November 3, 2008

Docket No. APHIS-2008-0054
Regulatory Analysis and Development
PPD, APHIS
Station 3A-03.8
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Riverdale, MD 20737-1238

Comments to USDA APHIS on Environmental Assessment for the Determination of Nonregulated Status for X17-2 Papaya Resistant to Papaya Ringspot Virus

USDA APHIS is evaluating a petition to deregulate genetically engineered ("GE") papaya resistant to the papaya ringspot virus ("PRSV"), transformation event X17-2 (hereinafter referred to as "GE papaya" or "PRSV papaya") and has issued an environmental assessment ("EA"). Pursuant to the USDA September 2, 2008 Federal Register notice, vol. 73, no. 170, 51267-51268, the Center for Food Safety ("CFS") submits the following comments concerning the inadequacy of the agency's EA accompanying the University of Florida petition for deregulation (04-337-01P). CFS appreciates the opportunity to comment on the EA of GE papaya, as well as the petition for deregulation, and to raise a number of issues concerning potential environmental impacts that are not adequately addressed by the EA or the petition.

The Center for Food Safety (CFS) is a non-profit, membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture. CFS represents 67,000 members throughout the country that support organic agriculture and regularly purchase organic products.[1] In addition to the comments submitted herein, CFS is concurrently submitting 7,873 comments from CFS Food Network members opposing the deregulation of GE papaya (Docket No. APHIS-2008-0054) from.[2]

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[1] See generally http://www.centerforfoodsafety.org.
[2] Letter from Kevin Golden, staff attorney, Submission of 7,873 comments opposing Docket No. APHIS-2008-0054 from Center for Food Safety True Food Network members, November 3, 2008 (Attachment 1) (Also submitted under separate cover to Docket No. APHIS-2008-0054 with comments attached.)

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INTRODUCTION

In general, the University of Florida claims in support of its Petition for Determination of Nonregulated Status for the X17-2 Line of Papaya (hereafter "Petition") that there has been no reported adverse environmental impacts from the commercial planting of PRSV papaya. However, the history of PRSV papaya tells a very different story. Those who grow non-GE papaya in Hawaii have been devastated by the introduction of GE papaya. While the petitioner claims that PRSV papaya has "revitalized the Hawaiian industry," (Petition at 1), the petition completely fails to address significant adverse effects to the non-GE papaya industry in Hawaii resulting from wide spread biological contamination and the related adverse economic harm to Hawaiian papaya growers, and how similar adverse effects will likely befall growers in Florida, Puerto Rico, and anywhere else this new GE papaya may be grown.[3] APHIS similarly ignores the recent history in Hawaii when it failed to address biological contamination and the interrelated economic consequences. Thus, the following comments illustrate why the proposed deregulation should not be finalized until APHIS prepares an environmental impacts statement ("EIS") to fully review the significant environmental effects of this possible deregulation.

At its core, the National Environmental Policy Act ("NEPA") directs federal agencies to prepare an EIS for all "major federal actions significantly affecting the quality of the human environment."[4] An EIS must "rigorously explore and objectively evaluate all reasonable alternatives" to the proposed federal action.[5] An EIS must also include a full and fair discussion of the proposed action's effects and their significance.[6] Relevant effects may be "ecological . . . aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative."[7]

In the recent federal court decision *Geertson Seed Farms v. Johanns,* the United States District Court held, and the United States Court of Appeals for the Ninth Circuit affirmed, that where biological contamination of a non-GE crop is made possible by the deregulation of its GE counterpart, APHIS must prepare an EIS to disclose and analyze the contamination as well as the interrelated adverse economic effects. There is ample evidence from the deregulation of PRSV resistant papaya for Hawaii that such adverse impacts are not only possible, but highly likely. Additionally, in its EA APHIS fails to evaluate potential adverse impacts to threatened and endangered species, organic papaya growers and the choice of consumers to eat non-GE papaya, the adverse impacts associated with the pesticidal viral coat protein, and the cumulative impacts of an additional national deregulation of a GE PRSV papaya variety. For the reasons set forth below, the Center for Food Safety respectfully request APHIS to prepare an EIS to evaluate these impacts prior to deregulation.

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[3] The scope of deregulation for this new GE papaya "is considered to cover the entire U.S. and its territories," thus APHIS must address potential environmental impacts for anywhere this GE papaya could be grown including Florida, Puerto Rico, Hawaii and anywhere else papaya is grown in the U.S. (EA at 7).
[4] 42 U.S.C. § 4332(2)(C).
[5] 40 C.F.R. § 1502.14(a).
[6] 40 C.F.R. § 1502.16.
[7] 40 C.F.R. § 1508.8.

