Meeting Report page

Final Session and Executive summary: 9 November 2006.

1. Most participants considered the Workshop useful and valuable for professional networking and discussion of contemporary regulatory and risk assessment issues for symbiotic control/paratransgenesis, genetically engineered insects, *Wolbachia*, and microbial pesticides. Some considered it even necessary and should be repeated on a regular basis. A frequency of every-other-year was suggested.

2. Regulatory agencies provide good advice on permit registration applications on their websites and individually; however, it is important to identify appropriate and knowledgeable people within each agency.

3. The inertia of the Federal website approval process prevents rapid editing and updates. Institutional Biosafety personnel and others have difficulty getting information from Federal websites.

4. APHIS receives 400 phone calls a day about permits for movement of organisms, primarily commercial requests, which detracts from actually writing the permits. Freely available guidance would relieve some of this burden.

5. It was agreed that a neutral outlet such as the website from this Workshop would help provide non-binding guidance that would avoid some of the inertia mentioned above.

6. The REBECA [http://www.rebeca-net.de/] approach (Regulation of Biological Control Agents) adopted in Europe was suggested as a good model to follow.

7. To improve communication, advertisements could be taken out in Newsletters of pertinent Societies giving guidance and suggestions for applications. These would be most useful if they provided contact and resource information including websites and the telephone numbers of knowledgeable persons who serve as ombudsmen. Biotechnology is a truly interdisciplinary endeavor. Natural divisions between scientific fields and therefore societies complicate communication.

8. The IR-4 website has good `links to information for permit and grant seekers including applicants from Canada.` The IR-4 program is limited in its resources, funding, and scope or areas where it may provide assistance. An expanded IR-4 program would have increased value for the regulatory requirements of small-market biotechnology products for which large multinational companies have insufficient economic incentive to pay for regulatory requirements and processes.

[http://ir4.rutgers.edu/biopesticides/RWP/]

9. e-Permits is a new initiative that might speed the regulatory process. Potential users must obtain passwords and register to use e-Permits.

10. Georgia Folley was hired recently by APHIS as a Communication Specialist to assist in information exchange between the agency and user groups (stakeholders).

11. Mary Purcell-Miramontes announced that CSREES is discussing new ways to enhance networking activities, which could potentially facilitate improved communication between the research community and regulatory agencies.

12. Boards of review or Ombudsman positions were raised several times by participants as mechanisms to improve communication.

13. Brian Belliveau of Health Canada said Environment Canada has a "Regulatory Roadmap" very useful to applicants and is a good model.

    [http://199.212.18.76/substances/nsb/pdf/roadmap_e.pdf]

    BPIA is a membership organization for which subscription may be necessary to obtain detailed regulatory information. EPA, BPPD provides a contact list of many pesticide regulatory consultants on their website who are available to assist in the EPA registration process.

14. New issues occur periodically that should be brought to the attention of stakeholders. Michael Firko mentioned that the Office of Science and Technology Policy suggested recently that equipment that synthesizes nucleotide sequences should be regulated. This would be difficult to implement by a Federal agency due to lack of, or inadequate, congressionally issued statutory authority, laws, or Acts and if the equipment has other laboratory applications. Bill Schneider mentioned that EPA has an exemption that names devices pesticides. Exemptions from regulations are important to announce.

15. Pamela Marrone and others mentioned that BPIA (Biopesticide Industry Alliance) provides valuable assistance to companies seeking registrations.

    [http://www.biopesticideindustryalliance.org/html/home.htm]

16. Frank Richards suggested that a single committee (perhaps a Virtual Committee) composed of members of several relevant Regulatory Agencies would act as a clearing house for all new biotechnology applications. Such a de facto pre-application process would steer new applications to the relevant agencies, co-ordinate safety requirements of several different agencies and suggest appropriate safety studies acceptable to the relevant Regulatory Agencies. This would reduce uncertainty about applicable regulations and probably decrease the time and expense of certification.

17. Bob Rose made one final comment after the meeting adjourned. He said the University of California Washington Center at 1608 Rhode Island Avenue, NW, Washington DC 20036 [http://www.ucdc.edu/] is neutral "turf" valuable for discussing interagency issues such as jurisdiction of a regulated article. The Center is, in fact, an educational institution, part of the University of California. Its use must be approved by the director, who is open to suggestions.

These points are a compilation of comments at the final discussion session and the Executive session held after the meeting adjourned. Executive Session attendance:

Brian Belliveau
Michael Braverman
Michael Firko
Phil Hutton
Tom Miller
Mary Purcell-Miramontes
Frank Richards
Bob Rose
Bill Schneider
Anne Vidaver

This executive summary was drafted by Tom Miller and circulated to the list of people above and the Steering Committee members for comment and correction.

Comments from Bill Schneider 14 Nov 06:

2. Regulatory agencies in the US Federal government have difficulty advising the public how to apply for permits and registrations without triggering laws against favoritism.

Not sure what this refers to. We don't have difficulties in providing printed or internet information or in giving direct advice to the public on this subject - we do it all the time. Maybe this refers to the comments on not being able to recommend specific commercial consultants because of ethical considerations. I don't know if this common-sense restriction is actually in a law or just in ethical guidance documents.

6. The REBECA [http://www.rebeca-net.de/] approach project (Regulation of Biological Control Agents) adopted in Europe was suggested as a good model to follow.

REBECA isn't exactly an "approach" that was adopted. It is a EU-funded project to make recommendations on how to improve their biological control and botanical pesticide regulatory process. Changes in red above might be more accurate.

14. New issues occur periodically that should be brought to the

attention of stakeholders. Michael Firko mentioned that the Office of Science and Technology Policy suggested recently that equipment that synthesizes nucleotide sequences should be regulated. Bill Schneider mentioned that EPA has an exemption in their pesticide regulations that names removes most regulatory requirements for pesticidal devices pesticides. Exemptions from regulations are important to announce.

One of our exemptions is for devices so perhaps there was a typo in this sentence.

Bill

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