Role of State Advisory Bodies in Decisions to Commercialize Biotech Crops: California’s Pharma Rice Experience

The Issue in Brief

Much of the concern about biotech crops at the state level involves issues related to containment of biotech crops and preservation of market access for the state’s agricultural producers. These concerns are heightened when the time comes to consider moving from field trials to commercialization of a biotech crop. In the case of pharma rice, California has followed a procedure that gives a state-chartered, industry-based advisory body, the California Rice Commission (CRC), a role in the decisionmaking process. Under a statutorily-prescribed procedure applicable to all rice varieties, the commission evaluated whether the commercial planting of pharma rice in California would have an adverse impact on the marketability of conventional rice by virtue of possibly outcrossing or physically contaminating conventional rice, and it made recommendations concerning containment procedures that would be sufficient to prevent such adverse impact. The California experience provides an example and may offer lessons for how states might approach decisions on minimizing any possible negative impacts certain biotech crops may have on state agricultural interests.

California’s Interests

California ranks second in the United States behind Arkansas in rice production, accounting for 20% of the U.S. total production of 43 million hundred weight (cwt). The value of California’s rice industry is $500 million, with $214 million of this attributed to growers and the balance to milling and subsequent stages of rice production. While U.S. rice production accounts for less than 2% of global production and its total value is small relative to the much larger international markets for corn, soybeans, and

262 USDA ERS 2001; California Agricultural Statistics Service n.d.. 1cwt=100 pounds.
wheat, the U.S. and California rice industries rely heavily on access to foreign markets. Of the rice produced in the United States, 40% is exported, accounting for almost 12% of the global rice trade. Of the different grain types traded internationally—short, medium, and long—California is the largest U.S. producer of medium-grain rice, with major export markets in Japan, Turkey, and Jordan. The United States supplies almost half of Japan’s rice imports, making Japan the largest U.S. rice export market.

The international rice market is described as “thin, volatile and risky,” compared with other commodity markets. Only 6% of total annual world production of rice is traded internationally, compared with 18% and 25%, respectively, of wheat and soybeans. In addition, the current market outlook for U.S. rice exports is not positive. The U.S. share of the world rice trade has declined since the mid-1970s, from 28% in 1975 to 12% currently, and further declines are projected for 2004.

These facts increase the sensitivity of U.S. rice producers to anything that could further jeopardize their markets, and the commercialization of pharma rice has emerged as a potential threat to the export market. Ventria Bioscience, a California-based biotech company, has developed a variety of rice genetically modified to produce two pharmaceutical proteins, lactoferrin and lysozyme, which are natural antibiotics used to treat both humans and animals. Concerns have been raised by members of the rice industry and others about the possibility that even small amounts of the pharma rice could find its way accidentally into nonpharma conventional rice, making it unacceptable for food use. Japan, which is California’s largest export market (importing 40% of California’s production), has been forthright in expressing concern about biotech products in general and the commercialization of pharma rice specifically. In a letter to the CRC, the Japanese Rice Retailers Association stated that,

![Image]

This marketplace resistance presents a dilemma to those California rice growers who see the potential benefits of biotech rice. According to the

---

266 USDA ERS 2001.
268 Evans 2003.
270 Japanese Rice Retailers Association letter, quoted in Massa 2004(a).
Rice Producers of California, a group representing rice growers on public issues, “Biotechnology is seen as perhaps the most important new resource for achieving varietal improvement.” According to one rice grower, however, the California rice industry is justifiably concerned that pharma rice “would have serious consequences on our ability to sell California rice.”

Beyond the interest of the California rice industry in its export markets, others have expressed views on pharma rice and other pharma crops that are relevant to the public discussion in California. State and national consumer and environmental groups, such as Sierra Club California, Environment California, Consumers Union, and the Center for Food Safety, contend that, beyond the economic issues, there are many environmental and public health concerns raised by pharma rice. The Biotechnology Industry Organization (BIO) argues, on the other hand, that the health benefits of pharma crops outweigh the risks and that the risks are adequately regulated by the federal government. The industry also points out that the tremendous knowledge that exists about the genome of major food crops make them good platforms for pharma crop development and production. However, a recent report by the National Research Council on the biological containment of genetically modified organisms concluded that crops used to produce common food products would be a “poor choice” for use to produce pharma and industrial crops unless they can be grown under “stringent conditions of confinement.”

