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The Trials of Genetically Modified Food

BT EGGPLANT AND AYURVEDIC MEDICINE IN INDIA

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Abstract

Although planting of genetically modified (GM) crops has topped 148 million ha worldwide, direct consumption of GM foods remains extremely rare. The obstacles to GM foods are highly varied and they can provide windows into important cultural dynamics. India's heated controversy over its would-be first GM food—Bt brinjal (eggplant)—is driven not only by common concerns over testing and corporate control of food, but by its clash with the Ayurvedic medical establishment. GM brinjal may outcross with wild relatives commonly used in Ayurvedic medicine, and claims that outcrossing would not affect medical efficacy miss the point. Ayurveda emphasizes polyherbal treatments and has developed an epistemology oriented towards complex combinations of compounds. As such it does not recognize the authority of specific studies of transgene effects. The conflict is not with genetic modification per se, but with the reductionism that is central to the biotechnology approvals process. This opposition has played a significant role in the government moratorium on the plant.

Keywords: biotechnology, genetically modified food, Ayurveda, India, regulation

Introduction

At the heart of the struggles over genetically modified (GM) organisms has been the question of whether regulatory approvals may be based on factors other than safety to environment and public health.¹ This question has been especially pressing for substances that are directly consumed—whether conceived as food, medicine, or something in between—as they carry meanings and raise issues far beyond

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biosafety considerations. Even eighteen years after the first sale of GM crops, and with over 160 million ha. of GM crops planted worldwide and seventeen countries dubbed “biotech megacountries” (James 2012), plantings of GM crops for direct consumption remain miniscule, and voluntary (and knowing) consumption of GM foods is virtually nil. Indeed, several major GM foods have been withdrawn from the pipeline or market. This aversion stems from cultural factors that are highly variable and often country-specific. Dan Glickman, the US Agriculture Secretary when the first major GM crops were first adopted in the United States and contested in Europe, said that “We’ve got to make sure that sound science prevails, not what I call historic culture, which is not based on sound science ... Europe has a much greater sensitivity to the culture of food, as opposed to the science of food” (Shiva 2002). Yet even in the supposedly science-minded United States, the introduction of GM foods has been repeatedly thwarted for essentially non-scientific reasons:

- Monsanto’s early decision to market recombinant bovine growth hormone (rBGH)—which is not even directly consumed, but given to cows to boost milk production—is still widely seen as a strategic blunder.² Not only did its 1994 introduction coincide with a milk glut, but it clashed with cultural notions of children’s health (DuPuis 2000: 286). It led to bans on US milk, a surge in demand for organic milk in the United States, and eventually to some US processors refusing milk from rBGH-injected cows (Schurman and Munro 2010: 144).
- Calgene introduced the United States’ first GM food crop—tomatoes modified to delay rotting—in 1994. Campbell’s Soup sponsored the research, but then pointedly kept the tomatoes out of its soup for fear of compromising the brand’s wholesome image (Bray 2003). The Calgene tomato disappeared from the market in 1997 (Harvey 2004; Martineau 2001).
- Soon after Monsanto introduced GM potatoes in 1995, fast-food and snack-food producers (including McDonald’s and Frito-Lay) refused to use the potato, leading to its rapid disappearance from the market (Kilman 2001). These companies were concerned about damaging branded products made from the “totem vegetable of modernity,” closely linked to US national identity and the pervasiveness of contemporary US consumer culture (McHugh 2007: 32).
- In 1999 Novartis, although a leading producer of GM seeds, went to considerable trouble and expense to remove GM soybean and GM corn ingredients from its own Gerber baby foods, explaining that it wanted “our mothers to be comfortable” (Lagnado 1999). Heinz then removed GM ingredients from its line of baby foods.
- In 2004, Monsanto abandoned a major investment in GM wheat, not only due to farmers’ concerns about losing exports to Europe but also because of American consumer qualms about tinkering with such a culturally loaded grain (Schurman and Munro 2010). In addition to the meanings of bread, the director of the Food Policy Institute pointed out that wheat is “the communion wafer and the matzo crackers ... It’s the staff of life and the place where food stops being just about nutrition and takes on a sort of symbolic role” (Lee 2003).
- In 2011, AquaBounty’s GM salmon appeared to be heading towards release until it was blocked in Congress. The primary opposition stemmed from the economic

concerns of salmon-farming states, but the politicians were quick to couch their statements in the narratives of “unnaturalness” and “frankenfish.” (Alaska Dispatch 2012)

Today, the only directly eaten GM food products sold in the United States are Hawaiian papaya and some summer squash (both modified to resist certain viruses); very few shoppers are even aware of this.³

Directly eaten GM food outside the United States is almost non-existent. In Europe, no GM foods are sold, and even GM food ingredients occur at very low levels. China plants extensive acreage of GM cotton but its only three approved GM food crops—potato, sweet pepper and papaya—are grown on a very small scale (Liu 2009: 191). Approval of GM rice, under consideration for years in China (Lei 2004), has been highly controversial; critics have pointed to a range of considerations including food sovereignty (R. Stone 2011). GM papaya has long been refused by Japan, Hawaii’s largest export market.⁴

GM foods face a veritable minefield, with hazards that vary widely with plant, culture and country. A current controversy in India provides a particularly revealing case. This pivotal country for GM organism struggles has for the last five years struggled with whether to approve its first GM food crop. The crop is eggplant (*Solanum melongena*)—called *brinjal* in India—modified with an insecticidal gene from the bacterium *Bacillus thuringiensis*, or Bt. Concerns about “Bt brinjal” go far beyond the normal considerations of safety to health and environment; a key issue is that wild relatives of brinjal are important ingredients in medicinal formulations in classical, folk and popular traditions. In particular, wild brinjals are used in Ayurvedic medicine, which is a thriving industry—especially in Kerala state, which has emerged as the center of Ayurvedic tourism and as a global brand for Ayurvedic products. Ayurveda embodies a philosophy of medicinal herb use that, as we argue, has intrinsic incompatibilities with the philosophy underlying the regulation of GM organisms.

