

**U.S. Environmental Protection Agency
Office of Research and Development**

**BOARD OF SCIENTIFIC COUNSELORS BIOTECHNOLOGY SUBCOMMITTEE
CONFERENCE CALL SUMMARY**

**August 20, 2004
1:00 p.m. - 2:00 p.m. EDT**

Ms. Lorelei Kowalski (EPA/OSP), Designated Federal Officer for the EPA Board of Scientific Counselors (BOSC), asked the participants to identify themselves and then provided a brief history that led to the preparation of the draft letter report on the Office of Research and Development (ORD) Biotechnology Research Program. An overview of the program was presented to the BOSC on May 13, 2004, at the meeting in Research Triangle Park, NC. This was the third time that the BOSC had been briefed on the Biotechnology Research Program. Following the May meeting, Dr. Jerry Schnoor (University of Iowa), former Chair of the Biotechnology Subcommittee, prepared a draft letter report on the program. This draft report was circulated to members of the Subcommittee for review and comment. Because Dr. Schnoor's term on the BOSC ended on May 31, 2004, Dr. George Daston (Proctor & Gamble) agreed to serve as the Chair of the Biotechnology Subcommittee and to oversee completion of the letter report.

Ms. Kowalski noted that this conference call was announced in the Federal Register on August 4, 2004, and although several members of the public expressed interest in joining the call, no one requested time on the agenda to make an oral presentation. She pointed out that the letter report is written as if it is the final version; however, the purpose of this call is to discuss the letter and finalize it for submission to the entire BOSC at the September 2004 meeting. Dr. Daston will revise the letter as necessary based on the comments received during today's call.

Dr. Daston said that he wanted to quickly review the highlights of the letter report and then go back and solicit specific comments on each paragraph. Dr. Schnoor made an effort in the draft letter report to state the BOSC's understanding of EPA's role and statutory authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The letter makes it clear that EPA is not the only federal agency responsible for addressing biotechnology issues. The letter states that the four areas of research that ORD has identified in its program—risk to human health, risk to non-target organisms, the potential for gene flow, and insect resistance and management plans—are important and appropriate. The BOSC suggests that ORD place greatest emphasis on addressing genetically modified crops that contain genes for production of *Bacillus thuringiensis* toxin (Bt) because these could conceivably cause all four effects: allergenicity, resistance in target populations, risks to non-target organisms, and conveyance of a selective advantage to cross-hybridized wild-type plants.

With regard to human allergenicity, the BOSC recommends that it not be restricted to digestibility, but should include respiratory allergenicity. Also, SAR-based approaches, such as

epitome mapping, should be considered. The BOSC encourages EPA to collaborate with other agencies interested in the same biotechnology issues. There is considerable work being done within ORD on the risks to non-target organisms and the environment, and the BOSC agrees that ORD's findings thus far indicate that no serious effects are anticipated on non-target organisms. The BOSC cautions EPA, however, to be ever-vigilant to the possibility of subtle, long-term effects that are difficult to measure without an extensive monitoring program. The BOSC concurs with ORD's approach to monitor a few key indicator organisms and habitats over a long period of time.

Dr. Daston indicated that gene transfer is adequately addressed in the program. The framework document outlines a good program to study gene flow from transgenic plants to non-crop hybrids using genomic techniques to confirm expression of transgenes and to evaluate the fitness and ecological effects on crops and non-crop hybrids.

The BOSC agrees that insect resistance and management plan is an important component of the research portfolio of ORD's biotechnology research program. The BOSC recommends that ORD consider adding some social/behavioral research regarding performance of the recommended practices as well as a population genetics study of resistance genes in root worm populations under Bt-crops. The BOSC also suggests that there may be too many resources allocated to this research component given that there are only two organisms that have ever been reported to become resistant to Bt-toxin in 30 years of use as a pure insecticide.

Following the presentation in May, the BOSC discussed social justice issues of biotechnology, especially those in the developing world. The BOSC acknowledges that it is not EPA's role to regulate intellectual property, global trade, or food security impacts, but the Board recommends that ORD be aware of and sensitive to these concerns as they develop research products, interact with federal agencies, and communicate risks to the public.

Following his overview of the letter report, Dr. Daston asked for specific comments from the Subcommittee members. He asked Ms. Kowalski to fill in the meeting dates left blank in the first paragraph.

