The following statement was read by Clint Nesbitt, Chief of Staff of APHIS' Biotechnology Regulatory Services, in a stakeholder call on November 14, 2011:

- As you know, APHIS has a process by which developers of new genetically engineered organisms may petition APHIS to grant the organism nonregulated status if the organism does not pose a plant pest risk.

- The process has been a part of APHIS regulations since 1992, and we have considered well over 130 petitions in that time. Over the course of the last decade or so, however, the time it takes the agency to reach a decision has increased significantly—it now often takes 3 years or more—and the timeframe varies considerably from petition to petition.

- APHIS understands the importance of making timely decisions, while carrying out its mission of protecting U.S. agriculture and the environment from the harmful impacts of potential plant pests.

- Over the course of the last year, I led a team of APHIS subject matter experts and, using "Lean Six Sigma" business process improvement techniques, we have taken a hard look at the way we have been reviewing petitions.

- To do this, we reviewed the process that all petitions followed since 1992, and took a much more detailed look at the petitions we have reviewed in the last five years.

- We used this information to identify the causes of the delays and timeline variability, and have developed innovative solutions specifically tailored to address those key root causes.

- As a result, we have created an improved petition process that we think will cut the overall timeline in half and reduce its variability significantly, without cutting any corners on the quality of analyses supporting our decision making.

- That last point is worth repeating. The process improvements we're talking about are just that—*process* improvements—that is, changes to the behind-the-scenes steps we follow, who does what steps, the timing of the steps, how we allocate staff resources, and so on—improving process efficiency. We were very deliberate in not making any changes that would adversely affect the *quality* of the decision-making. In fact, we think some of these changes will have the added benefit of *improving* the quality of our decision making and the documents that support them.

- Most of the improvements in the overall timeline come from standardizing and streamlining process steps behind the scenes and improving the overall efficiency of the process. There are a few changes, however, which will be more visible to petitioners and stakeholders, and I want to take the time to walk you through some of those new features now [these are roughly in the order they occur in the process].

    - First, at the beginning of the process, APHIS will greatly compress the amount of time it takes to review the petition for completeness. Within one month of submission of a new

petition, petitioners should expect to hear back from APHIS whether the petition has been deemed complete or whether APHIS needs additional information. We are able to gain this time savings largely by changing the way we allocate staff resources to petitions as they are received.

- Another change to the completeness review period is that it will be focused entirely on a review of data required by 7 CFR 340.6; that is, data needed by APHIS to prepare its plant pest risk assessment. No NEPA specialists will be involved in the completeness review, and any NEPA-related supporting documents submitted by petitioners will be reviewed later in the process.

- If APHIS does require additional information from the petitioner, APHIS will ask that the petitioner respond to the request within 30 days. Most companies are currently responding within that timeframe, but some responses may require additional experiments or analysis and take considerably longer. If a petitioner is unable to respond to APHIS request within 30 days, the petition will be treated as "incomplete" and will be given a new petition number once the petitioner responds. This is primarily an administrative change on our part, to take the petitions we are waiting on off of our books and free resources to do other things. The petitioner should not perceive any significant change—they are still free to resubmit a revised petition at any time and it shouldn't take any longer to review once it comes back in— it will just be given a new petition number, and depending upon how long it takes for the petitioner to respond, it may or may not be assigned a different reviewer.

- The next big change to the process is that as soon as the petition has been deemed complete, we will publish the petition itself in the *Federal Register* for a 60-day public comment period (i.e. within a few months of receipt). This is the way the process is described in 7 CFR 340.6, and the process we followed in the 90's. By publishing the petitions for comment earlier in the process, we will be able to use the feedback as scoping for preparation of our NEPA analysis, and use that input to prepare our analysis up-front—that is, to help us inform the issues we should be analyzing in our environmental analysis— as opposed to waiting for and responding to public input after we have prepared our analysis. We hope that this change will help make more effective use of stakeholder input in our decision making process. Holding this comment period early in the process is also a time-savings, because it allows us time to prepare some other work in parallel with the comment period.

- Next, using the public input as scoping, APHIS would spend the next 6 months preparing its environmental analysis, at which time the process would take one of two possible paths:

    - For more routine petitions— those petitions that are very similar to things we have reviewed in the past and don't raise any new issues— we would publish the EA with a preliminary determination to grant nonregulated status to the organism for a 30-day public review period. At the end of that period, the decision would become effective unless APHIS receives new information that would cause us to change the decision.

- For petitions that might raise new issues—either those we identify in our scoping notice or those raised during the comment on the petition—we would publish the EA as a draft and solicit public comment for 30-days. After this time, we would prepare a response to comments and revise our documents if needed, and then publish the final documents and decision in a subsequent notice.

- We will be publishing a *Federal Register* notice in the near future which will describe in more detail the changes we intend to make in the way we solicit public input, and we will not implement any of those particular changes until after the notice is published.

- Altogether, we expect these process changes to represent a timeline that will take approximately 13-16 months to complete, from first receipt of a petition to final determination.

- I want to stress that the process I've described is the process that we expect *most* petitions to follow, based upon past experience. However, there are a few notable exceptions I should mention that would cause a petition to follow a different timeline:

  1) If we receive a very large number of substantive comments during a comment period, it will likely take us more time to review and respond to them.

  2) Timeline assumes that we are able to reach a FONSI after preparation of our EA. If we are not, and preparation of an EIS is necessary, the timeline will likely be considerably longer.

  3) It should also be stressed that not every petition will be granted. If the organism is found to pose a plant pest risk, then the petition process will take a different path.

- In terms of implementation, these improvements will not take place overnight, but will be phased in gradually over the course of the next several months. We are still working out some of the last details about when and how the new changes will be implemented. We will keep stakeholders informed as implementation plans are finalized.

- It is also important to recognize that we currently have a backlog of 22 pending petitions under consideration. Even once we implement the process changes, the backlog will continue to slow the overall process until we catch up. Our preliminary estimates are that it may take a year or more before we are fully achieving the new timeframes. How to address that aspect of the transition is part of what we are still working out.

- Finally, we will be hosting a stakeholder meeting on December 13 in Riverdale, MD, and the process improvements will be one of the topics we discuss. So we hope to have more details about implementation plans to give you by then.

- So please stay tuned. More details will follow in the near future. We'll keep you informed through a combination of email, web postings, the Federal Register, and at our upcoming stakeholder meeting.

- Thank you. At this time, the operator will open the lines if you have any questions for [APHIS-BRS Deputy Administrator] Mike Gregoire or me.