If the foundering of GM foods in the United States reflects cultural meanings of bread and milk, maternal anxieties, the marketing of soup, and the influence of the fast food industry, India’s Bt brinjal controversy reflects cultural differences in concepts of *food* and *medicine* and the politics of scientific reductionism. Of particular importance in “regulatory epistemology” is the unit of analysis in assessing the safety and healthiness of foods. Nestle (2002) and others have identified the rise of a “nutritionist” ideology that focuses on small-scale units such as the ingredient or the individual nutrient rather than the “food” or the plant. GM crops have helped to bring such reductionism down to the scale of the expression of the single gene. But in Ayurveda, this trend has met an opponent with its own well-established theories of consumption and health, and with a resolute focus on more synthetic levels of analysis.

We use the case of Bt brinjal to explore how an attempt to regulate a GM food on the simple basis of “safety” becomes enmeshed in these conceptual tensions. We examine, in turn, GM brinjal, Ayurvedic medicine, and their intersection in a national debate and decision on the crop. We then return to the problems of the food,



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medicine and reductionism, and their implications for regulation of genetically modified goods.

Bt Brinjal

Genetic modification is a category of biotechnology that alters life forms by direct manipulation of DNA. Typically, DNA from different species is recombined into genetic constructs that are inserted into target species (Stone 2010). Although many types of modifications have been accomplished in the laboratory, only a few have been marketed to farmers, and two modifications overwhelmingly dominate GM plantings. The most common, by far, is herbicide tolerance, which allows the crop to survive applications of specific weed killers. The second is insect resistance from genes from the soil bacterium *Bacillus thuringiensis* (Bt); these genes encode proteins that kill some caterpillars that are crop pests.

India approved its first GM crop—Bt cotton—in 2002 after years of pitched battle. Bt cotton has been cited as a success story for genetic modification, although a more equivocal picture is now emerging (Kranthi 2011; Smale *et al.* 2006; G.D. Stone 2011). Many food crops have been genetically modified in Indian laboratories, but Bt brinjal is the first to seek regulatory approval.

Brinjal is an interesting choice for several reasons. *Solanum* is one of the world's most important food genera; among its 2,000+ species are eggplant, tomato, potato and capsicum. Brinjal is the fourth most widely grown vegetable in India, and it is a significant export crop (Government of India 2009). Three subspecies of *S. melongena* are grown, providing a remarkable array of sizes, shapes and colors. The common dark-colored egg-shaped fruits are *var. esculentum*; the long, slender types are included under *var. serpentinum* and the dwarf brinjal plants are grouped under *var. depressum* (Choudhury 1976). In Indian vegetable markets it is common to see five to seven varieties of brinjal, the only vegetable sold in such variety. Brinjal is cooked in a wide variety of ways across India, the best known dishes including the popular South Indian vegetarian soup *Sambar* and *Vangibat* (brinjal-rice) and the North Indian *Bharta* side dishes. Brinjal dishes are popular for weddings and festive occasions.

In some regions local varieties take on considerable importance. The *Matti gulla* variety from Udupi district, Karnataka state, has its own geographical indication (Raghuram 2010) and is also considered sacred because of its association with a Hindu figure (Hebbar 2011). The *Mararikulam* variety is named after a coastal Kerala village known for its aggressive promotion of homestead-level vegetable cultivation for self-sufficiency (this village played a prominent role in the backlash against Bt brinjal as noted below).

A bane of brinjal cultivation is the caterpillar pest *Leucinodes orbonalis*, known as the “fruit and shoot borer” as it bores into young shoots and later into the fruits. As unblemished fruits fetch a premium in the market, farmers often apply copious amounts of insecticide. The pest has developed resistance to insecticides, and breeders have yet to develop insect-resistant plants (AVRDC 2003). The Indian seed company Mahyco (partly owned by Monsanto) began to develop a GM brinjal in 2000 (with collaboration from Cornell University, the US Agency for International Development and Tamil Nadu Agricultural University), using its own proprietary

brinjal line. By 2002 it had begun to breed the transgenic trait into various brinjal cultivars and to test the product.

India has the most developed regulatory apparatus for GM organisms of any developing country. The basic legal framework governing GM crops and foods is the Environment Protection Act 1986 and the 1989 Rules that mandate risk assessment for every proposed release of GM organisms (Gupta 2002). Regulatory authority is divided between the Ministry of Science and Technology—in particular the Department of Biotechnology (DBT)—and the Ministry of Environment and Forests (MoEF)—mainly the Genetic Engineering Approval Committee (GEAC). The DBT is responsible for approving transgenics research and small-scale field trials; the GEAC approves large-scale field trials and commercial releases. Parameters for testing are framed on a case-by-case basis, depending on the features of the GM crop.

Between 2002 and 2004, confined field trials were conducted to study pollen flow, germination, aggressiveness and weediness, and to conduct biochemical, toxicity and allergenicity studies. In 2004, the GEAC approved Mahyco to conduct small-scale trials of five Bt brinjal hybrids in eleven locations (Bunsha 2006), and in 2006 it approved large-scale field trials after reviewing biosafety data from Mahyco (GEAC 2009).