Dr. Rogene Henderson (Lovelace Respiratory Research Institute) asked that the second paragraph be revised to mention that Dr. Daston replaced Dr. Schnoor as Chair of the Subcommittee when Dr. Schnoor's term expired on May 31, 2004. Dr. Jim Johnson (Howard University) asked that his full name be used in the second paragraph—James H. Johnson, Jr.

Dr. Johnson pointed out that ORD's biotechnology research framework document identifies five research science issues, rather than the four mentioned in the third paragraph of the draft letter report. He suggested that the letter report be consistent with the ORD document. Dr. Henderson commented that Dr. Schnoor combined risk management with development of resistance. She added that the ORD document sometimes uses four and at other times mentions five research issues. Dr. Johnson said that the Subcommittee should use the number that is most consistent with the ORD document. Dr. Daston suggested changing "four" to "five" in the third paragraph and editing the last line of that paragraph as follows: "... these could conceivably cause all five effects or concerns ..."

With regard to the third sentence in the fourth paragraph, Dr. Larry Reiter (EPA/ORD) said that ORD staff do not assume that they know how to detect all allergenicities to humans. He suggested that the sentence be deleted and Dr. Daston and the other Subcommittee members agreed. Dr. Reiter also indicated that ORD will be addressing respiratory allergenicity.

Dr. Johnson noted that “expensive” in the sixth line of the fifth paragraph should be changed to “extensive.” Dr. Gary Saylor (University of Tennessee) proposed deleting the last four lines of the fifth paragraph. He said that he did not know enough about the Northwest Science & Environmental Policy Center to concur with the statement. Dr. Daston and the other Subcommittee members agreed that those lines should be deleted. Dr. Reiter asked that the BOSC make it clear that the tracking of the use of pesticides on genetically modified cropland mentioned in the fifth paragraph is not a research activity. Dr. Daston agreed to acknowledge that this is not a research activity in the letter report.

Dr. Henderson questioned the meaning of the sixth paragraph. After a brief discussion, the Subcommittee members agreed that the sixth paragraph should be deleted.

There were no comments on the seventh paragraph.

With regard to the eighth paragraph, Dr. Daston proposed deleting the last sentence. Dr. Jim Clark (Exxon Mobil) agreed that the sentence should be deleted and the other members concurred.

Dr. Clark asked if the statement “BOSC asks that EPA and ORD be aware and sensitive ...” used in the ninth paragraph would result in any action from ORD. Dr. Reiter replied that he is not sure what action would be taken in response to the suggestion. Dr. Clark said he agreed that the point should be made and included in the letter report. Dr. Bill Farland (EPA/ORD) agreed that the statement should remain in the report. He proposed adding a sentence that ORD should be aware that they may be able to address biotechnology issues outside U.S. boundaries if they consider these issues in the design of their biotechnology research program.

Dr. Johnson suggested adding a sentence to the tenth paragraph about the BOSC being please to have the opportunity to review the program and provide feedback to ORD. Dr. Daston asked Dr. Johnson to send the wording for the additional sentences to him.

Dr. Daston agreed to correct Dr. Johnson’s name in the signature line. The Subcommittee members unanimously agreed that the changes should be adopted and the revised letter report submitted to the entire BOSC at the September meeting. Ms. Kowalski asked if anyone had joined the call since the initial roll call and no one responded. Dr. Farland asked if the revised letter report would be available before the September meeting. Dr. Daston replied that he hoped to complete the changes today. Ms. Kowalski said that the revised letter report will be posted on the BOSC Web Site in the near future. Dr. Johnson thanked everyone for their participation and comments. He agreed to send Dr. Schnoor a note thanking him for his excellent work on the draft letter report.

Action Items

- ✧ Dr. Daston will revise the letter report based on the comments received during the conference call.
- ✧ Dr. Johnson will send the wording for the additional sentence(s) for the closing paragraph to Dr. Daston for inclusion in the revised letter report.
- ✧ Dr. Johnson will send Dr. Schnoor a note thanking him for his excellent work on the draft letter report.
- ✧ Ms. Kowalski will ensure that the revised letter report is posted on the BOSC Web Site prior to the September BOSC meeting.

List of Participants

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