Biological Contamination of Non-GE Papaya

The potential for biological contamination, through pollen flow and uncontrolled seed movement of GE papaya, triggers the requirement that APHIS prepare an EIS for this GE papaya deregulation. In discussing potential impacts from gene introgression (EA at 11), APHIS only considers the potential for introgression into papaya of the genus *Vasconcellea*, but gives no attention whatsoever to the potential for gene introgression into non-GE individuals of the same species (*Carica papaya L.*). This flies directly in the face of *Geertson Seed Farms v. Johanns*.[8]

The term "biological contamination" refers to the unintended comingling of GE crops with non-GE crops. "Biological contamination can occur through pollination of non-genetically engineered plants by genetically engineered plants or by the mixing of genetically engineered seed with natural or non-genetically engineered seed."[9] As the *Geertson* Court noted: "Once the gene transmission occurs and a farmer's seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread."[10]

As the *Geertson* Court found, once a GE crop is deregulated "the government will not be able to impose isolation distances on the growers of [the GE crop]; in other words, it cannot ensure that farmers using genetically engineered seed will be more than two miles away from seed farmers who do not wish to grow [the GE crop]."[11] In this case, there is ample evidence from the introduction of GE papaya in Hawaii that contamination is not only possible but highly likely where the PRSV papaya is allowed to be grown without restriction. For example, in the report, HAWAIIAN PAPAYA: GMO CONTAMINATED, Hawaii SEED illustrates that after the 1998 deregulation of PRSV resistant papaya, within six years contamination rates as high as 50% were found on the island of Hawaii.[12] To further support this evidence of contamination Hawaii SEED sent papaya seed from organic farms, backyard gardens and wild trees to Genetic ID, one of the world's leading independent scientific laboratories for genetic contamination testing. "The results revealed widespread contamination on the Hawaii Island," including in one variety of non-GE papaya seeds being sold by the University of Hawaii.[13] News reports in the fall of 2004 corroborate that such genetic contamination was a widespread phenomenon in Hawaii.[14] In addition to biological contamination through cross-

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[8] 2007 WL 518624 (N.D. Cal. Feb. 13, 2007) *aff'd*, 541 F.3d 938 (9th Cir. 2008).
[9] Id. at 5.
[10] Id.
[11] Id.
[12] Melanie Bondera & Mark Query, *Hawaii Papaya: GMO Contaminated*, Hawaii Seed, 11-13 (2006) (Attachment 2); *Facing Hawaii's Future, Harvesting Essential Information About GMOs*, Hawaii Seed, 44 (2006) (Attachment 3).
[13] *Facing Hawaii's Future, Harvesting Essential Information About GMOs*, Hawaii Seed, 44 (2006) (Attachment 3).
[14] Andrew Pollack, Can *Biotech crops Be Good Neighbors?*, N.Y. Times, September 26, 2004 (Organic papaya farmer cut down all 170 papaya trees due to positive contamination tests) (Attachment 4); Paul Elias, *New 'Gene Flow' Problems Concern Crop Producers*, The Associated Press, September 23, 2004 ("We are finding widespread contamination and farmers are concerned") (Attachment 5); *Genetic Traits Spread to Non-Engineered Papayas in Hawaii*, Environmental News Service, September 10, 2004

pollination and seed mixing, GE papaya can be dispersed through unintentional human action, such as throwing papaya seeds into a compost bin or into a field.[15]

The Hawaii case is a cautionary tale of what can happen to organic and other non-GE papaya growers. A study conducted by the Cooperative Extension Service of the University of Hawaii demonstrated that cross-pollination between GE papaya and organic papaya "will occur in immediately adjacent fields."[16] In the Extension Service's study, contamination rates as high as 70% were detected in organic papaya fields adjacent to GE papaya fields.[17] Although the study indicated that cross-pollination rates tended to decrease with increasing distance, the study did not test at distances great enough "to determine an adequate isolation distance beyond which genetically engineered pollen disappeared."[18] Although it made no mention of it in the EA, USDA-APHIS apparently approves an isolation distance of 500 meters for papaya field tests in Florida.[19] That APHIS established an isolation distance for the field tests demonstrates APHIS's knowledge that cross-contamination from GE papaya is possible. Yet, APHIS completely ignores this issue in its EA. Thus, an EIS prepared by APHIS for GE papaya should address this issue.