Backlash

Egged on by India's ever-active non-governmental organization (NGO) sector, skepticism regarding Bt brinjal began to grow in 2006. That summer, anti-GM activists protested the large-scale field trials, claiming the testing to be inadequate to assure food safety (*Economic Times* 2006). Members of the Coalition for GM Free India (a loose confederation of voluntary organizations) also expressed concerns about the potential exploitation of farmers by multinational corporations (Ramakrishnan 2006).

In September 2006, after public interest litigation led the Supreme Court to halt field trials, the GEAC formed the Expert Committee I (EC-I) to look into these concerns. In 2007, the EC-I recommended seven more biosafety studies to reconfirm data from the confined multi-location trials, but also gave a green light to large-scale trials. Subsequently, the Supreme Court lifted the ban on GM crop field trials subject to certain conditions, such as isolation distance. As per GEAC direction, the Indian Institute of Vegetable Research (IIVR) ran large-scale trials of the brinjal at ten research institutions across the country in 2007 and eleven in 2008.

By 2008, resistance was sufficiently widespread that a group of farmers staged a funeral march for Bt brinjal (Kurunganti 2008). In Bombay, brinjals with suicide notes were put in key parts of the city (*The Hindu* 2008). In Kerala, the state agriculture minister inveighed against GM crop trials in his state, emphasizing its status as a mega-biodiversity hotspot. He also signed an anti-GM banner to be displayed in Delhi (Kurunganti 2008).

In January 2009, the IIVR submitted the results of the large-scale trials. Due to concerns raised by several stakeholders including national and international experts, the GEAC convened its Expert Committee II (EC-II), to review the adequacy of biosafety data. In October, based on the report of this committee, the GEAC voted



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to approve the release of Bt brinjal. However, mindful of the controversy swirling around the topic, the GEAC voted to make its ruling advisory to the government, leaving the final decision with the Minister of Environment and Forests, Jairam Ramesh.

Ramesh was a widely respected polymath and author, educated in engineering and science policy at IIT, Carnegie Mellon and MIT. Although hardly anti-development, Ramesh had irked various industrialists in the past by what they felt to be an undue concern for environmental protection. Soon after the Bt brinjal decision landed on his desk he devised a program to solicit a wide spectrum of viewpoints. He sought opinions from India's state governments and from the international scientific community. He also took an interest in public voices, organizing a series of open meetings around India in early 2010; these attracted over 8,000 people, including farmers, scientists, consumer groups, NGOs, and concerned citizens.

Coinciding with general anti-GM sentiment at the meetings was a barrage of anti-GM editorials, protests, and even fasts (Chandra 2010). The protests received enthusiastic support from the state government of Kerala, where the Agriculture Minister even urged Keralites to join the fast (Mathew 2010). The concerns driving the opposition were varied. There was the general unease with genetic modification and with corporate control of seeds. Some complaints were at the level of national sovereignty, such as the concern expressed by the head of a major agricultural university of Monsanto's control over the food chain (Ramesh 2010: 6). Intellectual property issues were also a point of friction; Bt brinjal incorporates patented genes but uses public varieties (and the National Biodiversity Authority later filed suit against Monsanto-Mahyco for illegally using traditional brinjal varieties) (Jebaraj 2011).

Objections were raised by Ayurvedic doctors alleging that Bt brinjal would contaminate wild relatives of brinjal used in Ayurvedic formulations. Their cause was spearheaded by the Ayurvedic Medical Association of India (AMAI), an umbrella organization of practitioners in Kerala. Together with doctors from other medical systems like Siddha and homeopathy, AMAI formed the association, Doctors for Food and Bio-safety to lobby against Bt brinjal at the national level.⁵

Other concerns were local in nature, including fears of losing niche markets. Mararikulam village in Kerala, with high stakes in the traditional variety noted above, mounted a campaign against Bt brinjal, even hosting a brinjal festival and a seminar of brinjal experts and scientists. This festival also highlighted the Ayurvedic physicians' objections and emphasized the medicinal properties of brinjal (Press Trust of India 2010). But in the end, no issue was quite as thorny as the problem of outcrossing—gene flow from Bt brinjal to its wild relatives.

Outcrossing

Gene-flow research on GM crops has had a troubled history. Appearances and disappearances of transgenes from wild and landrace populations are poorly understood, as the ongoing saga of Mexican maize reminds us (Ortiz-García *et al.*

2005; Piñeyro-Nelson *et al.* 2009; Quist and Chapela 2001; Soleri *et al.* 2006). Gene-flow research has been marred by patent-holders blocking field studies (Dalton 2002) and extraordinary attacks on some published findings of transgene outcrossing (for examples, see Monbiot 2002 and Waltz 2009).

Research on gene flow in Bt brinjal has had its own irregularities. Outcrossing is of particular concern because brinjal, while often described as a self-pollinated plant, has been found to have a cross-pollination rate as high as 48 percent (Indian Institute of Vegetable Research 2009). Numerous studies show convincingly that *S. melongena* can cross with wild relatives, including *S. melongena* var. *insanum* (Rao 1979), *S. melongena* var. *incanum* (Behera and Singh 2002; Nishio *et al.* 1984; Rao 1979), *S. indicum* (Behera and Singh 2002; Rajasekharan 1969), *S. integrifolium* and *S. gilo* (Rao 1979). However, the report issued by the MoEF and DBT to inform the evaluation process, after acknowledging some of this literature, unaccountably concluded that “as such there is no natural crossing among cultivated and wild species of brinjal” (Government of India 2009). Furthermore, writing by biotechnology advocates stressing that *S. melongena* itself is not used in classical medicines ignored the research on gene flow (for example, Rao 2011).

