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April 28, 2006

Edward H. Hammond
Director
The Sunshine Project
PO Box 41987
Austin, TX 78704

Dear Mr. Hammond;

Thank you for your inquiry of 13 March, 2006. You will find attached our minutes of March 2004 and March 2006. Certain confidential business information has been redacted from the minutes, in accordance with the NIH Guidelines related to Voluntary Compliance.

This represents a complete set of minutes in regards to the time interval requested. The interval between these meetings was devoted to working both internally and in conjunction with NIH to re-design our IBC process to take advantage of internal databases and to enhance our gene review process. This was successfully accomplished, and a comprehensive review of all gene activity was performed in preparation for the 2006 meeting. You may wish to note that the application process discussed at length in the March 2004 Minutes ultimately was not adopted due to the implementation of new databases. These data resources permitted a vastly improved process as discussed in the minutes of March 2006.

In regards to your specific question regarding a written policy for the "identification, review, and oversight" of "experiments of concern" identified in the NAS report, *Biotechnology Research in an Age of Terrorism*, we would reply as follows:

> Monsanto is engaged primarily in the development of plants with improved agronomic and nutritional characteristics. We do not presently engage in experimentation which would fall into the any of the seven categories of concern raised in the report. Further, there is no reason to believe that such an experiment would ever be necessary in pursuit of our business goals. Given

that we do not engage in any such activity, and do not anticipate any reason to do so in the foreseeable future, we have not put in place a specific written policy to deal with this issue. However, our policy regarding IBC review and our new IBC process using internal databases, provides excellent assurances that any such activity would come to the attention of the IBC.

Sincerely;

Daniel A. Goldstein, M.D.
Chair, Monsanto St. Louis IBC

MONSANTO

St. Louis

RECOMBINANT DNA COMMITTEE (IBC)

Meeting Minutes
March 14, 2006

An rDNA Committee meeting was held in E316C on March 14, 2006 from 1:00 to 3:30 PM CST.

Members in attendance:

Dan Goldstein (Chair)
Donn Cahill (Biosafety officer)
(Reg. Law)

(Community Representative)

Members absent:

(Community representative)

Material was circulated to all members in advance, and extended discussion was had electronically with <absent community member>, who was unable to attend due to a scheduling error on the part of the Chairperson.

The AGENDA was as follows:

TIME:	AGENDUM
1:00	**Introductions**
1:15 -1:45	**Evolution of the new rDNA Committee Process & Status with NIH-OBA (Dan Goldstein)**
1:45-2:00	**Overview- Biotech Organization ( )**

2:00 **Break**

2:10-2:40 **LEADS review process, donor sources, and gene report (Dan Goldstein)**

2:40-3:00 **Discussion/approval: new rDNA Committee process and procedures.**

3:00 **Break**

3:15-4:00 **Other specific approvals / decisions**

- **Biosafety level, genes derived from Stenotrophomonas**
- **Action regarding plant pathogens**
- **New gene sources**
- **Other applications**

PowerPoint presentations were utilized throughout the meeting to introduce material and guide the agenda. These are attached for reference. It should be noted that these presentations contain confidential business information. The minutes below are intended to be appropriate for unrestricted use, i.e. confidential business information is not present.

1) The new database driven gene stewardship program was outlined to the rDNA Committee members, discussed, and then approved with the following observations and action items:

- Some rDNA activity does occur in laboratories prior to the nomination process to the LEADS database for exploratory research purposes. We do not have a systematic way to capture this research in the database. It could be picked up via the Biosafety Application, but we need to further investigate this area. This activity is small scale, contained (BL-1), and involves a variety of single or small-number gene transfers using exempt vector systems. There is very little reason for concern regarding this research given the nature of the work at Monsanto, but **further investigation into feasibility of capture should take place.** The chair will pursue this effort. On the positive side, all of these activities should be captured in LEADS well before any large scale efforts at commercial transformation would take place.

- Some areas of activity exist outside of the Biotech Organization and are not captured. This was previously recognized, and these will be identified via the Biosafety Review process and brought to the committee via traditional means (see 3 instances of this noted below). A number of laboratories outside of the Biotech Organization do work on materials which are in the Biotech Organization's pipeline or are already marketed, and review of these laboratories would be redundant. Prior to this meeting, all existing Biosafety Reviews were checked, and we believe that we have picked up all such activity at this time.

- The group was raised as an example of this concern. This group does not have rDNA work on site at this time, but will in the future. A specific stewardship effort is in place around this program. **The Chair will present the issues to the rDNA committee at the next meeting, and the rDNA work will be brought to the committee as well when appropriate.**

2) The committee approved our continuing effort to communicate with the NIH OBA regarding approval of the new program, as well as participation in a broader industry effort to develop formal programs appropriate to the high throughput research environment. The Chair will follow up with NIH OBA.

3) The gene source list was presented and discussed. Two issues were identified in advance of the meeting for discussion. No other issues were raised.

