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2 **Safe Pesticides/Safe Products (SP2) Subcommittee**
3 **Conference Call Summary**
4

5 **Tuesday, April 25, 2007**
6 **3:00 p.m. – 4:40 p.m. EDT**
7

8 **Welcome**

9 *Dr. Anna Harding, Oregon State University, Chair, Safe Pesticides/Safe Products (SP2)*
10 *Subcommittee, Board of Scientific Counselors (BOSC)*
11

12 Dr. Anna Harding, Chair of the Safe Pesticides/Safe Products (SP2) Subcommittee of the Board
13 of Scientific Counselors (BOSC), welcomed the participants to the teleconference and reviewed
14 the agenda. She explained that the purpose of the call was to review the progress on the draft
15 report and determine where any further work is required. The agenda included a designated time
16 for public comment, in accordance with the requirements of the Federal Advisory Committee
17 Act (FACA). Dr. Harding stated that she and Dr. Barry Ryan, Vice-Chair of the SP2
18 Subcommittee, will continue their work on the report next week. Once the report is finalized, it
19 will be submitted to the BOSC Executive Committee for review during its meeting in late May.
20

21 Dr. Harding then asked Ms. Lorelei Kowalski to provide an overview of the administrative
22 procedures.
23

24 **Administrative Procedures**

25 *Ms. Lorelei Kowalski, Designated Federal Officer (DFO) for the BOSC Executive Committee,*
26 *Office of Research and Development (ORD), U.S. Environmental Protection Agency (EPA)*
27

28 Ms. Kowalski thanked the Subcommittee members for their attendance and introduced herself as
29 the Designated Federal Officer (DFO) for the BOSC Executive Committee. Ms. Kowalski was
30 acting on behalf of Ms. Heather Drumm, the regular DFO for the SP2 Subcommittee, who could
31 not be present. Ms. Kowalski provided a brief overview of progress to date and some
32 administrative details. The SP2 Subcommittee is a federal advisory committee that has been
33 asked to respond to charge questions as part of a program evaluation of the SP2 Research
34 Program. This call is the sixth public meeting of the SP2 Subcommittee. Four previous calls
35 were held on January 17 and 29, 2007, March 22, 2007, and April 3, 2007. A face-to-face
36 meeting took place February 7-9, 2007, in Research Triangle Park, North Carolina. The
37 Subcommittee currently is finalizing a draft report that will be evaluated by the BOSC Executive
38 Committee at its meeting on May 24-25, 2007. The report then will be submitted to the Office of
39 Research and Development (ORD).
40

41 As the liaison between EPA and the SP2 Subcommittee, the DFO attends and ensures that all
42 meetings comply with FACA regulations. FACA meetings, whether by telephone, e-mail, or in
43 person, must be open to the public; this rule applies to any meeting that is attended by more than
44 one-half of the Subcommittee members. Notice of public meetings must be placed in the

1 *Federal Register* 15 calendar days in advance of the meeting. In addition, documents received
2 by the Subcommittee must be made available to the public. Ms. Kowalski indicated that one
3 member of the public had registered to make a comment prior to the call. She asked that anyone
4 on the call who wishes to make a comment at 3:20 p.m. identify himself/herself and limit
5 comments to 3 minutes.

6
7 Ms. Kowalski reminded the participants to keep track of their non-meeting work hours on their
8 homework sheets and to fax the sheets to Ms. Drumm once completed.

9 10 **Subcommittee Discussion**

11
12 Dr. Harding stated that the Subcommittee would discuss the draft report section by section. She
13 emphasized the importance of including an appropriate mixture of substantive recommendations
14 for improvement as well as comments about how the SP2 Research Program is performing well.
15 She asked that, after reviewing the report on today's call, the Subcommittee members send
16 additional recommendations via e-mail to her and Dr. Ryan.

17 18 *I. Summary*

19
20 Dr. Harding stated that a two-column table will be added to this section. It will list the report's
21 recommendations in one column and any affiliated explanatory comments in the second column.
22 The recommendations also will remain in their respective places within the report. The
23 Subcommittee members agreed with this organization.