Potential biological contamination in GE papaya is not something new to GE crops. In the Union of Concerned Scientist ("UCS") report, "Gone to Seed," UCS found that about 50% or more of the certified non-GE corn, canola, and soybean seed has been contaminated with transgenes.[20] The level of contamination was typically 0.05%-1.0%, far greater than the minimum levels that can be detected. "Gone to Seed" demonstrated that the frequency and levels of contamination of soybean seed was found to be about as high as for corn. Soybeans are largely self-pollinating (do not pollinate other soybean flowers very often), while corn is highly out-crossing. Therefore, the contamination of soybean seed is likely to be largely from causes other than cross-pollination. Such causes could include seed mixing or human error, and suggests that these sources may be at least as important as cross-pollination.

For example, two academic ecologists addressed this in a peer-reviewed paper, and conclude that contamination by GE crops due to human error or other means has

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("Engineered papaya genes are showing up in fruits and seeds that were thought to be traditional . . . Contamination was also found in the stock of non-genetically engineered seeds being sold commercially by the University of Hawaii") (Attachment 6).

[15] *Facing Hawaii's Future, Harvesting Essential Information About GMOs*, Hawaii Seed, 45 (2006) (Attachment 3); Nancy Redfeather et al., *Protect What is Here Now: The Fight Over Hawaii's Agricultural Heritage*, GeneWatch, 10 (May-June 2006) (Attachment 7).

[16] Richard Manshardt, *Is Organic Papaya Production Threatened by Cross-Pollination with Genetically Engineered Varieties?*, Cooperative Extension Service, College of Tropical Agriculture and Human Resources, University of Hawaii at Manoa, 2 (October 2002) (Attachment 8).

[17] Id.

[18] Id.

[19] Environment Directorate, Joint Meeting of the Chemical Committee and the Working party on Chemicals, Pesticides and Biotechnology, Consensus Document on the Biology of Papaya (Carica papaya), 27 (October 21, 2005) (hereinafter "OECD 2005") (Attachment 9).

[20] M. Mellon and J. Rissler, Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply, Union of Concerned Scientists, 2004 (Attachment 10).

occurred numerous times, and is likely to continue to occur. This paper documents many instances where GE crops are known to have contaminated non-GE crops or food.[21] Thus, biological contamination through human error and human behavior, such as composting, exchanging seeds, and spilling seeds must be addressed in an EIS.

Another report, "A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops," UCS enlisted the assistance of several academic experts in agricultural sciences to determine whether GE pharmaceutical-producing crops could be kept out of food. This report demonstrates how difficult this is, even for pharmaceutical crops that would be grown on small acreage and under stringent confinement, to avoid contaminating food. The authors of this report examined confinement methods, such as field separation, cleaning of farm equipment, segregation of seed, and others, and found that it would still be difficult to ensure the absence of contamination.[22] The experts felt that contamination might be prevented by taking heroic means, such as geographical isolation from food crops. Union of Concerned Scientists concluded that even though it may be theoretically possible to prevent contamination, it would not be economically feasible.

In a prominent previous contamination incident, StarLink genetically engineered corn, approved by USEPA only for animal feed use, contaminated a large part of the domestic food corn supply, resulting in hundreds of millions of dollars in recalls and other remediation. In that case, the company that owned the corn, Aventis, assured EPA that it could keep it out of the human food supply. It was only grown for about two years before it was detected in corn products in the US. It was also only grown on between about 0.5% and 1.0% of the corn acreage, and despite this, the contamination was widely dispersed in the food supply.

Recent contamination events in other crops illustrate how difficult it is to prevent contamination at detectable and economically important levels. Of particular interest is the massive contamination of commercial rice grown throughout the southern rice belt by the unapproved GE variety known as LL601 "Liberty Link" rice. This GE rice was grown only in limited-acreage field tests, rather than on a commercial scale, and under the regulatory auspices of APHIS, which includes confinement recommendations. It had not been grown after 2001, but contamination of the US rice supply was detected five years later at low levels that have nonetheless caused severe economic harm to US rice farmers and the US rice industry as a whole.

By one estimate, rice farmers lost $150 million due to rejection of LL601-contaminated rice shipments by countries in Europe and elsewhere, and the consequent sharp drops in rice prices.[23] Affected rice farmers were forced to sue Bayer CropScience, the developer of LL601, in an effort to recover their losses. In response to a petition from

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[21] M. Marvier and R. Van Acker, "Can crop transgenes be kept on a leash?" Front. Ecol. Environ., 2005, vol.3, p.95-100 (Attachment 11).
[22] David Andow, et al., *A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops*, Union of Concerned Scientists, December 2004 (Attachment 12)
[23] Weiss, R. (2006). "Gene-altered profit-killer," Washington Post, Sept. 21, 2006 (Attachment 13).

