BSCC ADDRESSES SCOPE OF OVERSIGHT

WASHINGTON, D.C.—A revamped federal Biotechnology Science Coordinating Committee (BSCC), fighting an uphill battle to restore its credibility, is trying to settle critical biotechnology oversight issues. As part of this process, in early February the committee seemed ready to propose a revised and carefully clarified definition of "scope" for determining what organisms should be scrutinized before being released for field testing.

The scope issue is far from settled, however, as the unpublished BSCC definition still being considered by officials from several federal agencies also awaits public airing, and thus is assured of criticism from several corners—and likely further revision. Meanwhile, two key federal agencies represented on the BSCC, the Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA), still have not published their own long-promised proposed rules and guidelines for evaluating field tests of genetically engineered organisms.

BSCC has come under fire in recent months. At an open session late in December, some critics recommended abolishing the committee. Created in 1985 by the President's Office of Science and Technology Policy (OSTP), BSCC was sharply criticized last year for losing its effectiveness and becoming too politicized (*Bio/Technology* **8**:13, Jan. '90). At the December meeting Margaret Mellon, director of the National Policy Center for Biotechnology at the National Wildlife Federation (Washington, DC), said "The BSCC should be dissolved, and a different entity created. The committee seems to have no purpose or substance." Instead of tackling the scientific and regulatory issues that "cut across agency lines," she adds, the "BSCC has been active behind the scenes trying to thwart EPA's rulemaking."

Recent steps toward reform, such as excluding high-level political appointees from working meetings, could help to reduce political pressure on the BSCC, notes one close observer. And Luther Williams of the National Science Foundation (NSF, Washington, DC), who recently became chairman of the committee, thinks that the recent criticisms perhaps can be used as "stimuli...to help make BSCC a more active body." Williams envisions the committee meeting in open sessions "if we want a broad array of inputs to synthesize current views" or when a "specific goal or instance...is substantial" and public meetings would prove valuable. Outsiders would be invited "to participate, not just observe," he notes. "But," he adds, a BSCC meeting still "can be closed if we need it to be."

The scope of regulations remains the central and most controversial biotechnology issue for officials from EPA, USDA, and other agencies on the BSCC to address. A BSCC subcommittee, chaired by USDA Assistant Secretary for Science and Education Charles Hess, recommended last year that, apart from six broad categories of exceptions, all organisms "deliberately modified by the introduction into or manipulation of genetic material" should be subject to regulatory oversight. Besides objections from several BSCC representatives, members of the EPA Biotechnology Science Advisory Committee (BSAC), which met in December, and of the Agriculture Biotechnology Research Advisory Committee (ABRAC), which met in January, criticized several of the exemption categories for being too vague and subjective.

The new BSCC proposal (see box) adds a great deal of explanatory material to the draft definition of scope. "Familiarity" with a genetically modified organism, for example, remains part of a proposed broad exemption from oversight. But the new draft interprets the term in a footnote: while not "necessarily" implying safety, it suggests that "enough information...to judge" the degree of risk exists. Members of the EPA and ABRAC advisory panels, along with other federal officials, recommend such refinements to avoid repetitive regulatory reviews, particularly in cases where "existing oversight mechanisms [are] adequate."

—Jeffrey L. Fox

ORGANISMS PROPOSED TO BE EXEMPT FROM REGULATION

The earlier version of the scope regulations encompassed "Organisms deliberately modified by the introduction into or manipulation of genetic material in their genomes," with the following exceptions:

1. Plants and animals that result from natural reproduction or from the use of familiar, traditional breeding techniques such as hand pollination of plants, and artificial insemination, superovulation, and transfer of embryos in animals.
2. Microorganisms resulting solely from chemical and physical mutagenesis, transduction, transformation or conjugation by known physiological processes.
3. Plants regenerated from tissue culture, including those produced through selection of somaclonal variants or use of embryo rescue in plants.
4. Vascular plants that were developed from protoplast fusion of cells from vascular plants.
5. Organisms that have been modified by the introduction of non-coding nucleotide sequences and that serve only to mark the organism.
6. Organisms resulting from the use of new techniques of biotechnology (modification by the use of recombinant DNA or similar techniques) when the person responsible for the planned introduction into the environment can demonstrate that the resulting genotype could readily be produced or selected through the techniques listed in 1–5 above, and that there is sufficient familiarity with the genotype to predict no adverse effects on human health or the environment.

The revised BSCC draft encompasses:

"Organisms deliberately modified by the introduction of genetic material into, or manipulation of genetic material within, their genomes," but excludes:

1. Plants and animals that result from natural reproduction or the use of traditional breeding techniques. These include: for vascular plants, mutagenesis and hand pollination; and for vertebrate animals, artificial insemination, superovulation, and transfer of embryos.
2. Microorganisms modified solely: (a) through chemical or physical mutagenesis; (b) by the movement of nucleic acids using physiological processes including but not limited to transduction, transformation, or conjugation; or (c) by plasmid loss or spontaneous deletion. If nucleic acid molecules produced using *in vitro* manipulation are transferred using any of the techniques listed in (a) through (c), the resulting organisms do not fall under this exclusion.
3. Vascular plants regenerated from tissue culture, including those produced through selection of somaclonal variants, embryo rescue, protoplast fusion, or treatments that cause changes in chromosome number.
4. Organisms that have been modified by the introduction of non-coding, non-expressed nucleotide sequences that cause no phenotypic or physiological changes in the parental organism.
5. Organisms other than those exempted in 1–4 above, if it can be demonstrated that: (1) they could be readily produced by the techniques listed above; and (2) there is sufficient familiarity with the organism to foresee environmental effects equivalent to those associated with past safe introductions of similar organisms in similar target/test environments.