Yeah, you can look at your audience. Next is Doug Gurian-Sherman.

MR. GURIAN-SHERMAN: These, of course, are cursory, you know, overview statements and we will expect to submit more detailed comments during the comment period. I am Doug Gurian-Sherman, Director of Sustainable Agriculture and senior scientist for the Center for Food Safety in Washington, D.C.

We appreciate the opportunity to comment on the federal government's initiative to revise the coordinated framework for the regulation of genetically engineered organisms.

The 1986 framework was a guidance document rather than having the weight of law, and was without requirements for rigorous and adequate regulation, and this has resulted in current failure to adequately protect the public and the environment.

To remedy these failures, several principles must be followed. First, there must be mandatory regulation for any organisms developed using genetic engineering processes. This includes new methods such as genomic editing and RNA interference. Second, regulations must be develop that fully regulate engineered foods and organisms for all types of risks, including long-term food safety risks and indirect environmental harm, which are currently inadequately regulated.

Third, choice on the part of consumers and farmers must be implemented, and therefore contamination of non-GE crops must be prevented. The burden for contamination that does occur should not be borne by those that are harmed, that is the non-GE farmers. Similarly, mandatory labeling should be required for all engineered foods.

Examples of the failures of the current coordinated framework that must be remedied include FDA's regulation of engineered foods under the generally recognized as safe provisions of the Food, Drug and Cosmetic Act. This results in a voluntary

system in which the types and methods of testing are the responsibility of the regulated industry, and in which the agency never approves the safety of the foods.

The meager and understandardized tests thereby performed do not instill public confidence in the technology or provide adequate safety. Mandatory regulation under the food additive provisions of the FFDCA should be required under the new framework.

At USDA, a cramped interpretation of the plant pest provisions of the Plant Protection Act of 2000, the lack of detailed regulations under the Act and the lack of implementation of the broad authority provided by the Act to regulate engineered plants as noxious weeds has left gaping holes in USDA's risk assessment process, and resulted in newer crops that are entirely unregulated.

Major indirect risks and harm such as the epidemic of glyphosate-resistant weeds are currently not determined to be plant pest risks, as an illustration of the weakness of the current interpretation of the laws. These weaknesses must be

remedied by implementing a broad, noxious weed authority under the Plant Protection Act.

Similarly, EPA should develop regulations for engineered pest-protected crops that include assessment of long-term food safety risk rather than simply acute risks as is currently done, and indirect environmental risks appropriate for these plants, rather than relying on microbial testing guidelines.

A benefits assessment should be based on whether the pesticide is beneficial in sustainable, agro-ecological farming systems, not just under the current unsustainable industrial systems, since FIFRA is a risk-benefit statute.

Until these changes are made, the public will justifiably continue to lack confidence in genetic engineering technology and its safety, and additional engineered crops should not be approved. Thank you.

DR. BARBERO: Next is Michael Hansen.

MR. HANSEN: Thank you. My name's Michael Hansen. I'm a senior scientist at Consumers Union. I want to start with our bottom line, which is that all

genetically engineered organisms should be required to go through a mandatory systemic safety assessment for both human and environmental impacts, and any products derived from such engineered organisms sold to the public should be required to be labeled. Thus, we should regulate by the process, not by the product.

In addition, the definition of genetic engineering should be broad enough to include all the new gene editing technologies in RNAI. We believe that using the Codex definition of modern biotechnology will be broad enough. We also think that fundamentally, we need to admit that the coordinated framework is broken.

We need regulation that recognizes the potential and unique risks of engineered organisms, whereas the coordinated framework does not do this and simply uses existing regulation. What they're doing is trying to put square plugs into round holes.

For example, USDA regulates engineered plants under the Plant Pest Act, only considering whether the engineered plants are weeds and excludes clearly engineered plants from regulatory authority if

they don't contain plant pest DNA.

For example, the Roundup-Ready Kentucky Bluegrass, we've heard that over 30 of these engineered plants have not regulated by the USDA, but they may be considered engineered by FDA and EPA. USDA regulates engineered insects under regulations that only allow them to look at health risks to livestock and not the broader environmental and ecological risks, which could be the real problems.

EPA regulates engineered microorganisms under TSCA, while the risks of engineered microorganisms that can reproduce and spread are fundamentally different than risks from toxic chemicals. FDA regulates engineered animals as new animal drugs, which makes no sense, but at least there's a mandatory safety assessment.

FDA regulates engineered plants under the '92 policy, which says GE is just an extension of conventional breeding, doesn't raise health risks. Yet the 2001 premarket biotech notification policy directly contradicts the 1992 policy, and admits that genetic engineering does differ from conventional

breeding and does raise potential health issues, such that FDA proposed requiring data submissions from each separate transformational event.

Though neither the '92 nor 2001 policies have been finalized, we urge FDA to take the approach of the 2001 policy, since it regulates GE plants by the process, not by the product. On labeling, we do believe that FDA has the authority to require labeling of engineered foods, either by treating the engineered organisms as ingredients, or using the material fact analysis.

We note that material facts are not just restricted to organoleptic changes, but also include information that's of importance to consumers. As noted by the 1985 decision to require labeling of irradiated foods, which in 2007 the FDA tried unsuccessfully to narrow such labeling only to irradiated foods with organoleptic changes. Materiality is more than just organoleptic changes.

So in conclusion, the coordinated framework is broken. We need regulations that recognize the potential unique risks of engineered organisms rather

than using existing regulations, and we'll be submitting more detailed comments by November 13th, particularly how to do proper safety assessments of engineered plants and organisms, which I think we can use based on what has come out of Codex. Thank you.