Bayer CropScience, APHIS subsequently deregulated LL601, but did nothing to redress the economic harms to rice farmers. Rather than accept responsibility for the episode, Bayer CropScience blamed farmers and an "Act of God" for the contamination episode.[24] At least one identified source of contamination by LL601 occurred at Louisiana State University (LSU), where LL601 had been grown in small-scale field trials. One of the scientists in charge of the field-testing stated that LSU had grown LL601 under conditions that met and exceeded APHIS confinement recommendations considerably, but still experienced contamination.[25] Just months later, still another unapproved GE rice variety developed by Bayer CropScience, LL604, was found contaminating a popular variety of conventional rice sold to farmers as seed rice (Clearfield 131). APHIS responded by issuing several emergency action notifications to distributors of Clearfield 131 to halt sales of the contaminated seed rice.[26] As a result, rice farmers in the South experienced a severe shortage of seed rice for the 2007 season.[27] APHIS conducted an investigation into the contamination episodes, but was unable to determine precisely how they occurred.[28]

Furthermore, there is substantial variation in the results from different experiments when measuring biological contamination through pollen transfer. This has been seen for virtually every crop studied. Many factors affect gene flow frequencies, including weather conditions (precipitation, wind, temperature, humidity), which will affect bee behavior, pollination levels, and the duration of pollen viability. The relative size of the pollen recipient and pollen production fields also has a very big impact on the distances and frequencies of gene flow. As one example, a field trial of creeping bentgrass containing 286 plants revealed contamination at up to about 1400 feet, while one of 400 acres had cross-pollination at 13 miles.[29] Small canola field trials (a bee pollinated crop) often have significant cross pollination at several hundred to several thousand feet, while a study in Australia at the commercial scale observed contamination at up to about 3 kilometers.[30] Here, APHIS completely failed to analyze the potential contamination levels by gene flow, and must do so in an EIS.

Despite evidence of widespread contamination after the deregulation of GE PRSV resistant papaya for the Hawaiian Islands and in virtually all GE crops, APHIS failed to

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[24] Weiss, R. (2006). "Firm Blames Farmers, 'Act of God' for Rice Contamination," Washington Post, Nov. 22, 2006 (Attachment 14).
[25] Vogel, G. (2006). "Tracing the transatlantic spread of GM rice," Science, 2006, vol. 313, p. 1714 (Attachment 15).
[26] USDA APHIS (2007). "Statement by Dr. Ron DeHaven regarding APHIS hold on Clearfield CL131 long-grain rice seed," March 5, 2007 (Attachment 16). http://www.aphis.usda.gov/newsroom/content/2007/03/content/printable/gericeseed_statement.doc.
[27] Bennett, D. (2007). "Arkansas' emergency session on CL 131 rice," Delta Farm Press, March 1, 2007 (Attachment #17).
[28] USDA (2007). "Report of LibertyLink Rice Incidents," October 2007 (Attachment 18).
[29] JK. Wipff and C. Fricker, "Gene flow from transgenic creeping bentgrass (Agrostis stolonifera L.) in the Willamette Valley, Oregon," International Turfgrass Society Research Journal, 2001, vol. 9, p. 224 (Attachment 19);LS Watrud et al., "Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker," 2004, PNAS (Attachment 20).
[30] MA Rieger et al., "Pollen-mediated movement of herbicide resistance between commercial canola fields," Science, 2002, vol. 296, p. 2386-2388 (Attachment 21).

address in its EA the potential for biological contamination once GE PRSV resistant papaya is deregulated in this case. Instead, APHIS stated that because "Hawaii's industry has implemented a segregation system to separate non-transgenic from transgenic papaya . . . there is no apparent potential for significant impact." (EA at 17). In this case as in *Geertson*, "APHIS's reasons for concluding that the potential for the transmission of the genetically engineered gene is not significant are not 'convincing' and do not demonstrate the 'hard look' that NEPA requires."[31] Thus, APHIS must prepare an EIS to disclose and analyze the potential for biological contamination of non-GE papaya prior to deregulating the GE papaya variety at issue here.

Impacts on Organic and Other Papaya Growers

The potential for the elimination of organic papaya varieties and the potential to harm organic growers' organic certification trigger the need for APHIS to prepare an EIS. In addressing potential impacts on organic, however, APHIS merely concludes that contamination of organic papaya "will not affect the status of an organic product or operation" because "organic certification of a production or handling operation is a process claim, not a product claim." (EA at 18). This is precisely the same legal argument that failed in *Geertson Seed Farms*.

