In spring of 2014 the Dean of OSU's College of Agricultural Sciences charged a faculty committee to review and summarize key considerations related to genetically engineered (GE) organisms. The committee chose five topics that engaged faculty expertise and that reflected public interest regarding GE organisms in agriculture.

Committee members drafted these white papers as a service to the public for the purpose of providing information from several scientific perspectives. These papers have been reviewed by all committee members and are intended to help inform public conversations about genetically engineered organisms in agriculture.

FOOD SAFETY ASSESSMENT AND REGULATIONS FOR GENETICALLY ENGINEERED ORGANISMS IN AGRICULTURE

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INTRODUCTION

The safety of our food supply is an important public concern, whether the food is derived from conventional methods, organic production, or biotechnology. The assessment of the safety of genetically engineered (GE) organisms, in particular, in our food supply is critical. The available scientific evidence suggests that the biotechnology currently used in genetically engineered organisms does not present food safety issues that differ from traditional agricultural or breeding practices. Furthermore, there is no verifiable scientific evidence that consumption of a GE organism has resulted in adverse health effects. This paper explores questions related to food safety and regulations for GE organism s in agriculture.

WHAT ARE FOOD SAFETY CONCERNS WITH GENETICALLY ENGINEERED ORGANISMS ?

When assessing food safety, many regulatory agencies test the final product and not the process of developing the food. If the new food produced through biotechnology is essentially the same as its existing counterpart, regulatory agencies generally conclude the new food to be equally safe. This concept is known as *substantial equivalence* and serves as the basis for evaluating the safety of GE organism s in the U.S. and many countries. If the food and/or its new ingredients are *substantially equivalent* to existing

foods or ingredients, it is treated like conventional foods with respect to certain aspects of its safety. Food or food ingredients that have been used safely over long periods of time, or foods that are *substantially equivalent* in nutritional characteristics, do not require additional extensive safety testing. However, GE-associated traits or substances that raise scientifically-based safety issues require additional testing in the laboratory or in animal models. In this assessment, we do consider differences in nutritional content between conventional and biotechnology-derived foods, as well as the potential for production of allergens and novel toxins.

WHAT REGULATIONS EXIST TO TEST GENETICALLY ENGINEERED FOODS?

GE food commodities and products made from them are under the regulatory control of three U.S. federal agencies:

The Food & Drug Administration

The Food & Drug Administration (FDA) is responsible for the safety and labeling of foods and animal feeds from all crops, including those that are genetically engineered. The FDA requires full evaluation of GE foods by chemical, biochemical, and nutritional analyses to assess: uncharacterized DNA sequences; significantly altered nutrient levels, or anti-nutrients; different composition relative to existing foods; potentially allergenic or toxic proteins; and/or new selection marker genes (EPA 2012). Specific testing includes: total food and feed analysis by composition data and proximate analyses of fats/oils, carbohydrates, proteins, minerals, water content; amino acid homology; potential allergen assessment; digestibility; acute oral toxicity; animal performance; and identities and levels of toxicants.

The FDA's labeling policy for GE foods is the same as for conventional foods, and it assures that consumers are given information about changes in nutrition, health safety, or food quality in the end product. FDA-mandated labels are not used to provide information about the process by which the food is grown or produced. However, if a GE food is significantly different from its conventional counterpart, the food must be labeled to indicate the difference. For example, changes in the nutritional profile are declared if the GE food is created using genetic information from a previously recognized allergenic source (such as peanut, soy, or wheat) or if the new protein has characteristics of known allergens.