Experimental studies conducted by Mahyco in 2002 also show that the Bt trait does outcross, with the transgenic brinjal pollen traveling up to 20 meters. The fact that the studies were conducted by Mahyco, and were initially kept confidential, caused some suspicion (Purkayastha and Rath 2010). Objections to the adequacy of outcrossing tests were one reason the EC-II ordered further studies by the IIVR. These studies found significant outcrossing with *S. incanum*, with pollen traveling up to 30 meters (IIVR 2009). Still, the report flatly claimed that neither natural cross-pollination nor outcrossing of the Bt trait imparts “any aggressiveness or weediness”, and “the addition of Bt trait in *S. melongena* is unlikely to have any impact on the existing diversity of *Solanum* species” (IIVR 2009). (Not considered was whether outcrossing might endanger the integrity of brinjals being produced for niche markets. By 2011, the *Matti gulla* variety, noted above, was reportedly endangered by contamination, with illegal Bt brinjal plants being one suspected culprit (Raghuram 2011).

The IIVR report was lauded by biotechnology proponents. However the entomologist asked by MoEF to evaluate the GEAC report found a long list of problems with it and elsewhere in the dossier (Andow 2010). He found insufficient support for the claims of no ecological danger posed by outcrossing, and further pointed out the risk of cultivated varieties establishing feral populations. Whether or not the prospect of transgene flow to relatively obscure varieties of *Solanum* would have been a significant issue without Kerala’s Ayurveda boom is something we will never know. In the United States, one of the first GM foods seeking approval also had major unanswered questions concerning outcrossing (Parker and Kareiva 1996: 195–6), but it was a squash whose wild kin had no constituency, and it was quickly approved over generic environmental protests. With brinjal, potential gene flow took on special significance because of Ayurveda’s underlying philosophy which made it a stakeholder with something real to lose.



Ayurveda and Brinjal

Ayurveda is the largest of the four classical Indian systems of medicine (the others being Unani, Siddha and Sowa-Rigpa), with 453,661 registered doctors (Planning Commission of India 2000) and 7,900 Ayurvedic manufacturing units (AYUSH 2007). Medicines worth US\$1.8 billion are produced annually, growing at 10–15 percent per year (Sharma 2008).

Kerala state, in the southwestern tip of the India, is the most active Ayurvedic production and consumption center in the country, with around 1,000 manufacturers. In the past two decades, Kerala has emerged as a center for Ayurvedic tourism, with a large domestic clientele and a smaller, but highly lucrative, foreign clientele. Major services include therapies, wellness treatments and massages (especially those associated with *Panchakarma* purifying therapies). “Kerala” has emerged as a brand name for Ayurveda both within and outside the country, developing its own niche in the larger context of India’s emergence as a global biomedical tourism hub. This perception has also caused a surge in national interest in lucrative global markets.

Ayurvedic formulations are mostly polyherbal decoctions, with each ingredient conforming to a complex Ayurvedic pharmacological logic⁶ in which substances are classified according to tastes (*Rasas*), post-digestive taste (*Vipaka*), quality (*Gunas*), pharmacologic action (*Karmas*) and potency (*Veerya*).⁷ The classic texts provide information on the pharmacological attributes of each drug (Table 1). Ayurvedic polyherbal formulations normally combine many active ingredients and adjuncts that act as potentiators or moderators of the efficacy and toxicity of active ingredients (Balachandran and Govindarajan 2007). For example, black and long peppers are routinely used to enhance bioavailability (Atal *et al.* 1985).

First codified around fifth to third century BC, the classic Ayurvedic literature continued to grow into the eighteenth century, accumulating a large corpus of associated commentaries, diagnostic manuals and dictionaries. The Drugs and

Table 1: The Pharmacology of Kantakari (*Solanum xanthocarpum*), a Brinjal Relative Common in the Ayurvedic Pharmacopeia.

Pharmacological parameter	Attribute
Taste (<i>Rasa</i>)	Pungent (<i>Katu</i>), bitter (<i>Tikta</i>)
Quality (<i>Guna</i>)	Light (<i>Laghu</i>), dry (<i>Rooksha</i>)
Potency (<i>Veerya</i>)	Hot (<i>Ushna</i>)
Post-digestive taste (<i>Vipaka</i>)	Pungent (<i>Katu</i>)
Action (<i>Karma</i>)	Stomachic (<i>Deepana</i>), digestive (<i>Pachana</i>), throat-supportive (<i>Kanthya</i>), edema-relieving (<i>Sothahara</i>), digestive-disorder ameliorating (<i>Amadoshahara</i>)

Cosmetics Act 1940 lists fifty-six texts as approved sources for Ayurvedic formulations; formulations based on these sources are called “classical medicines.” Manufacturers may create proprietary formulations only after registering with the Ayurveda Drugs Control Authority in the relevant state. Documented recipes for medicinal formulations number over 100,000 (Balachandran and Govindarajan 2007: 1,633); around 1,500 classical formulations and 30,000 proprietary formulations are found in the market (Sharma 2008). As at 2011, the Ayurvedic Pharmacopeia Committee has published standards for 635 Ayurvedic formulations, 540 monographs on single drugs, and 101 monographs on formulations (CCRAS 2011).