DR. BARBERO: Okay. Next is Ryan Lee. Is Ryan here? Okay. After Ryan is Shah Nawaz (ph). Also not here. Next is Tim Schwab.

MR. SCHWAB: I'm Tim Schwab, a researcher at Food and Water Watch. We're a national non-profit advocacy organization that does not agree with the regulatory process in which genetically engineered organisms or GMOs are currently commercialized.

The coordinated framework is not working and has never worked. Federal agencies must dramatically rethink how GMOs are regulated, in order to protect the public, the environment and the economy from the risks associated with these products.

Under the coordinated framework, FDA allows companies to self-regulate the safety of foods according to voluntary generally recognized as safe process. This cavalier approach to regulation

conflicts with independent science, which shows unique potential food safety risk with GMOs, which the FDA clearly should be reviewing, with a mandatory premarket approval process.

FDA should also do a comprehensive post-market surveillance, a process that should include labeling of foods containing GMOs. The failures of the coordinated framework can also be clearly seen in the discrepancies and contradictions in how different GMOs are regulated, or in some cases not regulated at all. If a company markets a GMO algae product as an industrial chemical, it undergoes some minimal environmental assessment by the EPA.

If a company markets this same GMO algae product for use in food products, it undergoes no government review at all. The company simply, if it wishes, engages in a voluntary notification process with the FDA, in which the company asserts that based on its own scientific opinion, it believes the GMO algae to be safe for humans to consume. Under this GRAS process, there is no environmental assessment at all.

Likewise, different federal agencies are regulating the GMO mosquito and GMO moth using different levels of regulatory scrutiny, even though both insects employ the same technology and are produced by the same company, and even though the risk assessment for these two insects should have significant overlap.

Federal regulations of GMOs under the coordinated framework are also enormously biased, because regulators depend almost entirely on scientific studies furnished by the GMO product sponsors, and rarely if ever pursue independent research.

FDA and other the regulators should conduct mandatory safety reviews of all GMOs according to independent science, not industry science. This point is highlighted well with FDA's bizarre regulation of GMO salmon (inaudible) and salmon, a food animal that FDA is regulating not as a food but as an animal drug, with limited food safety risk assessment.

FDA has advanced its regulatory review on this fish based on company data and assertions that

we've seen again and again, that are at odds with independent sources. This includes the key environmental safety questions. We have learned that the company has experienced numerous biosecurity failures that cast enormous doubt that the company can safely contain this fish as promised, but also fundamental biological claims, such as whether this fish can achieve faster growth rates as the FDA has made a preliminary determination to be true, based on a very limited study furnished by Aquabounty (ph).

There's now a wealth of evidence showing that existing non-GMO salmon already grow as fast or faster than Aquabounty sponsor claims for GMO salmon. The coordinated framework seems designed to advance commercialization of GMOs, not to ensure their safety. The FDA and other federal regulators now have the opportunity to change the course of their regulatory review, and adopt an approach that look first and foremost at ensuring GMOs are safe.

We would urge them to take this opportunity to do so. Thank you.

DR. BARBERO: Next, Sapna Brown. Did I say

that correctly?

MS. BROWN: Sapna.

DR. BARBERO: Sapna.

MS. BROWN: Thank you. I would like to thank Drs. Holdren and Barbero and each of our agencies representing the CF roles. I am pleased to see such initiatives and I appreciate your time today. As Dr. Barbero stated and I agree, we need to look at how does our current coordinated framework work now, and until we've conducted a lessons learned or an after-action report of the existing coordinated framework, we cannot begin to move forward on the update of it and the respective regulatory standards.

There are several concerns I'd like to demonstrate and compliance standard violations that we need to be aware of and address before we can move forward. Let's start with the compliance. There is blatant violation against federally mandated compliance that is taking place here.

Federal Acquisition Regulation, Section 9 entitled "Contractor Qualifications," specifically 9.5, Organizational and Conflicts of Interest, and

also at the USDA agency level, the AGAR, which is Agriculture acquisition regulation, which states the same principles.

To use an analogy, this is like a software company creating a software tool and at the same time developing the virus that infiltrates that very tool. This is what is occurring with the current procurement of goods and services between the USDA and Monsanto and all of its subsidiaries. Contracting officers should be enforcing the FAR by use of documented internal controls and other methods.

Given the current goal in providing transparency with the current framework update, it is of our due diligence and I am speaking to everyone in this room, to investigate the compliance violations. Separation of powers is the very basis for which our government was built upon, and in the security industry we call it separation of duties.

Here today, it is relevant with the conflicts of interest, with many of the biotech companies and federal agencies. I am pleased that Mr. Turner mentioned the CFR, the Code of Federal

Regulation. However, there are some inconsistencies.

The current framework and GMO models contradict the CFR. Under 340.3, if plant materials are shipped, they must be shipped in such a way that viable plant material is unlikely to be disseminated while in transit, and it must be maintained at the destination facility, that there is no release into the environment.

It's also stated that it should be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release. For example, we have a plant quarantine branch and can't bring plant goods back from Hawaii.

However, we have uncontrolled GMO pollen commingling with non-GMO plants and other organisms. This makes no sense.

In addition, we need to inventory and itemize the lobbying practices, as per the Lobbying Disclosure Act of 1995. In addition to the compliance violations, the scope should be categorized and integrated into a holistic risk assessment that looks

at these projects or products, excuse me, individually and collectively.

I'm referring to GMOs in our environment, farm animal feed for consumption, GMOs in our food and GMO impact to other organisms, and there should be other areas to be determined that should be a constant scientific investigation process.