U.S. Department of Agriculture

The U.S. Department of Agriculture – Animal and Plant Health Inspection Service (USDA-APHIS) regulates and oversees the environmental consequences, safety, and field-testing of biotechnology-enhanced plants. The agency's role is to ensure that field tests of GE crops are conducted under controlled conditions and that any unusual occurrences are reported. APHIS approval must be obtained prior to field-testing or marketing a biotechnology-derived plant. A bio-safety peer-review committee of scientific experts provides oversight. Factors considered before approval is granted for release of a new GE plant variety are:

1) the genetic material is stably integrated;
2) plant modification does not contain genetic material derived from an animal or human pathogen;
3) the function of the genetic material is known, and its expression does not result in plant disease;
4) introduced genetic material does not produce an infectious entity, or encode substances likely to be

toxic to non-target organisms likely to feed on the plant; and,
5) new GE sequences do not pose significant risk for creating a new plant virus.

Once the appropriate and sufficient data have been collected and submitted to the agency regarding the environmental impact of a biotech-derived plant, the developers of the plant can petition APHIS for "nonregulated status." This status means that the plant no longer needs to be regulated as a potential risk or pest.

U.S. Environmental Protection Agency

The U.S. Environmental Protection Agency (EPA) evaluates food safety and environmental issues associated with plants and microbiological organisms that produce new pesticides and pesticide products (insecticides, herbicides). Bt (*Bacillus thuringiensis*) corn and the pesticide Bt product it contains fall under EPA's jurisdiction, for example. The agency reviews effects of the plants on the environment (toxicity) and fate in soils (residuals); sets tolerance levels for pesticide residues; determines acute oral toxicity, typically in animals; evaluates human health and safety data; reviews an insect resistance management plan; approves experimental use permits; and authorizes product registration for new pesticides.

WHAT TOXICOLOGICAL STUDIES ARE CONDUCTED TO DETERMINE POSSIBLE RISKS FROM CONSUMPTION OF A GENETICALLY ENGINEERED ORGANISM?

Since the composition of genetically engineered foods differs little from their conventional counterparts, the potential for adverse health effects should not differ substantially. However, given the importance of food safety issues, several types of toxicological testing have been developed to assess GE foods. Most of these are based on single chemical assays, such as structural analysis or allergen testing (SOT 2002).

Food allergies restrict millions of people in the U.S. from eating natural and conventionally produced food. While new or higher levels of allergens would not be expected in genetically engineered foods compared with their conventional counterparts, scientists have a variety of approaches to assess this risk. The first is to determine if there is structural similarity with proteins of interest and known allergens. Another approach is to determine if new proteins react with specific antibodies, known as IgE antibodies. A separate technique determines the digestibility of the protein of interest in simulated gastric fluid. A good correlation exists between resistance to digestion and potential for allergenic properties. These approaches, while robust, cannot completely characterize all possibilities for all allergenic individuals.

Before making a regulatory decision about genetically engineered pesticides used on plants, EPA requires several types of toxicological data (EPA 2012). These data include identification of any new proteins or genetic material; mammalian toxicity tests of the new proteins; comparison of the new proteins with known allergens; several ecological toxicity tests; and the amount of time it takes for the new protein to degrade. EPA conducts these tests on a range of doses, including doses that are 100 times higher than those expected in normal conditions.

WHAT DOES THE SCIENTIFIC COMMUNITY SAY ABOUT THE SAFETY OF GENETICALLY ENGINEERED ORGANISMS IN FOOD?

Extensive food safety testing is conducted on genetically engineered foods prior to their release.

Therefore GE foods have undergone considerably more scrutiny than conventional foods, which have been bred using classical breeding and mutation methods. Does this mean that GE foods are 100% safe? A statement that claims 100% safety cannot be made about *any* food – be it conventional, genetically engineered, or organic. For example, a peanut, whether grown conventionally, organically, or genetically engineered, can cause severe allergies in sensitive individuals.

Based on the perspective of government regulators and independent scientists who have studied the safety and applications of modern biotechnology, the overwhelming consensus is that genetic engineering technology is safe in foods. GE technology has been endorsed by the Institute of Food Technologists, the U.S. National Academy of Sciences, American Association for the Advancement of Science, National Research Council, American Dietetic Association, American Medical Association, Center for Science in the Public Interest, and the World Health Organization, among others.

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