The California Rice Commission and the Ventria Request to Commercialize Pharma Rice

The California Rice Commission was created by the government of California to serve the interests of the California rice industry by expanding and maintaining the industry’s markets. It is composed of equal numbers of rice producers and rice handlers, with the option of including one “public member.” The commission is funded by an assessment placed equally on producers and handlers based on the volume of their production. In 2000, the California legislature, in response to a proposal advanced by the CRC, enacted the Rice Certification Act of 2000 with the broad intent of

---

271 Rice Producers of California n.d.
272 Massa 2004(a).
274 Kelly 2004.
276 California Food and Agricultural Code, section 71000 et seq.
277 California Food and Agricultural Code, section 71050 (a).
278 California Food and Agricultural Code, section 71120 (a).
279 California Food and Agricultural Code, California Rice Certification Act of 2000, section 55000 et seq.
Ensuring the consistently high quality of the rice produced, milled, distributed, or otherwise handled in the state by informing consumers, maintaining consumer confidence, and enhancing and protecting the reputation of California’s rice industry throughout the nation and around the world.280

In furtherance of this intent, the Rice Certification Act focused on rice having “characteristics of commercial impact,” which it defined as “characteristics that may adversely affect the marketability of rice in the event of commingling with other rice,” including characteristics that require specialized equipment to identify, create a significant economic impact in their removal from commingled rice, or whose removal is infeasible.281 The central thrust of the statutory scheme is to “maintain the integrity and prevent contamination of rice which has not been identified as having characteristics of commercial impact” by requiring that commercial impact rice comply with an identity preservation program and appropriate containment measures.282

The role of the CRC under the Rice Certification Act is to evaluate rice varieties, through its advisory board; identify ones having characteristics of commercial impact; identify and recommend appropriate identity preservation and containment measures; and recommend to the Department of Agriculture the regulations required to achieve the purposes of the act. The advisory board consists of 20 members appointed by the California Department of Agriculture and includes farmers, handlers, University of California specialists, and representatives from California Crop Improvement and the seed industry. The commission’s advisory board recommends to the secretary of agriculture the conditions and systems for production and containment that it considers necessary to provide the needed protection.283 Based on these recommendations, the secretary decides whether to initiate the recommended rulemaking, declines to do so, or asks for more information.284 It is unlawful under the Rice Certification Act to produce or handle commercial impact rice varieties in a manner that does not comply with these regulations.285

In the fall of 2002, Ventria began formal discussions with the CRC on its intent to commercially plant its pharma rice during the 2004 planting season, and, in December 2003, Ventria submitted an application to APHIS to renew its California field trial permits.286 In order for Ventria’s pharma rice

280 California Food and Agricultural Code, California Rice Certification Act of 2000, section 55001.
281 California Food and Agricultural Code, section 55009.
282 California Food and Agricultural Code, sections 55040–55052.
283 California Code of Regulations n.d.(b). Specifically, the committee is mandated to “identify rice varieties that have characteristics of commercial impact and to propose appropriate regulations establishing terms and conditions for planting, production, harvesting, transporting, drying, storing, handling rice, seed application, field buffer zone, handling requirements, and identity preservation requirements.”
284 California Food and Agricultural Code, section 55022.
285 California Food and Agricultural Code, section 55050.
product to be commercialized in California, APHIS would have to authorize the necessary planting through the issuance of an appropriate permit.\textsuperscript{287} Regulating pharma crops under permits—rather than granting them nonregulated status as the basis for commercial-scale planting—enables APHIS to continue to impose and enforce containment and other measures intended to avoid adverse impacts, such as contamination of the food supply.

