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FOR IMMEDIATE RELEASE

Composition of Altered Food Products, Not Method Used to Create Them, Should Be Basis for Federal Safety Assessment

WASHINGTON -- Federal agencies should assess the safety of genetically altered foods -- whether produced by genetic engineering or by other techniques, such as conventional breeding for desirable traits -- on a case-by-case basis to determine whether unintended changes in their composition could adversely affect human health, says a new report from the National Academies' National Research Council and Institute of Medicine. The scope of each safety evaluation should not be based solely on the technique used to alter the food, said the committee that wrote the report, because even traditional methods such as cross-breeding can cause unexpected changes. Instead, greater scrutiny should be given to foods containing new compounds or unusual amounts of naturally occurring substances, regardless of the method used to create them.

"All evidence to date indicates that any breeding technique that alters a plant or animal -- whether by genetic engineering or other methods -- has the potential to create unintended changes in the quality or amounts of food components that could harm health," said committee chair Bettie Sue Masters, Robert A. Welch Foundation Distinguished Professor in Chemistry, University of Texas Health Science Center, San Antonio. "The possible impact of such compositional changes should be examined on a case-by-case basis to determine whether and how much further evaluation is needed."

The report uses the term "genetic modification" to describe the broad array of breeding techniques -- ranging from traditional cross-breeding to genetic engineering to the use of chemicals or radiation -- used to alter plant and animal traits that can be inherited from one generation to the next.

"Genetic engineering" refers to a specific type of alteration that uses molecular biology techniques to delete genes or to transfer genes for particular qualities from one species to another. For example, plant breeders have engineered crops to resist pests by inserting a protein from a soil bacterium, and efforts are under way to develop foods with enhanced nutritional content.

Adverse health effects from genetic engineering have not been documented in the human population, but the technique is new and concerns about its safety remain. The U.S. Department of Agriculture, the Food and Drug Administration, and the U.S. Environmental Protection Agency commissioned the National Academies to assess the potential for adverse health effects from genetically engineered foods compared with foods altered in other ways, and to provide guidance on how to identify and evaluate the likelihood of those effects.

Genetic engineering is not an inherently hazardous process, the report says, but the resulting food, along with foods created from other methods of genetic modification, should be examined to determine if the inserted genes produce toxins or allergens. Unexpected changes are more apt to occur if genetic material is transferred between distantly related species. Genetic engineering is more likely to cause unintended changes than some techniques, such as simple selection, but less likely to do so than other currently used methods, such as those that use radiation or chemicals. Because all methods can cause these changes, the committee concluded that attempts to assess food safety based solely on the method of breeding are "scientifically unjustified."

Instead, foods modified by any method that changes genetic composition should, when warranted by their individual characteristics, be evaluated on a case-by-case basis before their commercial release. The report offers a framework to guide federal agencies in selecting the route of safety assessment. A new genetically modified food whose composition is very similar to a commonly used conventional version may warrant little or no additional safety evaluation. But if an unknown substance has been detected in a food, a more detailed analysis should be conducted to determine whether an allergen or toxin may be present. Likewise, foods with nutrient levels that fall outside the normal range should be assessed for their potential impact on consumers' diets and health.

Scientists' current ability to predict whether such changes will cause adverse health effects is limited, and more research is needed in this area, the committee cautioned. In some cases, evaluation should continue after products are on the market -- especially for foods with new substances or unusual nutrient profiles -- to assess and validate how well pre-market evaluations are working. Barriers to this type of surveillance exist, however. For example, currently there is no way to track altered foods in the marketplace or identify consumers who have used them. The committee urged the agencies to improve their ability to detect consumer trends in purchasing genetically modified foods, and to enable the traceability of these foods. Also, better epidemiological and survey tools should be developed that can detect changes in the population's health that may be caused by these foods.

The committee was also asked to examine safety issues related to foods from cloned animals. Safety evaluation of foods from these animals should also focus on the product itself rather than the process used to create it, said the committee, which recommended that the evaluations compare foods from cloned animals with those from noncloned animals. At present, there is no evidence that foods from cloned animals pose an increased risk to consumers. However, cloned animals that are engineered to produce pharmaceuticals should be kept from entering the food chain, the committee stated.

The report was sponsored by the U.S. Department of Agriculture, the Food and Drug Administration of the U.S. Department of Health and Human Services, and the U.S. Environmental Protection Agency. The National Research Council and Institute of Medicine are private, nonprofit institutions that provide science and health policy advice under a congressional charter. The Research Council is the principal operating arm of the National Academy of Sciences and the National Academy of Engineering. A committee roster follows.

Copies of [Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects](#) are available from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at <http://www.nap.edu>. The cost of the report is \$35.00 (prepaid) plus shipping charges of \$4.50 for the first copy and \$.95 for each additional copy. Reporters may obtain a copy from the Office of News and Public Information (contacts listed above).

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