I've heard today a lot about risk and safety. However, a robust, integrated risk assessment is lacking. The principles of molecular ecology, forensic botany, specifically palynology, the study of pollen granules and soil composition need to be integrated to formulate an all-inclusive, holistic risk approach that collectively evaluates impact to our health and environment, and based on these quantitative results of the aforementioned areas, we have to develop standards and methodology.

An example of how that is missing in our current framework is the lack of identification of a key risk and that we cannot control pollen. We also need enforcement and a system of audit in place. A corrective action plan needs to be managed for the

current framework and compliance violations.

We also need standards to be developed by an independent party such as NIST, and a system of audit should be in place by an independent third party. Regarding any legal impacts of pollen germination, we need a standard or legal precedent in place to protect non-GMO seeds and farmers of them, and regulation on what can be patented within the biotech products.

Also, what is the trigger for the GMO need? Can I get a show of hands who was asked if they wanted an apple or potato that didn't turn brown? Exactly. How much did that cost our federal government from cradle to grave? --

DR. BARBERO: Can I interrupt? We're a little bit over time. Can I ask you to wrap up shortly and then submit the rest via comment?

MS. BROWN: Yes sir, I can certainly do that. So as I was saying, were we not discussing a continuing resolution weeks ago, and now we have apples and potatoes that don't turn brown, but our federal government barely has the financial means to operate.

Until investigation of audit can occur of the current compliance violations, or validation that there is no violation, we should not introduce any new legislation, example H.R. 1599, or continue with our existing growth of biotech products in American soil. Thank you.

DR. BARBERO: Next is Kelly Drinkwater.

MS. DRINKWATER: Hello and thank you for offering us the opportunity to speak. My name is Kelly Drinkwater, and I'm from iGEM, the International Genetically Engineered Machines competition, the premier synthetic biology competition for college and high school students. I lead the Safety Program and I lead our efforts to grow a culture of safe and responsible engineering among our participants.

We're well aware that synthetic biology and biotechnology present challenges to regulators, and we appreciate the forthright way in which you're approaching a really difficult task.

So I'd like to offer some of our experiences in getting young innovators to care about responsible engineering, that may reflect some of your own

experiences and may also inform the revision of the coordinated framework.

Synthetic biology is charging ahead ever quicker, and challenges are definitions of new, modified gene and indeed our definition of organism. In order for young innovators to take seriously the concept of regulation then, it needs to be shown to be relevant to their direct experiences.

I urge the three agencies to harmonize their definitions of modified organism, and to make them broad and flexible to encompass gene editing as well as the addition of non-coding regulatory parts. At iGEM, we have some genes in our registry that present risks such as virulence factors and teams using these genes in our projects are flagged for greater oversight.

But that by itself is a really blunt instrument, and we have a number of much higher level triggers for oversight as well, such as whether a team is using innocuous parts but has a goal to increase the growth rate or host range of a bacterium, or envision and application in the human body or with

environmental release.

This is a products not process approach, and we find it's the only way to encompass the unimaginable diversity of synthetic biology projects. I was happy to hear earlier about the USDA's are we regulated letters, the FDA's emphasis on consulting early and often, and similar consultative processes that each agency has.

These echo our experience. The most effective safety interventions with teams are not through paper work but through early email exchanges as they're brainstorming their ideas.

Early and informal has been the key, even when the project is entirely hypothetical, which for you would mean that what you say will have to be non-binding. To make this available to people who identify as biotechnologists, I would suggest setting up an interagency consultation process that conserves an early single point of entry.

By the way, it's hard to incentivize this unless you really put yourselves out there and make yourselves available. I get safety questions on

Twitter. Speaking of engagement, one of our favorite agencies is the FBI. A full disclosure. They are a sponsor of our program.

As part of their mandate to ensure biosecurity, they've developed a really brilliant program of engagement and outreach with DIY biologists, community labs and young synthetic biologists, including iGEM. With this program, they've managed to turn a potentially adversarial and fear-laden relationship into an incredibly positive one.

Their talks are hit with iGEM participants and they build trust, foster a positive culture of security, and also they get to find out about all the newest and wackiest ideas in the field. Jason Kelly said to predict what biotech will look like in the next five years, looking at iGEM projects will give you lots of clues.

To that end, and in mindfulness of your budget constraints, I invite you all to come to iGEM's annual jamboree, whether as speakers, recruiters, judges or simply as distinguished guests. We would be

delighted to have you. I learn a lot from these students and all my collaborators tell me that they do too. Thank you.

DR. BARBERO: Next is Val Giddings, and I apologize if I am mispronouncing names. Feel free to correct me.

MR. GIDDINGS: You got mine just fine. Thank you. First, I'd like to thank the Office of Science and Technology Policy for taking on this difficult and thankless task. My congratulations also to the administration, all the regulators involved. As a taxpayer, I thank you. I know how difficult your jobs are, and we appreciate your efforts.

I have been involved in following closely crops improved through biotechnology and regulatory issues associated with them since 1973. I've been working full time in this area since 1984.

When we created the regulatory system out of the coordinated framework, we knew it was driven less by any need to deal with genuine safety issues associated with crops improved through biotechnology, but rather more by a need to provide some kind of

safety assurance for a public that was uncomfortable with these then-novel technologies.

We knew that the crops improved through biotechnology were going to have the same kinds of traits as crops we've been growing for decades. For example, 95 percent of the corn and soybeans grown in the U.S. in 1984 were already tolerant to different herbicides, 25 years before the first biotech improved crop was commercialized.

These crops had a long history of safe use. Of hundreds of thousands of new crop varieties that had been produced through conventional plant breeding, only a very small handful had ever created any problems for safety or health, and those were discovered quickly and eliminated very rapidly.