Of the 84 permits for the field testing of pharma crops that APHIS has issued nationwide,\textsuperscript{288} nine have been issued for trials in California, including for pharma rice, but APHIS has not to date authorized commercial production for any pharma crop. It is important to remember that an APHIS permit is only one regulatory hurdle developers of pharma crops must clear. The pharmaceutical substances the plants produce are subject to strict FDA premarket approval requirements.\textsuperscript{289}

The commission referred Ventria’s proposal for commercial planting to its advisory board. In its discussions with the commission, Ventria stipulated that its pharma rice had characteristics of commercial impact.\textsuperscript{290} The focus of the commission’s and advisory board’s work was thus to determine conditions for planting and handling that would ensure adequate identity preservation and containment of the pharma rice consistent with the objectives of the Rice Certification Act.\textsuperscript{291} In the course of its deliberations, the advisory board worked with Ventria to develop proposed conditions for the production and handling of the company’s pharma rice. These included growing the pharma rice in Southern California, which is outside the state’s rice belt; not seeding the rice from the air (a typical production method); ensuring a buffer zone of 100 feet between biotech rice and other crops; ensuring seed containers are sealed and numbered and silos are labeled and locked in order to keep pharma rice separate from other rice; and testing for the presence of the biotech pharma trait.\textsuperscript{292}

The advisory board was reported to be “deeply divided” on the Ventria application,\textsuperscript{293} with rice farmers on and off the board voicing objections to allowing commercial planting of the pharma rice because of concerns about negative market impacts like those detailed in the letter from Japanese rice retailers.\textsuperscript{294} On March 29, 2004, by a vote of six to five, the advisory board recommended to the secretary of agriculture conditions and protocols under which Ventria’s pharma rice could be planted commercially with adequate identity preservation and containment.\textsuperscript{295}

\begin{itemize}
\item \textsuperscript{287} Specifically, the agency has stated that “APHIS envisions that plants which produce drugs and biologics will always be grown under APHIS permit and will be regulated concurrently by FDA and USDA.” USDA APHIS n.d.(d).
\item \textsuperscript{288} Information Systems for Biotechnology 2004(c).
\item \textsuperscript{289} U.S. FDA 2002.
\item \textsuperscript{290} Nunenkamp 2004.
\item \textsuperscript{291} California Rice Commission 2004(a).
\item \textsuperscript{292} Sacramento Bee 2004; California Rice Commission 2004(b).
\item \textsuperscript{293} Jacobs and Krieger 2004.
\item \textsuperscript{294} Japanese Rice Retailers Association letter, quoted in Massa 2004(a).
\item \textsuperscript{295} Silver 2004; California Rice Commission 2004(a).
\end{itemize}
There is no unanimity of opinion among rice growers or other groups in California on biotechnology in general or on pharma rice in particular.\textsuperscript{296} The board vote elicited a sharp response, however, from stakeholders who are generally opposed to biotechnology or who have particular concerns about its application to pharma rice. Californians for GE-Free Agriculture disagreed with the board’s vote and acceptance of the rice protocols, stating that “contamination is inevitable under this protocol and the CRC did not act in the best interests of California rice farmers or consumers.”\textsuperscript{297} Organic rice producer Bryce Lundberg concurred, reiterating concerns about the contamination of organic rice with pharma rice.\textsuperscript{298} One rice farmer called the decision “bad news for farmers and California’s rice industry.”\textsuperscript{299}

Given the timing of the commission’s recommendation, Ventria needed a quick decision from the Department of Agriculture in order to have any chance of planting its pharma rice crop during the spring 2004 planting season. To expedite the process, the commission recommended that Ventria be granted an emergency exemption by the California Department of Food and Agriculture (CDFA), which would mean placing the regulations recommended by the commission in effect pending the normal public hearing and rulemaking process.

