FTS-USDA-APHIS

Moderator: Ed Curlett
October 6, 2008
2:00 pm CT

Coordinator: Welcome, and thank you all for standing by. At this time I would like to remind parties that your lines are in a listen only mode until the question and answer session, at which time you may press star followed by 1 to ask a question. Today's call is being recorded, if you have any objections you may disconnect at this time.

I will now turn the meeting over to Karen Eggert, thank you and you may begin.

Karen Eggert: Thank you. Good afternoon this is Karen Eggert Media Coordinator with USDA Animal Implant Health Inspection Services. Thank you for joining us today to learn about purposed changes to APHIS Biotechnology regulations.

We are going to begin the call with some remarks and then we are going to open it up for questions and I want to remind everyone that the questions portion of this call is for reporters only and we would like you to limit yourselves to questions on the proposed rule. All other Biotechnology questions can be referred to Rachel Iadicicco at 202-720-2511. She will be available after this call. We would also like you to state your name and affiliation and limit yourself to one question each so that we can get to all of you on the call. And I also want to encourage you to check our web site, www.aphis.usda.gov. We are going to be posting documents pertaining to the announcement on our home page. I'm now going to turn it over to APHIS administrator Cindy Smith and thank you again for calling in.

Cindy Smith: Thank you Karen. Well, good afternoon everyone and thank you for joining us on the phone today. I'm Cindy Smith the Administrator of USDA's Animal and Plant Health Inspection Service. With me is Michael Gregoire, Deputy Administrator for APHIS Biotechnology Regulatory Services (BRS) Program. Also present is Beverly Simmons, Associate Deputy Administrator for BRS and John Turner the Director for BRS' Policy Coordination program.

As many of you may know I personally have a strong interest in BRS activities as a former BRS Deputy Administrator, and I am particularly pleased to be here today with the BRS leadership as we announce the publication of the proposed rule to revise our current biotechnology regulations.

While we have made several changes to our regulations for GE organisms since 1987, this is the most comprehensive review of our regulatory structure and will allow the USDA to provide affective oversight of the technology for years to come.

The proposed regulatory changes reflect APHIS's experience and incorporate lessons learned to improve program administration. APHIS has been regulating certain GE organisms for more than 20 years. Based on this experience, as well as the input from a range of stakeholders, the changes we are proposing incorporate lessons learned to improve program administration.

These proposed changes will improve our regulatory processes so they are more transparent to stake holders and the public. They are also intended to make more efficient use of agency resources and eliminate unnecessary regulatory burden. The strengths of the proposed rule are its flexibility,

transparency, accountability and ensuring that regulation is commensurate with risk.

I'd like to turn it over now to Mike Gregoire who will provide you with more specifics on our proposal. Mike.

Michael Gregoire: Thank you Cindy and good afternoon, I'm going to provide you with a brief overview of some of the proposed changes and then we will open the phone lines for questions.

First, we are proposing changes to better align our biotechnology regulations with provisions of the Plant Protection Act of 2000, which gives APHIS the authority to regulate certain GE organisms.

The proposed changes will help clarify the GE organisms that are regulated. Specifically, APHIS proposes regulating the importation, the interstate movement and the environmental release of certain GE organisms - those that might pose a plant pest or noxious weed risk, or if the plant pest or noxious weed risk is unknown. APHIS will offer to consult with developers if they have questions about whether their GE organisms falls within the scope of the regulation.

APHIS will replace the current notification and petition procedure with a multiple category permitting system based on potential plant pest and noxious weed risk. We think a multiple category permitting systems will provide for more flexible risk appropriate oversight, better regulatory enforcement and improved transparencies for releases into the environment.

Under this proposed system we would eliminate the notification procedure. Currently, specific conditions are not attached to notifications and that is one

reason why the notification procedure would not be part of the proposed regulations. All authorizations under the proposed rule would be done under the permitting procedure. With the proposed permitting system we are also looking to establish a new provision to approve conditional exemptions.

Under this system APHIS could approve conditional exemptions for specific GE organisms that would keep them under the scope of the regulations and impose certain conditions but would remove the need for the permit for certain types of actions involving those organisms.