- Genes from plant pathogens were identified. In all cases it appears that the genetic material was obtained without direct use of the organism on site, i.e.- it was obtained from another location or assembled here without resorting back to handling the original organism. This does not raise any safety issue relative to experiments using pathogenic organisms. **The chair moved that the list of organisms identified as plant pathogens be forwarded to the Site Biosafety Committee, and that the chair would be responsible for identifying any future gene source nominations for plant pathogens to the Biosafety Officer. This would serve as an ancillary tool to help in tracking plant pathogens in the event that future work involves direct handling of pathogenic organisms. There was no objection.**

- The gene for resistance is sourced from *Stenotrophomonas maltophilia*, an NIH Risk Group 2 human pathogen (formerly Pseudomonas maltophilia). The gene sequence was obtained externally without handling of the organism. The genetic material utilized here was well characterized and codes for a very similar to those found in other species across the phylogenetic tree. This enzyme has no identified role in bacterial pathogenicity. Further, the genes have been optimized for plant function and carry a non-bacterial promoter as well as, in the case of corn, introns not compatible with bacterial gene function.

The chair moved that these experiments be managed under BL-1 conditions. The motion passed without opposition.

4) Three specific applications for work outside of the Biotech Organizations were brought forward to the committee for approval:

- **BST research, large scale.** This is an on-going low risk project with BST and other bovine proteins in exempt vector systems. **APPROVED (no objections)**

- **Protein sciences.** This involves research with proteins previously reviewed within the Biotech pipeline or in commercial products. Arguably, this activity is

captured via the LEADS database, but in any event there was no identified concern. **APPROVED (no objections).**

(original applicant, now off project) / -

Development of Cell Based Bioassay. This is an application pending from the prior rDNA process. The chair and other members of the group were not able to recall sufficient details to fully understand the information provided in the application. The nature of the research does not raise any concerns regarding approval (in fact, notification only would be required). Nonetheless, the committee felt that a better understanding of the project was appropriate on general principle. The project team will be invited to the next rDNA Committee meeting so that the committee can be further enlightened. No action is necessary in the interim. **DEFERRED to next meeting. / No action required by investigators.**

The committee voted to have all non-Biotech Organization approvals (assuming all Biotech rDNA work captured in LEADS) brought to the committee by the investigators to facilitate understanding and discussion. The committee agreed that the chair should exercise discretion in this regard, and that it might not be necessary to bring an investigator in for projects that we already understand or projects that are very simple, etc.

5) Other items:

- Representation to the rDNA committee was discussed and determined to be appropriate at this time.

- Committee wishes to get additional information regarding safety assessment of Chair will undertake to arrange same.

- A committee of all Monsanto IBC chairs should be created to facilitate communications among IBC/rDNA committees. The chair noted that this was previously undertaken, but served no purpose until the St. Louis rDNA process could be established. Chair will now re-institute this effort.

- <1 item redacted>

- It was suggested that the rDNA committee should further review genes moving to stage 2 of research (i.e. – moving into potential commercial development).This is a small number of genes each year and would not be burdensome. It is not clear what the rDNA committee would do at that juncture, as the NIH Guideline issues would have been addressed previously. Nonetheless, it would be good for us to understand which genes are moving ahead, and will take responsibility for letting us know when a gene moves to stage-2.

- <1 item redacted>

MINUTES

Monsanto St. Louis Recombinant DNA Committee (IBC)

Monday, March 8, 2004
D-Building, Adventure Room

Members in attendance: Daniel Goldstein (Chair) , ---------- (Legal Counsel) , ---------- (Community Member),---------- (Community Member), Donn Cahill (Biosafety Officer), ----------, ----------, ----------l, ----------.

Also in attendance: ----------, representing the Biotechnology research organization in reference to improvements in the application process.

Documents incorporated by reference:

1) Agenda
2) List of projects for IBC review / approval
3) Roster of current IBC membership
4) Gene Shuffling slide deck

The meeting was convened by the Chair at approximately 9:05 AM.

Agenda Item-1: Greetings and general update.

Roundtable introductions were done, and the group updated on the status of the IBC and reporting to NIH. Specifically, the Chair would prepare the annual report to the NIH as required. The IBC is now fully functional, with nine applications to be reviewed at this meeting. Improvements are clearly needed at this time in the application process to accommodate the structure of the research organization and to improve efficiency.

The general issue of "exempt" experiments was discussed. Because of the relatively small number of applications and the need to tie in to biosafety evaluations independent of the status of rDNA activity, the chair has generally brought all applications to the IBC for review, even if technically exempt. The group agreed that this practice was reasonable and should continue.

Agenda item- 2: Review of IBC Structure / Membership

The chair requested input from the group regarding any needed changes is structure or representation as a result of any changes within the Biotechnology Organization. The chair was not aware of any changes, and this was essentially confirmed by the members in attendance. Julia O'Neil indicated that her BST research is now formally part of the Chemistry organization

following elimination of the Dairy and MPT groups as a separate business operation. As Julia represents her group to the IBC, no actual changes in representation are necessary as a result of this reorganization.