24
25 Dr. Harding mentioned that this section now includes an expression of gratitude from the
26 Subcommittee members for the work and commitment by everyone who was involved with the
27 Program review. The Subcommittee members agreed with this inclusion.

28 29 *I.A. Summary Assessments*

30
31 The Subcommittee members agreed with Dr. Harding that the section for LTG 1 reads well.

32
33 Dr. Harding stated that the summary assessment for LTG 2 requires more explanation to justify
34 the "satisfactory" rating. Recommendations made will be placed within the proper location
35 within the report. The Subcommittee members concurred with this plan.

36
37 The Subcommittee members agreed with the summary assessment provided for LTG 3 and had
38 no further comments.

39 40 *II. Introduction*

41
42 There was agreement among the Subcommittee members that this section reads well.

43 44 *III. Relevance*

45
46 Dr. Judy Graham asked if the recommendation to include an approach that considers migration
47 potential and related questions (page 12, lines 460-466) adequately addresses question 1. This
48 question asks: "How consistent are the Long Term Goals (LTGs) of the program with achieving

1 the Agency’s strategic plan and ORD’s Multi-Year Plan?” Dr. Graham wondered whether that
2 new approach would improve the consistency of the LTGs. Dr. Harding stated that she and
3 Dr. Ryan would reexamine the phrasing in the recommendation to determine if it could be placed
4 in a more suitable location within the report.

5
6 Dr. Harding asked the Subcommittee members if the word “none” should be used in cases where
7 recommendations have not been made. Dr. Ryan and Dr. Jerry Ault stated that “none” is suitable
8 because it indicates clearly that recommendations were not omitted. Dr. Graham suggested “no
9 significant recommendations” in place of “none.” Alternatively, Dr. Ryan suggested inserting
10 “no recommendations made.” Dr. Harding stated that the report will contain either one of the
11 two suggestions.

12
13 Dr. Craig Adams asked if the completed draft report will be reviewed by a technical editor for
14 formatting, typographical errors, and related details. For example, the word “none” on page 13,
15 line 528, should not be in bold font. Ms. Kowalski stated that the contractor will edit the final
16 version of the draft report.

17 18 *IV. Structure*

19
20 Dr. Harding asked Dr. Ryan to lead the discussion on this section. Dr. Ryan stated that this
21 portion of the report was the most difficult section to work through, and that it still requires
22 improvement. He explained that he organized the section by LTG and inserted several
23 comments for Dr. Harding’s consideration. Dr. Harding added that, to streamline the document,
24 posters referred to as research examples are identified by code (e.g., LTG 2-5) rather than by
25 their full titles and authors. Drs. Harding and Ryan noted that the references to specific LTGs
26 will be removed throughout the document, unless it is critical to have points refer to individual
27 goals. The Subcommittee agreed that this section should maintain its current length and include
28 the context of any critiques provided.

29
30 Dr. Graham suggested deleting lines 605-610 on page 15, beginning with the recommendation:
31 “More concise language might include the requirement for a written report, or ‘white paper,’ to
32 be forwarded to management.” Dr. Graham objected to this recommendation, stating that
33 management already has enough documentation covering the issues at hand, so it would not be
34 advisable to provide them with more to read. She pointed out that the next sentence, lines 606-
35 607, indicates that “the number of APMs varies significantly from year to year without
36 explanation.” Dr. Graham stated that a given researcher does not know in detail what Annual
37 Performance Measures (APMs) will exist in 3 to 5 years; upfront, however, there should be
38 many APMs defined. Dr. Ryan added that the sentence on line 610 was truncated inadvertently.
39 The Subcommittee members agreed to delete lines 605-610.