In a letter to Secretary of Agriculture A.G. Kawamura, dated April 1, 2004, consumer and environmental groups asked the secretary to deny Ventria’s request for an emergency exemption, claiming that public input was not only essential in the decision to commercialize the first pharmaceutical crop, but that the health and environmental impacts of the pharma rice had not been sufficiently assessed by the company or a federal agency.\textsuperscript{300} Tim Johnson, president of the CRC, said in a press report that many varieties of rice are currently kept separate and the rules put together for the biotech rice should suffice.\textsuperscript{301}

CDFA Secretary Kawamura denied the recommendation of the commission’s advisory board for an emergency exemption, finding that, while he “was prepared to go forward with a modified package on a non-emergency basis,” he would not act on an emergency basis because it was unclear if the company had obtained federal approval and “it is very clear that many wish to comment prior to any planting made possible in any way by implementation of this regulation.”\textsuperscript{302} He returned the matter to the commission with instructions for further review. Ventria Chief Executive Officer Scott Deeter called this a minor setback and said the company has plans to reapply in California next year and is also considering other options, such as planting in Hawaii and states in the South.\textsuperscript{303} Ventria and the biotech industry still asserted

\textsuperscript{296} Johnson 2004.
\textsuperscript{297} Renata Brillinger, quoted in Silber 2004.
\textsuperscript{298} Lundberg 2004.
\textsuperscript{299} Massa 2004(b).
\textsuperscript{300} Consumers Union 2004.
\textsuperscript{301} Silber 2004.
\textsuperscript{303} Elias 2004.
that the health benefits of the technology outweigh the risks, claiming that producing these proteins through crops is the most cost-effective and efficient means of reaching the most people. Planting 65 acres of pharma rice, they say, could generate 1,400 pounds of lactoferrin, which would be enough to treat 650,000 children with dehydration, a condition that kills 3 million infants each year worldwide, mostly in developing countries.\textsuperscript{304}

Some California rice producers saw the decision as providing an opportunity to look to the future. The president of the Rice Producers of California has expressed a desire to educate farmers about the issue through town meetings, as the Ventria decision is certainly not expected to be the end of pharma rice or other pharma crops in the state.\textsuperscript{305}

Following the California decision, the press reported that the U.S. Department of Agriculture’s Biotechnology Regulatory Services subsequently denied a renewal of Ventria’s field test permit because the rice was being grown too close to other crops destined for the food supply.\textsuperscript{306} Scott Deeter, Ventria’s CEO, said “the company would address the USDA’s concern with its permit renewal application and still expected to receive approval to continue growing the genetically engineered rice on its current plot.”\textsuperscript{307} Ventria has since received APHIS approval to continue field testing its biotech rice in California.\textsuperscript{308}

In anticipation of more companies applying for permits to field test pharma crops, the USDA recently published a notice in the \textit{Federal Register} detailing its plans to enhance APHIS regulation of field tests involving food plants and crops that have been engineered to produce pharmaceutical and industrial compounds. The regulations APHIS is considering would include more stringent permit conditions, such as containment measures, an increase in compliance inspections, and increased communication between the agency and the public.\textsuperscript{309}

\textbf{Implications and Questions}\textsuperscript{304}

The CRC provides an example of how state-chartered advisory bodies could participate in state decisionmaking about biotech crops and foods. The commission was chartered, of course, to address the potential impact on

\begin{flushleft}
\textsuperscript{304} Lee and Lau 2004.  \\
\textsuperscript{305} Garofoli 2004.  \\
\textsuperscript{306} \textit{San Luis Obispo Tribune} 2004.  \\
\textsuperscript{307} \textit{San Luis Obispo Tribune} 2004.  \\
\textsuperscript{308} Information Systems for Biotechnology 2004(b).  \\
\textsuperscript{309} USDA APHIS 2003(a).  \\
\end{flushleft}

The commission was chartered, of course, to address the potential impact on marketability of rice varieties produced by any means, not just biotechnology, and its statutory charge, once characteristics having commercial impact have been found, is the relatively technical one of determining conditions for identity preservation and containment.
marketability of rice varieties produced by any means, not just biotechnology, and its statutory charge, once characteristics having commercial impact have been found, is the relatively technical one of determining conditions for identity preservation and containment. Varieties produced by conventional techniques but having characteristics of commercial impact—while important to trade and consumer interests regarding product quality and integrity—are likely to be less controversial than biotech varieties in general and pharma crops in particular.