Agenda Items 3 and 8- ---------- and Education Content of Meetings

A brief presentation on ---------- was presented by the chair as a new technology which is becoming increasingly important to Monsanto----------
---

----------It appears that NIH RAC discussed ---------- in the minutes of the Decmber 1997 meeting, but no further information was available on the website or on discussion with Allan Shipp of the NIH OBA Outreach office.

Discussion ensued regarding the impact of ---------- on the designated "source" of genetic material and whether the use of ---------- per-se would have an effect on the IBC process. It was noted that novel products with unanticipated properties could be created during the ---------- process. However, the guidelines would impose appropriate practices on these uncharacterized genetic elements. Particular care should probably be taken regarding destruction of otherwise uncharacterized elements which are not selected for further research in the screening process. Those genetic elements selected by the process will presumably have a well characterized function and activity and can be managed accordingly.

It was also noted that the existing gene inserts had a number of characteristics that had made the "gene source" issue relatively less important over time. Specifically, many of our inserts contain (at least for research purposes- not necessarily in commercial events) a range of genes and regulatory elements from plants, bacteria, fungi, and occasionally even mammalian species (MPT or for research purposes). Plant regulatory sequences, plant introns, and codon optimization are essential for efficient plant gene function and thus are going to be present in most experiments involving plants.

Overall, the group concluded that ---------- probably did not represent anything which was terribly unique relative to existing gene insert practices, particularly for plant experiments. In these latter experiments, gene source is usually multiple and mixed for a complete functional genetic element and is further varied when a multi-enzyme pathway is inserted. In effect, gene source is still considered, but other factors relating to gene product and gene product function are much more relevant to hazard determination and appropriate biosafety practice.

The group determined that educational content of a similar nature- relevant to IBC issues and technically sophisticated enough to be of use to the majority of members- would be of benefit. The chair agreed to look for appropriate content for future meetings and to poll the membership in regards to interest in a particular topic or topics.

Agenda Item- 4:---------- <Item redacted>

Agenda Item-5: Approval of projects.

A list of projects (attached) was circulated in advance of the meeting. This was done in place of transmitting the complete applications, as we are currently operating with a very long application form and without electronic submission for most applications. Additional information was available to members on request and full applications were brought to the meeting.

Members indicated that they had reviewed the applications. Highlights were pointed out by the Chair including the existence of one renewal which was large-scale (> 10 L), but is a longstanding project. No additional information was desired by the members.

The attached list of proposals was approved by the group without objection from any of the members present. The chair will undertake the appropriate notifications to investigators.

Agenda Item-6: Application Process.

Several months ago, the Chair and Biosafety officer met with members of the Biotech research organization to discuss the application process. Steve Padget and the committee were extremely supportive of IBC efforts, but did raise questions regarding the application process as it relates to current research activity. In the past, we have worked on a project-by-project basis, but at that time the IBC was predominantly dealing with pharmaceutical issues due to the large number of pharmaceutical projects and the fact that most plant projects use standard transformation techniques and genes of low concern, whereas some pharmaceutical projects raised more complex issues. At this time, we are almost exclusively dealing with agricultural plant transformation and related discovery and sequencing activity. Further, the research organization has changed structure so that plant transformations are now usually done in a species-specific facility using standard techniques- i.e.----------. As a result, the vast majority of projects cross over to multiple sites. Further, the investigators doing (for example) gene discovery or trait development do not always have direct access to the IBC information requested regarding the transformation, and should not have to use their time digging out mundane details such as the room numbers where transformation takes place. Such information would also be redundant. It was suggested that research group management might be the appropriate place to locate line responsibility for IBC applications. The IBC chair also suggested that the form could be modified to allow researchers to simply indicate that they are using the standard transformation facilities. The Chair and Biosafety Officer could take the responsibility for fully understanding the standard transformation vectors, lab safety practices, etc. ---------- requested that ---------- work with the biotech organization to propose a better application process.

---------- presented the results of her efforts to the IBC. She suggested that we should identify research functional units consistent with the organizational structure of the biotech research organization, and that the leadership of these functional units be responsible for IBC applications within their group. These groups would largely correspond to the structure of the Biotech research organization, but groups could be defined in other ways. (As noted above, BST

research is now part of the Chemistry organization, but could nonetheless constitute a functional group. The leaders of these groups would have line responsibility to assure applications from within the group structure regarding their specific activity. Corn transformation, for example, is a separate group. They would report on all activity in the corn transformation lab. A gene discovery group would report their activity on site as well, but not the activity in the transformation lab. The application could be modified to allow people to indicate the source and destination of the materials across the plant transformation process (a sample form was shown) so that, for instance, a project involving gene discovery, followed by corn transformation in the standard facility ----------, followed by return of materials to the original investigator for study, could indicate as much on the form. The person filling out the form would, however, only be responsible for reporting the details of the work they are doing within their group and would not need to report details on the ---------- transformation lab, which would report separately.

