

Advisory Committee on Biotechnology and 21st Century Agriculture (AC21)

AC21 Guidance subgroup meeting

February 23, 2016

Conference Call Summary

A telephone meeting of the Guidance ad hoc subgroup was held on February 23, 2016. The official members of the subgroup are Mary-Howell Martens, Paul Anderson, Gregory Jaffe, Alan Kemper, Darren Ihnen, Lynn Clarkson, and Angela Olsen. All members participated in the conference call except Mr. Kemper, Mr. Ihnen, and Ms. Martens. AC21 member David Johnson also participated. Michael Schechtman, AC21 Executive Secretary and Designated Federal Official, convened the call.

Participants started the conversation by thanking Lynn Clarkson and Angela Olsen for drafting proposed frameworks for a guidance document for the group. The participants indicated that the two documents should be merged. Mr. Clarkson's document was noted to be the more comprehensive one, and it was thought that the sections of that document should be rearranged, starting with the set of numbered characteristics of all IP systems, followed by the first set of bullets, which might be entitled "new challenges."

There was considerable discussion on the section Knowledge of the Seed. One participant suggested that language on seed purity from the previous AC21 report could be added to provide context.

One participant noted that the issue of information on GE content in seed is critical and that some seed companies are not informative or truthful on the issue to their customers. He acknowledged that providing this information would be a new request of seed companies. Not all participants agreed this was a good idea. A participant described the disclosure requirements under the Federal Seed Act, suggested that the report should recommend that farmers deal with reputable seed companies and carefully read the information on the tags, and added that the guidance document should not call into question the practices of the entire seed industry. It was suggested that seed companies who provide specific information on GE content to their customers could be filling a niche market requirement.

One participant suggested that sometimes seed lots can be purchased by an entity that contracts with farmers for IP production, tested for GE content by that entity, and then distributed to those farmers. He also wondered whether major seed companies might not consider channeling tight-specification European-grown seed for GE-sensitive U.S. producers. Another participant suggested that the important thing for the guidance document would be to explain the issue and its importance to farmers and put the onus on them and seed companies to work together to get what they need. A complication was noted, that many contracts specify a particular hybrid, which can only be obtained from one source. A participant then suggested that there would need to be a relationship developed between farmer, seed company, and contracting party.

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Dr. Schechtman then raised the overall issue of drafting of the guidance, and he suggested that one reason for the AC21's success in developing its previous report with recommendations had been the he and the Chair had taken on the responsibility of listening to all views and taking on the drafting, as called for in the revised Charter. He wondered whether, in the interests of not having all members argue over individual words, the same practice should be applied here. Participants agreed that this was appropriate. One participant suggested that the guidance document should offer principles, identify issues, etc., and leave the details to experts, in order to enhance its credibility.

It was noted that one subgroup member who was not able to participate on the call had written this type of guidance for her area and had the appropriate type of expertise, but other participants noted that detailed guidance may be region-specific, and the committee should aim for higher-level advice. Another participant noted that only reasonable advice, not absolute instructions, should be given. Farmers have responsibilities to make their own decisions, and are in any case subject to factors beyond their control, e.g., thunderstorms that can transport pollen long distances.

Dr. Schechtman asked participants whether the guidance document should point users to sources of detailed information. One participant suggested that it could point people in a particular direction, but need not be comprehensive. A number of potential information resources were noted, notably the University of Minnesota, Iowa State University, the University of Wisconsin, Michigan State University, University of California at Davis, the Association of Official Seed Certifying Agencies (AOSCA), the American Seed Trade Association, and various farming organizations. One participant suggested that this information might be posted on a USDA webpage.

Several participants noted that they would have a number of suggested edits to the two proposed framework documents and Dr. Schechtman indicated that comments should be submitted to him to aid in crafting an appropriate framework. He added that he hoped to get this meeting summary finished and distributed to all members within a few days, so that comments on the proposed framework(s) should then be submitted by the end of next week, i.e., by COB Friday, March 4. Dr. Jaffe offered to provide a suggested rational grouping/structure around the various types of considerations that farmer will be facing.

Dr. Schechtman noted that the expectation would be that there would not be a draft guidance framework document available for discussion at the next AC21 plenary session on March 14-15, but that the progress of the subgroup could be discussed at that time.

Several specific points contained in Mr. Clarkson's proposed guidance framework were discussed:

- One participant felt that CRISPR technology shouldn't be singled out among all the potential types of gene editing technologies.
- Another participant noted that AOSCA has determined appropriate isolation distances for separation of particular crops carrying typical agronomic traits, and wondered whether they might be encouraged to work with functional trait developers to

determine appropriate isolation distances in those instances. Another participant supported that idea.

- On the Knowledge of the Seed section, one participant questioned whether the concept of having USDA require the development of test kits as a condition of permitting was within USDA's authority and noted that some traits, like knockouts, might not be easily detectable. Another participant noted that some markets require their products to be PCR-tested, and that new technologies that might enable PCR use on a more routine, commercial basis might be available by 2017. There was further discussion about whether this was a matter of encouraging makers of test kits to work with tech providers, and about the complexities involved in defining what is to be tested for versus what USDA actually regulates.

The discussion then turned to guidance on having conversations with neighbors.

One participant noted that in his experience, what has often worked is that a farmer planning to produce an identity-preserved (IP) crop writes a letter to his/her neighbors telling them what he/she is growing, what inputs are planned to be used, and what sorts of market sensitivities he/she might experience. The letter would ask neighbors to share their plans to see if there are any things they need to discuss more. Such an approach is often well received. Dr. Schechtman inquired whether such letters might also inquire if there was anything the IP farmer was doing that could affect the neighbors' production. That was thought to be a good idea.

It was agreed that having samples of such letters would be useful, but that productive conversations could be had via mail, E-mail, orally, or face-to-face.

Angela Olsen and Lynn Clarkson offered to communicate with the American Farm Bureau and the Illinois Farm Bureau, respectively, to see if any such letters or models might be found.

Greg Jaffe agreed to report out on the work of the subgroup at the upcoming AC21 plenary.

TO DO:

- *Subgroup members and other interested AC21 members provide comments on the two proposed framework documents via redline to highlight concerns or issues omitted or potential reorganization to Michael Schechtman by COB Friday, March 4. Members should note that:*
 - *The concepts in the two framework documents will be merged but the framework will be redrafted to accommodate the concerns raised.*
 - *Additional material will be excerpted as appropriate from the previous AC21 report.*
 - *Additional citations to useful reference materials or more specific references to materials from sources noted in this summary will be gratefully received*

though it is not the intent of the guidance document to provide an encyclopedic reference source.

- *Angela Olsen and Lynn Clarkson to communicate with the American Farm Bureau and the Illinois Farm Bureau, respectively, to try to obtain examples of letters successfully used by farmers to alert neighbors to his planting intentions and crop sensitivities.*