Division of Food Chemistry and Technology, HFF-415 Division of Contaminants Chemistry, HFF-420

Points to Consider for Safety Evaluation of Genetically Modified Foods. Supplemental Information.

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INTRODUCTION

This document is concerned with whole foods or food components derived from plants with genetically modified traits. Historically, plants used as food sources were selected on the basis of their beneficial characteristics. Since the advent of plant breeding plants were genetically improved using hybridization and selection of sexually compatible species. Recently developed techniques of genetic engineering allow to transfer genetic material between sexually-incompatible organisms, for example, between plants and insects or plants and bacteria.

The areas of intense research include introducing genetic material into plants that makes them resistant to pests, tolerant to herbicides, and tolerant to environmental stress. Other genetic improvements relate to nutrient composition, and technological or sensory characteristics of crops. Published information on these subjects is briefly summarized below in the "BACKGROUND INFORMATION" section. Pest-resistant plants have been excluded because they are under the jurisdiction of the Environmental Protection Agency.

biochemical assay (bacterial chloramphenicol acetyltransferase) (ref.), or to monitor using reactants that produce coloration of plant tissue (bacterial β -glucuronidase) (ref. 11 from Toriyama, Biotechn. 1988) or light emission (bacterial or firefly luciferase (ref.). It is not clear as yet if the scorable marker genes will be used in genetically engineered plants proposed for commercialization.

All the above marker genes produce proteins that are new with respect to plants. Because the background exposure to these proteins, e.g, from microorganisms present in the environment, would be negligible (see Chemistry memoranda), they should be considered to be new proteins in the human diet and be subjected to safety evaluation. Because the marker genes are inserted randomly in the plant genome, each insert behaves essentially as a separate gene. As a result, subsequent crosses between two independently obtained transformants may lead to the amplification of a marker gene in the progeny. This possibility should be taken into account in the projections of exposure to any protein, especially however, to proteins produced by the marker genes because they are used repeatedly within the same species.

6. Pleiotropic effects.

The insertion of any DNA into the plant genome may result in various phenotypic changes (desirable or undesirable) referred to

as pleiotropic effects. Undesirable phenotypes may include, for example, poor growth, reduced levels of nutrients, increased levels natural toxicants, etc. Pleiotropic effects occur in genetically engineered plants obtained with Agrobacterium-mediated transformation at frequencies up to 30% (Ref.). Most of these effects can be managed by the subsequent breeding and selection Nevertheless, some undesirable effects such as procedures. increased levels of known naturally occurring toxicants, appearance of new, not previously identified toxicants, increased capability of concentrating toxic substances from the environment (e.g., pesticides or heavy metals), and undesirable alterations in the levels of nutrients may escape breeders' attention unless genetically engineered plants are evaluated specifically for these changes. Such evaluations should be performed on a case-by-case basis, i.e., every transformant should be evaluated before it enters the marketplace. [A similar approach was recommended by the International Food Biotechnology Council (Ref.)].

To address unrecognized toxic substances that may unexpectedly appear in transgenic plants or to evaluate plants that normally contain many toxic substances at very low levels, toxicological evaluation of the edible plant tissue may be more appropriate than using chemical identification and quantitation procedures.