Pros and cons were discussed at length:

Concern was expressed that this might not meet the definition of a principle investigator (PI) in the NIH guidelines. However, the guidelines do not formally define the research role of the PI. Rather, they require that the PI assume certain responsibility for work they are conducting. The NIH guidelines do not appear to preclude this structure.

There is an advantage to this approach in that it creates an administrative line responsibility not present in our earlier attempts to go directly to the PI. Further, while the structure of the organization changes, the business organization chart always allows us to identify all group leaders. The same cannot be said of PI's, who also change frequently, but in a way that is harder to track. Without the functional group leader's involvement, the IBC has no way to track PIs and has no administrative authority or system to assure compliance.

Another advantage is the fact that this approach is a function-by-function and location-related approach which corresponds much better with the other site Biosafety activities and allows IBC and Site Biosafety to track activity in parallel. The "functional unit" approach can be just as easily applied to biosafety issues beyond rDNA and can be used to track groups needing blood borne pathogens training, handling animals, using non-recombinant pathogens, etc., etc. Further, this keeps the St. Louis IBC disentangled from other IBC's at the other sites- we can oversee the work here, but if a soy project is using the lab at ----------, the transformation work should rightly fall under the ---------- IBC.

Discussion ensued about whether we would get too many or too few applications or could miss applications under this system. It appears that the number of applications needed is not likely to change. It was clarified that we did NOT expect a single IBC application per functional group- on the contrary, this is to be determined within the group. ———————————

———————————

———————————

One concern is that some labs (corn transformation) may not be able to totally predict in advance the nature of the genes being used. This would be captured for genes coming from our site (presumably), but not from other sites. It will be necessary to periodically check (perhaps

every 30-60 days) with a group of this type to be sure that no genes are being used that would trigger unusual concerns (toxins, etc.). Fortunately, given the nature of our work, this is highly unlikely. We are aware of no such projects now and do not anticipate them in the future, but should verify this periodically in any event.

The consensus of the group was that this was a reasonable approach. ---------- will present this plan to ---------- and the biotech research organization shortly to obtain their buy-in. The chair and biosafety officer are already working on application changes and will pursue the necessary organizational (files, notifications, etc.) necessary to implement this plan if approved.

Agenda Item-7: Proposed Name Change.

The Chair related the experience he has had in training research groups. It has been impossible to clearly distinguish the IBC from the Site Biosafety Committee, and it is apparent that we need to change the name of the committees in such a way as to reflect their purpose and function. Since the site biosafety committee appears to be properly named, the chair proposed changing the name to the "Recombinant DNA Committee". This would not only serve to clarify the role of the committee with investigators, but would help with the business folks as well. There has long been a perception that the IBC evaluates all aspects of product suitability and long term safety for biotechnology products. This has never been the case, nor should it be the case, as we approve many things for research purposes which would not be appropriate for commercial development. These other aspects of stewardship are thoroughly addressed in other committees and are not part of the IBC mandate.

---------- pointed out the need for external clarity and suggested that the "IBC" name be retained as a parenthetical. Thus we would be formally known as the Recombinant DNA Committee (IBC). There was no opposition to this suggestion.

Agenda Item-8: Educational agenda- See Item 3, above.

Agenda Item-5: Roundtable of issues

---------- indicated that the University of Missouri had an effort regarding agro-terrorism which was relevant to our activities and our security concerns. He offered to provide web-link information (action already completed).

No other items or issues were identified.

The meeting was adjourned at approximately 10:25 AM.

Signature: _____ Date: _____

Daniel A. Goldstein, M.D.
Chair, Monsanto St. Louis, IBC

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POSTMARK 11/1/07

October 31, 2006

Mr. Edward Hammond
The Sunshine Project
P.O. Box 41987
Austin, TX 78704

Dear Mr. Hammond;

We are in receipt of your letter of October 12, 2006 regarding the Monsanto Company, Mystic Campus. We refer you to the letter from Dr. Daniel Goldstein regarding the Monsanto, St. Louis facilities, submitted on April 28 in response to your earlier request. As you will note in the St. Louis IBC minutes provided, Monsanto is in the process of developing a coordinated multi-site gene review program. This process effectively covers activity at the Mystic site, and we have no separate minutes to provide to you relevant to the time frame of your inquiry.

In response to your specific question (in the March 2006 request) regarding a written policy for the "identification, review, and oversight" of "experiments of concern" identified in the NAS report, *Biotechnology Research in an Age of Terrorism*, we would reply (as per Dr. Goldstein's letter, which is relevant to all Monsanto sites) as follows:

> Monsanto is engaged primarily in the development of plants with improved agronomic and nutritional characteristics. We do not presently engage in experimentation which would fall into the any of the seven categories of concern raised in the report. Further, there is no reason to believe that such an experiment would ever be necessary in pursuit of our business goals. Given that we do not engage in any such activity, and do not anticipate any reason to do so in the foreseeable future, we have not put in place a specific written policy to deal with this issue. However, our policy regarding IBC review and our new IBC process using internal databases, provides excellent assurances that any such activity would come to the attention of the IBC.