40
41 Dr. Graham commented that the “Examples of Excellence” provided on page 17 appear better
42 suited for inclusion in the section addressing question 2 (page 18, lines 726-727), which asks:
43 “How appropriate is the science used to achieve each LTG (i.e., is the program asking the right
44 questions, or has it been eclipsed by advancements in the field)?” Dr. Ryan stated that he had
45 raised this point in his comment on page 17, that the recommendations appear to be misplaced in
46 the document. Dr. Harding noted that she included a comment in response, suggesting that the
47 examples given could be moved to the summary assessment, as has been done for LTG 1 and, to
48 a lesser extent, for LTG 3.

1 Dr. Ault commented that an earlier draft of the report contained a brief introduction to this
2 section, as it pertains to LTG 2, to place the text provided in better context. He agreed to resend
3 that portion of the earlier draft to Drs. Harding and Ryan; they will determine what should be
4 reinserted in the report.

5
6 Dr. Graham noted that a recommendation related to the points made on page 21, lines 846-853,
7 should be placed above question 3, on page 22. The recommendation should read “Include
8 criteria for selection of chemicals for LTG 1C.”

9
10 Dr. Graham suggested moving the paragraph on page 21, lines 872-878, to the recommendations
11 section that immediately follows. The Subcommittee agreed.

12
13 Dr. Joel Coats asked whether the report should mention that more experiments, such as the
14 Agricultural Health Study (AHS) (page 19, lines 781-785), are required to address the lack of
15 exposure-related research under LTG 1. An alternative option would be to mention that more
16 exposure data would be helpful, without naming the AHS. A third option would be to lighten the
17 report’s criticism of the lack of exposure research. Dr. Graham suggested the use of a stronger
18 word than “noteworthy” in the sentence on page 21, line 882, which reads: “The chemical-
19 specific exposure program under LTG 1C is noteworthy.” Dr. Harding pointed out that the
20 sentence that follows (lines 882-883) indicates that the chemical exposure program is only a
21 “minor fraction” of the LTG 1 program. Dr. Coats agreed that the existing explanation appears
22 to cover the shortcoming of exposure research under LTG 1.

23
24 Dr. Ryan commented that the sentence on page 23, lines 939-940 (“... this APG should be
25 revised to better reflect the reality of the research.”) is a recommendation and should be placed
26 elsewhere. Dr. Graham responded that this point appears to be covered under the
27 recommendation on page 24, lines 991-993, “. . . an APG (Annual Performance Goal) should be
28 accomplishable over the life of that APG with the resources available. This is primarily an issue
29 of clarification because the projects themselves flow well.” The Subcommittee members agreed
30 to leave the phrasing as is for both locations and revise later if necessary.

31
32 Regarding the paragraph on page 23, lines 931-940, Dr. Ryan referred to his comment stating
33 that it appears unusual if it is not within the purview of ORD to validate the programs it
34 develops. Dr. Graham noted that the Office of Prevention, Pollution and Toxic Substances
35 (OPPTS) is outsourcing the validation work for methods developed in the Endocrine Disruptors
36 Screening Program. For regulatory use of methods, EPA must involve the Organisation for
37 Economic Co-operation and Development (OECD).

38
39 Dr. Elaine Francis confirmed the point that ORD does not perform validation. ORD conducts
40 enough research to demonstrate that the methodologies it develops are performing as required
41 and that they evaluate the end points that seem appropriate to test. The methodologies then are
42 sent to laboratories for validation. In this regard, the term “validate” is a poor word choice; the
43 APG should indicate that ORD is demonstrating protocol but not performing validation. A
44 suggestion is to replace the word “validate” with “demonstrate.”

45
46 Dr. Graham suggested preceding the sentence on page 23, lines 932-933 with “For regulatory
47 test methods.” The original sentence reads: “The word ‘validate’ implies an intense effort.” She

1 explained that for EPA to require all chemical-producing companies to use a particular chemical
2 assay requires more substantiation than research conducted in one individual's laboratory.