When confronted with this logic, the *Geertson* Court found that "[E]ven APHIS is uncertain whether farmers can still label their products organic under the federal government's organic standards. Second, many farmers and consumers have higher standards than what the federal government currently permits; to these farmers and consumers organic means not genetically engineered, even if the farmer did not intend for his crop to be so engineered. . . . Third, and most importantly, APHIS's comment simply ignores that these farmers do not want to grow . . . genetically engineered alfalfa, regardless of how such alfalfa can be marketed."[32] Here, as in *Geertson*, "APHIS reasoning that farmers will not 'necessarily' be prohibited from labeling their products as organic is wholly inadequate."[33]

Furthermore, during the implementation of the Organic Food Production Act, the USDA indicated that the presence of GE contaminants would render a product unmarketable as organic. The Department explained, "[C]onsumers have made clear their opposition to the use of [GE] techniques in organic food production. **This rule is a marketing standard**, not a safety standard. **Since use of genetic engineering in the production of organic food runs counter to consumer expectations, [GE foods] will not be permitted to carry the organic label**."[34]

Beyond the concern of labeling and marketability of organic papaya, there is the very real potential that through biological contamination, organic papaya and organic papaya markets may be eliminated. APHIS states that because "flesh of papaya fruit is

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[31] 2007 WL 518624 at 6.
[32] Id.
[33] Id.
[34] 65 Fed. Reg. 13534-35 (Mar. 13, 2000) (emphasis added).

exclusively derived from the maternal tree and the cells of the flesh are genetically identical to the cells of the maternal tree," cross-pollination will not be a problem because edible fruit will not contain the GE material. (EA at 19). However, this fails to account for cross-pollination and the great potential for seeds to become contaminated, causing biological contamination if GE papaya trees of subsequent generations. The EA even states that "Papaya trees are normally propagated by seed." (EA at 18). Thus, contamination of organic papaya through seed contamination is a potential environmental impact.

The Hawaii case is again instructive on why comprehensive environmental review is necessary in this case. There, organic papaya growers were directly harmed by contamination with GE papaya. For example, Mr. Lahti, an organic papaya farmer had to cut down all 170 of his papaya trees due to positive contamination tests.[35] Another organic farmer, John Caverly, also was forced to cut down his entire papaya plantation.[36] The entire organic papaya market in Hawaii has been undermined by the introduction of GE papaya. The same thing could happen to more farmers if this new GE papaya is deregulated and grown in Florida and Puerto Rico, eliminating their choice to grown organic papaya. Such potential contamination, and the resulting harm to organic farmers' choice to grow non-GE papaya, constitutes a significant environmental impact to the human environment that AHIS must review in an EIS.[37]

Thus, APHIS must prepare an EIS to address the potentially significant environmental impacts to organic papaya and the organic papaya market.

Potential Socio-Economic Impacts

APHIS completely fails to address potential adverse socio-economic effects from the deregulation of GE papaya. Potentially significant adverse socio-economic impacts trigger the need for APHIS to prepare an EIS.

NEPA requires that economic effects are relevant and must be examined "when they are interrelated with natural or physical environmental effects."[38] As the court explained in *Geertson Seed Farms*: "The economic effects on the organic and conventional farmers of the government's deregulation decision are interrelated with, and, indeed, a direct result of, the effect on the physical environment; namely, the alteration of a plant species' DNA through the transmission of the genetically engineered gene to organic and conventional alfalfa."[39] The court continued, "APHIS was required

[35] Andrew Pollack, Can *Biotech crops Be Good Neighbors?*, N.Y. Times, September 26, 2004) (Attachment 4).
[36] Alan McNarie, *Plenty GE papaya problems on Hawaii*, Hawaii Island Journal (April 1, 2003) (Attachment 22).
[37] *Geertson Seed Farms*, 2007 WL 518624 at 8 ("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:")
[38] *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 944 (9th Cir. 2005) (quoting 40 C.F.R. §1508.14).
[39] 2007 WL 518624 at 8.

to consider those effects in assessing whether the impact of its proposed action is 'significant.'"[40]

APHIS is similarly required to consider such economic effects in this case as well. In addressing potential impacts on commercial use (EA at 16-17), APHIS admits that foreign markets, such as the Japanese market, do not accept GE papaya. In response to its own assertion, APHIS simply states that "Hawaii's industry has implemented a segregation system to separate non-transgenic from transgenic papaya." However, APHIS completely ignores the possibility of such effects in Florida, Puerto Rico, or any where else that this new GE papaya may be grown after it approves a nation wide deregulation.

