



## International Genetic Engineering Campaign

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Background Information

01/00

### "MAN-MADE BACTERIA ON THE LOOSE"

In 1997, the United States Environmental Protection Agency (EPA) approved a genetically modified organism (GMO), a bacterium for agricultural use. The bacterium, a strain of the soil bacteria *Sinorhizobium meliloti*, was genetically modified in an attempt to increase its ability to fertilize alfalfa. After a slipshod review that was roundly criticized by the agency's scientific advisory committee and by scientists within the agency, EPA approved the product for release on millions of acres of farmland.

The U.S. government claims that its' regulation of biotechnology is based on "sound science" and is thus the tightest regulatory system in the world. Yet EPA approved the Rhizobia (dubbed RMBPC-2) despite the recommendation expressed by five of six members of its own Biotechnology Science Advisory Committee (BSAC), that the engineered bacteria should not be released without further information on the risks to human health and the environment. As it became clear that EPA was unwilling to take scientific concerns seriously, one member of the BSAC resigned, stating that the final report was "(L)ittle more than a long argument to support an affirmative decision already made before the subcommittee met."<sup>1</sup>

Shortly thereafter, EPA scientists released a whistleblower report blasting the approval process and EPA's lax attitude about the scientific risks of GMOs. "Overeager to promote biotechnology," the Public Employees for Environmental Responsibility (PEER) report states, "EPA has either deliberately ignored or actively suppressed concerns raised by staff and independent scientists."<sup>2</sup> PEER scientists suggested that the case of RMBPC-2 illustrates the pressure on EPA to promote biotechnology, pressure exemplified by the statement from then-Senator Al Gore: "A central purpose of any governmental effort in this area must be to encourage and facilitate the growth of biotechnology research, development and implementation."<sup>3</sup>

RMBPC-2 is produced today by the U.S. company Urbana Labs, who sells it under the name Dormal Plus as a soil inoculant for alfalfa growers. In addition to genes from five different species, RMBPC-2 also contains uncharacterized DNA sequences. It may be the only GMO approved without full knowledge of the genetic elements introduced. The PEER report states "Uncharacterized DNA is an issue because it raises uncertainties about the behavior and characteristics of the engineered organism when compared with the normal parent strain. Scientists are learning that, in microorganisms, even small amounts of DNA can code for very complicated functions."<sup>4</sup>

Scientists warned EPA that the engineered bacteria could spread in the environment, with the potential for enhancing the hardiness of certain weeds. They noted that the company conducted few field experiments, and most of the experiments submitted for review were done on an engineered strain different than the approved version. As a scientist involved in the early deliberations noted, the company seemed incapable of conducting competent trials or controlled experiments<sup>5</sup>. Some studies were so faulty that EPA weakly explained that the irregular data "probably seems most likely" to be the result of "laboratory error."<sup>6</sup>

Scientists also warned the agency of health risks from the potential spread of the antibiotic resistance genes used as a marker in the engineered bacteria. While EPA acknowledged the potential for problems associated with these "marker" genes<sup>7</sup>, the agency consistently dismissed human health and

environmental risks as “insignificant” without any basis for determining what would constitute a “significant” risk.<sup>8</sup> Doctors and scientists around the world have recently warned that the use of antibiotic resistance genes in GMOs poses an unjustifiable risk of increasing the spread of resistant disease.

The EPA's approval process for GMOs is not based on science but on wishful thinking. The approval of RMBPC-2 was based in part on the agency's belief that an insignificant number of bacteria would be released from the production facility into the environment. A year after making this claim, the agency's own assessment found that billions of the bacteria would be discharged several times a year.<sup>9</sup>

EPA's “risk-benefit” analysis is similarly based on unscientific assumptions. When EPA looked at risks, it found that yields in alfalfa grown with the engineered bacteria were within the range of yields of alfalfa grown with natural rhizobia, implying that therefore the risks were also no different.<sup>10</sup> Yet when EPA turned to describing the benefits of RMBPC-2, it stated that yields were significantly improved with the use of the engineered strain.<sup>11</sup> In fact, data showed that yields increased significantly at just one of several test sites.

The Biotechnology Science Advisory Committee of the EPA concluded that several areas of further study should be undertaken before approval. EPA instead ruled that no further experimentation was necessary. When the agency polled the Subcommittee members for their position on whether RMBPC-2 should be approved, only one scientist spoke for approval, while four spoke against and one expressed no position but noted that the issues raised by ecologists were a concern. Again, EPA ignored their science advisors and approved RMBPC-2. When questioned publicly about their approval of the bacteria and the PEER scientists' concerns, EPA responded that they were planning further review of the product. No such review has ever been released.

Greenpeace calls for countries to agree to a Biosafety Protocol to the Convention on Biological Diversity that protects against the irreversible consequences of the environmental release of GMOs, based not on lax U.S. standards but on international safety rules applying the precautionary principle.

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<sup>1</sup> Prof. Conrad Istock in a letter dated Feb. 22, 1995, to EPA announcing his resignation from the BSAC (Biotechnology Science Advisory Committee of EPA), EPA docket number 51786, D1-16. Prof. Istock was at that time Prof. in the Dep. of Ecology and Evolutionary Biology at the University of Arizona, Tucson. After his retirement he now holds a courtesy position at the Cornell University.

<sup>2</sup> “Genetic Genie: The Premature Commercial Release of Genetically Engineered Bacteria,” A white paper prepared by PEER, - Public Employees for Environmental Responsibility, September 21, 1995. Executive Summary, p. v. PEER, 2001 S Street NW, Washington DC 20009.

<sup>3</sup> IBID, p. 10, note 24.

<sup>4</sup> IBID, p. 35.

<sup>5</sup> Jane Rissler, personal communication, January 12, 2000.

<sup>6</sup> Gwendolyn McClung, EPA scientist, in a memo titled „addendum to the 1994 BSAC exposure assessment for the commercialization of RMBPC-2“, undated, TSCA-Docket number B4-029

<sup>7</sup> Lidia Watrud, Ramon Seidler, USEPA Laboratory, Corvallis, Oregon, in a letter to E. Mileswski, OPPTS, dated December 30, 1994; also Human Health Assessment for a recombinant of *R. meliloti* strain RMBPC-2, final draft report, September 6, 1994, prepared for EPA by Dynamac Corporation, Rockville, MD, page 8

<sup>8</sup> PEER report, p. 15.

<sup>9</sup> Gregory Macek, Chemical engineering branch, EPA: Engineering Report. Exposure and release assessment commercialization of P-92-403, December 6, 1994. TSCA Docket number B1a-10

<sup>10</sup> Consent order, issued by EPA on Sep 8, 1997 to finally approve the commercial use of RMBPC-2. pp. x, xiv

<sup>11</sup> Consent order, issued by EPA on Sep 8, 1997 to finally approve the commercial use of RMBPC-2. page xiv