3
4 Referring to the next sentence, lines 933-934, Dr. Adams pointed out that performing "round
5 robins" is not true validation. If several laboratories perform testing using the same
6 methodology and all of them return the same result, then that is a measure of precision of the
7 methodology, not validation. In this regard, even though the validation might be performed
8 elsewhere, EPA still has the responsibility to ensure that it is done properly. Dr. Graham
9 suggested adding "for accuracy and precision" to the sentence as follows: "First, the method has
10 to be developed and then validated for accuracy and precision, with the latter step requiring
11 round robins in several laboratories, etc."

12
13 Dr. Ault explained that calibration involves developing a model and then presenting data that
14 demonstrate a good fit with minimum error. Validation of the model is achieved when that
15 calibrated model is compared to a new set of independent random data, and the same answers are
16 produced or the researcher arrives at the same conclusions. Thus, the process developed is
17 robust enough to stand up to additional information to support the basic hypothesis.

18
19 Dr. Graham stated that the process of validating methods is different from that of validating
20 models. Dr. Adams concurred, explaining that when methods are validated, accuracy is tested in
21 addition to seeing how well the method fits new data; this type of work requires spike recovery
22 experiments and may not necessarily employ round robins. Dr. Ault added that the validation
23 process is a test of both accuracy and precision. Dr. Graham suggested deleting "with the latter
24 step requiring round robins in several laboratories, etc." from lines 933-934. The Subcommittee
25 members agreed with this suggestion. Dr. Graham will send the revised language via e-mail to
26 Drs. Harding and Ryan.

27
28 Dr. Ryan asked for clarification of the sentence on page 23, lines 971-972. That sentence reads:
29 "While parts of the LTG 3 components of the MYP up to 2007 have been met, it is not clear if all
30 APMs listed up to 2007 have been met (Table 3, page 59 SP2-MYP)." Dr. Harding replied that
31 she addressed this sentence with an inclusion in section V (Performance), page 27, line 1121,
32 "For LTG 3, the APMs were met 100% in years 2003 and 2006, and 86% in year 2005."
33 Drs. Harding and Ryan will reexamine the section under LTG 3, pages 23-24, lines 971-978, to
34 determine if any of this information should be removed.

35 36 *V. Performance*

37
38 Dr. Graham suggested that the section on page 27, lines 1126-1130, include mention of how
39 much progress is being made in the areas highlighted (e.g., the mobility, persistence, and
40 bioavailability of gene products in the environment). Dr. Harding added that comments made on
41 progress could be moved to section IV under the response to question 2 that addresses
42 "Appropriate Science Currently Being Undertaken" (page 18, line 734).

43 44 *VI. Quality*

45
46 Dr. Harding included information in this section on how peer review is conducted and the types
47 of peer reviews underway. She asked if the statement made on page 30, lines 1271-1274, is a
48 quality issue or an issue for performance/progress. The statement reads: "The Subcommittee,

1 however, was concerned that the level of funding for LTG 3 appears to be on the low side
2 relative to that for LTGs 1 and 2, and wondered if the level of funding might negatively impact
3 the ability of the researchers to complete APMs related to biotechnology research.”

4 Dr. Harding also asked if the mention of funding would fit better elsewhere in the document.

5 Dr. Coats responded that it is not a quality issue for LTG 3 because the caliber of the work is
6 solid. Dr. Graham mentioned that the portion under question 2 titled “Discussion of Science Not
7 Currently Being Emphasized” (page 19, line 796) indicates research not being done and,
8 therefore, implies that money is required to achieve that research. Dr. Harding stated that she
9 and Dr. Ryan will check the information in that section to determine if anything needs to be
10 added pertaining to funding.

11
12 Dr. Graham commented that the phrasing “The Subcommittee believed” is used in two places in
13 close proximity in the document (page 28, lines 1150-1151 and 1165). Dr. Harding stated that
14 this portion likely was cut and pasted. The phrasing on line 1165 will be reworded to avoid the
15 repetition.