Monsanto does not charge for the preparation, copying, or transmission of this material, nor have we ever required that a FOIA request be submitted in order to obtain this material. We would further note that Monsanto research is not federally funded, and that Monsanto's compliance with the NIH guidelines is entirely voluntary in nature.

Sincerely,

T. Michael Spencer
Project Lead and IBC Chairman
Monsanto – Mystic Research
62 Maritime Drive
Mystic, CT 06355

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November 16, 2006

Mr. Edward Hammond
The Sunshine Project
1920 Stuart Street
Berkeley, CA 94703

Dear Mr. Hammond,

We are in receipt of your letter of October 12, 2006, regarding the Monsanto Company, Agracetus Campus. Minutes of the relevant meetings are attached. We would also refer you to the letter from Dr. Daniel Goldstein regarding the Monsanto, St. Louis facilities, submitted on April 28 in response to your earlier request.

In response to your specific question (in the March 2006 request) regarding a written policy for the "identification, review, and oversight" of "experiments of concern" identified in the NAS report, *Biotechnology Research in an Age of Terrorism*, we would reply (as per Dr. Goldstein's letter, which is relevant to all Monsanto sites) as follows:

> Monsanto is engaged primarily in the development of plants with improved agronomic and nutritional characteristics. We do not presently engage in experimentation which would fall into the any of the seven categories of concern raised in the report. Further, there is no reason to believe that such an experiment would ever be necessary in pursuit of our business goals. Given that we do not engage in any such activity, and do not anticipate any reason to do so in the foreseeable future, we have not put in place a specific written policy to deal with this issue. However, our policy regarding IBC review and our new IBC process using internal databases, provides excellent assurances that any such activity would come to the attention of the IBC.

In passing, we would note that Monsanto does not charge for the preparation, copying, or transmission of this material, nor have we ever required that a FOIA request be submitted in order to obtain this material. We would further note that Monsanto research is not federally funded, and that Monsanto's compliance with the NIH guidelines is entirely voluntary in nature.

Sincerely,

David A. Somers, Ph.D.
Site Director

das/kls

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING

Thursday, June 26, 2003
3:00 pm
Room 204

MEETING MINUTES

Committee Members Present:
Chair:
Vice Chair:
Agracetus Members:

Community Members:
Guest:
Minutes:

1. **Review of March 27, 2003, Meeting Minutes and Action Items**
   - **1.1.** Motion by [redacted] second by [redacted] to approve meeting minutes.
   - **1.4.** Minutes were amended to reflect the change in the meeting date from June 19 to June 26.
2. **Review Status of New Recombinant Proposals**
   - **2.1.** **Biosafety Review 416: PI –** [redacted]
     Motion by [redacted] second by [redacted] approval by committee, to approve as submitted with the following contingencies:
     - **2.1.1.** On page 1, number 1; indicate that the project had been reviewed previously as BRF 390.
     - **2.1.2.** On page 6, number 2; indicate whether or not each element in the table is a known allergen/toxin.
3. **Review Status of New Movement Permits – None to review**
4. **Other Business**
   - **4.1.** Discussion regarding what should be done with viable seed stored at Agracetus when a project has been retired (question from [redacted] in MPT). [redacted] will bring this issue up at the monthly Ag Biotech Safety teleconference and get back to us with a cross-site recommendation.
   - **4.2.** [redacted] will email to the committee members a draft of the Biosafety Guidelines for working with recombinant organisms. IBC members should review and return the document to [redacted] by mid-July so that it can be included in the ESH Manual.
5. **Adjournment**
   Motion by [redacted] second by [redacted] to adjourn at 3:45 p.m.

Action items:
[redacted]

2. [redacted] will forward a recommendation to be used by all the sites for seed archival/disposal when a project has been discontinued.

3. [redacted] will email a draft of the Biosafety Guidelines to committee members and they should send their edits/comments to [redacted] by mid-July.

Please mark your calendars for the remaining IBC meetings in 2003:
Thursday, September 18, 3-4:30, room 204
Thursday, December 18, 3-4:30, room 204

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING

Thursday, September 18, 2003
3:00 pm
Room 204

MEETING MINUTES

Committee Members Present:
Chair:
Vice Chair:
Agracetus Members:

Community Members:
Absent:
Minutes:

1. **Review of June 26, 2003, Meeting Minutes and Action Items**
   1.1. Motion by , second by to approve meeting minutes.

   Action item: will forward a recommendation to be used for seed archival/disposal when a project has been discontinued.

2. **Review Status of New Recombinant Proposals**
   Biosafety Review 417: PI –

   2.1.3.

