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Biotechnology Regulatory Services
Animal and Plant Regulatory Services
United States Department of Agriculture
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To whom it may concern:

Florida Certified Organic Growers and Consumers, Inc. (FOG) submits the following comments on the draft environmental assessment (EA) conducted by USDA regarding University of Florida Petition ("Petition") 04-337-01P seeking a Determination of Nonregulated Status for X17-2 Papaya Resistant to Papaya Ringspot Virus.

FOG is a 501(c)(3) not-for-profit corporation committed to promoting organic and sustainable agriculture and just food systems through educational outreach and collaboration with producers and consumers, schools and community stakeholders, universities, allied non-profits, government agencies and policymakers.

FOG's staff conducts, coordinates, and participates in educational events in a diversity of areas relating to organic agriculture at local, state, regional, national, and international venues. FOG staff members administer a wide range of programs including public policy analysis and development, local food systems development, organic and sustainable agriculture educational outreach, agricultural social justice, and an organic certification program. To meet the demands of the rapidly growing organic industry, FOG operates Quality Certification Services (QCS), one of the country's leading organic certification programs that provides verification of the organic integrity of organic farming and processing systems, providing agricultural operators a valuable means for differentiating their products in the marketplace.

FOG urges the USDA/AHPIS to deny deregulation of X17-2 Papaya Resistant to Papaya Ringspot Virus because of the significant harm which may ensue from deregulation. If USDA/APHIS continues to consider deregulation, an environmental impact statement (EIS) is necessary because this project will have significant effects on the human environment. The following comments detail some of the significant negative effects of X17-2 Papaya Resistant to Papaya Ringspot Virus.

I. APHIS's Regulatory Obligations for Genetically Engineered Crops under the Plant Protection Act and its Implementing Regulations

The Plant Protection Act of 2000, 7 U.S.C. §§ 7701-7772 (2000) ("PPA"), gives the United States Department of Agriculture broad regulatory power to prevent the spread of plant pests and noxious weeds. Plant pests are subject to strict regulation. No one can "import, enter, export, or move in interstate commerce any plant pest" without a permit from APHIS, and regulations regarding the importation of plant pests must be based on sound science. 7 U.S.C. § 7711(a), (b). Noxious weeds, and other regulated articles – "plants, plant products, biological control organisms, noxious weeds, articles, and means of conveyance" – are covered under § 7712. This section gives the USDA broad permission to regulate the trafficking of crops:

> The Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, . . . [or] noxious weed . . . if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.

7 U.S.C. § 7712(a). APHIS is given the power under § 7712(f)(1) to "publish, by regulation, a list of noxious weeds that are prohibited or restricted from entering the United States or that are subject to restrictions on interstate movement within the United States." Once that list has been established, any person may petition APHIS to have plants added or removed from the list of plants regulated under this subsection. APHIS must base their decision regarding such petitions on sound science. § 7712(f)(2), (3).

Many GE crops are engineered using plant pests as gene donors. The USDA has promulgated 7 C.F.R. § 340 to cover the regulation of GE crops. This singles out crops created with donor genes from plant pests for regulation, a full listing of taxa and genera of plant pests can be found at 7 C.F.R. § 340.2. Papaya modified to resist papaya ringspot virus (PRSV) is a plant that falls under this categorization since the engineered trait comes from expressing a viral coat protein taken from the virus itself. 340.6 allows for a party to petition to have an engineered crop completely deregulated, as the University of Florida has done here with its X17-2 papaya. At the time of this writing, an applicant is required to show the following:

> (4) A detailed description of the phenotype of the regulated article. Describe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: *. . . weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, . . . effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products*…

7 C.F.R. § 340.6(c)(4) (emphasis added). "Weediness" is undefined in this subpart, but is used and defined in § 340.3(b)(1) which describes which plants are regulated but considered "safe" enough to introduce without a permit. "Noxious weeds" listed by APHIS in 7 C.F.R. § 360 as well as any plants "considered by the Administrator to be a weed in the area of release into the environment" are not be eligible for nonregulated status.

GE papaya could quite easily be termed a "noxious weed" per the definition in 7 U.S.C. §7702(10). It has many characteristics of a weed, indeed it is considered to be a weed in many areas it grows in because so many papaya trees sprout out of seeds discarded after human and animal consumption. Therefore, full account must be taken of the environmental and social realities of papaya's use and cultivation, including its common occurrence in home gardens, vacant lots, roadsides and waysides, indeed anywhere in the regions of its cultivation where its seeds are cast intentionally or unintentionally. The pollen contamination issues affecting organic farmers, discussed in more detail below, constitute direct or indirect injury to crops and other agricultural interests. If APHIS wishes not to classify GE papaya as a noxious weed – a plant that does harm to crops or other agricultural interests – then it must do so based on sound science which shows definitively that no injury to organic farming and papaya exports will be caused by the nonregulated use of the new crop,

APHIS is not required to ban *all* noxious weeds, however its decision not to ban a noxious weed cannot be arbitrary and capricious. In *ICTA v. Johanns*, 473 F.Supp.2d 9 (D.D.C. 2007), APHIS denied a petition to have two Roundup-ready grasses listed as noxious weeds on grounds that the court partially found arbitrary and capricious. APHIS argued noxious weeds must be "new or not known to be widely prevalent," which Kentucky bluegrass and creeping bentgrass (and papaya) are not. This language was taken from 7 C.F.R §7714 which allows APHIS to hold, treat, or destroy items "to prevent the dissemination of a plant pest or noxious weed that is new or not known to be widely prevalent" and is a holdover from older statutes

supplanted by the PPA which originally only gave the USDA the authority to control foreign weeds & pests. This old limit on agency action is not present in §7702(10)'s definition of a noxious weed, so APHIS's reliance on this language was arbitrary & capricious. The court remanded the petition back to APHIS to be more thoroughly analyzed. The *ICTA* court also found APHIS to have violated the National Environmental Policy Act (NEPA) for deciding that no EIS was required for this field trial.

In making a determination regarding X17-2 Papaya, APHIS is required to seriously consider whether GE papaya is a noxious weed or plant pest. To properly make a scientific determination regarding this issue, APHIS must produce an EIS which thoroughly explores these issues.

II. NEPA

a. The Principles of the National Environment Policy Act

NEPA requires government agencies to evaluate the impacts of their proposed actions on the human environment. APHIS is required to produce an EIS when it takes a major action that may significantly affect the quality of the human environment. NEPA § 102(2)(C), 42 U.S.C. § 4332(2)(C) (2006). Determining the significance of its proposed impacts "requires considerations of both context and intensity." 40 C.F.R. § 1508.27 (1999). APHIS' consideration of deregulation for X17-2 papaya rises to the level of significance requiring an EIS.

b. The Environmental Assessment Inadequately Assesses Global Impacts

Florida Organic Growers believes key facts were omitted in APHIS's Draft Environmental Assessment (EA). FOG believes that APHIS did not consider all of the relevant significant impacts when conducting its analysis.