Ayurveda’s pharmacopea uses 1,587 plants besides minerals and animal products, of which 688 are found in trade (Ved and Goraya 2007). Wild brinjal species are among the most important plants in this pharmacopeia. Six *Solanum* species are used in classic Ayurvedic texts; the most frequently used parts are roots, but whole plants are used as well. Key examples in the pan-Indian Ayurvedic pharmacopeia are the species known by the Sanskrit drug names of *Brhati* and *Kantakari*, used in fifty-five and forty-seven formulations respectively. These two are part of the class of *Dashamoolas* or *ten roots*⁸ that go into numerous common formulations including the highest-selling Ayurvedic medicine in India (*Chyawanaprasha*), and the highest-selling traditional Ayurvedic medicine formulation in Kerala (*Dashamoolarishtam*) (Central Council for Research in Ayurvedic Sciences 2008). Although *S. melongena* is not officially part of the Ayurvedic pharmacopeia, it enters the Ayurvedic commodity chain as an adulterant or substitute. By and large, manufacturers in Kerala use wild and cultivated varieties of *S. melongena* as a substitute for *Brhati* and *Kantakari* (Sivarajan and Balachandran 1994) although more conservative manufacturers consider this as an adulterant, and some end up using it unknowingly.⁹

It is significant that, like most plants in classical Indian medicine, the brinjal relatives used in Ayurvedic medicine are sourced almost entirely from the wild. These plants grow along roadsides and other commons areas and are gathered mostly by small-scale collectors. Recent estimates are that between 67 percent (Exim Bank of India 2003) and 81 percent (Ved and Goraya 2007) of medicinal plants are sourced from the wild; in Kerala only 7 percent of the raw drugs used in Ayurvedic production come from cultivation (Sasidharan and Muraleedharan 2000).¹⁰ Interviews with large and small Ayurvedic medicine manufacturers in Kerala reveal that all the varieties of *Solanum* were sourced from the wild,¹¹ except for micro-scale garden cultivation by pharmacies and traditional practitioners.

Ayurveda and Reductionism

Objection from the various systems of medicine, the most vocal being that of Ayurveda, has been surprisingly consequential in the debate. While some see Ayurveda as rejecting genetic modification out of Ludditism (e.g. Joshi 2010) or “blind aversion” (Rediff Business 2010), we argue that the real disagreement has to do not with genetic modification *per se* but with resistance to reductionism which contradicts classical principles of Ayurvedic pharmacology. Ayurveda represents, in Thompson’s (1997) terms, a classic example of a *hybridizing* approach to food and



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medicine, rejecting the process of *purification* that Balkanizes impacts into discrete categories of moral significance. Lacking in neither rigor nor rationality (Alter 1999), the epistemology underlying Ayurveda's approach to herbal medicines fits with the reliance on synergistic effects of polyherbal formulations for which conventional clinical trials are poorly suited. As Bode (2009) puts it, Ayurveda follows "its own rationality in determining interactions between materia medica and human biology and physiology," separate from "positivistic pharmacology" that may be blind to effective medicines because they do not lend themselves to reductionistic studies. The actions of any herb as a whole, as the president of the Association of Manufacturers of Ayurvedic Medicines stresses, may be different than any of its biochemical components individually (AMAM 2005); with multiple herbs the potential for synergistic effects becomes enormous. As Naraindas (2006) points out, the co-opting of specific indigenous medical technologies and materials apart from their original theories is problematic, and Pordié (2010) sees the therapeutic evaluation of Ayurveda as driven by the political economy of the biomedical model.

Though there is much scientific and corporate interest in Ayurvedic knowledge for research on phytochemicals, Ayurveda has been more of a contributor than a benefactor. The phytochemical industry with its interest in specific metabolites¹² and the bio-medical pharmaceutical industry with its eye on molecules, find it meaningful to engineer plants to raise yields of select compounds. Although the Ayurvedic industry relies on knowledge of specific phytochemicals understanding in designing new formulations, it does not aim at selective modification of plants given its interest in the holistic profile of plants. In 2008, biologists at the Rajiv Gandhi Centre for Biotechnology were reported to be developing GM varieties of four important herbs in Ayurveda; the aim was to develop breeds with high yields of compounds like bacosides from the *Brahmi* plant for pharmaceutical products. But this was not in line with Ayurveda's approach to plant pharmacology. A scientist at the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in Delhi, said "Scientists may pursue R&D on herbal plants but officially GM is not permitted in Ayurveda. Scientists believe in increasing a single positive attribute but Ayurveda insists on using the holistic character of a plant" (Dasgupta 2008).

Ayurveda's issue with reductionism came to the fore when the government of India was considering use of hydro-alcoholic extracts in the production of Ayurvedic medicine. Though a section of the industry favors the use of extracts, the Ayurvedic Drug Manufacturers Association objected, pointing out that this compromised the principle of synergy (Kamath 2007, 2008). The Chief of Technical Services of South India's largest Ayurvedic manufacturer points out that use of extracts is incompatible with Ayurvedic logic: "There is no reason to believe that more of a certain set of ingredients is what causes the efficacy, and because of the limitation of chemical tests in revealing the underlying nature of a polyherbal product whose content and efficacy is mainly based on synergy, we find it safe to stick to traditionally laid procedures."¹³