On the list of causes of morbidity and mortality that feature in CDC's weekly reports and in daily news cycles, death from the products of plant breeding is conspicuous by its absence.

So the regulatory system that we have today under the coordinated framework was not in fact created to deal with significant or real risks to

human health or the environment, but to address public perceptions of risks.

Our intention at the time was to regulate these products, to show the public that there were no unique problems, and then to decrease the regulations. The small number of examples of cases where regulations have in fact since been decreased, in accord with accrued experience since then, are the exceptions that prove the rule. For the most part, the more we have learned and the stronger the demonstrations that we have seen of the safety of these products, has resulted counterintuitively in the increase in regulatory burdens.

We have learned in the intervening 30 years that a rigorous regulatory system does not in fact quiet public concerns, especially when those expressing concerns make their living by selling concerns.

We have also learned that once you set up a regulatory process that involves premarket approval before entering the marketplace, the requirements for approval will only increase because regulators will

always demand more information, without regard for whether or not it would actually be useful in assessing risks, and developers will provide that information, because they need to get products to market.

We also learned the regulations don't go away no matter how safe products are shown to be. Can we please change this broken cycle? It would be nice if this review of the coordinated framework would actually take serious its responsibilities as articulated, to restore some semblance of balance between the degree of regulatory oversight and the level of hazard presented by the products that are subject to that oversight.

That started out as a wedge. It has now become a chasm. It's time to correct that and bring things back into alignment. Unless we do that, we will not succeed in the intention of enabling innovation, which is desperately needed to meet the challenges for food, feed and fiber that we can see looming in our very near future. Thank you very much.

DR. BARBERO: Next is Jaydee Hanson.

MR. HANSON: I want to thank the OSTP and the other agencies for making this comments session possible. I'm Jaydee Hanson, Policy Director at the International Center for Technology Assessment. We're funded by foundations. We don't get any funding from any of the companies that have an interest in this work.

With all due respect to the federal employees here, the coordinated framework is not a very coordinated framework. It's a weak policy guidance document that gives an illusion of regulation, while failing to coordinate agency actions and failing to stimulate needed regulations specific to new GM organisms.

I hope this process to review the coordinated framework will give impetus to new and clear regulations. Let me give a few examples where the coordinated framework is failing, in the areas of GE insects and animals. We've heard this morning already that both the USDA and the FDA regulate genetically modified insects.

The FDA regulates genetically modified

insects through their new animal drug authority. Thus, they make the huge leap that the genetically engineered construct introduced into the insect is actually a drug for the insect. The first GE insect drug that we know FDA is reviewing is mosquito engineered to breed with and sterilize other wild mosquitos.

I say that it's the only one that we know they're reviewing, because by using the drug authority, the FDA is obligated to keep secret the existence of the insect drug until its approval. We know about this mosquito because its engineer, the UK company Oxitech, revealed the application.

Note that the insect is going to be released into an environment to breed with other mosquitos and sterilize them. In this respect, it's more like a pesticide than a drug, and should perhaps be reviewed by the EPA and not the FDA.

Ironically, it seems that the FDA is reviewing this mosquito because the wild type can carry dengue fever, a human disease. As to whether GE insects engineered by this same company, a cotton bull

worm and a moth whose worms feed on cabbage, are being reviewed by the USDA because they're considered to be plant pests.

The USDA APHIS section was asked by the USDA Inspector General in 2011 to develop new regulations for GE insects and animals, and APHIS agreed with the recommendations but has not developed new regulation.

Instead, APHIS has approved field trials of genetically engineered diamond-backed moths with little public input, a short public comment period and then, basically in secret, approved the trial. We found out about the trial only because one of our colleague groups learned that the trial had been approved.

So the coordinated framework for GE insects is just an ad hoc framework. The same basic techniques are used by all the company's products, but staffs in two different agencies are reviewing them. Who would review a honeybee genetically engineered to fly around more and produce more honey? It's not a plant pest; it doesn't carry a human disease.

What about a mosquito engineered to fight

bird malaria? Would Fish and Wildlife review it because it's targeted for wild birds? Staff resources in all agencies are limited. It would be best if we had one agency that could develop the expertise needed to review genetic engineered insects, not pressing out to review in an ad hoc manner and depending more on the expertise of the company than on the expertise of government staff.

GE animals at least --

DR. BARBERO: Excuse me, you're a little bit over time now. I ask you to close up and submit the rest.

MR. GIDDINGS: Okay. I will. All right. I will submit the rest. I would say that one of the real flaws is transparency and lack of information. The FDA guidance for GE animals used to require a public meeting before the approval.

When I asked the agency staff when they were going to have that review because it was listed in the guidance, two weeks later, the FDA without notice changed their guidance, so it's no longer required to have a public meeting. We would like more

transparency than that. Thank you.

DR. BARBERO: Next is Claire Maris (ph). Pass. Next is Randy Gordon.

MR. GORDON: Hi, good morning and thank you for your time today. The National Grain and Feed Association and the North American Export Grain Association appreciate the opportunity to present this joint statement at this public meeting. Our members are involved in the grain handling export grain processing feed manufacturing sector of U.S. agriculture, and we do strongly support the utilization of biotechnology and other safe technologies in modern agricultural production practices that enhance the production of a safe, affordable and sustainable food and feed supply for U.S. and world consumers.

But achieving the objective of preserving a fungible and affordable supply of grains and oil seeds to feed a growing world population also necessitates that the grain handling and marketing industry be able to competitively, cost-effectively and seamlessly source and market U.S. agricultural products, and

provide for continued consumer choice in domestic and foreign markets.