X17-2 papaya will have consequences on the human environment worldwide. NEPA specifies that an agency should "recognize the worldwide and long-range character of environmental problems." NEPA § 102 (F). Executive Order 12114 clarifies NEPA's international scope, requiring consideration of actions outside the U.S. that "significantly affect natural or ecological resources of global importance." Exec. Order ("EO") No. 12114, 44 C.F.R. § 1957 (1979), *reprinted in* 42 U.S.C. § 4321 (2006). APHIS identifies in its EA that papaya is

"cultivated worldwide in tropical and subtropical climates." USDA/APHIS, *Draft Environmental Assessment* ("EA"), In Response to Univ. of Fla. Petition 04-337-01P, 7 (Sept. 2, 2008). The Petition (at 16) states "The target region for cultivation of X17-2 line papayas includes south Florida, the Caribbean Region, and perhaps parts of Mexico and Central America." Petition at 16. X17-2 papaya will reach communities outside of the United States. Papaya is a natural resource of global importance; it is an important and nutritious food for people around the world. In addition to food uses of immature and mature papaya fruits, the leaves, seeds, and roots of *Carica papaya* L. are used in culinary and medicinal applications by cultures worldwide and by a diversity of cultures within Florida. Papaya enzyme is an extremely popular digestive enzyme used widely sold at natural food stores. Indeed, ethnopharmacological and contemporary medical uses *and potential uses* of papaya fruits, seeds, leaves and roots, too numerous to describe here but well documented in scientific literature, are devoid of mention in the Petition EA, which limit discussion of papaya's uses to that of a desert fruit and green vegetable. APHIS must consider the myriad ethnopharmacological and contemporary medical uses of *Carica papaya* L. or risk violating NEPA's requirements. Factors for consideration include the possibility of cultural rejection of a GE papaya for culinary and medical use, and the possibility that genetically engineering papaya will change the medicinal properties of any useful plant part. According to the World Health Organization of the United Nations:

> Traditional Medicine is able to contribute significantly to the common goal of health for all by its capacity to maintain health and treat diseases…The use of medicinal plants and their preparations are [one of] the most important forms of traditional medicine…and are part of the cultural and social heritage of many countries.

Development of National Policy on Traditional Medicine. World Health Organization Western Pacific Region. 2000. In addition, WHO states that countries "in Africa, Asia and Latin American use traditional medicine (TM) to help meet some of their primary health care needs. In Africa, up to 80% of the population uses traditional medicine for primary health care." WHO Fact Sheet No. 134 Traditional Medicine. Revised May 2003.

Papaya, like all foods in a globalized food system, is traded around the world. Deregulation of X17-2 papaya will have global effects. When people eat papaya they dispose of the seeds, which are known to sprout voraciously. X17-2 papaya may thus inadvertently grow in nations which have not approved, or declined to approve, this genetically engineered tree. Each

nation has to make its own choices regarding GE foods. This is a difficult decision requiring consideration of human health, environmental, and trade concerns. Global export of X17-2 papaya will take the decision away from other nations, thus it is the type of action covered by EO 12114. APHIS has failed to give adequate consideration to this important issue in its EA, and must more thoroughly explore these issues in an EIS. In addition, feral populations of papaya thrive in "tropical habitats of North, Central and South America as well as the Caribbean." *EA*, 7. Deregulating X17-2 papaya will substantially affect not only global agriculture but also wild habitats stretching though tropical habitats of the Western Hemisphere. APHIS must study the impacts X17-2 papaya would have on wild habitats and their inhabitants, including protected species, in a detailed EIS.

APHIS notes that the highland papaya has not been known to hybridize with the related genus of X17-2 Papaya. *EA*, 11. This information is inadequate; further study is required to determine whether hybridization is possible. The presence of a non-native, genetically engineered tree with prolific offspring will significantly affect tropical regions, regardless of the plant's abilities to hybridize. APHIS does not give international impacts of X17-2 papaya adequate consideration; it simply dismisses any significant international impact. *EA*, 21. For the reasons discussed above, X17-2 papaya's pervasiveness will indeed have a significant impact. Papaya's ability to grow, cultivated or uncultivated, in international tropical and subtropical climates, indicates that it will indeed have a significant impact. APHIS should give this global impact careful consideration through an EIS before deregulating X17-2 Papaya.

c. **An EIS is Necessary to Study the Effects of Deregulating X17-2 Papaya**

FOG believes that deregulating X17-2 Papaya will have a significant effect on the human environment and an EIS is required.

i. <u>Contamination & Impacts on Organic Agriculture</u>

Due to contamination, X17-2 Papaya will significantly affect organic agriculture, putting a financial burden on the industry. FOG does not think that APHIS adequately understands the affect of contamination on organic papaya. The EA states that "the unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded method and has taken reasonable steps to avoid contact with

the products of excluded methods as detailed in their approved organic system plan. Organic certification of a production or handling operation is a process claim, not a product claim." *EA*, 18. FOG urges APHIS to reevaluate the impacts of contamination. The unintentional presence of X17-2 papaya will affect organic farming operations, as discussed more thoroughly *infra*. Many accredited certifying agencies may interpret NOP regulations to prohibit certification of papaya if contamination is suspected to be unavoidable or may feel, to uphold due diligence in cases of proximate organic and GE papaya cultivation, that testing for genetic contamination should be performed, even if not required, which could result in negative outcomes for the certified producer. Additionally, it is inequitable to place the burden on organic farmers to take steps beyond those taken now to prevent contamination from GE crops.

FOG points to Hawaii as a case study. The EA hints at the burden placed on organic farmers while trying to portray the situation as benign. "Growers of organic papayas in Hawaii have been coexisting with conventional and GE papaya growers for a number of years and have information available to them to guide them in their continuing operations." *Id*. The quote demonstrates that through information to "guide" them, organic farmers are instructed as to how to deal with the changing impacts on their farming environment. Due to the presence of GE papaya and the inevitability of contamination, organic growers in Hawaii have stopped growing papaya. These farmers have lost the freedom to grow their crops of choice and been forced to switch to other crops. This is a significant effect to the human environment which must be studied in an EIS.

Given Hawaii's experience with contamination of organic and conventional papaya, if GE papaya is to be deregulated, APHIS must require of any licensing agreement that the patent holder and contracted GE papaya growers bear responsibility for taking measures to prevent surrounding organic and conventional papaya producers' papaya from being contaminated and to assume the financial responsibility for economic losses to organic and conventional producers when contamination does occur.

ii. Genetically Engineered Products are Highly Controversial with Unknown Risks

When implementing NEPA, the agency must also consider possible effects that are "highly controversial," "highly uncertain or involve unique or unknown risks." 40 C.F.R.