Of course, complex synergistic effects are not intrinsically unstudyable, but such studies are exceedingly difficult as "the extreme chemical diversity of compounds in Ayurvedic drug formulations simultaneously targets most systems of the body,

resulting in an array of potent and diverse biochemical outcomes” (Balachandran and Govindarajan 2007). Nevertheless, some researchers are devising methods to examine synergistic effects of Ayurvedic polyherbal medicines (see Patwardhan and Mashelkar 2009; Ulrich-Merzenich, *et al.* 2010), as other Ayurvedic concepts are finding their way into scientific research.¹⁴

In the case of brinjal, Ayurveda’s distrust of genetic modification is amplified by the fact that the medicinal plants in question are not being transformed under controlled conditions, but rather might be transformed by unintended outcrossing. The potential for such outcrossing to impact medicinal properties of wild brinjal used in Ayurveda is a central scientific question. A scientist on the GEAC responded with an argument common in discussions of genetic modification, that the only change the Bt gene brings in brinjal is in its ability to fight the fruit and shoot borer; “Every other quality of Bt brinjal remains the same as that of non-Bt brinjal” (Thacker and Sinha 2010). However, given Ayurveda’s focus on the polyherbal mixture, assurances based on specific secondary metabolites have little weight. Even from a reductionist biomedical perspective, it is significant that pleiotropy—the occurrence of multiple phenotypic traits from a single gene—is not uncommon in transgenic plants, and the presence and effects of pleiotropic traits are often discovered years after release. For instance, one of the first two GM foods still sold in the United States, the virus-resistant squash, is now known to have had pleiotropic effects affecting pollinator behavior (Prendeville and Pilson 2009). It has also been found that the herbicide-resistant gene in GM canola has pleiotropic effects on flower production (Pierre *et al.* 2003).

It is notable that Ayurveda is not alone in its reliance on synthetic concepts of food/medical identity and legitimacy. Western regulatory dogmas rely on the ill-defined synthetic notion of “substantial equivalence.” In the United States this concept was adopted as an expedient by the Food and Drug Administration (FDA), which was deciding how to regulate GM foods just as it was under enormous pressure to approve a large backlog of biotech drugs. Unlike Europe’s process-based regulation, which weighs food production methods, the United States’ distinctive “product framework” exempts from special approval any foods deemed equivalent or similar to foods “generally regarded as safe” (Jasanoff 2005: 131–2). But how does one reckon *similarity* in items with so many axes of variability? The principle of “substantial similarity” was introduced ambiguously into regulatory philosophy by FDA chief David Kessler: “Substances that have a safe history of use in food and substances that are substantially similar to such substances generally would not require extensive premarket safety testing” (Kessler and Taylor 1992: 1,832). But lacking a clear definition of what constitutes substance in food, this is dangerously close to proposing that substances are equivalent if they are equivalent in their substance.¹⁵

For foods, the FDA’s 1992 guidelines emphasized analytical tests of chemical composition as a basis of substantial similarity (Levidow *et al.* 2007). But, writing in *Nature*, Millstone *et al.* (1999: 525) pointed out that “the degree of difference between a natural food and its GM alternative before its ‘substance’ ceases to be acceptably ‘equivalent’ is not defined anywhere.” Moreover, defining “substance” purely in terms of chemical composition ignores biological and immunological



effects that cannot be predicted from chemical composition alone (Levidow *et al.* 2007; Millstone *et al.* 1999). Even among FDA scientists there was a consensus that GM crops could have unpredictable differences from conventional crops and required long-term testing for effects (Freese and Schubert 2004).

Moreover, Millstone *et al.* see this core concept of regulatory “science” as geared to the inhibition of scientific inquiry:

Substantial equivalence is a pseudo-scientific concept because it is a commercial and political judgment masquerading as if it were scientific. It is, moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests. It therefore serves to discourage and inhibit potentially informative scientific research. (Millstone *et al.* 1999: 526)

Nevertheless, the concept quickly developed traction in international circles (Magaña-Gómez and Calderón de la Barca 2008) and eventually became lodged in the Indian regulatory philosophy. Thus at the center of the process of “scientifically” assessing Bt brinjal we find the maker, Mahyco, applying the “fundamental principal of substantial equivalence” and determining that “Bt brinjal is substantially equivalent in its composition to control brinjal and thus the food and feed derived from Bt brinjal will also be substantially equivalent to food and feed derived from non-Bt counterpart” (Mahyco 2006).

The Decision

In deciding the fate of the India’s first GM food, Minister Ramesh was in uncharted territory. Despite his unusual expansion of the debate, most observers assumed he would approve the crop. Indeed, in the public forums he had often argued in favor of Bt brinjal. Mahyco was moving ahead with its plans for release, and a major food activist warned that Ramesh was “Trying to legitimise the GEAC fraud” (Sharma 2010). Yet in February, Ramesh (2010) issued a nineteen-page report declaring a moratorium on Bt brinjal. The report is an intriguing text that delves into a wide range of issues. It includes a long list of considerations, but the first, and clearly one of the most telling to Ramesh, is the reaction of the states. Ramesh had solicited opinions from the six top brinjal-growing states, and letters also arrived from the chief ministers of three additional states including Kerala. All the state officials expressed “apprehension,” but while most simply urged caution and further testing, the then Chief Minister of Kerala, V. S. Achuthanandan, wrote that his state had:

taken a decision to prohibit all environmental release of GMOs and keep the state totally GM free. We would request the Honourable Prime Minister to reconsider the policy of GM in a national scale and declare a moratorium at least for the next fifty years. (Ramesh 2010)

Achuthanandan’s letter is an interesting statement on the nexus of commerce, plant ecology and cultural systems of assigning value. It goes on to maintain that:

Kerala is a State heavily depended on international market for its agricultural commodities. Any contamination from genetic modification can cause further damage in the trade prospects of the State.