The Hawaii case, however, proves the point that potential impacts must be addressed. After the 1998 deregulation of GE papaya for the Hawaii market, papaya production and papaya prices in Hawaii suffered greatly from the introduction of GE papaya.[41] As a starting point, GE varieties fetch a much lower price, as much as two-thirds less, than non-GE varieties.[42] After GE papaya was introduced, farmers received at least 35% less per kilogram on average for their fruit.[43] Depressed prices for the GE papaya have driven many papaya farmers out of business.[44] As of 2006, this had cut the number of Hawaii papaya farmers in half.[45] While GE papaya advocates claim that GE papaya has 'saved' the Hawaii papaya market, the fact is that since the introduction of GE papaya in Hawaii, the Hawaiian papaya market has declined by at least 28%.[46]

Furthermore, as APHIS acknowledges in the EA (EA at 17), "much of the world, including the lucrative Japan market, still remains closed to [GE papaya]."[47] When GE papaya was introduced in 1998, for example, "Hawaiian exports to Japan fell from $10.3 million in 1998 to $4.6 million in 2005."[48] And although consumption of papaya by U.S. consumers has increased by one-third just 10 years ago,[49] production of papaya in Hawaii has been in a free-fall while papaya producing and exporting countries where GE papaya is not grown have shown steady increases in production over the same period of time.[50]

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[40] Id.
[41] Sean Hao, *Papaya Production Taking a Tumble*, Honolulu advertiser (March 19, 2006) (Attachment 23).
[42] *Big Isle Papaya Crops Tainted*, The Hawaii Tribune-Herald, front page (April 7, 200) (non-GE Kapoho Solo papaya sells for $0.60, while GE Rainbow papaya sells for $0.20) (Attachment 24); The Failure of GE Papaya in Hawaii, Greenpeace, 3 (May 2006) (The price of papaya fell from an average of $1.23 per kilogram to $0.89 per kilogram "when traditional buyers of Hawaiin papayas, such as Japan and Canada, rejected the GE fruit.) (Attachment 25).
[43] The Failure of GE Papaya in Hawaii, Greenpeace, 3 (May 2006) (Attachment 25).
[44] Alan McNarie, *Plenty GE papaya problems on Hawaii*, Hawaii Island Journal (April 1, 2003) (Attachment 22).
[45] Nancy Redfeather et al., *Protect What is Here Now: The Fight Over Hawaii's Agricultural Heritage*, GeneWatch, 10 (May-June 2006) (Attachment 7).
[46] The Failure of GE Papaya in Hawaii, Greenpeace, 3 (May 2006) (Attachment 25).
[47] Alan McNarie, *Plenty GE papaya problems on Hawaii*, Hawaii Island Journal (April 1, 2003) (Attachment 22).
[48] The Failure of GE Papaya in Hawaii, Greenpeace, 3 (May 2006) (Attachment 25); Sean Hao, *Papaya Production Taking a Tumble*, Honolulu advertiser (March 19, 2006) ((Attachment 23).
[49] Sean Hao, *Papaya Production Taking a Tumble*, Honolulu advertiser (March 19, 2006) (Attachment 23).
[50] The Failure of GE Papaya in Hawaii, Greenpeace, 5 (May 2006) (Attachment 25).

Given the adverse effects of the GE papaya on the once robust Hawaiian papaya market, it is likely that similar negative impacts will affect the papaya markets in Florida, Puerto Rico, and anywhere else that his new GE papaya is grown. However, APHIS incredibly ignores this possibility altogether. Prior to deregulating this new GE papaya, APHIS must evaluate the socio-economic impacts in an EIS.

Impacts from the Weedy Characteristics of Papaya and Potentially Enhanced Weediness of GE PRSV Papaya

APHIS failed to consider the potentially significant impacts of GE PRSV papaya as a weed. Rather, in two short paragraphs, APHIS cursorily dismisses the potential for GE papaya to become a weed problem.

There is ample evidence, however, that papaya often escapes from cultivated sites and becomes established in natural environments in feral (i.e. wild) populations as a weed. Additionally, GE PRSV papaya may have enhanced weediness relative to non-GE papaya, and feral populations of GE PRSV papaya may become reservoirs for transgenic DNA and become a source of further biological contamination to cultivated non-GE papaya. These are all potentially significant environmental impact that APHIS must considered prior to deregulating this new GE papaya.

The Organization for Economic Co-operation and Development ("OECD"), an intergovernmental organization of 30 industrialized countries, presented sufficient evidence to demonstrate that papaya in fact exhibits significant weedy characteristics and readily grows as feral papaya.[51] The following statements made in this report and supported by peer reviewed studies, indicate that APHIS must take a hard look at the weediness potential of feral GE PRSV papaya:

- "Papaya in different regions is variously described as an incidental escapee from cultivated sites, an opportunist, a pioneer species, or sometimes an invasive or potentially invasive species. Papaya may persist beyond cultivation for indefinite periods of time."[52]

- "Little and Wadsworth (1964) state that 'Through the tropics they grow almost as weeds, bearing fruit the first year from seed and spreading along roadsides and in waste places'; they report that in Puerto Rico papaya is widely cultivated, escaping, and naturlised."[53]