1508.27 (b) (4), (5) (1999). The EA concludes that there are no "highly controversial" effects on the human environment. *EA* 20. FOG does not believe this to be true. Genetic engineering is a relatively new technology that has disrupted millennia of agricultural practices. There is a woefully inadequate body of research concerning the effects of genetic engineering on human health and the environment. GE papaya, and GE foods in general, is a highly controversial issue.

Informed consumers have been wary of GE foods. Indeed, consumers have undertaken heroic efforts to create a labeling system to identify GE products in the marketplace. Citizens have also enacted local bans on growing GE crops, further indicating there is significant controversy surrounding GE crops. Because GE papaya would be the first GE tree commercially cultivated in the mainland United States it involves unique and unknown risks which require further study. GE trees pose unique and novel risks that have not been adequately studied. APHIS must consider the controversy as well as unique and unknown risks associated with this highly controversial project. Deregulating this GE papaya without adequate consideration of these issues is a violation of NEPA.

iii. Deregulating X17-2 Will Establish Unwanted Precedent

When implementing NEPA, an agency is required to consider the intensity of impacts caused by its actions, specifically considering "the degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration." 40 C.F.R. 1508.27 (b) (6) (1999). There are currently no GE trees grown commercially in the mainland of the United States. Choosing to deregulate this GE tree may open a floodgate of petitions to deregulate other GE trees in the mainland of the United States. Approximately 80 species and varieties of trees are currently undergoing gene splicing research and development for commercial use. Many of these are native species vital to ecosystems in much of the US. APHIS should not act to set a low standard for the future deregulation of such trees, many of which carry the same risks of permanently altering their industry and affecting their wild counterparts if planted unchecked. Irreversible changes should not be considered lightly. APHIS must give careful study to this deregulation petition and consider the type of precedent it wishes to establish regarding its disposition on petitions for deregulation of other GE trees.

III. The Endangered Species Act

APHIS has failed to consider the impacts X17-2 papaya may have on other flora and fauna. It is possible that this papaya may be harmful for other species. APHIS has an affirmative obligation under Section 7(a)1 of the Endangered Species Act to use its authority to conserve listed species. *Sierra Club v. Glickman*, 156 F.3d 606, 616 (5th Cir. 1998). APHIS has violated this obligation by ignoring the role papaya may play in the diet of listed species. APHIS is also ignoring its obligations under Section 7(a)(2) of the Endangered Species Act by failing to ensure that X17-2 papaya be not reasonably anticipated to result in jeopardy to any listed species. APHIS must consult with the United States Fish and Wildlife Service and the National Marine Fisheries Service to determine whether any listed species live in areas that would be impacted by deregulation of X17-2 papaya. If so, APHIS must complete a Biological Assessment prior to committing any more agency resources to deregulation of this GE tree.

IV. FOG's Specific Concerns

FOG operates a USDA accredited organic certification program, Quality Certification Services (QCS). QCS certifies 406 entities, which includes organic crop, livestock, and processing/handling operations, both domestically and internationally. Within Florida, QCS certifies 161 entities, 101 of those being certified organic farms. QCS currently certifies ten farms that grow papaya in Florida.

FOG is deeply concerned about the impact deregulation of X17-2 papaya will have for the certified organic growers of Florida, the Caribbean, Mexico and Central America. Deregulation of this GE papaya in Florida is likely to have a detrimental effect not only on the organic growers in Florida, but also the wider region. While the EA de-emphasizes the problem of contamination by GE pollen in other crops, FOG believes that GE-contamination is an important issue for organic growers. As one example, "introduction of transgenic herbicide-tolerant canola in western Canada destroyed the growing, albeit limited, market for organic canola. Liabilities and Economics of Transgenic Crops. Nature Biotechnology. June 2002. Regardless of what the NOP permits, consumers and certifiers expect that organic produce is not genetically modified and free from GE contamination. Contamination of organic products in many ways negates the value of organic certification. The reality is, as was seen in Hawaii, that

deregulation of GE papaya will result in contamination and an economic threat to organic papaya growers.

Not only does the threat of contamination from GE-papaya affect current growers, but it also harms future growers. In an economy that is seeing an unprecedented increase in consumer demand for organic and sustainable produce, increased demand for organic papaya is likely. However, consumer enthusiasm for organic papaya from Florida and other venues will be squashed if consumers learn they are paying a premium for organic food that is genetically contaminated. Increasing GE foods, and therefore the risk of contamination, is harmful to current and future producers of organic produce.

The increase in consumer desire for organic produce is clear. *See* Carolyn Dimitri and Catherine Greene, *Recent Growth Patterns in the U.S. Organic Foods Market*, Agriculture Information Bulletin No. (AIB777) 42 pp, (USDA Economic Research Service, September 2002). According to USDA's own estimates, there has been a 20% or more growth in retail sales of organic food since 1990, and U.S. certified organic cropland doubled between 1992 and 1997, to 1.3 million acres. *Id.* By all accounts, the organic industry continues its impressive expansion. Organic products are now available in 73% of conventional grocery stores, as well as at nearly 20,000 natural foods stores in the U.S. *Id* at 1. The explosive growth of farmers markets has also provided significant opportunities for organic farmers. Deregulation of GE papaya in Florida will disadvantage organic farmers. APHIS should not gamble with the future of existing and future organic farmers by deregulating a crop that will contaminate organic papaya crops. This GE papaya is a threat to the health and welfare of farmers and consumers in the U.S. and abroad and would sacrifice aspirations and opportunities for expanding organic agriculture.

FOG is also deeply concerned about papaya grown in home gardens in sub-tropical Florida and the Caribbean. Papaya is a very common tree in home gardens and landscaping. The de-regulation of GE papaya presents two foreseeable problems in this regard; first, that many of these home gardeners, while not certified, practice organic gardening, and will view GE contamination as an assault on their choice to grow and consume organically grown papaya. Secondly, home gardens may become a *source* of GE pollen spread and contamination if GE papaya is commercialized and marketed, especially because current law does not require GE

labeling of produce, and seeds from consumed fruits become the intended or unintended planting stock for home garden papaya. A number of Florida farms certified by FOG, possibly including certified organic papaya growers, are located in suburban settings, where GE contamination from neighbors' gardens could become an issue.

Florida Organic Growers certifies hundreds of entities, including 10 farms in Florida that grow organic papaya. FOG is deeply concerned about these farmers losing their right to grow organic papaya without GE pollen contamination. Considering the increased consumer demand for organic produce, it is essential that this market for organic papaya be protected. With the high standards applied by FOG and expected by the consumer, GE papaya contamination will severely threaten the existing and future organic papaya growers' ability to market their choice of produce.

