Testimony of

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Mr. Chairman and Members of the Committee, Consumers Union thanks you for the opportunity to testify at these hearings. I request that our prepared statement be included in the record in full. I will summarize our statement within the time allowed.

We congratulate the Committee for holding these hearings. Biotechnology policy is one of the most important issues of our time. It presents both opportunities and serious concerns. Commercially product development and marketing, especially of genetically modified food products, are well ahead of the policies needed to assure public health, environmental safety and the rights of consumers. We can only hope that no serious damage occurs before public policy catches up. We must act to assure that public policy catches up quickly.

As you know, *Consumer Reports* magazine, in its September 1999 issue, carried a major article on "bio-tech" foods, entitled “Seeds of Change.” I would l like to offer a copy of the September issue for the Committee’s use and to request that it be included in the record or in the Committee’s files, as the Chair deems appropriate. In addition, our organization is part of an effort by a large number of citizen organizations to get mandatory labeling of genetically engineered foods and to prevent the U.S. government from using the World Trade Organization as a forum for challenging non-discriminatory labeling requirements of other governments.

Burgeoning use of genetically engineered crops. As the article "Seeds of Change" indicates, today, a mere three years after the first large-scale commercial harvest of genetically engineered crops, such crops cover one-fourth of U.S. cropland. Almost 55 percent of all soybean acreage, more than 35 percent of all corn acreage and nearly half of all cotton acreage in the U.S. are growing genetically engineered product. Fifty genetically engineered crop plants have been approved by the Department of Agriculture (USDA), including potatoes, tomatoes, melons and beets, although some are not yet grown in large numbers. Other crops such as rice, wheat, cucumbers, strawberries, apples, sugarcane and walnuts are being grown on test sites as part of the USDA approval process.

Americans are already eating a variety of genetically engineered foods. Consumers Union's testing of foods purchased from supermarket shelves and fast food chains demonstrates that Americans are eating genetically engineered products in a wide variety of foods: baby formula, tortilla chips, drink mixes, taco shells, veggie burgers, muffin mixes. But consumers are not informed that they are eating genetically foods that are -- or contain -- a genetically engineered product. And so, despite the fact that there are important reasons some consumers may prefer to select the more traditional equivalents of these products, they do not have the information needed to do so.

Genetically engineered foods and food safety. *Consumer Reports* stated quite clearly: there is no evidence that the genetically engineered foods now on the market

present safety problems. At the same time, neither can it be said that they have been proven “safe”. These products have been in use for too short a time, and our regulatory framework is too fragmented and to reliant on industry self-regulation to say that either experience or the government assures safety.

Despite this, many grower and food producer industries as well as federal regulators characterize these foods as “safe” because there is no evidence of harm to consumers. However, the “safe-unsafe” dichotomy may be false. Between these two categories lies a chasm of uncertainty due to lack of knowledge and experience. The dichotomy also obscures the reality that we need to evaluate every genetic transformation individually – each one may carry a new and unique potential for risk. Many, perhaps all, of these foods may in the long run prove to be as safe for consumption by the general population as their traditional counterparts. But we cannot say this with certainty at this stage of experience. In addition, there are specific concerns that the regulatory system has addressed, but it has done so inadequately.

Potential for new allergenic foods. One concern is allergenicity. An introduced gene may produce proteins, which are not present in the traditional equivalent of a genetically engineered food, and some number of consumers may allergic to that protein. Genetic engineering can achieve organism cross-breeding that cannot be achieved using traditional cross-breeding methods.

Where the source organism is a known human allergen, the Food and Drug administration (FDA) guidelines seek to address this in a way that would result in detecting the problem before the new food variety is marketed.

It is true that in the one case where it is known that an allergen was introduced into a new variety using genetic engineering methods -- Pioneer Hybrid International introduced a Brazil nut gene into a soy bean -- the company voluntarily withdrew the product. However, it is not clear that the FDA guidelines are adequate to assure that the outcome will always be as fortuitous as in the Brazil nut instance. The FDA guidelines are not specific about what must be done to detect such a problem, and it was only because Pioneer took many extra steps that the problem was detected. Pioneer is to be commended for its diligence. However, occasionally but with serious public health effects companies do not act responsibly to assure that unsafe products are not marketed. Consider the instances of the Dalkon Shield IUD, the Shiley heart valve, asbestos, tobacco and polychlorinated biphenyls.