- "*Carica papaya* is regarded as a pioneer species in fairly natural habitats. Papaya can occur in forest gaps and within the early succession, since it has such characteristics as rapid growth in response to disturbance and high light intensity, and prolific production of seeds and an attractive fruit. Its

[51] OECD 2005.
[52] Id. at 36.
[53] Id. at 36-37.

pioneering ecological strategy includes a short life cycle with seed dormancy and a seed bank."[54]

- "As an opportunist, papaya has the capacity to establish significant seed banks." "In a post-hurricane study of regeneration that compared feral *C. papaya* with a similar-sized native pioneer tree species (*Trema micrantha*) in Florida hammock habitats, papaya had a broader niche for regeneration (Kwit et al., 2000). They averred that dormant seed supply seed for population return following natural disturbance."[55]

- "Nakasone and Paull (1998) characterise papaya as "a rapid volunteer in areas where the tree vegetation has been disturbed". Subsequent to major hurricane damage (1992) in southern Florida (USA), papaya recruited abundantly and rapidly in unmanaged and managed areas. In the 1st and 2nd years, it comprised 76% and 40% of all stems respectively in the unmanaged areas (Horvitz and Koop, 2001)."[56]

* "Randall (2002) reported weedy papaya infestations on some tropical islands and in localised areas of New Zealand."[57]

- "Wiser et al. (2002) stated that it [papaya] should be considered a potentially serious invader. In coastal Queensland (Australia), "small, low-density self-perpetuating populations" may be found (OGTR, 2003a). In the Hawaiian Islands, papaya is sparingly naturalised on four main islands, with some plants even occurring on nearly vertical rock faces (Wagner et al., 1999; Oppenheimer and Bartlett, 2000). In a wet-forest region of coastal Ecuador near the Andean foothills, Dodson and Gentry (1978) found papaya to be common in second-growth areas, including a forest regenerating from an agricultural clearing about 18 years previously."[58]

- "Reports are scarce on efforts to reduce feral *C. papaya* in relatively natural habitats (e.g. Horvitz and Koop 2001), which may be important for ecological restoration or to reduce genetic contamination in orchards from feral off-types."[59]

Based on the OECD's conclusions, it is clear that *C. papaya* is invasive, pioneering, weedy, and grows as a feral species in Florida, Puerto Rico, and many other areas worldwide. Based on a cursory review of a limited number of lists, including the Federal Noxious weed list, and Weed Species Lists from Hawaii, California and Florida, APHIS concludes that "[b]ecause papaya is not described as a weedy species . . . there

[54] Id. at 37.
[55] Id.
[56] Id.
[57] Id.
[58] Id.
[59] Id.

should be no impact from increased weedy characteristics." (EA at 11-12). However, the OECD demonstrates that papaya does in fact exhibit weedy, invasive, and feral characteristics.

APHIS erred by limiting its review to only these four lists and the narrow definition of "noxious weed" and "weed" underlying these lists. Given the significant potential impacts of the release of GE papaya, APHIS must investigate the weedy characteristics of papaya and the potentially enhanced weediness of GE papaya, and the associated adverse environmental impacts that may result.

For example, feral GE papaya with virus resistance may exhibit the above weedy characteristics, but have enhanced weediness because of the adaptive advantage of virus resistance. If it is true that PRSV resistance will confer an advantage to cultivated papaya, it must also be true that PRSV resistance will also confer an advantage to populations of PRSV papaya that become feral. Additionally, once feral GE papaya becomes established in areas near non-GE papaya growing fields, such GE feral papaya will serve as a reservoir for transgenic biological contamination of non-GE papaya crops, causing biological contamination in conventional or organic non-GE papaya. Hence, GE feral papaya represents a second source of biological contamination (in addition to cultivated GE papaya). APHIS must consider these potential environmental impacts in an EIS.

Impacts on Biodiversity and Choice

In discussing potential impacts on biodiversity (EA at 13), APHIS gives an extremely cursory review of effects to biodiversity. For example, it does not address the possibility of reducing or eliminating non-GE varieties. As *Geertson Seed Farms v. Johanns* explained, "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*.'"[60] Specifically, NEPA aims to "maintain, wherever possible, an environment which supports diversity and variety of individual choice."[61] Accordingly, "[a] federal action that eliminates a farmer's choice to grow non-genetically engineered crops, of a consumer's choice to eat non-genetically engineered food, is an undesirable consequence."[62] Furthermore, "An action which potentially eliminates or least greatly reduces the availability of a particular plant-here, non-engineered alfalfa-has a significant effect on the human environment.[63]

Here, APHIS completely failed to address the possibility that biological contamination may eliminate the choice of farmers to grow non-GE organic or conventional papaya varieties. Thus, APHIS must prepare an EIS and do so.