V. Scientific Concerns

This petition for deregulation raises significant scientific concerns. USDA's environmental assessment admits that the GE papaya readily hybridizes within its species *Carica papaya*. Thus, there may be a significant potential for gene flow into native and naturalized perennial papaya varieties. GE papaya trees will be long lived, and capable of contaminating orchards and native papaya tree populations indefinitely into the future. One GE papaya tree will be able to produce many thousands of GE seeds and extensive quantities of pollen, and will be capable of spreading fertile GE papaya seeds and pollen into the environment for many years. The petition did not adequately evaluate the relative fitness of GE papaya varieties as compared to native papayas; it is possible that the GE varieties would become more successful in natural settings, and out-compete non-GE varieties; or, that X17-2 line papayas could harbor unforeseen deleterious genetic traits that permanently negatively impact native (non-GE) papaya populations through cross contamination.. Further study is required to determine the risk posed by GE papaya outcompeting and/or contaminating local papaya varieties. FOG challenges APHIS' claim that contamination would be positive by reducing potential reservoirs for harboring PRSV in the wild. This claim is not supported by any data, and it ignores the possibility that there may be unknown risks associated with X17-2 papaya which could have harmful effects in the wild. Furthermore, the X17-2 derived lines are not truly immune to PRSV, they are merely resistant. They can therefore still be carriers of the disease. APHIS runs the risk of causing significant

damage to wild papaya and to commercial organic farming if GE papaya contaminates wild papayas or outcompetes them in the wild.

There are serious and mounting concerns about a broad range of health effects associated with exposure to GE pollen and consumption of GE crops, and honey derived from GE crops. For example, consumers may suffer allergic reactions due to unexpected toxins in GE foods. The GE papaya pollen may produce unintended effects such as allergic reactions in sensitive individuals and the APHIS has not properly evaluated the potential for allergic reactions. APHIS must consider the potential health impacts not just on the healthy members of the population, but also the most sensitive people including those with weak or compromised immune systems. Indeed papaya's benefits to digestive ailments and disease point to its importance to these segments of the population that may be most sensitive to changes resulting from genetic transformation.

The USDA has also failed to consider the potential for allergens or other novel substances in the GE papayas, GE papaya pollen, or GE papaya-produced honey to interfere with pharmaceuticals being used by consumers. The papaya fruit, seeds, latex, and leaves contain carpaine, an anthelmintic alkaloid that could be dangerous in high doses to the heart (it affects myocardium directly) and the circulatory system. Carpaine is one of the major alkaloid components of papayas, and has been studied for its cardiovascular effects. APHIS has not fully evaluated the health effects of alkaloids such as carpaine and related alkaloids on consumers eating GE papaya, pollen, honey or fruit juices and foods containing GE papaya ingredients. The USDA has not fully studied whether the GE papaya trees produce a different alkaloid chemistry or overall phytochemistry compared to organic, conventional or wild papayas. Other papaya alkaloids and phytochemicals have not been adequately studied for their human health effects, especially in light of the extensive ethnopharmacological uses of *Carica papaya* L fruit, seeds, leaves, and roots mentioned *supra*. This is particularly egregious because there is widespread evidence that genetically engineering plants can alter the expression of genetic traits apparently unrelated to the intentionally inserted trait. APHIS runs the risk of causing significant damage to the Florida organic and conventional farming industries if this GE tree has traits that cause unintended health consequences. APHIS must conduct further study on the potential impacts X17-2 papaya fruit, seeds, leaves, and roots may have on human health.

There are also serious concerns about the genetic stability of the artificial gene combinations and the artificially inserted genes used in GE papaya trees. The USDA claims that the papaya ring spot viral resistance gene and other inserted genes are sufficiently genetically stable, but the testing has only been performed for approximately ten years and not the entire, decades-long pollen-producing life span of a papaya tree. Over the long life of a papaya tree, an RNA virus such as papaya ring spot virus is susceptible to many cycles of recombination, leading to the creation of new plant viruses that could infect a wide variety of plants. This can also occur with the viral DNA that has been inserted into these papayas. The University of Florida's Petition states that "[e]xtensive deployment of a single resistance gene…might select for PRSV populations that can overcome the resistance; however the mechanism by which this might occur is not clear and the possibility of it occurring is low. Petition at 17. FOG believes this statement highlights the need for further investigation into the potential for "extensive deployment of a single resistance gene" (as may especially apply to X17-2 specimens that establish long-lived feral populations) to select for resistant PRSV strains. FOG asks for clarification as to the scientific basis of the claim that "the possibility of [overcoming a single resistance gene] [i]s low," given that in nature overcoming of single resistance genes appears to be the rule not the exception.

APHIS, in its FONSI for the SunUp and Rainbow cultivars, determined that it had no need to consider transcapsidation risks because there are no other viruses infecting papaya in the US. While this is currently the case, there is no guarantee that no other papaya virus will make it to US shores after the new cultivar's genes become well-established in the population at large. Study of the risks of new plant pest introduction should not be denied purely because it may not be a problem *now* as the changes to the plant will become permanently established in the wild and in agriculture after the plants are allowed to pollinate freely. The same consideration should be applied not just to new papaya viruses but also to different/new strains of PRSV which may reach Florida's shores and to which X17-2 could be susceptible. APHIS needs more information on PRSV strains occurring in Florida so it can better understand how the number of virus strains and the genetic characteristics of these strains has changed over time in order to appropriately consider whether resistance conferred by X17-2 papaya is of any value. Additionally, the SunUp and Rainbow cultivars contain a non-functional fragment of the *tetA* tetracycline-resistance gene from the agrobacterium strain used to introduce the genes into the initial test plants. While this

particular fragment is incomplete and non-functional, APHIS needs to ensure that the X17-2 genome doesn't contain any genes that do have a risk of enhancing other diseases. In addition, APHIS needs to conduct further analysis of the stability of integration in the donated sequences. APHIS must fully examine the stability risk of the X17-2 genome and commission study of the plant's interaction with other viruses in order to avoid this risk of enhancing existing plant pests or making the future introduction of plant pests worse.