Kerala is also an important centre of diversity of medicinal plants and heritage of traditional medicines like Ayurveda. Serious concern has already been expressed by the Ayurveda practitioners on GM research being undertaken on various crops.

You would be delighted to note that the State has already declared an Organic Farming Policy, Strategy and Action Plan in 2008. Accordingly, the entire food crops would be converted to organic within five years and the cash crops within another five years. This will, apart from helping to feed the people with non-poisoned food, enhance our export possibilities with a high premium. However, introduction of GM crops will certainly defeat the very purpose of organic farming, because GM crops/foods are more disastrous than those from crops raised using chemical pesticides and fertilizers. It would also kill the State's trade prospects. (Ramesh 2010)

Ramesh's report explicitly recognized the potential for deleterious effects on medicinal use of brinjal:

I have also been informed that the Indian Systems of Medicine including ayurveda, siddha, homeopathy and unani use brinjal as a medicinal ingredient, both in raw and cooked form, for treatment of respiratory diseases and that the entire brinjal plant is used in such preparations.¹⁶ There is fear that Bt-brinjal will destroy these medicinal properties due to loss of synergy, differences in the alkaloids and changes in other active principles. (Ramesh 2010)

Kerala's objections, with their emphasis on Ayurveda's concerns, were not only noted prominently as a criterion for rejection, but they gave added weight to one of his other prominent criteria: the unanswered questions about outcrossing. Ramesh detailed the letters from international scientists raising questions about the environmental impact assessment; several (including one from American gene-flow specialists Allison Snow and Norman Ellstrand) stressed concerns about gene flow to brinjal relatives and reservations about the EC-II report.

Ramesh did not explicitly address the underlying question of reductionism versus Ayurveda's more synthetic level of assessment. However, he did implicitly recognize the potential for unrecognized pleiotropic effects as noted above: "The plant family *Solanaceae* to which brinjal belongs appears to be more problematic than others because it contains several natural toxins that can resurface when metabolism is disturbed."

Prime Minister Manmohan Singh supported Ramesh's decision but he faced sharp disagreements in the cabinet. Leading the group in favor of Bt brinjal was Agriculture Minister Sharad Pawar, who insisted on the need for science and



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technology to solve India's food shortages (NDTV 2011). However, Ramesh's report had anticipated the question of food shortages: addressing the question "why Bt brinjal?," Ramesh noted that "there does not seem to be any over-riding food security, production shortage or farmer distress arguments" for it. The question of whether "we really need more brinjal," posed at one of Ramesh's public consultations, turned out to be a good one; the subsequent months brought reports of a "heavy flow of [brinjal] produce due to high yields has resulted in a slump in prices" bad enough to lead vendors to abandon their piles of brinjal in disgust (*Times of India* 2011a).

In July 2011, Ramesh was replaced at MoEF and "promoted" to the lower-profile position of Minister of Rural Development. The *Wall Street Journal's* headline read "India fires environment minister who held up projects" (Sharma 2011). The role of Pawar and other influential GM organism enthusiasts was unclear, but Bt brinjal is certainly an example of a held-up project. The final section of this article considers the point made by Ramesh's detractors, specifically that the approval of GM crops is inherently "scientific" while disapproval is "unscientific."

Regulating Food and Medicine

Especially when it will be directly consumed, each GM crop enters a minefield that varies with time and place. Bt brinjal is the topic of current controversy in other countries (e.g. the Philippines; Galvez 2011), but the nature of the clash in India has been distinct. At the outset, Bt brinjal seemed like an obvious intervention for agribiotechnology in India. Brinjal had a pest problem difficult to remedy through conventional breeding; the pest was vulnerable to the very Bt toxins that were already in use in India's cotton fields; and India had an established science-based regulatory apparatus. But unlike cotton, brinjal and its interfertile relatives are consumed directly, and in the minefield of GM comestibles, the plant's use in Ayurvedic medicine was a major mine. This meant that the threat was not simply to "the environment" in the abstract, but to a major player in the economy of India's most prosperous state. Ayurveda's intervention was an intriguing case of the transformation of a philosophical case into an economic case and finally into a biological case.

Note first that Ramesh's decision to refuse the release of Bt brinjal was based in part on biological grounds because India's regulatory apparatus is weighted towards biosafety considerations (Gupta 2002). The GEAC had framed the question so it turned on risk science despite objections by civil society actors to this narrow mandate (Shah 2011: 31).¹⁷ Proponents of GM organisms complained that the decision was "not science-based" but the result of "ill-informed activism" (Rao 2011). However, there were ample "scientific" (biological) arguments against the crop. Pleiotropic effects are common and may not be discovered until after a crop is released into nature. Ramesh's wording about the plant's metabolism being "disturbed" may have sounded quaint, but the basic point was quite reasonable given what is known about genetic modification. Secondly, the potential for outcrossing of the Bt trait—let alone other pleiotropic traits—is also quite real, and the ecologists who wrote to Ramesh were just as much "scientists" as were the microbiologists who worked on the genetic modification. The studies showing

outcrossing within *Solanum* (largely ignored by the government report) were in the scientific literature.

