Market-based alternatives to more government regulation of foods and dietary supplements

Food Risks and Labeling Controversies

BY HENRY I. MILLER AND PETER VANDOREN

QUESTIONS ABOUT FOOD SAFETY AND REGULATION abound, among them: How safe are biotech foods—foods derived from gene-spliced organisms? Should they be labeled? Should herbal dietary supplements continue to be exempt from federal regu safety, effectiveness, and labeling?

The European Union passed legislation in late 1998 requiring labeling to identify all foods containing genetically modified (i.e., gene-spliced) ingredients, which caused large retailers to remove all such foods from their shelves. Responding to those events and to intimidation by Greenpeace, two of the United States' largest producers of baby food, Heinz and Gerber, have announced that they will use only non-biotech ingredients in their products. Demonstrators in Europe and the United States have protested the marketing of biotech foods. And fearing that many or most U.S. consumers will reject biotech foods, some U.S. farmers have canceled orders for genetically engineered seeds.

The professional risk analysis community believes that biotech foods are just more precisely constructed versions of plants engineered with other long-established techniques. Mandatory labeling of foods to indicate the presence of gene-spliced products would incorrectly signal to consumers that the government believes there is something to worry about—or, at least, that there is something fundamentally different about such products. The Food and Drug Administration's oversight of biotech foods—which is based on potential risk, not the use of certain techniques—is appropriate and adequate to ensure food safety.

In contrast, the risk-analysis community is alarmed by the state of virtual anarchy in the market for herbal supplements. Many of the products are known to be toxic, carcinogenic, or otherwise dangerous (ephedra and chaparral, for example), although only a few supplements, including saw palmetto for treating enlarged prostate glands and gingko biloba for enhancing memory in Alzheimer's patients, have been shown to be efficacious. There is no shortage of information available to consumers about dietary supplements, but it is heavy on advocacy and light on scientific proof.

Nevertheless, the lack of scientific evidence for dietary supplements' safety and effectiveness seems not to faze many con-

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sumers, who spend a fortune on unproven nostrums and jeopardize their health using dangerous ones. Known, serious side effects include blood-clotting abnormalities, high blood pressure, life-threatening allergic reactions, cardiac arrhythmia, exacerbation of autoimmune diseases like arthritis and lupus, and kidney and liver failure. Even persons who believe that the process for approval of new drugs is too stringent argue for controls on dietary supplements.

The concept of substantial equivalence in new foods—a form of regulatory shorthand—applies to those foods that do not raise safety issues requiring special case-by-case scrutiny.

In view of the recent—and continuing—attacks on biotech foods, we begin by assessing the lack of scientific merit in those attacks. We then turn to the question of labeling for biotech foods and dietary supplements. We argue that market forces can serve consumers' interests, obviating the need for additional Food and Drug Administration (FDA) scrutiny of biotech foods or dietary supplements.

SCIENCE AND BIOTECH FOODS

The Scientific Consensus In 1986, the Paris-based Organization for Economic Cooperation and Development (OECD) issued *Recombinant DNA Safety Considerations*, in which OECD's Group of National Experts on Safety in Biotechnology found that

> genetic changes from gene-splicing techniques will often have inherently greater predictability compared to traditional techniques, because of the greater precision that the gene-splicing technique affords; [and] it is expected that any risks associated with applications of gene-spliced organisms may be assessed in generally the same way as those associated with non-gene-spliced organisms. (p. 31)

A landmark 1989 report of the U.S. National Research Council, *Field Testing Genetically Modified Organisms: Framework for Decisions*, went even further, observing that "with organisms modified by molecular methods, we are in a better, if not perfect, position to predict the phenotypic expression" (p. 13). That statement expresses the scientific consensus that our ability to predict "phenotypic expression"—the very essence of risk assessment related to environmental protection and public health—is superior for gene-spliced foods.