So for our industry, and we would submit for the future competitiveness of U.S. agriculture and for the benefit of the entire value chain, including the world's consumers, the biggest challenge concerning this modernization exercise is not the competence of the objective, science-based U.S. regulatory framework that ensures the safety of biotech enhanced commodities. We believe the safety of this technology is well-proven, and although increased transparency and public understanding hopefully will be an outcome of this review process.

Rather, to create a truly workable biotech regulatory framework for the future and as part of a long-term strategy that you're evaluating, NTFA and NEGA (ph) believe this review must address the challenge of achieving regulatory coherence and compatibility in the global market.

Export markets and market stakeholders need to be part of a broad trade facilitation initiative that to our understanding the U.S. government

regretfully does not currently plan to undertake as part of this effort. A broad and effective trade facilitation effort has been made even more essential by the increasing lack of coherence and various nation's regulatory systems regarding safety reviews and approval of new biotech enhanced events, combined with the increasing practice of biotechnology, providers release into commerce new biotech-enhanced events before obtaining import approvals from governments and importing countries. There is no shortage of documented cases of this happening. These incidents point to the fact that despite best efforts, it is commercially impossible to effectively manage the presence of GE events and commodity shipments to a zero tolerance or to non-detectable levels.

This lack of global regulatory coherence and compatibility regimes for addressing the life cycle of crop biotech not only results in negative impacts on the marketability and acceptance of all U.S. crops, but also affects access to important production technology.

Specifically, we think a trade facilitation

effort of which we speak needs to encompass how the U.S. biotech regulatory system informs all stakeholders and interacts with counterpart regulatory systems in foreign countries to increase predictability and reduce the current disruptions in trade that result when biotech traits are approved in the country of export, but not yet in the country of import.

This encompasses, but is not limited to, developing a U.S. policy that addresses the low level presence of biotech enhanced events that have been scientifically reviewed and approved as safe by a competent government authority in the country of export, but not yet by the importing country.

In addition, and I'll wrap up here. The review underway, we would suggest to modernize the regulatory system for biotech traits needs to address the issue of appropriate government oversight of biotech-enhanced traits that have functionally different traits as well, and look at the new breeding technologies that are coming online.

In this regard, let me close with posing a

couple of questions that we believe need to be considered within the context of this review. First, how can the notable achievement of the first-ever biotechnology section in a major trade agreement, as has reportedly been achieved through the Trans-Pacific Partnership Trade Agreement, be leveraged to bring about increased international coherence and compatibility when it comes to science-based regulatory systems for reviewing and approving biotech-enhanced traits?

Second, how should the restructuring at USDA to create a new undersecretary position focused on trade-related issues be integrated into a comprehensive approach to facilitate increased U.S. government communication and trade facilitation efforts with foreign governments?

In closing, we ask you to look at these global impacts as you conduct your long-term strategic review. Thank you.

DR. BARBERO: Next, Marek Cuhra.

MR. CUHRA: Chura.

DR. BARBERO: Chura, close.

MR. CUHRA: Thank you for the opportunity. I am from Norway. My name is Marek Cuhra. I have a Ph.D. in GMO soybeans and glyphosate ecotoxicology, and I think that biotechnology is good for several things. I think that biotechnologically produced drugs such as human analog growth hormone and human analog insulin are excellent, and I think these are really great inventions.

However, most products of biotechnology are in open cultivation and are not subject to control. We have investigated the GTS-40-3-2 soybean, known as the Round-up Ready Soybean, which has been in open cultivation since 1995. So it's two decades, and we find this soybean, when it has been cultivated in representative systems, to have very high residue levels of glyphosate.

These residue levels are not found in tests performed by industry, because these tests are being performed without the complimentary sprays. Now we see also that in U.S. you have a pragmatic adjustment of the MRLs, the residue levels, and these are not based on health concerns. These are based on other

interests.

This comes down to the question of substantial equivalence, which I think is very important to review in the coming revision. These questions are important not only in the USA but also globally, because these are main feed ingredients, which are used -- here, it's used for food, but in Europe we use it for farmed animals and in Norway for farmed salmon.

Voices in Europe say FDA says that it's safe, it's predictable, it does not need to be labeled. So why do we in Europe have to label and regulate? It's a good question, and to answer that, we have been looking at little bit into the process of the 1992 policy, and we see that the FDA had several very important deliberations, and that these deliberations were taken out of the final version of the document, and I think that is a very important point.

Now Woodrow Wilson, before he became President in 1887, he wrote about the Autonomy of State Administration, and I think that it is important

to highlight that, the principle of administrative autonomy. We see that the FDA policy of 1992, the existing regulation or rather deregulation is politically influenced.

From Europe, we see that FDA is a high competent environment, and I hope that no matter the outcome of the coming elections, that this time the FDA will be allowed to do its work unhindered by political influences and dictates.

Now as some of the speakers before have said, independent research brings supplementary insight. I think that is very important. Just as medical drugs are openly available to independent researchers, so should products of biotechnology. Now you are allowed to eat it, but we as European scientists are not allowed to analyze it.

Post-market monitoring plans are also important. I have several other things that I would like to discuss with the FDA. I will be here for the coming weeks before I go back to Europe. So if any of you would be willing to have a few words with me after the meeting, I would be happy. Thank you.

DR. BARBERO: Next is Nina Fedoroff.

MS. FEDOROFF: First, I'd like to thank the Committee and OSTP for taking this on. My name is Dr. Nina Fedoroff. I'm a molecular biologist and geneticist, and I was one of the first to apply molecular techniques in plant biology commencing in the 1970's.