Further, the Brazil nut instance involved the transfer of a gene from a common food that bears a known food allergen. Unlike traditional cross-breeding, genetic engineering also permits a gene transfer from a non-food organism to a traditional food organism. In such an instance it may not be known in advance whether humans will develop food allergies to proteins produced by the non-food gene. Allergies may develop only after repeated exposure to a substance. Unless the new substance undergoes long-term clinical testing, there cannot be certainty as to the safety of the new variety.

Potential for toxic new foods. Genetic transfers also can result in increased toxicity. Traditional plants may contain constituent chemicals that are toxic at higher levels but not present in the food at sufficient levels to cause harm. For instance, edible potatoes contain alkaloids that, at higher levels, would be toxic. It is of concern that genetic engineering of a potato, or of another plant that presents this problem, could result in a dangerous increase in toxicity. Indeed, at least one new variety of conventionally cross-bred potato went onto the market and had to be withdrawn because it contained toxic levels of alkaloids that made people ill. Internal FDA memos recently made public show that when the FDA was developing its current industry self-regulatory proposals, staff from the FDA Center for Veterinary Medicine (CVM) raised the concern that the agency would not be able to assure the safety of animal feed containing genetically modified materials. They recommended FDA review of genetically modified products for toxin problems, but they were overruled.

Potential for new lower-nutrient foods. Genetic transfers may also result in changes in the levels of food plant nutrients. A recent study has shown, for example, that heart-protective phyto-estrogens are lower in one of the new genetically engineered soy varieties than in its traditional counterpart. While changes like this may be small and incremental, and appear unlikely to cause a major dietary deficiency, such changes could add up over time and impact public health in ways that are difficult to detect and hard to control. Such effects may well be small compared to the effects of the national

tendency to consume non-nutritious foods or to consume inadequately balanced diets. Nevertheless, they should be monitored to assure that they do not become a problem.

Antibiotic market genes. The FDA says that there is a "vanishingly small" risk that antibiotic "marker" genes in genetically engineered food will be transferred to disease-causing bacteria. It is therefore taking no regulatory incentives for the industry to use other kinds of markers. However, other experts, including the British Medical Association, are concerned.

Imported foods not monitored. While FDA's oversight may have deficiencies, most countries at this point have no system at all in place to assess the safety of genetically engineered food. We know such foods are being grown in Brazil, Argentina and China, and a number of countries have their own research programs. Yet FDA does not even require that it be notified when genetically engineered foods enter the U.S. We currently have no idea what or how much genetically engineered food developed or raised in other countries may be in U.S. supermarkets. Nor do we have a requirement that such imported foods be subject in the national of production or development at least to guidelines equivalent to the FDA's.

FDA's guidelines for assuring the safety of genetically engineered foods are inadequate. FDA does have guidelines saying that genetically engineered food products should be tested for safety. The guidelines provide a "decision tree" to determine whether full-scale FDA product review is required. The "tree" asks questions

such as whether the plant's characteristics warrant analytical or toxicological tests. The companies themselves answer these questions and decide whether to talk to FDA about the product. Companies only need certify to FDA that they will comply with the guidelines. Companies that choose to call the FDA's pre-marketing attention to their product need only supply testing summaries, not the full data.

Environmental concerns. There are environment concerns about the crops from which these foods are taken, as evidenced by the Cornell University study published in *Nature* last May which raised concerns about the effects of genetically engineered Bt corn on monarch butterfly larvae.

As indicated in "Seeds of Change," there are other environmental concerns as well, including the possible effects on other plants if so-called "terminator" genes escape and cross over to other plants, rendering them sterile. Discovery of detrimental environmental effects after the crops have been approved for commercial use is exceptionally troubling because there is no way to retrieve the genes that have been placed in the field. While we are reliant on the U.S. regulatory process to prevent such unintended effects, the case of the monarch butterfly indicates that this process is not yet adequate.