The University of Florida's petition for deregulation completely ignores potential effects on bees and other pollinator species. Today honey bee colony collapse disorder known as CCD is a serious and growing problem for apiaries and bee-pollinated crops in Florida where the GE papaya trees will be grown. Although unintended effects are common in GE crops (and are part of regulatory human health assessments), there is extremely little assessment of possible environmental impacts from unintended effects. There are no studies that would allow us to evaluate the potential hazards of GE papaya tree pollen (or any GE tree pollen) for a variety of insects or for consumers of honey. This information is necessary for APHIS to consider all the consequences of deregulating X17-2 papaya. We also do not know how animals and insects that browse on papaya leaves might be affected, including animals and insects useful to agriculture or endangered species. APHIS must study this issue to avoid the risk of endangering Florida apiculture, the honey industry, and potentially endangered pollinators. Subtropical Florida serves as a winter home to bees employed in commercial agriculture pollination of economically important crops grown throughout the U.S. Effects of X17-2 papaya pollen on bees must be rigorously investigated as negative impacts to bees in Florida could have profound, negative national agricultural and economic implications.

There has been no short-term or long-term safety testing or feeding trials for toxicity or other adverse effects of the construct of genes inserted into the GE papaya trees. GE papayas have not been tested on animals, birds or humans for safety. Toxicity tests are necessary since unintended genetic effects are known to occur with gene splicing. Potential examples include the possible allergen and carpaine changes mentioned *supra.* APHIS has ignored the need for scientific studies of gene splicing and for comprehensive studies of the environmental consequences of GE plantings since the USDA has not adequately consulted with the Food and

Drug Administration or the U.S. Environmental Protection Agency for their regulatory input. APHIS must work with other agencies to achieve a better understanding of these risks.

VI. Genetic Contamination

Genetic contamination is a serious and growing threat. The deregulation of genetically engineered (GE) papaya in Florida will cause contamination of traditional, or non-GE, papaya crops as wells as organic papaya crops and pose serious consequences to the farmers of traditional and organic papaya. Contamination of non-GE papaya by GE papaya is inevitable through pollination and the incorporation/commingling of GE seeds with non-GE seeds. Flowers and seeds in organic and conventional papaya groves can become contaminated with GE papaya genes via pollen transported by bees and other insects that travel many miles in search of pollen. The result is that organic and conventional papaya growers could lose their markets for non-GE papayas, as farmers in Hawaii already have as a result of GE papayas. Farmers may see their livelihoods threatened as a result of no longer being able to grow and sell non-GE papaya, and they will have to face the risk of exposure to lawsuits from the GE papaya patent holders, as could home gardeners who may unknowingly sow GE papaya seeds from unlabeled, purchased fruit. An organic tree might remain organic itself, but the pollen, honey and seeds will be contaminated, and trees planted from the GE papaya seeds will bear contaminated fruit. APHIS must show "the realistic measures, if any, that may be taken to prevent or at least reduce such contamination." *Geertson Seed Farms, et al. v. Mike Johanns*, 2007 Lexis 14533, 6 (U.S. Dist. February 13, 2007).

a. Reproduction and Pollen Dispersal of Papaya

Due to the variance of papaya reproductive methods as well as the year-long pollen viability, papaya plants are particularly susceptible to cross-contamination by GE varieties. Papaya plants can include both hermaphrodite stigmas and single sex stigmas, meaning the hermaphrodite stigmas can either self-pollinate or cross-pollinate and the separate male and female plants must necessarily cross-pollinate. Pollen is produced all year, though the quantity and reproductive viability of that pollen may vary according to season and environmental conditions. Though pollen quantity and viability may increase or decrease during certain seasons, papaya stigmas remain highly receptive consistently throughout the year; if successfully pollinated, papaya plants can produce fruit all year long. Australian Government: Department of

Health and Ageing Office of the Gene Technology Regulator, *The Biology and Ecology of Papaya (paw paw), Carica papaya L., in Australia,* www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/papaya-3/$FILE/biologypapaya08.pdf (last updated September 2, 2004.)

While hermaphrodite papaya plants may completely self-pollinate, lowering the risk of GE infiltration in those particular plants, pollination of female plants may occur in a variety of ways. Female plants can be pollinated by hand-pollinating male and female plants, but usually occurs by bees or wind, both of which are inevitable processes that farmers cannot completely protect against. *Id* and Greenpeace, *Genetically Engineered Papaya-Unknown Plant,* http://www.greenpeace.org/seasia/en/press/reports/genetically-engineered-ge-pa (June 1, 2003). Seed dispersal, another mechanism of contamination, also occurs by way of wind, water, birds, and other animals. *Id.* While farmers are encouraged to bag the flowering buds of hermaphrodite papaya plants to ensure that they will entirely self-pollinate, and thus, not be contaminated by GE strains, this procedure is not completely preventative in protecting conventional papaya plants. Richard Manshardt of the University of Hawaii at Manoa discusses the risks of pollination of conventional papaya crops by adjacent GE crops. The College of Tropical Agriculture and Human Resources (CTAHR) in Puna, Hawaii, found that, though the percentage decreases as the distance between the adjacent crops increases, there still exists a risk of contamination of non-GE crops by GE crops, especially of female plants. Though Manshardt concludes that, in distances of more than a quarter mile, "[c]ross-pollination will be, at most, a rare event." Richard Manshardt, Department of Tropical Plant and Soil Sciences, University of Hawaii at Manoa, *Is Organic Papaya Production in Hawaii Threatened by Cross-Pollination with Genetically Engineered Varieties?* www.ctahr.hawaii.edu/oc/freepubs/pdf/BIO-1.pdf (October 2002). Evidence from the experiences of rice farmers in Arkansas whose rice crops were unintentionally contaminated by GE strains show that even a "rare event" can prove to be devastating.

b. Genetic Contamination is a Very Serious Threat to Farmers

In 2006, the USDA announced that the US long grain rice industry had been contaminated by GE material. Press Release, USDA, Release No. 0306.06: Investigation of Regulated Rice in Commercial Rice Samples (Aug. 18, 2006) The unexpected contamination of

the long grain rice industry cost the US rice industry almost one billion dollars due to market rejection. U.S. Rice Produces Association, Analysis of GM Impact of Rice in Rice Industry (March 3, 2008) (unpublished spreadsheet, on file with Rice Producers Association). The burden of these losses fell on rice farmers, and the consequences were severe. Some farmers had to stop farming so they could support their families; others had to switch to other crops or less desirable rice varieties. Families suffered severe economic and social consequences. It is unknown where long grain rice from the United States will ever again be considered GE-free.