16
17 Dr. Graham noted that page 29, lines 1194-1195, indicates that two division program reviews
18 were conducted within the National Risk Management Research Laboratory (NRMRL) in 2005
19 and in 2006. She suggested also mentioning that NRMRL will have a mid-cycle review in 2007.
20 An additional suggestion is to add “was very supportive” after mention of *The Measure of Star*
21 report on page 30, line 1261.

22
23 Dr. Graham pointed out that the report mentions that the Science To Achieve Results (STAR)
24 Biotechnology Program has not undergone a BOSC review (page 30, lines 1268-1269). It is
25 mentioned earlier, however, that “the STAR program in general has been reviewed by two
26 BOSC Subcommittees” (line 1256). In addition, lines 1266-1267 state “Related to SP2 research,
27 the STAR Computational Toxicology Program was reviewed by a BOSC Subcommittee as part
28 of the review of the entire Computational Toxicology Program.” Dr. Graham suggested stating
29 that the Biotechnology Program has not yet been reviewed by the BOSC, but that it was peer
30 reviewed. Dr. Ault proposed adding a general comment on peer review, to justify why that
31 statement would be included. Agreeing with Dr. Ault, Dr. Graham suggested that another option
32 is to not reference specific programs within STAR and mention instead that the BOSC reviewed
33 the STAR Program as part of its charge. Dr. Harding stated that she and Dr. Ryan will revisit
34 this section to see how it might be modified.

35
36 Dr. Graham suggested the deletion of the investigators’ names from page 31, line 1301,
37 considering specific researchers are not mentioned elsewhere in the document.

38 39 *VII. Scientific Leadership*

40
41 There were no comments on this section.

42 43 *VIII. Coordination and Communication*

44
45 Dr. Graham commented that the phrasing “avoid duplication of effort” (page 34, line 1457) in
46 question 2 would be taken rather seriously by management; moreover, the response given to this
47 question does not comment directly on that point. She suggested including a sentence stating
48 that the Program avoids unnecessary duplication of efforts. Dr. Harding noted that Dr. Francis

1 had explained previously how the programs work and that they are integrated.

2
3 Dr. Graham commented that the bulleted statements on page 35, lines 1473-1482, refer to
4 internal matters; however, the question they are addressing refers to interactions with external
5 organizations. She suggested placing this point under question 1, on page 34. That question
6 reads: "How effectively does the program engage scientists and managers from ORD and
7 relevant program offices in its planning?"

8
9 Dr. Adams noted that "RfP" on page 34, line 1445, should be "RFP."

10
11 *IX. Outcomes*

12
13 Dr. Graham commented that the first two paragraphs addressing question 2, page 37, are generic
14 enough to address all three LTGs. She suggested that the points can be presented for LTG 1,
15 followed by the LTG 3 section, and then the LTG 2 portion. Dr. Harding stated that a
16 concluding paragraph will be added to the document. In response to Dr. Graham's question,
17 Dr. Harding stated that an executive summary will not be written yet for the report.

18
19 *Draft Report Next Steps and Schedule*

20
21 Dr. Harding stated that she and Dr. Ryan will complete the report and fill in the portions that
22 require further work. They plan to complete this work next week and then distribute a copy of
23 the report to the Subcommittee members for their final comments on May 3 or 4, 2007. After
24 final edits are made, the report will be submitted to the BOSC Executive Committee.

25 Ms. Kowalski stated that she will require the report by May 7, 2007, for inclusion in the
26 background materials binders, which are being mailed to the BOSC Executive Committee
27 members on May 9.

28
29 Drs. Harding and Ryan will present the report to the BOSC Executive Committee on May 24,
30 2007. If substantive changes are required, the report might need to be revisited by the
31 Subcommittee at a later date.

32
33 **Public Comment**

34
35 At 3:22 p.m., in accordance with FACA requirements, Ms. Kowalski called for public comment.
36 No comments were offered.

37
38 **Adjourn**

39
40 Dr. Harding thanked the members for their participation and adjourned the call at 4:40 p.m.