I've been involved in the regulatory issues around modern genetic modification, GM as we all call it, since the early 1980's, when I served on the NIH Recombinant DNA Advisory Committee. I was also one of the authors of the 1987 National Academy of Sciences White Paper titled "Introduction of Recombinant DNA Engineered Organisms Into the Environment: Key Issues."

Then as now, there was no evidence and is still no evidence that unique hazards attend the use of modern GM techniques or in the movement of genes between unrelated organisms.

The paper further states the risks associated with the introduction of recombinant DNA into organisms are the same in kind as those

associated with the introduction of unmodified organisms in organisms modified by other methods, and concludes that assessment of the risks of introducing recombinant DNA engineered organisms into the environment should be based on the nature of the organism and the environment into which it is introduced, not on the method by which it was produced.

The President's recent directive creates an unprecedented opportunity for the EPA, USDA and FDA to one, review the evidence that has accumulated in the intervening 30 years of biosafety research and field experience. Two, to move the regulatory system from de facto process-based to truly risk-based.

Going forward, it is critically important to facilitate the use of GM techniques in agriculture. The warming climate among other factors is changing pest and disease profiles and distributions. This necessitates a far more rapid adaptation of responses, particularly for crops than can be achieved through the older breeding approaches.

And because so many different corps and

animals are being and will be affected, the participation of many more skilled scientists will be necessary to meet these challenges, than just those employed by big biotech companies.

Tragically, today our public sector agricultural scientists have all but ceased using GM techniques for crop and animal protection and improvement. This is largely because the cost and time involved in obtaining regulatory approval for a GMO release is simply prohibitive. It's therefore imperative that the present regulatory restructuring yield a framework that is truly risk-based and readily traversed at reasonable cost.

The kinds of decision trees that should be developed, albeit based on current knowledge and decades of experience, were already laid out as long ago as the 1989 NRC report titled "Field Testing Genetically Modified Organism: A Framework for Decisions."

This is especially important in the face of emerging gene modification technology, such as the CRISPR/Cas (ph) system, that provide unprecedented

control over what genes are modified and how, something that has never been possible in the entire history of agriculture. Thank you.

DR. BARBERO: The next speaker is Alexis Baden-Mayer, this time representing herself.

MS. BADEN-MAYER: Thank you so much. To everyone at the White House, the FDA, the EPA and the USDA, who have had a hand in convening this opportunity for public comment. I'm Alexis Baden-Mayer. I'm here today representing Moms Across America and Zen Honeycutt (ph), who directs that organization, as well as Organic Consumers Association, where I work as a political director. Zen and I represent some of the millions of people who are searching for the hidden truth about genetically engineered foods.

People who are trying to navigate a marketplace where foods contain secret ingredients, and 99.7 percent of the GMOs grown in the world today are pesticide plants, genetically engineered to either increase our exposure to dangerous herbicides, or turn our foods into toxic insecticides or both.

Many of our members share a similar story. Whether it's breast cancer or reproductive issues or painful digestive problems, gallbladder removal, kidney disease, diabetes, obesity, the story is always the same. I was sick. I got medical treatment. I was still sick. I got GMOs out of my diet and I started to get my health back.

And of course this story can also be about loved ones, and that's what Zen experienced. Her children had life-threatening allergies and autism spectrum symptoms, but their health improved when she put them on a non-GMO diet. The U.S. must begin to put this inherently risky technology in check, and finally grant to U.S. citizens the same kind of sensible regulations that just about every other country has conceded are necessary.

GMO labels, premarket safety testing of GMOs and restrictions on where GMOs may be grown. We need a moratorium on the GMOs that turn our food into insecticides or allow our food to soak up dangerous herbicides. Genetically engineered crops led to an increase in overall pesticide use by 404 million

pounds from the time they were introduced in 1996 through 2011.

It's time to take glyphosate off the market. Now that the World Health Organization has declared it a probable human carcinogen. Over 80 percent of all GMOs grown worldwide today are engineered to absorb this carcinogenic herbicide. Glyphosate absorbed into an engineered plant cannot be removed, and we are consuming it at levels far above what has been shown to cause harm.

There are hundreds of scientific studies that show how human health can be seriously harmed by GMOs and related pesticides, and we'll submit these in our written comments.

DR. BARBERO: Next is Megan Parker.

MS. PARKER: Hello. Thank you for having me. I do not have a fancy degree. I'm representing the American consumer, Jane Smith, Joe Schmo. Here we are.

First of all, I would like to draw your attention to one of the pre-reading documents titled "Clarifying Current Roles and Responsibilities in the

Coordinated Framework for the Regulation of Biotechnology," etcetera, etcetera, in which it states "In 1986, the Office of Science and Technology Policy issued the coordinated framework, which outlined comprehensive federal regulatory policy for ensuring the safety of biotechnology products."

This is the important part. "The CF sought to achieve a balance between regulation adequate to ensure the protection of health and environment, while maintaining sufficient regulatory flexibility to avoid impeding innovation."

Now to me, that shows me that you're making the statement here and you're blatantly admitting that you are willing to compromise human health to advance and accommodate biotechnology. I mean there's really -- I don't know if you had an attorney review this before you wrote this, but this is very incendiary, to make that statement.

Also regarding transparency and trust of the American consumer, we simply do not trust you. There's a growing distrust and I'm not exaggerating it. I talk to people who see Monsanto commercials on

TV, and what are they doing? They're laughing at them. It's absurd, it's a joke to consumers. They understand that it's propaganda and it's a joke.

