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THE FIRST WORD

CODIFYING COMMON SENSE

Now, *Bio/Technology* has published some 700 editorial pages in this volume alone. Six hundred of these consisted of news, feature, or research articles. (The remainder carried opinion, new products, tables of contents, and the like.) Of those 600 pages, three-quarters have by design covered topics of interest or utility to researchers, developers, and producers of pharmaceuticals. (More pages, we're proud to say, than any other publication in the field offers.)

Yet this column, and our other opinion columns, continue to deal disproportionately with the problems of free release of engineered microorganisms. Why is that? And why are we going to do it again?

Despite their variety, the industries dependent on biotechnologies do have critical areas of common interest. The commonality in the lab is obvious: the same tools and the same tasks feed product R&D across the spectrum, so the biotech industries should be expected to join together to support basic life-science research. And, in part because of that unity in the laboratory, the biotech industries are lumped together in the public perception; that gives drug-makers, seed-breeders, and others a common stake in laying the biotech *bête noir* to rest. Finally, in part because of public opinion, politicians in North American and Europe persist in lumping together all molecular manipulations of life.

Thus, whether or not genes can be transferred between species in the wild, there is obviously considerable cross-over of interest in free release among regulators and researchers.

Thus, among the authors of a recent article[1] proposing a new "algorithm" for regulating environmental-release experiments are an official of the U.S. Food and Drug Administration and a member of the Office of Recombinant DNA Activities of the U.S. National Institutes of Health.

The proposal seemed curiously light on first reading. At bottom, it posits that some release experiments are harmless, others should be prohibited, and some fall in between. And the authors suggest what seems like a ponderous mechanism for deciding which is which.

First, using a scale of 1 (no environmental concern) to 5 (for a known virulent pathogen), categorize unmodified wild-type organisms for their: pestiferousness or pathogenicity; hardiness in establishing themselves in new habitats; influence on other organisms sharing the same ecosystem; potential for genetic change; suitability for monitoring and control. From these, derive a composite figure for "overall level of concern."

Next, evaluate the proposed genetic manipulations, deciding whether they a) reduce the level of concern; b)leave it unchanged, or c) increase concern (and by how many levels). Then modify the overall level of concern accordingly.

Finally, the regulations would prescribe permissible combinations of level of concern, level of field confinement, and level of oversight (from *carte blanche* to institutional biosafety committee review to U.S. Department of Agriculture review to complete prohibition).

True, the paper appeared without the tables that form the heart of the proposal: long lists of wild-type organisms classified; matrices of overall concern levels yielded by specific manipulations on particular classes of parent strains; block diagrams of oversight levels appropriate to field confinement and level of concern. These tables do make the proposal clearer. But the very mass of the apparatus makes the modesty of the proposal even more obvious. It is nothing but a codification of common sense.

But then again, that is what so much regulation is all about: constructing cumbersome, sometimes absurd, reassuringly solid frameworks to contain events within the bounds common sense, that uncommon commodity, would naturally dictate.

—Douglas McCormick

1. Henry I. Miller (FDA), Robert H. Burris (U. Wisconsin), Anne K. Vidaver (U. Nebraska), and Nelson A. Wivel (NIH), 1990. "Risk-Based Oversight of Experiments in the Environment," *Science* **250**:490-491, 26 Oct.