In the pharma rice case, the commission found itself at the center of a contentious public debate about whether pharma rice should be commercialized in California. This occurred despite the fact that the Rice Certification Act empowered the commission only to help determine the conditions of planting that would ensure adequate identity preservation and containment, not to provide a forum for deciding whether to allow planting of commercial impact rice varieties. The Department of Food and Agriculture considers the decision on whether to allow planting of pharma rice to be reserved to the federal agencies.310

One lesson from the CRC experience with pharma rice concerns the difficulty of drawing a bright line between the technical issues of identity preservation and containment and the broader economic and market integrity concerns that have made the pharma rice case controversial. Potential impact on the “marketability” of rice is what makes a rice variety, such as pharma rice, subject to the identity preservation requirement of the Rice Certification Act. However, there is a subjective component to the concept of “marketability,” which means that the technical criteria for accomplishing identity preservation might satisfy one party but be unacceptable to another. If the Japanese Rice Retailers Association is correct, any planting of biotech rice in California will affect the marketability of all California rice in Japan. It is not surprising that the commission process was seen by some as a forum for debating whether pharma rice should be planted in California.

Advisory bodies, such as the CRC, can play a very useful role in bringing relevant expertise and perspectives to bear on government decisions. One of the questions posed by the Ventria pharma rice case is whether, in the sensitive public context of agricultural biotechnology, the advisory body role can be successfully performed by an industry-based organization that represents some “but not all” commercial interests and is not charged with considering broader public and consumer interests. In the California case, comments made by farmers, the food industry, and consumer and environmental groups following the advisory board’s recommendation suggest some stakeholders felt their concerns had not been adequately considered. The experience has raised several questions. Should the CRC’s process be changed to deal with the unusually sensitive issues posed by biotech crops,

and especially pharma crops? Should representation on the advisory board be broadened? Should the statutory charge of the commission be broadened to take into account more subjective factors, such as consumer perception and foreign customer preferences, which influence whether a crop will have an adverse impact on the industry but that are not addressable through identity preservation and containment plans?

Alternatively, should an advisory process be developed to deal specifically with biotechnology-related issues, to consider issues and interests beyond those of the affected commodity sector, such as matters relevant to other commodity producers and handlers and consumers? This could be in addition to or as a substitute for a commodity-specific, industry-based advisory body. Clearly, the CDFA anticipated more public involvement in the ultimate decision about whether and under what conditions to approve pharma rice, but through what process? The advantage of a formal advisory body over isolated stakeholder comments is that it provides a vehicle for a group representing a range of interests and perspectives to become well-versed on the issues and deliberate in a way that can generate new ideas and solutions. The limitation is that it is rarely possible to comprise a body that truly represents all interests in a way that all interests find adequate, especially when recommendations or decisions run counter to a particular group’s strongly held view.

Another approach to gaining input is to convene purely scientific advisory bodies. Many states currently solicit expertise from scientists in land grant universities or other institutions to aid regulatory officials in the oversight of biotechnology. Most, if not all, of these bodies or advisory committees are not paid, are convened on an ad hoc basis, and have no clearly defined mandate. Should more states formalize these entities to ensure adequate technical expertise is brought to bear on biotech issues? How distinct are the scientific and technical issues from the business concerns, market acceptance issues, and consumer confidence issues that are so prevalent at the state level? Is it possible and better to keep scientific advisory efforts separate, or to foster dialogue among experts and stakeholders who approach the issues from different knowledge bases and value perspectives?

In the end, on controversial issues, there is no substitute for transparent processes in which the responsible decisionmaking authority provides all interested parties with opportunities to present relevant information and offer their views and then renders its decision with a clear and well-documented explanation. There are many ways to structure such a process and gain the needed input. The California pharma rice experience illustrates one approach, and its possible pitfalls.