The other thing is this incest that's going on, the USDA, the FDA, Board of Directors, Monsanto, employees going back and forth between all of these government organizations. Who would trust that? Who would trust that you all have the best interests of the consumer and the consumer safety at heart?

It's corruption, and we don't trust that, and we're demanding that the regulatory system is revised, because this is -- you're going to bleed out money. You're losing money and the organic industry is growing astronomically. I think you all need to prepare for that, because it's basically your future. Thank you.

DR. BARBERO: Next is Megan Palmer.

MS. PALMER: Hello. My name is Megan Palmer. I am a senior research scholar at the Center for International Security and Cooperation at Stanford University. I'm a biological engineer by background, and for the last five years led research programs in

shaping policies and practices to ensure the responsible development of biotechnology through a number of venues, including the National Science Foundation's Synthetic Biology Engineering Research Center and, as Kelly noted, the International Genetically Engineered Machine Competition.

This is involved working with leading researchers, companies, as well as policymakers, to identify and mitigate gaps, uncertainties and ambiguities in our systems of governance, that present themselves alongside new knowledge and technologies around advances in biotechnology.

I would like to thank OSTP for taking this important step in revisiting and involving our regulatory systems, to ensure the development of biotechnology is in the public interest. Biotechnology is becoming increasingly important to our national and international prosperity and security.

As a scale of complexity and importance of biological technologies increases, it is essential that we built the infrastructure that helps everyone

better understand biotechnology, its benefits, its risks and its policies and practices.

Over the last five years, I've experienced the frustration of practitioners and regulators alike, who are trying to understand how they can better navigate and help evolve the systems to assess this risk and benefits.

I'll expand upon these comments in written form, but I want to highlight two points to consider in this process. First, it's critical that build systems that can promote transparency and access to the process and the evidence base on which we assess the efficacy and safety of new biotechnology products. This is not a trivial task, and it requires investment in innovation and processes and platforms that can leverage the way we organize and communicate today.

We must create improved instruments through which to collect data on the performance, including the failures of our regulatory systems before and after we develop products. We must build metrics and adapt standards for information sharing, and harmonization that can work better across agencies.

Data and public access will be essential to ensuring accountability and providing a foundation for learning how we might adapt systems to better identify and resolve problems over time.

Second, we need to treat the regulation of emerging biotechnologies as a sustaining challenge that is going to require ongoing research and engagement. To meet this challenge, we need programs and people who are willing and able to identify, articulate and work on both immediate and long term challenges.

As Kelly from iGEM noted, we need to explore and experiment with mechanisms like iGEM, that incentivize and empower the best minds who are developing these new technologies, to also care about regulation. I urge USTP to consider how to build research programs that create better partnerships between agencies, practitioners and universities.

We piloted some of these efforts within our Engineering Research Centers, where we have embedded research programs and policies and practices alongside science and technology innovation, and a continued

commitment is critical. I just want to highlight that these improvements are not cheap and they are not easy.

We need to ensure that the people who are attempting to face these challenges are resourced to meet the increasing number and sophistication of new products in biotechnology. I want to thank you again for the opportunity to comment and for your commitment to ensuring biotechnology is in the public interest. Thank you.

DR. BARBERO: Next is Terry Medley.

MR. MEDLEY: Good afternoon, thank you. I want to thank you for hosting this public meeting, and also for initiating a process to clarify, update and improve the U.S. regulatory system for biotechnology products. I think everyone sitting here today realizes that it is quite a challenge.

My name is Terry Medley. I'm the Global Director of Corporate Regulatory Affairs for DuPont. DuPont is a global science company operating in three priority areas: agriculture and nutrition leading to food production; advanced materials; and bio-based

industries looking at alternative fuels.

Our company has a rich history in chemistry and material science and strengths in biology and biotechnology. Biotechnology is an important area of knowledge with potential for continued new growth, opportunities for food production and bio-based businesses.

The broad fill of biotechnology presents important opportunities that should be explored and developed, to identify those safe and commercially viable applications that bring significant benefit to society.

The July 2nd memorandum initiates a process to modernize the federal regulatory system for the products of biotechnology, and to establish mechanisms for periodic updates of that system.

The U.S. government has a long and proud history of designing and implementing regulations that maintain high standards, that are based on the best available science, and that deliver appropriate health and environmental protection.

We applaud and support your belief that the

government can help improve public understanding and acceptance of biotechnology by increasing efforts to clarify in simple terms its role in the regulatory process and engaging more robustly in the public biotechnology conversation.

It is our hope that this public meeting and the associated process will promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement. We are pleased that the memorandum supports the continued product and risk-based focus for the U.S. regulatory oversight of products of biotechnology.

Consistent with this focus, we've identified the following regulatory policy priorities, call them objectives or hopefully deliverables from this process. They are promoting a comprehensive U.S. import and export policy; adopting a workable low-level presence policy for food, feed and seed; accommodating new technology with regulatory requirements that are commensurate with risk; expedite reviews for familiar products through streamlined review processes and appropriate exemptions;

minimizing redundancies of federal oversight of products of biotechnology.

In closing, we look forward to continued participation in the government's efforts to improve consumer confidence, predictability, increase efficiency and reduce uncertainty in the U.S. regulatory process. I thank you for the opportunity to make these comments.

DR. BARBERO: And our last remark is Tyrone Spady.

MR. SPADY: I'd like to start by joining the previous speakers in thanking OSTP and the federal agencies for undertaking the current review of the coordinated framework and the development of a long-term strategic plan for the regulation of biotech products.

I'm Tyrone Spady. I'm the Director of Legislative and Public Affairs for the American Society of Plant Biologists.