In the case of the Arkansas rice farmers, protections were taken to prevent contamination, including the precautions taken by expert GE farmers, similar to the precautions papaya farmers are urged to take to *prevent* contamination. USDA, Report of Liberty Link Rice Incidents 2 (2007), www,aphis.useda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf. The experience of long grain rice farmers indicates that contamination can occur regardless of the employment of management practices. When genetic contamination of a non-GE crop occurs, the effects can be devastating, and once it happens, the biological and economic effects are irreversible

Courts have recognized the risk of genetic contamination as a significant effect under NEPA. Alfalfa farmers have been successful in preventing commercial growth of GE alfalfa while APHIS prepares an EIS. *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. 2007). Genetic contamination can occur through the mixing of GE seeds with conventional or organic seeds and through pollination by bees. The *Geertson* court recognized the severity of the risk posed by genetic contamination. Once contamination occurs, the effects are irreversible, thus it is critically important for an agency to properly analyze the risk of contamination prior to deregulating a GE crop. APHIS "[d]id not conclude that gene transmission would *not* occur." (emphasis added) *Id.*, 16. Because it could not be concluded with any certainty that contamination would *not* occur, but rather there was high likelihood that it *would* occur, APHIS was required to generate an EIS. In *Geertson,* Defendant and Intervenors argued that the economic setbacks to farmers was not a sufficient reason to release an EIS; an EIS is only required when the action will have a significant impact on the human environment. The court, however, decided that "an action which potentially eliminates or at least greatly reduces the availability of a particular plant—here, non-engineered alfalfa—has a significant effect on the human environment." *Id.*, 27. X17-2 papaya is similar to the Round-up Ready alfalfa in

Geertson in that the risk of genetic contamination is sufficient in both crops that an EIS is required to comply with the requirements of NEPA.

As further evidence of the seriousness of contamination, California passed a law on September 27, 2008, attempting to provide some regulation of GE crops and to protect farmers from potential lawsuits from the contamination of traditional and organic crops by GE crops. The bill, AB 541, primarily focuses on compensating farmers' market losses when their crops, through no fault of their own, are contaminated by GE crop. It also attempts to protect farmers from being sued for patent or contract infringement by GE manufacturer conglomerates when the farmers' crops become contaminated by the GE crop. AB 541 allows for farmers to be able to trace the contamination via crop sampling to its starting point. AB 541 was supported by agricultural groups in California, including the California Farm Bureau, because the risk of genetic contamination is widely accepted to be a very serious risk.

Because genetic contamination is a recognized harm that creates severe problems for farmers, FOG urges APHIS to deny this petition for deregulation. In order to comply with NEPA, APHIS must study the risk of contamination in an EIS.

VII. **Implications for Organic Certification**

The National Organic Program (NOP), which develops and implements organic production standards, forbids "certified organic" producers from employing methods of genetic modification. In fact, NOP expressly characterizes genetic modification practices as "Excluded Methods." According to NOP, "Excluded Methods" are defined as "a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the position of genes when achieved by recombinant DNA technology)." Code of Federal Regulations, National Organic Program, Title 7 §205.1. NOP emphasizes that its organic certification standards are process-based, not product-based. As a result, NOP has vowed not to decertify organic producers who crops become contaminated. NOP states, "As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan,

the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation." NOP Standards Applicability Preamble, p. 9-10. Nevertheless, the proposed de-regulation of X17-2 papaya poses grim choices for organic papaya growers.

If deregulated, contamination from the genetically modified (GMO) X17-2 papaya would threaten organic producers' crops and market. In a study from Hawaii, where two kinds of genetically modified (GMO) papaya were introduced in 1998, organic papaya producers showed considerable GMO contamination. Just four years after the introduction of GMO papayas on the Island of Hawaii, the contamination rate was as high as 50 %. The study reported that even a non-GMO seed source of papaya showed a perceptible level of GMO-contamination. *GeneWatch:* Protect What IS Here Now, May-June 2006, pg. 10. De-regulation of X17-2 papaya paves the road for contamination in other places beyond Hawaii, such as Florida, and even beyond our country's borders. It closes off some foreign organic markets as well. For example, all papaya with contamination levels of 0.9% or higher would be prohibited from being sold as organic throughout the European Union. Shield, Peter. Organic Consumers Association, *GMOs Threaten Organic Standards*, June 13, 2007.

In an effort to maintain the integrity of their produce, many papaya producers in Hawaii have opted out of organic certification altogether to avoid misleading consumers who might otherwise assume "certified organic" to mean GMO-free. If further proposed deregulation of papaya occurred, organic producers in Florida and beyond would face the same tough decision. Some might pass on organic certification altogether. Through no fault of their own, producers choosing to relinquish their organic status would lose their premium and their market for organic produce. Alternatively, producers choosing to maintain their organic status would run the risk of marketing GMO-contaminated papaya as "organic." Beyond potentially creating an unfair impression for consumers, producers who chose this option would bear disproportionate burdens to mitigate contamination of their crops. NOP acknowledges, "[o]rganic operations have always had to worry about the potential for drift from neighboring operations… It has always been the responsibility of organic operations to manage potential contact of organic products with other substances not approved for use in organic production systems, whether from the nonorganic portion of a split operation or from neighboring farms." NOP Standards Applicability Preamble at 9.

"Certified organic" has become a market standard, one that until now has been

associated with GE-free agriculture. *Genetic Engineering and Organic Food Production Systems* explains the challenge organic producers face when contamination occurs: "[i]f there is detectible GE [genetically engineered] material in their product, organic growers may have difficulty selling their crops if they have made contractual agreements with buyers to deliver 'GMO-free' products. They could be forced to sell in a conventional market, forfeiting the organic premium price that they would otherwise have received for their product." Ronald, Pamela & Fouche, Benny, *Genetic Engineering and Organic Food Production Systems,* ANR University of California.

Through the contamination of certified organic papaya, the proposed deregulation of X17-2 will effectively water down the NOP organic certification process as a whole. The more contamination of papaya that occurs, the more GE-contaminated papaya makes its way into the market under the pretext of organic. This undermines the force of NOP's certification process as a whole and irreparably changes both the agricultural landscape and the consumer landscape as well. Accredited certifying agents would be placed in an untenable position as they determine whether it is appropriate to provide organic certification to papaya grown in proximity to GE papaya. Certifiers' interpretation of NOP rules regarding genetic contamination of organic crops could differ from the NOP's. Certifier determinations which deny certification to organic producers' papaya may then only be overturned on appeal to the USDA. Assuming the grower wishes to undertake a lengthy formal appeal process, it is nearly certain that the appeal would not be decided until long after negative economic consequences of the decertified papaya are realized. Should a certifier, on the other hand, certify an organic producer's papaya on the basis that reasonable steps were taken to avoid GE contamination, and that certified organic papaya is found to be contaminated by GE papaya, the certifier (and indeed the USDA NOP) risks negative media exposure for 'organic certification of GMOs.'