But Ramesh made clear that he was heavily influenced by the objections of the state governments, which were not entirely biological in nature. The prominent letter from Kerala's Chief Minister stressed the *economic* importance of Ayurveda, citing both local service providers and the international marketing of medicinal products. But among Ayurvedic practitioners in Kerala, aversion to genetic modification runs much deeper than the economic incentive to protect its brand; Ayurveda is intrinsically incompatible with the chemical reductionism at the heart of genetic modification and the apparatus for regulating it. Practitioners and adherents generally consider Ayurveda as a science in its own right, with a systematic body of knowledge and theoretical framework for pathology, diagnosis, pharmacology and therapeutics, underlain by its own epistemology. The regulatory process is designed to approve GM crops on the basis of whether a minute genetic alteration can be shown to be medically and environmentally safe; Ayurveda simply refuses to address that question, relying instead on textual and accumulated practical wisdom at the level of polyherbal combinations. Thus, the subsequent plan for Mahyco to conduct a "compositional analysis to find out if Ayurvedic principles are disturbed in Bt brinjal" (*Times of India* 2011b) misses the point.

The reductionist perspective certainly lends itself more readily to scientific research, and is certainly "scientific" in creating more work for scientists, but it is not inherently more effective at the "scientific" project of understanding and ameliorating human health. As Nestle (2002) argues, real progress in building a more robust theory of human health requires the synthetic examination of whole foods rather than the reductionist analysis of their ingredients; ingredients are more attractive targets for scientific studies and publication, but this is in effect "parking lot science."¹⁸ GM crops have helped to bring health impact reductionism down to the scale of the expression of the single gene. But in Ayurveda, Bt brinjal has met an opponent with its own deep theories of consumption and health, and a resolute focus on more synthetic levels of analysis—not the gene, not the ingredient, not even the food or plant, but the plant mixture.

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Notes

- 1 This issue helps explain the otherwise puzzling divergence between Europeans and Americans. In the United States, the fundamental ideas about regulation came from biologists' concerns about laboratory safety in the early days of genetic engineering, as opposed to the broader perspective adopted in the UK and Germany. As Jasanoff (2005) points out, in the United States, scientists set the regulatory agenda and the state endorsed it, while in Europe the state set the agenda then called on science experts to advise.
- 2 RBGH (which the industry prefers to call by the more obscure name "bovine somatotropin") is produced by genetically modified *E. coli* bacteria. This is a simplified account of an interesting episode in which initial efforts by activists were largely ineffective, but consumers began to reject the product over a decade later; see Schurman and Munro (2010).
- 3 In the United States, oils and sweeteners from GM soybean, canola, sugar beet and field corn are ingredients in many foods, but these plants are rarely eaten directly. Sweetcorn is consumed directly or in products such as flakes and chips; the amount of this crop that is genetically modified is vanishingly small (Sankula 2006). The biotech industry continues to succeed in blocking labeling despite a desire for labels by most US consumers (Hallman and Aquino 2005).
- 4 In early 2012, Japan announced it would allow GM papaya imports (Hay 2012).
- 5 Interviews with the General Secretary, Ayurvedic Medical Association of India, Angamaly, October 5, 2010 and Kottakkal, February 15, 2012.
- 6 Based on two Indian philosophical schools, Sankhya (School of Enumeration) and Vaisheshika (School of Atomism).
- 7 A sixth quality, "special power" (*Prabhava*), is sometimes also recognized, referring to how plants with similar physical properties may have different pharmacological effects.
- 8 Many of the popular and often-used Ayurvedic drugs are grouped into classes.
- 9 Chithrabha Kudlu, Field notes, ethnographic work 2008–2010.
- 10 Various Solanum species are also used widely for medicine outside the classical systems in rural households. Ved and Goraya (2007) studied the use of medicinal plants by rural households in five states, finding *S. anguvi* and *S. xanthocarpus* to be among the fifty-four most popular.
- 11 Chithrabha Kudlu, Field notes, ethnographic work 2008–2010.
- 12 Examples of products in the phytochemical market based on Ayurvedic plants are Bacopin, Boswellin and Bioperine.
- 13 Interviews with T. S. Muraleedharan, Chief of Technical Services, Arya Vaidya Shala, Kottakkal, February 15, 2009 and February 15, 2012.
- 14 For instance, Hankey (2001) shows the correspondence of Ayurvedic *doshas* (bodily humors relevant to medicinal effects) to body functions in terms of cellular metabolism. The new field of "Ayurgenomics" investigates relationships between human genomic

variation, pharmacogenomics, personalized therapeutics and Ayurveda (Hardy *et al.* 2008; Patwardhan and Bodekar 2008; Sethi *et al.* 2011).

- 15 The phrase “substantially similar” was replaced by “substantially equivalent” after the latter was adopted by the OECD (1993), and later by “similarity” (Levidow *et al.* 2007). It is interesting that a “like” concept was already used in regulating medicines; in new drug applications, the Federal Food, Drug, and Cosmetic Act, 21 USC §355(d) defines “substantial evidence” as “Evidence consisting of adequate and well controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved” (Roychowdhury 2011). “Substantial equivalence” is also used in the regulation of medical devices.
- 16 Ramesh was apparently referring to wild brinjal relatives; brinjal itself is rarely used in classical medicine.
- 17 Some argue that India’s biosafety risk assessments of GM biotechnology are themselves flawed as they are epistemologically and philosophically rooted in outdated versions of risk; see Shah (2011).
- 18 The allusion is to the story of the drunk who had lost his car keys, and was looking for them not where he thought he lost them but near the parking lot light because the light was better there. For overviews of this approach to nutrition, known as *nutritionism*, see Pollan (2008) and Scrinis (2008).

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