APHIS currently grants conditional exemptions, but only by amending the regulation. Using the proposed conditional exemptions process for the activities that pose a minimal plant pest or noxious weed risk would be more efficient. It would provide regulatory relief while ensuring the opportunity for public comment and participation.

The proposed rule also sets out to improve and clarify the procedures for petitions for non regulated status, whereby a GE organism is no longer subject to APHIS Biotechnology regulations. I want to point out that in the proposed rule all previous determinations of non regulated status made under the current regulation would continue to have non regulated status.

Our proposal also codifies our current low level presence--or LLP--policy, a policy APHIS announced in 2007 to respond to the presence of low levels of regulated GE plants or materials when mixed into commercial grain or seed. APHIS current regulations have no explicit provisions regarding LLP.

Finally, the proposed rule addresses several provisions from the 2008 Farm Bill regarding the improvement of the management and oversight GE organisms regulated under the Plant Protection Act of 2000. We are proposing

certain regulatory changes concerning permit applications information requirements, permit conditions, records and reports that address and comply with the biotechnology-related provisions in the Farm Bill.

The proposed bill allows for public input and comments for 45 days beginning this Thursday, October 9, when the proposed rule is published in the Federal Register. The comment period will close November 24.

We recognize the importance of public input and we have worked hard to insure that this rule making process is transparent and that it offers ample opportunities for public input. To facilitate the public comment process we are scheduling three public meetings. The first meeting will take place in California on October 28, followed by meetings in Missouri on October 30 and in the DC area on the November 13. The specific locations and times are listed in the docket we are publishing this week.

We are strongly encouraging the public to participate in the decisionmaking process by providing feedback through submission of public comments and participation in the public meetings. Karen, that concludes my remarks and we can take questions at this point.

Karen Eggert: Okay, (Rose), we are ready for questions.

Coordinator: Thank you. At this time if you would like to ask a question, please press star 1 on your touch tone phone and record your name so I can announce you for your question. If your question has been answered you may withdraw your question by pressing star 2. Again at this time if you have a question please press star followed by 1 on your touch tone phone.

Our first question is from Andy Pollack please state your name and affiliation.

Andrew Pollack: Yes, good afternoon, Andy Pollack from the New York Times. Although I think many of us on this core panel, we try to stay abreast of these regulations as best we could none of us are lawyers and follow it that closely. I was wondering if you might mention two or three examples of how something is done now and how something will be done under the new regulations, sort of make it concrete?

Cindy Smith: Okay. This is Cindy Smith; I'll take a shot at that. One of the things that gives us greater flexibility is this broadened regulatory authority that will be operating--that we are proposing to operate under--specifically the noxious weed authority. And under this broader authority we will be in a better position to anticipate, to have more flexibility to deal with technologies that we may not anticipate currently.

One specific aspect of this broadened authority is that it includes public health safety and so for regulating some things such as a crop that contains a pharmaceutical protein we will be able to consider any information that is available about whether that protein is safe to be in the food supply. So that is one concrete example.

Another concrete example could speak to the transparency of the new rule and that is that we are moving to - we are eliminating what we currently have as a notification system and a permitting system moving to just one system composed of categories of permits and you will find in the rule two factors that are used to - that will influence which category of permit an applicant will apply for. One speaks to persistence in the wild, one speaks to harm.

These two areas roughly relate to exposure and hazard which is how we, as regulators, determine risk. And with those categories the applicant will have

and the public will have an idea of where in the system their application for the product that they would like to field test would come in, how we would consider that as opposed to currently. If you applied for a permit we would look at all that information and we would determine how we are going to approach that.

These categories will allow some level of transparencies to help applicants and the public know how they might expect us to look at these applications when they come in.

I think we are ready for our next question.

Coordinator: Thank you again, if you have a question please press star followed by 1 on your touch tone phone. And I'm showing no questions at this time.

Karen Eggert: Okay, well I think we can wrap things up if there are no further questions and I appreciate everyone calling in today and any follow-up questions can be directed to our public affairs office at 202-720-2511.

END