41
42 **Action Items**

- 43
44 ✧ The Subcommittee members will fax their completed homework sheets to Ms. Drumm.
45
46 ✧ A two-column table will be added to section I, with one column listing the report's
47 recommendations and the other providing any affiliated explanatory comments.
48

- 1 ✧ More explanation will be provided for the LTG 2 summary assessment in section I.A.
2 Recommendations made will be placed within the proper location within the report.
3
- 4 ✧ The Subcommittee members will send any additional recommendations for inclusion in the
5 report to Drs. Harding and Ryan via e-mail.
6
- 7 ✧ Drs. Harding and Ryan will reexamine the phrasing in the recommendation on page 12, lines
8 460-466, to determine if it could be placed in a more suitable location within the report.
9
- 10 ✧ Dr. Harding will insert either “no significant recommendations” or “no recommendations
11 made” in place of “none” in the report.
12
- 13 ✧ Posters mentioned in the report as research examples will be referred to by poster code
14 (e.g., LTG 2-5).
15
- 16 ✧ References to specific LTGs will be removed throughout the document, unless it is critical to
17 have points refer to individual goals.
18
- 19 ✧ Lines 605-610 on page 15 will be deleted.
20
- 21 ✧ Dr. Ault will resend an earlier portion of the draft report to Drs. Harding and Ryan that
22 provides introductory text for LTG 2 under section IV. Drs. Harding and Ryan will
23 determine what needs to be reinserted in the report.
24
- 25 ✧ A recommendation will be added above question 3, page 22, that reads: “Include criteria for
26 selection of chemicals for LTG 1C.”
27
- 28 ✧ The paragraph on page 21, line 872-878, will be moved to the recommendations section that
29 immediately follows.
30
- 31 ✧ Dr. Graham will send the revised language for page 23, lines 932-934, via e-mail to
32 Drs. Harding and Ryan.
33
- 34 ✧ Drs. Harding and Ryan will reexamine the section under LTG 3, pages 23-24, lines 971-978,
35 to determine if any of the information should be removed.
36
- 37 ✧ Drs. Harding and Ryan will reexamine the information under the section that begins on page
38 19, line 796, to determine if anything related to funding needs to be added.
39
- 40 ✧ The phrasing “The Subcommittee believed” on page 28, line 1165, will be reworded to avoid
41 repetition of the phrase on lines 1150-1151.
42
- 43 ✧ The report will indicate on page 29, after line 1195, that NRMRL will have a mid-cycle
44 review in 2007.
45
- 46 ✧ The phrase “was very supportive” will be included after mention of *The Measure of Star*
47 report on page 30, line 1261.
48

- 1 ✧ Drs. Harding and Ryan will revisit the section on page 30, lines 1268-1269, to see how it
2 might be modified.
3
4 ✧ The investigators' names will be deleted from page 31, line 1301.
5
6 ✧ The bulleted statements on page 35, lines 1473-1482, will be placed under question 1 on
7 page 34.
8
9 ✧ The acronym "RfP" on page 34, line 1445, will be changed to "RFP."
10
11 ✧ A concluding paragraph will be added to the document.

Participants List

Subcommittee Members

Anna K. Harding, Ph.D., Chair

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Other Participants

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Contractor Support

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APPENDIX A:
Meeting Agenda



SAFE PESTICIDES/SAFE PRODUCTS (SP2) SUBCOMMITTEE

AGENDA

April 25, 2007

3:00 p.m. – 5:00 p.m. EDT

CONFERENCE CALL

Participation by Teleconference Only

3:00 – 3:15 p.m.	Welcome – Roll Call – Overview of Progress	Dr. Anna Harding Subcommittee Chair
3:15 – 3:20 p.m.	Administrative Procedures	Ms. Lorelei Kowalski BOSC Executive Committee DFO
3:20 – 3:25 p.m.	Public Comment	
3:25 – 5:00 p.m.	Subcommittee Discussion – Summary of Draft Report Progress – Draft Report Discussion – Draft Report Next Steps and Schedule	Dr. Anna Harding Subcommittee Chair
5:00 p.m.	Adjournment	