Indeed APHIS, in resting on the argument that the National Organic Program is a 'process' based and not 'product' based standard, ignores the manifest importance of consumer expectation that certified organic products be free from genetic engineering and the fact that ultimately the viability of the NOP depends entirely on consumer confidence. GE papaya is uniquely different from corn or canola, to draw comparison between two other commercially grown GE crops. A significant difference is that with corn and canola, the organic consumer essentially never purchases a product containing viable seed; the organic products contaminated

with GE corn and canola would most likely be products such as corn meal and canola oil and other processed organic foods. In stark contrast, cavalier allowance of GE-contaminated organic papaya to be labeled as "organic," will predictably result in cultivation of genetically engineered papaya, through sowing of GE seeds contained in the consumed fruit, in the home gardens of consumers who have taken steps in accordance with U.S. regulatory frameworks to avoid GE foods by purchasing certified organic fruit.

Further, many organic producers would forfeit their organic certification before they would sell products that are genetically contaminated. Many organic growers are deeply committed to the spirit of organic, a spirit that shuns the use of agricultural biotechnology and instead seeks out more sustainable methods of dealing with viruses. Producers with this commitment are uncomfortable deceiving buyers who rely on their integrity and not just their commitment to following the minimal NOP standards. For these reasons, FOG urges APHIS to consult exhaustively with the NOP in regards to the unique considerations surrounding GE papaya, as we view consequences of this determination on the status of X17-2 papaya as a matter that threatens to have serious negative effects on the $20-plus billion (and growing) U.S. organic food and beverage industry and indeed on the credibility of the National Organic Program itself.

Beyond NOP's organic certification process, other certifications exist which explicitly disallow GMO contamination in products. For example, one company offers a "Non-GMO" certification for producers, processors, and handlers of non-genetically modified food products. Another offers a "GMO-free designation." *See* Mothers for Natural Law: For Organizations working on Organic Certification, GreenPeople.org/foodsafety.htm.

The USDA/APHIS Draft Environmental Assessment on X17-2 papaya claims "there is no apparent potential for significant impact on conventional or organic farming if APHIS chooses either the "no action" alternative or grants nonregulated status to X17-2 papaya." A short history of GMO papaya in Hawaii demonstrates otherwise. "An important part of the damage done by the GE papaya in Hawaii is its impact on organic." Greenpeace, *The Failure of GE Papaya in Hawaii*, Briefing 2006. Although APHIS' claim of "no apparent potential for significant impact on conventional or organic farming" is entirely unsupported, to judge the validity of its assertion all one needs to do is ask those in the best position to judge the potential

impact of deregulation: the organic producers, certifiers, and marketers themselves. The organic community overwhelmingly opposes deregulation because of the deep and profound impact it would have on the industry.

VII. **Consumer Expectations for Organic Products**

Consumers of organic produce expect that it is GE free. People believe that when they pay a premium on organic produce, they are purchasing produce that lives up to their high standards. If consumers do not want to eat genetically modified foods, their only option is rapidly becoming organic foods. An increasing number of consumers are actively seeking out organic produce, and they expect that it will be free of pesticides, herbicides, and *not be genetically modified or GE contaminated*. Organic labels live up to the standards of their consumers by taking precautions against GE. Consumers' Union, *Fighting for a strong "organic" label*, http://www.consumerreports.org/cro/aboutus/mission/viewpoint/fightingforastrongorganiclabel0602/ (Feb 2006).

Consumer expectations drive the market for produce. After deregulation of GE papaya in Hawaii, the organic papaya industry suffered. Health-conscious consumers sought to avoid the GE papaya in America. Japan has completely rejected GE papaya. The vast majority of papaya sold in the U.S. is from Mexico, Central America and the Caribbean, where the papaya is not genetically engineered. Greenpeace International, *The Failure of GE Papaya in Hawaii*, 6 (Greenpeace International, May 2006). Deregulation of X17-2 papaya may lead to a complete rejection of U.S. papaya nationally and internationally by consumers who wish to avoid genetically engineered foods.

The Petition for Determination of Nonregulated Status for the X17-2 Line of Papaya states that cross-pollination with non-GE and organic trees is entirely possible. To avoid this contamination it concludes that organic and conventional farmers will have to shoulder the burden of covering their flowers to avoid contact with GE papaya pollen. Deregulation Petition at 19. In the EA, APHIS claims that no significant harm to organic papaya production in Florida will take place, because NOP standards, (which require organic farmers to use an accredited certifying agency and not to use any excluded methods, including genetically modified

organisms,) *do not* require testing for products for excluded methods (GE organisms). EA at 18. While the standards of the NOP may not require this, as discussed above, many organic farmers hold themselves to higher standards and *consumers* expect organic produce to be free of contamination from GE organisms. Additionally, even if NOP standards hold that contaminated papayas are still organic, the accredited certifiers, in whose hands the immediate status of crops rests, may very well determine otherwise. This puts the entire burden on organic farmers who need certification to be able to market organic produce, as consumers expect that "organic" means non-GE.

Farmers have a right to grow organic and non-GE produce and consumers have a right to choose not to consume it. Eliminating that right by de-regulating GE papaya and contaminating the rest of the non-GE and organic crop is a legally cognizable harm. *Geertson Seed Farms v. Johanns* 2007 WL 518624, 8 (N.D.Cal.,2007). In *Geertson*, the District Court found that the proposed de-regulation of GE alfalfa would have a significant impact on the human environment, and required an environmental impact statement. The court said that one of Congress's express goals in adopting NEPA was:

> to attain the widest range of beneficial uses of the environment without degradation, risk to health and safety, or other undesirable and unintended consequences*."* 42 U.S.C. § 4331(b)(3). A federal action that eliminates a farmer's choice to grow non-genetically engineered crops, *or a consumer's choice to eat non-genetically engineered food, is an undesirable consequence*: another NEPA goal is to "maintain, wherever possible, an environment which supports diversity and variety of individual choice.

Id. (emphasis added).While proponents of genetically engineered papaya want to minimize the necessity of protecting consumer rights to choose non-GE produce, federal courts recognize this right. Because consumers expect organic produce to be non-GE, the deregulation of GE papaya will eliminate the possibility of organic farmers to live up to the high standards of certifiers and the public. It is a against the public interest to take away the right of farmers to grow organic produce that lives up to consumer standards and thereby take away the rights of consumers to choose organic produce. NEPA mandates further study of this significant effect on the human environment.

VIII **Impacts of GE Papaya on the Environment and the Future of the Papaya Market**

X17-2 papaya should not be deregulated without careful consideration of the impact of deregulation on the future of the papaya market. This is an issue that must be dealt with utilizing the utmost care. "[G]enetically engineered organisms may have sobering ecological, social, and economic effects." *Benefits and Risks of Genetic Engineering in Agriculture,* 39 BioScience 606 (1989). Genetically-engineered papaya is one such organism that has already demonstrated these negative effects through its impact on the Hawaiian papaya industry. Deregulation of genetically-engineered papaya in Florida presents the potential for a repetition of these negative impacts which include economic, social, environmental, and ecological harm.