In 1993, OECD's Group of National Experts specifically addressed food safety, concluding in *Safety Evaluation of Foods Derived by Modern Biotechnology* that

> evaluation of foods and food components obtained from organisms developed by the application of the newer techniques does not necessitate a fundamental change in established principles, nor does it require a different standard of safety. (p. 13)

In the same report, the group of experts described the concept of "substantial equivalence" in new foods. The concept—a form of regulatory shorthand—applies to those new foods that do not raise safety issues that require special, intensive, case-by-case scrutiny. (The U.S. delegation suggested the use of "substantial equivalence," which is borrowed from FDA's definition of a class of new medical devices that do not differ materially from their predecessors and, thus, do not raise significant regulatory concerns.)

OECD has continued to explore the concept of substantial equivalence. In 1998, another expert group concluded in *Report of the OECD Workshop on the Toxicological and Nutritional Testing of Novel Foods* that

> while establishment of substantial equivalence is not a safety evaluation per se, when substantial equivalence is established between a new food and the conventional comparator [antecedent], it establishes the safety of the new food relative to an existing food and no further safety consideration is needed. (p. 15)

Fallacies and Conspiracy Theories Some recent attacks on biotech foods have been based on a misinterpretation of a laboratory experiment involving the monarch butterfly and on flawed experiments that purportedly showed toxicity in rats fed gene-spliced, lectin-enhanced potatoes. But a more fundamental attack is one on substantial equivalence by Erik Millstone, Eric Brunner, and Sue Mayer in their article, "Beyond 'substantial equivalence'," which appeared last year in *Nature*.

Millstone et al. call substantial equivalence a "pseudo-scientific concept because it is a commercial and political judgment masquerading as if it were scientific" (p. 526). Wholly ignoring empirical experience and scientific consensus, Millstone et al. suggest that gene-spliced foods should be treated "in the same way as novel chemical compounds, such as pharmaceuticals, pesticides and food additives, and [requiring] a range of toxicological tests, the evidence from which could be used to set acceptable daily intakes (ADIs)" (p. 526). Then, of course, we would need "regulations…to ensure that ADIs are never, or rarely, exceeded" (p. 526).

By considering all changes arising from gene splicing—but only those changes—as novel, Millstone et al. ignore the fact that many products on the market are derived from "wide crosses"—hybridizations in which genes are moved from one species or one genus to another to create a vari-

ety of plant that does not and cannot exist in nature. They demand extensive, difficult-to-perform, hugely expensive testing of foods from gene-spliced plants, but not of other foods from the dozens of new plant varieties produced by traditional techniques of genetic modification, such as hybridization, that enter the marketplace each year without premarket review or special labeling.

If new and draconian regulatory regimens are necessary for the new biotechnology, they are certainly applicable to traditional biotechnology as well. And in that regard, one must wonder how we would calculate ADI for the mutant peach called a nectarine or the tangerine-grapefruit hybrid called a tangelo. Such an exercise would clearly be absurd. And where it is not absurd—as when estimating the acceptable intake of foods such as potatoes and squash known to have high endogenous levels of natural toxins—the exercise has nothing to do with the method of genetic manipulation used to construct the plant.

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In sum, the argument advanced by Millstone et al. illustrates the fallacy that underlies many of the unscientific attacks on the new biotechnology—the assumption that somehow gene splicing introduces into organisms (and the foods derived from them) greater uncertainty or risk than older, less-precise genetic-modification techniques. Yet, neither scientific consensus nor empirical evidence supports that view. As *Nature* editorialized in 1992,

> the same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods....[Therefore] no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes. (Vol. 356, p. 1)

FDA Policy Although FDA does not use the term "substantial equivalence" in food regulation, it applies the concept in its risk-based policy toward "new plant varieties."

FDA does not routinely subject foods from new plant varieties to premarket review or to extensive scientific safety tests. Instead, it considers that the usual safety and quality-control practices used by plant breeders—mostly chemical and visual analyses and taste testing—are generally adequate for ensuring food safety.

FDA's policy defines certain safety-related characteristics of new foods that, if present, require special scrutiny by the agency. Those characteristics include the presence of a substance that is completely new to the food supply, an allergen presented in an unusual or unexpected way (for example, a peanut protein transferred to a potato), a change in the level of a major dietary nutrient, or an increase in the level of a toxin normally found in food.