   2.2. **Biosafety Review 425: PI –**
   Motion by second by approval by committee, to approve as submitted with the following contingencies:
   2.2.1. On page 1, number 1; change the Project Title to make it more descriptive.
   2.2.2. On page 1, number 3; under Molecular Sciences personnel, add and change title to Client Vectors Lead.
   2.2.3. On page 7, number 4A; change wording to "some plants *may* later be grown…"

   2.3. **Biosafety Review 426: PI –**
   Motion by second by , approval by committee, to approve as submitted with the following contingencies:
   2.3.1. On page 1, number 1; change the Project Title to make it more descriptive.

2.3.2. On page 1, number 3; under Molecular Sciences personnel, add [redacted] and change [redacted] title to Client Vectors Lead.

2.3.3. On page 7, number 4A; change wording to "some plants *may* later be grown..."

2.4. Biosafety Review 427: PI – [redacted]

Motion by [redacted] second by [redacted] approval by committee, to approve as submitted with the following contingencies:

2.4.1. On page 1, number 1; change the Project Title to make it more descriptive.

2.4.2. On page 1, number 3; under Molecular Sciences personnel, add [redacted] and change [redacted] title to Client Vectors Lead.

2.4.3. On page 2, number 8; check "human-derived materials..." and complete section C on page 10.

2.4.4. On page 7, number 4A; change wording to "some plants *may* later be grown..."

2.4.5. On page 7, number 5A; verify the number of plants expected.

[redacted]

2.4.8. On page 16, section L, number 8; add an explanation on screening for ectopic expression.

3. Review Status of New Movement Permits

3.1. Permits 418, 419, 420, 421, and 423

[redacted]

4. Other Business – None

5. Adjournment

Motion by [redacted] second by [redacted] to adjourn.

Action items (from 6/2003 meeting):

1. [redacted] will add the *Agrobacterium* use Best Practices Document to the ESH Manual that is available on the Agracetus intranet site.

[redacted]

Please mark your calendars for the remaining IBC meeting in 2003:

Thursday, December 18, 3-4:30, room 204

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING

Thursday, March 18, 2004
3:00 pm
Room 204

MEETING MINUTES

Committee Members Present:
Chair:
Vice Chair:
Agracetus Members:
Community Members:
Minutes:

1. **Review of September 18, 2003, Meeting Minutes and Action Items**
   1.1. Motion by [redacted] second by [redacted] to approve meeting minutes.
   [redacted] Action item: [redacted]
2. **Review Status of New Recombinant Proposals**
   [redacted] **Biosafety Review 428: PI –** [redacted]
   Motion by [redacted] second by [redacted] approval by committee, to approve as submitted.
   2.2. **Biosafety Review 429: PI –** [redacted]
   This proposal was not approved and will be reviewed at the next committee meeting.
      2.2.1. On page 1, number 1; under, "Has this project been previously reviewed by a Monsanto Biosafety Committee?" change to No. [redacted] has been reviewed before in St. Louis, but [redacted] has not been reviewed.
      2.2.2. [redacted] will follow up with [redacted] (at Calgene) to get allergen/toxin information for this proposal.
   2.3. **For Future Biosafety Reviews:**
      2.3.1. Add "Not Applicable" to the sections that are not relevant to the proposal so they will be easier to read.
3. **Other Business**
   3.1. **Sunshine Project**
      3.1.1. On January 30, the Sunshine Project formally requested the minutes from our last two IBC meetings. They are a non-profit group of scientists based in Germany that is trying to ensure that biotechnology is not being used to create biological weapons. (Ninety percent of all IBCs in the U.S. have received this request.) Dan Goldstein, the head of Monsanto's IBC, is working with Monsanto's legal group to coordinate a response for all sites.
   3.2. **MPT Shutdown**
      3.2.1. There is one remaining permit covering movement of seed to St. Louis.

3.2.2. All old MPT permits and proposals will be officially retired at the next IBC meeting.

4. Adjournment

Motion by [redacted] second by [redacted] to adjourn.

Action item:

[redacted]

Please mark your calendars for the remaining IBC meetings in 2004:
(3:00-4:30, room 204)
Thursday, June 17
Thursday, September 16
Thursday, December 16

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING
Thursday, June 17, 2004
3:00 pm
Room 204

MEETING MINUTES

Committee Members Present:
Chair:
Vice Chair:
Agracetus Members:
Community Members:
Committee Members Absent:
Minutes:

1. **Review of March 18, 2004, Meeting Minutes and Action Items**
   1.1. Motion by [redacted] second by [redacted] to approve meeting minutes. [redacted]
   1.3. Action item: The committee reviewed recombinant proposal #429 that was deferred from the last meeting in March. [redacted] provided an email statement from Dan Goldstein, Chair of the Monsanto IBC, that there is no safety concern regarding the two genes in this proposal [redacted]. Motion by [redacted] second by [redacted] to approve.
   1.4. Action item: Motion by [redacted] second by [redacted] to retire the following MPT proposals: 260, 268, 270, 382, 397, 408, 409, 413, 415, 416, 417, 425, 426, 427; and MPT permits: 206, 207, 208, 211, 212, 214, 216, 217, 224, 225, 226, 232, 234, 237, 238, 240, 255, 257, 274, 275, 309, 311, 312, 323, 324, 325, 326, 337, 339, 340, 341,342, 343, 344, 356, 357, 359, 360, 368, 371, 375, 386, 389, 395, 403, 422.
2. **Review Status of New Recombinant Proposals**
   2.1. **Biosafety Review 430: PI –** [redacted] attended the meeting in [redacted] absence and explained that this is a modification of a proposal that was approved by the Monsanto IBC on March 8, 2004. Two additional strains were added to the proposal as well as language specifying the need for more rigorous containment of the two strains (because they are not fully disarmed). Motion by [redacted] second by [redacted] approval by committee, to approve as submitted with the following contingencies:
      2.1.1. On page 6, number 6, item A; rephrase to include the other strain.
      2.1.2. On page 10, section G, number 1; include all of the strains from the original proposal.
      2.1.3. On page 11, number 3, item D; include the first two paragraphs from the same section of the original proposal, but do not include the third paragraph referring to future plans of using the new strains.
3. **Review Status of New Field Test/Movement Permits**
   [redacted]

[redacted]

4. **Update on the Sunshine Project**

4.1. [redacted] distributed a memo from the NIH Office of Biotechnology Activities that addresses the preparation of, and public access to, minutes of IBC meetings. This is in response to the request from the Sunshine Project for IBC meeting minutes. [redacted] and [redacted] will review our IBC meeting minutes from June 2003 to the present and remove committee members' names and confidential business information. They will then send them in Word Revision Mode to Dan Goldstein (Monsanto IBC Chair).

5. **Adjournment**

Motion by [redacted] second by [redacted] to adjourn.

Action item:

1. [redacted] and [redacted] will review the IBC minutes from June 2003 to the present and forward to Dan Goldstein.

Please mark your calendars for the remaining IBC meetings in 2004:

(3:00-4:30, room 204)
Thursday, September 16
Thursday, December 16

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING
Thursday, March 17, 2005
3:00 p.m.
Room 204

MEETING MINUTES

Committee Members Present:
Chair:
Vice Chair:
Agracetus Members:

Community Members:
Minutes:

1. **Review of June 17, 2004, Meeting Minutes and Action Items**
   - 1.1. Motion by [redacted] second by [redacted] to approve meeting minutes.
   - 1.2. Action item: [redacted] and [redacted] reviewed and sent the IBC meeting minutes from June 2003-June 2004 to Dan Goldstein at Monsanto in St. Louis.
2. **Review Status of New Recombinant Proposals**
   - 2.1. **Biosafety Review 443: PI –** [redacted]
     Reviewed a draft proposal from [redacted] "Production of transgenic plants with a [redacted]" After addressing [redacted] questions, the committee made the following recommendations for revision:
     - 2.1.1. On page 1, number 1; contact someone in St. Louis who is associated with the project to find out if it has been reviewed by the Monsanto IBC.
     - 2.1.2. On page 1, number 3; [redacted] should be listed as the only P.I. Add other personnel from Trait Development [redacted] and GAMA who are specifically working on the project. If there is not a specific person in GAMA, just list [redacted] as GAMA lead.
     - 2.1.3. On page 1, number 4; it is not necessary to list other sites.
     - 2.1.4. On page 2, number 6; needs more description since the goal and the process are not clear. Also needs to address segregation of materials and whether or not plants will be sprayed here.
     - 2.1.5. On page 2, number 7; answer should be No.
     - 2.1.6. On page 2, number 8; field tests should not be checked.
     - 2.1.7. On page 2, number 9; answer should be Yes, seed will be shipped for additional analysis.
     - 2.1.8. On page 4, number 15; Biohazard symbol should not be checked.
     - 2.1.9. On page 5, number 3; Do the strains listed pertain to this proposal?

     Dave Somers will discuss these and other changes with [redacted] An updated proposal will be sent to all committee members for approval.

[redacted]

[redacted]

4. **Annual Update of Committee Information to NIH**
   - 4.1. [redacted] will send updated committee information to NIH, which is requested annually. He will update chairman to Dave Somers and include Dave's c.v.
5. **Other Business**
   - 5.1. Both [redacted] and [redacted] would like their stipends for serving on the committee to be sent to the same charities as last year.
   - 5.2. For future meetings, it is important to send the documents to the committee members one week before the meeting so they have time to review.
   - 5.3. [redacted] will review the existing GFP proposal (#391) since when it was written it was not intended to go to seed in the greenhouse.
   - 5.4. The existing [redacted] proposal (#429) should either be updated to include the [redacted] project or a new proposal should be written to make sure all elements of the project are covered.
   - 5.5. [redacted] will review the existing Agro vector improvement proposal (#430) to be certain all strains are covered.
6. **Adjournment**

Action item:

1. Dave Somers will review the new [redacted] proposal with [redacted] to finalize for submission to the committee.
2. [redacted] will review the GFP proposal (391).
3. [redacted] will review the Agro proposal (430).

