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 regulation of 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 ginkgo 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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SCIENCE AND BIOTECH FOODS

The Scientific Consensus In 1986, the Paris-based Organiza-
tion for Economic Cooperation and Development (OECD)
issued Recombinant DNA Safety Considerations, in which
OECD’s Group of National Experts on Safety in Biotechn-
ology found that

genetic changes from gene-splicing techniques will
often have inherently greater predictability compared
to traditional techniques, because of the greater pre-
cision that the gene-splicing technique affords; [and]
it is expected that any risks associated with applica-
tions 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 organ-
isms modified by molecular methods, we are in a better, if
not perfect, position to predict the phenotypic expres-
sion” (p. 13). That statement expresses the scientific con-
sensus that our ability to predict “phenotypic expres-
sion”—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 M odern 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 differ-
ent 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. delega-
tion suggested the use of “substantial equivalence,” which is borrowed
from FDA’s definition of a class of
new medical devices that do not dif-
er materially from their predeces-
sors 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 Toxico logical and N utritional Testing of N ovel Foods that
while establishment of substantial equivalence is not a
safety evaluation per se, when substantial equiva-

cence 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 toxici-

ty in rats fed gene-spliced, lectin-enhanced potatoes. But
a more fundamental attack is one on substantial equiva-

cence 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 con-
sensus, Millstone et al. suggest that gene-spliced foods
should be treated “in the same way as novel chemical com-
ounds, such as pharmaceuticals, pesticides and food addi-
tives, and [requiring] a range of toxicological tests, the evi-
dence from which could be used to set acceptable daily
intakes (ADI)” (p. 256). Then, of course, we would need “reg-
ulations... to ensure that ADI is never, or rarely, exceed-
ed” (p. 256).

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-

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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 regimes 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 \( \text{ADI} \) for the mutant peach called a nectarine or the tangerine-grapefruit hybrid called a tango. 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.

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 solaninatoxins 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.

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 foods, who are we to say that they should have different products at different prices with differing levels of information, a separating equilibrium is possible. 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.
librium in which local non-gene-spliced foods would be undifferentiated from unlabeled (and presumably import-
ed) foods. But if European governments are accurately reflecting the sentiments of European consumers, there is likely to be a separating equilibrium in which all unla-
beled 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 anal-
ogous 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 produ-
ts (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 toma-
Ato 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 prefer-
ces, 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 gov-
ernment 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 prod-
ucts, 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 manu-
facturers’ long-term interests and integrity. Most important, self-regulation would assure consumers that certified prod-
Acts meet certain standards of purity, potency, and quali-
A, while preserving consumers’ freedom to choose non-
traditional medical therapies.

readings


• John E. Losey, Linda S. Rayor, and Maureen E. Carter. “Trans-


• Erik Millstone, Eric Brunner, and Sue Mayer. “Beyond Substan-