A product's composition, characteristics, or history of use may suggest the need for additional testing. For example, potatoes usually are tested for the glycoalkaloid solanine toxin because it has been detected at harmful levels in some new potato varieties that were developed with conventional genetic techniques.

The absence of characteristics correlated with heightened risk, in effect, defines a product that is substantially equivalent to antecedent products. FDA does not subject such food to premarket review, whether the plant arose by gene splicing or "conventional" genetic-engineering methods.

LABELING: MARKET SOLUTION OR GOVERNMENT INTERVENTION?

A SCIENTIFICALLY CONSISTENT RISK POLICY WOULD MAINtain the current FDA policy toward biotech foods but subject the supplement industry to additional scrutiny. But rather than argue that policy should be governed by scientific understanding—as opposed to unsound hysteria propagated by interest groups and political actors—we argue that market forces may obviate the need for more government intervention.

We focus, therefore, on whether markets can supply information that enables consumers to make informed choices about the risks they face in biotech foods and dietary supplements. Can we identify the conditions under which markets will supply information about products as part of the normal competitive process? Can we identify the conditions under which Gerber and Heinz, for example, will choose to market two or more types of food: one advertised as non-gene-spliced and higher priced, the other unpromoted, unlabeled as to its biotech ingredients, and sold at a lower price? Also, can "certified" dietary supplements command higher prices than "uncertified" supplements? If the answers to these questions are "yes," markets can serve everyone's preferences, no matter how misguided those preferences may be.

A Primer on Product Differentiation Firms will provide detailed information about their products in an attempt to distinguish them from other firms' products so long as it is profitable to do so—that is, so long as the extra price they can charge for the information exceeds the cost of providing it. A market condition known as a *separating equilibrium*

occurs if firms can offer different products with different amounts of information at different prices simultaneously. A *pooling equilibrium* occurs if firms cannot sustain markets for differentiated products at different prices.

To illustrate a separating equilibrium, let us assume that products are not labeled: consumers cannot determine whether dietary supplements are safe or effective or what they contain, nor can they determine the presence or absence of gene-spliced ingredients. Suppose one firm can then make more money by offering labeled food or dietary supplements. Will other firms be forced to follow, or will the market support a variety of products and information, including products with no information? If the market can support different products at different prices with differing levels of information, a separating equilibrium is possible.

There is not a clear case for FDA intervention in U.S. markets for food products or (perhaps) dietary supplements. FDA's present risk-based policy toward biotech foods is sound and should not be changed.

A pooling equilibrium can be one of two types. In one instance, firms will not label their products if consumers are not willing to pay enough to cover the extra costs of providing information (including extra production, handling, and packaging costs). Alternatively, firms may find it unprofitable to market unlabeled products because most consumers fear the worst and are willing to pay more for labeling.

The decisions by Gerber and Heinz to use non-gene-spliced ingredients suggest that both firms believe that a biotech-free pooling equilibrium is inevitable in the market for baby food; that is, firms will not profitably be able to offer both biotech-free and unlabeled baby food. The experience of a British firm supports that view. J. Sainsbury PLC, a British supermarket chain, in 1996 began selling a bioengineered tomato puree that was labeled voluntarily. Initially, the product sold well because its price was lower than that of conventional tomato purees. But sales of the bioengineered tomato puree fell as the European public became concerned about genetic modification, and Sainsbury has withdrawn the product from the market.

An important counterexample comes from U.S. experience with recombinant bovine somatrotropin (rbST), a biotech version of bST—a hormone that stimulates milk production in cows. In spite of widespread concern about rbST, which led to a temporary congressional moratorium on its introduction, econometric analysis of consumer behavior after the end of the moratorium found no evidence of short-term or long-term reluctance to consume rbST milk.