I speak on behalf of the Society, which publishes two of the top plant science journals and represents researchers, educators and extension

specialists throughout the country and the globe. Many of our scientists are actively involved in the development of new crop varieties via both conventional and biotech methods.

The American Society of Plant Biologists supports the continued use and further development of appropriate science-based procedures and regulations to reflect the risk and benefits of all new agricultural technologies and products, including those developed using genetic engineering.

The use of genetic engineering to modify plants represents an important advance in agriculture that builds on centuries of human involvement in the genetic modification of crop species. A comprehensive report published in 2010 by the National Research Council reviewed scientific studies on the impact of GE crops on farm sustainability, and found that GE crops can provide substantial net environmental benefits compared with non-GE crop varieties.

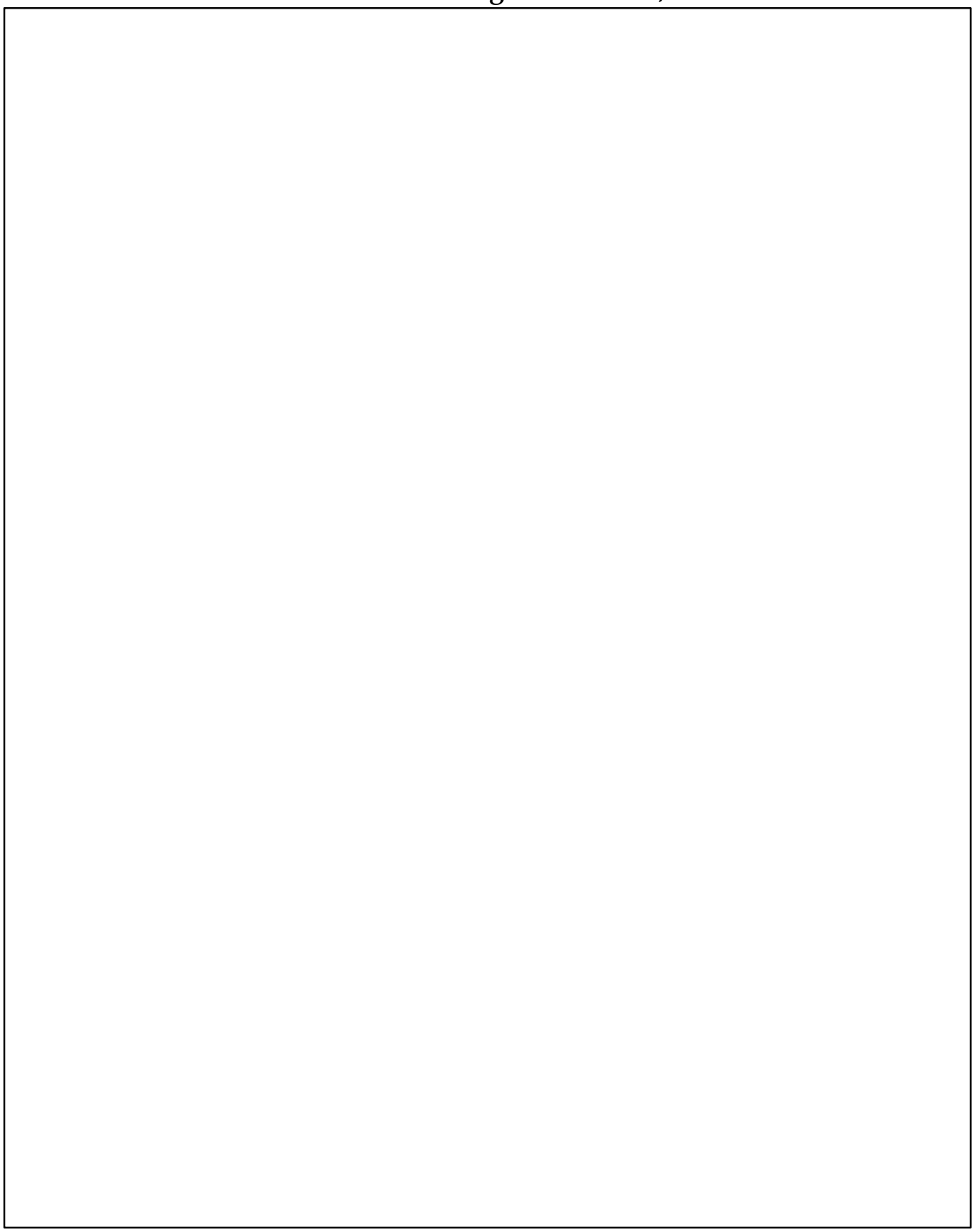
Such benefits include reduced erosion, nutritionally enhanced food and substantial reductions in the amount of insecticides farm workers are exposed

to and that are released into the environment. ASPB strongly urges OSTP, USDA, FDA and EPA to make sure that the policymaking process emphasizes the best available scientific information, and is committed to working with the agencies throughout this process. Thank you.

DR. NALUBOLA: That brings us to the end of the public comment session. I just wanted to remind everyone that you can submit electronic or written comments to the public docket. The deadline is November 13th at 5:00 p.m. Please visit www.regulations.gov and identify your comments with the docket number, FDA-2015-N-3403.

I remind you also that all comments received may be posted without change to regulations.gov, including any personal information that you provide. Thank you again for your interest, and I speak on behalf of OSTP, FDA, EPA and USDA when I say thank you and we look forward to continued engagement on this topic. Thanks again and have a great rest of the day.

(Whereupon, at 1:00 p.m., the public hearing was adjourned.)



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I, MARGARET CARAWAY HOLMES, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

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November 12, 2015 MARGARET CARAWAY HOLMES