In the event of papaya deregulation, extensive and unforeseeable harm could result which demands careful investigation so it may be weighed properly with the potential benefits. Even single releases of GE organisms pose environmental risks that cannot be accurately predicted. *Id.* "Serious problems have resulted from the intentional introduction of what were believed to have been beneficial organisms." *Id.* "11 of the 18 most serious weeds of the world are crops in other regions of the globe." *Id.* In fact, "crop plants are capable of transferring genes, by hybridization, over relatively long distance to related plants that differ markedly." Drake, *Environmental Biotechnology*, 38 BioScience 420, 422 (1988). Such hybridization is almost always likely because, "with only rare exceptions, all cultivated crops have wild relatives; therefore, escape of transgenes is a strong possibility somewhere else in the world." Daniel, *Environmentally Friendly Approaches to Genetic Engineering*, 35 In Vitro Cellular & Developmental Biology 361 (1999). 128 species of plants that have become pests after being introduced as crops. Pimentel, *Benefits and Risks of Genetic Engineering in Agriculture* at 608. Not only can the GE species become pests but they "could also speed the evolution of undesirable weeds..." Snow, *Commercialization of Transgenic Plants: Potential Ecological Risks,* 47 BioScience 86, 93 (1997). Deregulation of X17-2 papaya comes with the risk of serious harm to current agriculture and the environment at large.

Potential ecological impacts of genetically-engineered papaya are equally extensive. Genetically-engineered crops have the potential to displace native species and "may reduce biological diversity in ecosystems." Pimentel, *Benefits and Risks of Genetic Engineering in Agriculture* at 609. A result of this is an increase in the rapid decline of biological diversity already occurring and an increase in the extinction rate. *Id.* With this decline in biological diversity comes the added danger that a single mutation in either the genetically-engineered

papaya or one of its pests could be devastating. There are numerous instances where a "single gene change" has "overcome resistance in plant hosts" or created instances where the plants themselves have become pests. *Id*. Additionally, introduction of a new species or variation thereof could cause "formerly minor pests to become more abundant." Snow, *Commercialization of Transgenic Plants: Potential Ecological Risks* at 93. This change in species composition could indirectly result in a plummet in the populations of beneficial predators and parasitoids. *Id.* Scientists have also found "relatively minor changes in species composition of an ecological community have been shown to have a substantial impact on basic biogeographic chemical changes. Drake, *Environmental Biotechnology* at 422. At the extreme, yet still entirely possible, end of the spectrum of effects, this could even mean climate altering effects in the long-run. *Id*.

The economic costs of these effects can be unconscionably burdensome as well. As mentioned above, there is the possibility that genetically-engineered papaya itself, or through crossbreeding, could become an invasive species. Invasive species cost the United States "$64 billion annually in crop and livestock devastation" and may require environmentally destructive chemical treatments to eradicate. Pimentel, *Benefits and Risks of Genetic Engineering in Agriculture* at 607. In addition, "there are many economically valuable species of plants" threatened by the decrease in biological diversity. The plants are worth $40 billion per year in the world pharmaceutical market. *Id.* Furthermore, while benefits such as "higher crop yields will benefit consumers by providing lower food prices...farmers' profit margins will generally decline. On average for most crop...products, a 1% increase in yield will result in a 4.5% decrease in market price. Pimentel, *Benefits and Risks of Genetic Engineering in Agriculture* at 610. Yet another economic threat arises from cross-pollination. In the past, there have been several instances where cross-contamination between genetically-modified and traditional crops resulted in damaging recalls. For example, Starlink™ corn was not effectively separated from corn approved for human consumption and resulted in a massive recall. Brandner, *Detection of Genetically Modified Food: Has Your Food Been Genetically Modified?,* 64 American Biology Teacher, The 433, 435 (2002). Another example involved Terra Prima organic corn chip company having to "[recall] and destroy 90,000 bags of chips" resulting in "a significant loss to the small company" *Id*. Papaya farmers who understand the potentially devastating impacts of genetic contamination may quit the papaya business. Deregulation of X17-2 papaya will harm

current organic papaya farmers, and will discourage others from entering the organic papaya business.

IX **Potential Impacts on Agricultural Practices**

FOG disagrees with APHIS' determination that "there is no apparent potential for significant impact on agricultural practices if APHIS chooses either the "no action" alternative or grants nonregulated status to X17-2 papaya." EA at 17. Both the University of Florida Petition 04-337-01P and APHIS' EA make clear that the type of production systems within which PRSV is described as a concern of economic importance and for which X17-2 GE papaya is proposed as a solution, are intensive, commercial-scale monocultural production systems. "Typical planting densities are between ~525 and 875 trees per acre…" (EA p.7)) which utilize "typical" or "standard cultural practices." (UF Petition 04-337-01P, p. 17, 13 resp.) including "soil fumigation" (UF Petition 04-337-01P, p. 17), insecticides and fungicides (EA p. 9), herbicides (04-337-01P, p. 17), and synthetic (soluble chemical fertilizers.) There is no indication of efforts to investigate the prevalence and importance of PRSV in commercial operations employing sustainable agricultural practices such as intercropped and diversified cropping systems, trap cropping to lure and minimize aphid PRSV vectors feeding on papaya, and sound soil building and management practices that enable plants to develop robust immune systems. FOG views the petition to deregulate GE papaya as a 'silver bullet' approach to prop up failed commercial cropping systems; and believes that this approach fails to recognize the viability of farms emphasizing a systems approach and agroecological management.. A technological fix as proposed with X17-2 line GE papayas is not a long-term solution. Studies indicate that disease and pest epidemics can be averted through the use of sound farming practices and that organic production systems can be more resilient and productive than intensive monocultures in times of environmental stress. FOG urges APHIS to investigate the importance of PRSV in papaya grown in production systems that employ organic farming methods and agroecological approaches to pest and disease management. Further, FOG urges APHIS to acknowledge that this determination presents an opportunity to positively 'impact agricultural practices,' if a determination is made to reject UF Petition 04-337-01P. APHIS should investigate agroecological methods of producing papaya. If commercial producers adopt methods of sustainable agriculture, it may be possible for them to mitigate the effects of PRSV.

In light of all the adverse and potentially adverse effects discussed above, FOG urges APHIS to exercise its discretion and reject this petition for deregulation. However, if APHIS continues to consider this petition, it must consider all the issues discussed above in a detailed EIS. With so much at stake, deregulation of papaya cannot be done lightly. Harm caused by a miscalculated action now, may have irreversible detrimental effects well into the future.

Respectfully Submitted,

Marty Mesh
Executive Director
Florida Certified Organic Growers & Consumers, Inc.