Should the U.S. Government Intervene? The government should consider mandatory labeling only when a compelling case can be made that a market will fail in the absence of labeling. Suppose, for example, that every firm in a market—even those that have invested in differentiating their products—would go bankrupt if there were a scandal about contamination. Thus, in the not at all unlikely event of a scandal in the dietary supplement market, the pivotal question would be whether the conscientious firms could survive or whether the public would be unable (or unwilling) to distinguish the "good" firms from the "bad" ones?

Consider the analogous case of runs on banks. Runs occur if consumers lose faith in all banks when some banks go bankrupt. Professor Charles Calomiris has argued in *Regulation* (Vol. 22, No. 1) that consumers could differentiate "good" banks from "bad" banks even during the depths of the depression. That is, the market for information about banks worked better during the depression than conventional wisdom suggests it did. Bank information separated rather than pooled. Thus, government regulation and labeling (e.g., federal deposit insurance) arguably are not needed to avert runs on banks.

Similarly, producers of non-gene-spliced and organic foods and safe and effective dietary supplements can differentiate themselves from other producers without government mandates. Witness the growth of the Whole Foods and Wild Oats supermarket chains, both of which recently announced bans on gene-altered foods. Whole Foods, with 103 stores in 22 states and the District of Columbia, and Wild Oats, with 110 stores in 22 states and British Columbia, provide detailed information about their suppliers and products in an effort to assure consumers that they are buying genuine, high-quality, organic food products. To be sure, products sold by Whole Foods and Wild Oats cost more than similar products offered by conventional grocery stores, but Whole Foods and Wild Oats provide the type of food and information that some consumers want—and for which they are willing to pay.

POLICY RECOMMENDATIONS

IN SUM, THERE IS NOT A CLEAR CASE FOR FDA INTERVENTION in U.S. markets for food products or (perhaps) dietary supplements. In particular, FDA's present risk-based policy toward biotech foods is sound and should not be changed. But there are other motives and beliefs at work in the world, which U.S. firms must heed.

If Europeans want to consume local, more expensive, non-gene-spliced foods, who are we to say that they should consume our cheaper, more precisely crafted biotech foods? By requiring the labeling of biotech foods, European governments evidently believe there will be a pooling equi-

librium in which local non-gene-spliced foods would be undifferentiated from unlabeled (and presumably imported) foods. But if European governments are accurately reflecting the sentiments of European consumers, there is likely to be a separating equilibrium in which all unlabeled foods will lose market share to foods certified as local and non-gene-spliced. Under such circumstances, even if American producers win the political fight against mandatory labeling, most unlabeled American foods would not survive in Europe.

But current European sentiments may actually be analogous to American public sentiment toward rbST, which also was very negative at first. The American market now exhibits a classic separating equilibrium: although most dairy products are unlabeled, some premium, niche products (e.g., Ben and Jerry's ice cream) are labeled as rbST-free.

Should Gerber and Heinz have yielded to anti-biotech activists? Sainsbury's experience with biotech-based tomato puree suggests that there may not be a market for labeled biotech baby food—at least in Europe. And perhaps baby food is one of the markets in which unlabeled food would not sell because consumers—who want "the best" for their babies—would suspect that there are biotech ingredients in unlabeled products and would therefore buy only biotech-free labeled products. But Gerber and Heinz should consider the possibility that all customers, regardless of their preferences, can be served by products that differ in price and ingredients. There may be no more need for Gerber or Heinz to have a one-size-fits-all product than there is for the government to impose a one-size-fits-all regulation on food producers.

Finally, there is no pressing need for the additional government regulation of dietary supplements. Producers of supplements could contract voluntarily with a foundation that would operate like Underwriters Laboratories (UL)—a large, nonprofit organization that tests and certifies products, many of which are potentially hazardous to life and property. The UL certification offers assurance of safety but not of effectiveness, except in special cases where the two are inextricably linked (e.g., fire extinguishers and smoke detectors).

The adoption of similar, third-party certification by makers of dietary supplements would protect the manufacturers' long-term interests and integrity. Most important, self-regulation would assure consumers that certified products meet certain standards of purity, potency, and quality, while preserving consumers' freedom to choose non-traditional medical therapies.

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