Please mark your calendars for the IBC meetings in 2005:

(3:00-4:30, room 204)
Thursday, June 16
Thursday, September 15
Thursday, December 15

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING

Thursday, March 16, 2006
3:00 p.m.
Room 204

MEETING MINUTES

Committee Members Present:
Chair:
Vice-Chair:
Agracetus Members:
Community Members:
Committee Members Absent:
Minutes:

1. **Review of March 17, 2005, Meeting Minutes and Action Items**
   - 1.1. Motion by , second by , to approve meeting minutes.
   - 1.2. Action item: will review the new proposal (443) with to finalize for submission to the committee. Complete: proposal was reviewed by and received committee approval via email in July 2005.
   - 1.3. Action item: will review the GFP proposal (391). Complete: proposal was reviewed by and resubmitted as a new proposal (447) at today's meeting.
   - 1.4. Action item: will review the existing Agro vector improvement proposal (430). Complete: proposal was reviewed by and resubmitted as a new proposal (445) at today's meeting.
2. **Review Status of New Recombinant Proposals**
   - 2.1. **Biosafety Review 444: PI –** requested that this proposal be "tabled" until further consideration can be given to the materials which will be used for the outreach program. Motion by , second by , abstention by approval by committee, to review this proposal at a later date.

   Biosafety Review 445: PI –
   Motion by second by , approval by committee, to approve as submitted with the following revisions:
   - 2.2.1. On page 4, number 15; leave the "Biohazard" statement blank.
   - 2.2.2. On page 5, B.1; change statement to read, "None, except for the plant virus CAMV 35S and FMV promoter elements" and move from B.1 to B (Viral rDNA).
   - 2.2.3. On page 5, C and D; move "None" to top line.
   - 2.2.4. On page 10, section F, number 1A; list as, "Nicotiana tabacum, Glycine max, Gossypium hirsutum, Zea mays, and Brassica sp."
   - 2.2.5. On page 10, section F, number 1B; change to "Yes."
   - 2.2.6. On page 10, section F, number 1D; change to "Yes."
   - 2.2.7. On page 10, section F, number 1E; change to "No."
   - 2.2.8. On page 11, section G, number 1.A.2; add "Wisconsin" after Madison.

2.2.9. On page 12, section G, number 3D; change the wording to clarify what strains are disarmed.

[redacted] **Biosafety Review 446: PI –** [redacted]
Motion by [redacted] second by [redacted], approval by committee, to get revisions on proposals 445 and 446 and email to committee members for their approval.

2.3.1. On page 4, number 15; leave the "Biohazard" statement blank.
2.3.2. On page 5, B, C, D; add "None" to each section.
2.3.3. On page 5, number 3; change to, "Production of selectable marker-free plants."
2.3.4. On page 1, number 1; add Y (for yes), has been previously reviewed.
2.3.5. On page 9, section F, number 1; list as, "Glycine max, Gossypium hirsutum, Zea mays, and Brassica sp."
2.3.6. On page 11, section G, number 1; change to, "Agrobacterium tumefaciens A. rhizogenes: Rhizobium sp."

2.4. **Biosafety Review 447: PI –** [redacted]
Motion by [redacted], second by [redacted], approval by committee, to get revisions on this proposal and email to committee members for their approval.

2.4.1. On page 5, B, C, D; add "None" to each section.
2.4.2. On page 5, number 3; change to "GFP-expressing plants."
2.4.3. On page 9, section F, 1A; list as, "Glycine max, Gossypium hirsutum, Zea mays, and Brassica sp."
2.4.4. On page 9, section F, 1B; leave as Yes. Dave will check with Dan Goldstein from Monsanto's IBC about rephrasing this question.
2.4.5. On page 1, number 1; circle Y (for yes), has been previously reviewed.

2.5. **Biosafety Review 448: PI –** [redacted]
Motion by [redacted] second by [redacted] approval by committee, to approve as submitted with the following revisions:

2.5.1. On page 4, number 15, leave the "Biohazard" statement blank.
2.5.2. On page 11, section F; revise to include cotton or create a new proposal for cotton.

3. **Other Business**

3.1. Motion by [redacted] second by [redacted] approval by committee, to accept [redacted] as a new member of the committee. [redacted] will send a committee member update to the NIH.

[redacted]

4. **Adjournment**
Motion by [redacted] second by [redacted] to adjourn the meeting.

Action items:

1. [redacted] will contact Dan Goldstein about possibly changing the biosafety review form to rephrase the question regarding Presence of transposable elements (Section F, number 1B).
2. [redacted] will send IBC member update to the NIH.

[redacted]

[redacted]

Potential IBC meetings in 2006:
(3:00 p.m., room 204)
Thursday, June 15
Thursday, September 21
Thursday, December 21