Consumer awareness in the U.S. of genetically engineered foods. As the article "Seeds of Change" indicates, U.S. consumers, at least prior to the publication of the article, have been largely unaware of this issue. Only about one-third were aware that

genetically engineered foods were available in the supermarket. Half thought they were not.

Consumers want labeling for genetically engineered foods. But polls show that when consumers are made aware of the facts, they want to know through labeling which foods are genetically engineered. A Time magazine poll in January, 1999, found that 81 percent of respondents said genetically engineered food should be labeled as such. In short, consumers want the information needed to exercise choice.

Reasons for consumer preferences. Reasons for wanting this information may differ among consumers. Some consumers may want to try genetically engineered varieties of whole foods, especially if the industry in the future develops varieties that have demonstrable direct consumer benefits such as improved flavor or nutrition, benefits which have not to date been the focus of this technology. Others may prefer to select only traditional foods, or want to wait until there is greater experience demonstrating long-term food and environmental safety before they try genetically engineered varieties. Some who have severe and/or multiple food allergies may want to stick to an established dietary pattern that they have found to give them freedom from allergic food reactions. Some may have religious reasons for wanting to avoid particular genetically engineered foods and may want for this reason to be able to identify particular genetically engineered products, or to avoid the category altogether.

Lack of labeling deprives consumers the right to choose. But the lack of labeling denies consumers this choice. The USDA now says that genetically engineered foods will be barred from using the organic label when the Department finalizes its regulations on the use of the term "organic" on food labels, and that this will offer consumers a choice. This is laudable from the standpoint of defining what is "organic food," but is it not adequate for the purpose of assuring consumers that they can know whether foods they select in the marketplace have genetically modified content. Organic food is not widely available in may locations and is almost always higher priced. And production *may* not be sufficient to meet all of the demand for foods that is not genetically engineered. Barring genetically engineered food from using the organic label offers choice only to those who can afford and obtain a totally organic diet.

Powerful interests within the biotechnology, agriculture and food industries are working hard to prevent mandatory labeling, the approach that would offer choice to all consumers. They are joined by the U.S. Food and Drug Administration, which has chosen to been a cheerleader for this technology, rather than to administer vigorously the food safety and commercial deception laws which it is changed with enforcing.

FDA – cheerleader for a technology. FDA has stubbornly insisted that it has no authority to require labeling of genetically modified foodstuffs or processed foods containing them. It states that it is a science-based agency that can only require labeling where it has found scientific evidence of a health or safety risk. It quite

inaccurately characterizes consumers' desire for labels on these products as "mere consumer curiosity."

Instead, the FDA should be promoting the public interest by assuring that full, non-disparaging label information is available to protect all interests, including those of consumers who wish to exercise choice and of businesses who want a marketplace distinction between their traditional products and genetically engineered products. The FDA requires labeling on the basis of marketplace commercial distinctions in many instances that do not involve health issues, including chocolates and fruit juices. There is no compelling reasons it cannot do so in this instance – and there are compelling reasons why it should.

FDA has the authority to require labeling. FDA's very limiting characterization of its own legal authority is misplaced. I would like to submit for the record a copy of my own analysis showing why this characterization is wrong and why the case for labeling foods produced with biotechnology is virtually indistinguishable from the case FDA itself has made for labeling foods treated with irradiation processes.

FDA is in this instance making a legal argument in order to mask its policy preferences for promoting the success of the new food technology. This is not an appropriate role for the FDA.

Summary. In summary, genetically engineered foods hold out both opportunities and serious concerns for consumers. Public policy needs to address both the inadequacies of the regulatory system that should but does not yet assure us these products are as safe as they should be for consumers to eat and as safe for the environment as they should be to prevent serious environmental impacts. It also needs to address the rights of consumers to know what they are eating and to make informed choices in the marketplace.

Mr. Chairman, Consumers Union thanks the Committee for the opportunity to testify on this important subject.