

Problems with GM papaya

Potential Human Health Effects of Genetically Engineered/Genetically Modified (GE/GM) papaya

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SUMMARY

Papaya (*Carica papaya*) is grown throughout the tropics and subtropics. Papaya ringspot virus (PRSV) is a serious disease pest of papaya in many of the countries that commercially produce papaya. Genetically engineered (GE) PRSV-resistant papaya was developed in the late 1980s and grown commercially, only in Hawaii, USA, since 1998. These GE PRSV-resistant papaya were co-developed by scientists at Cornell University and the University of Hawaii. Based on the successful use in Hawaii, GE PRSV-resistant papaya are being developed, using basically the same methodology as those grown in Hawaii, and field tested in a number of countries in Asia (including Thailand, Malaysia and Singapore), Latin America and the Caribbean.

GE PRSV-resistant papaya was genetically engineered by firing a gene that expresses the coat protein (the outside) of the virus into that plant's own DNA, together with marker genes. This led to the papaya becoming resistant to infection by PRSV.

Genetically engineered crops are regulated in the United States by the Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).

USDA conducts a review only to determine that a transgenic plant does not pose a risk of becoming or creating a plant pest. The USDA review does not address human safety issues.

The U.S. EPA regulates the GE PRSV-resistant papaya as a plant pesticide, and should have examined the question of whether the inserted viral coat protein, which makes the papaya immune to papaya ringspot virus, poses any human safety hazard. EPA determined that consumption of the PRSV coat protein was safe based on verbal arguments/reasoning alone. EPA reasoned that since people have eaten PRSV-infested papaya over the years with no obvious adverse effects reported, the PRSV coat protein must be safe to consume. EPA did not require or review any safety data.

The U.S. FDA conducts voluntary assessments and considered whether potential changes in selected nutrients and toxicants in the GE PRSV-resistant papaya posed any human health risks. The sample sizes submitted for the nutrient studies were very small, less than 15 papayas per study, making statistical analysis of the results virtually impossible. The amount of vitamin C observed was slightly lower for one of the two GE PRSV-resistant papaya lines compared to the non-GE line. However, it was argued that the vitamin C level was within the normal range for papaya. Much larger sample sizes are needed to have valid conclusions.

According to the developer's submission to the U.S. FDA, eating green (unripe) papaya may induce abortion in pregnant women, connected to the presence of a plant compound (benzyl isothiocyanate, or BITC) found primarily in the latex in

green papaya tissue. The GE papaya developers reported no significant differences in this compound between GE and non-GE unripe and ripe papayas. However, experimental details are lacking and the sample size was again unacceptably small (less than 9 immature fruits). It is also unclear how many different papaya plants and locations were sampled; it is possible that only one plant per line and one location were sampled.

Since immature papaya fruits (called green papayas) are widely consumed in Thailand, careful study is needed of the BITC levels in the immature fruits from the PRSV-resistant papayas. Any increase in BITC levels in green papayas could have negative consequences on health of pregnant women as green papaya is often consumed every day. Such a study should include large sample sizes and should include comparisons of immature fruits grown in a range of different environments.

FDA did not address two important safety issues: potential to cause an allergic reaction and presence of genes coding for resistance to the antibiotics tetracycline and gentamycin.

One of the major safety issues associated with GE foods is the potential for allergic reaction. When the PRSV-resistant papayas were going through the approval process in the United States in the mid-1990s, no attention was paid to the question of allergenicity. Since that time, there has been an FAO/WHO global agreement on the protocol for testing all GE foods.

Using the WHO/FAO recommended protocol for allergenicity assessment, Dutch scientists found that the inserted trait in the transgenic papaya, the PRSV CP, had sequence similarity to a known human allergen that can cause a life-threatening allergic response. The scientists concluded that further clinical testing for potential allergenicity should be carried out.

The Codex Alimentarius “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants” states that “Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in foods” (CAG/GL 45-2003, para 58). Two different GE lines of PRSV-resistant papaya were created for field testing in Hawaii, which contain all or parts of three antibiotic resistance genes, those for kanamycin, gentamycin and tetracycline. We do not know what antibiotic resistance genes are present in the GE PRSV-resistant papayas being field tested in Thailand. This can be known only if a full and detailed characterization of the inserted DNA in GE papayas strains being field tested in Thailand is disclosed to the public.

There are several human food safety issues concerning GE PRSV-resistant papaya commercialized in Hawaii and regulated by US agencies, including whether it may cause life-threatening allergic responses, may contain less vitamin C and vitamin A, may contain increased levels of benzyl isothiocyanate, a toxin that occurs naturally in green papaya, or may contain genes for resistance to antibiotics that are used in human medicines. These concerns apply also to Thai PRSV-resistant papaya, but have not been adequately addressed in Thailand.