Impacts on Threatened and Endangered Species

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[60] *Geertson Seed Farms*, 2007 WL 518624 at 8 (emphasis in original) (quoting 42 U.S.C. § 4331(b)(3)).
[61] Id. (quoting 42 U.S.C. § 4331(b)(4)).
[62] Id.
[63] Id. at 9.

In discussing potential impacts on biodiversity (EA at 13), APHIS did not consider effects on threatened or endangered species whatsoever. Although the EA references endangered species in the index (EA at 2) and introduction (EA at 3), APHIS completely ignores threatened and endangered species in the text of the EA. Thus prior to a completion of the deregulation, APHIS must demonstrate that at the very least, it has consulted with the United States Fish and Wildlife Service ("FWS") and/or the National Marine Fisheries Service ("NMFS") and taken the first step in considering the impacts of an APHIS deregulation of GE papaya on threatened or endangered species.

The endangered species act ("ESA") requires APHIS to consult with FWS and/or NMFS to determine "whether any species which is listed or proposed to be listed [as an endangered species or a threatened species] may be present in the area of such proposed action."[64] Then if APHIS learns from FWS and/or NMFS that threatened or endangered species may be present, a biological assessment must be prepared to identify any endangered species or threatened species which are likely to be affected by such action.[65] The initial request for information from FWS and/or NMFS is a predicate to further agency action and cannot be ignored.[66]

In a recent case where APHIS approved field trials of GE crops in Hawaii, APHIS was found to have violated the ESA when it skipped this initial, mandatory step of obtaining information about listed species and critical habitats from FWS and/or NMFS.[67] The court emphasized that regardless of whether there is any evidence that species or habitat may be harmed in any way, "an agency violates the ESA when it fails to follow the procedures mandated by Congress, and an agency will not escape scrutiny based on the fortunate outcome that no listed plant, animal, or habitat was harmed."[68]

Here, there is no evidence in the EA that APHIS took the first steps of consultation with FWS and/or NMFS to determine whether the deregulation of GE papaya may harm listed species or habitat. Thus, prior to deregulation, APHIS must at the very least consult with FWS and/or NMFS prior to approving this deregulation.

Like Hawaii, both Florida and Puerto Rico have substantial numbers of threatened and endangered species. Florida has 59 animal species listed as endangered (39) or threatened (20),[69] while Puerto Rico has 29 animal species listed as endangered (18) or threatened (11).[70] Some or many of these threatened or endangered species may consume papaya, thus such potential impacts may not be cursorily dismissed. Two Scientific

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[64] 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12(c) (requiring federal agencies to request information regarding listed species and critical habitat from the Department of the Interior).
[65] Id.
[66] *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).
[67] *Center for Food Safety v. Johanns*, 451 F.Supp.2d 1165, 1182 (D. Hawaii 2006).
[68] Id.
[69] U.S. Fish & Wildlife Service, Threatened & Endangered Species System, Florida, *available at* http://ecos.fws.gov/tess_public//pub/stateListing.jsp?state=FL&status=listed.
[70] U.S. Fish & Wildlife Service, Threatened & Endangered Species System, Puerto Rico, *available at* http://ecos.fws.gov/tess_public//pub/stateListing.jsp?state=PR&status=listed.

Advisory Panels ("SAP") to the EPA addressed potential non-target impacts from exposure to GE crops containing viral coat proteins. Among the concerns addressed by these experts were potential adverse effects of viral coat proteins on pollinators, non-traditional non-target organisms, as well as potential indirect and sublethal effects of viral coat proteins, alone or in combination with other chemicals in the environment.[71]

Clearly, APHIS must assess these potential non-target impacts of PSRV-CP in X17-2 papaya as they relate to endangered and threatened animal species in Florida and Puerto Rico. Since the deregulation is not geographically limited, and the GE papaya in question could be legally planted in Hawaii as well, APHIS must conduct a similar ESA-compliant analysis in Hawaii as well.

Failure to Review Pesticidal Viral Coat Protein and Related Human Health Impacts

APHIS must conduct an analysis of the potential adverse human health effects of the pesticidal viral coat protein at issue here. Although APHIS states that "APHIS further considered potential effects on human health from a decision to grant Nonregulated status to X17-2 papaya" (EA at 19), neither University of Florida's petition nor APHIS's preliminary EA provides any substantive assessment of potential adverse human health impacts from deregulation of transgenic papaya line X17-2.

Rather than conduct the proper NEPA analysis here, APHIS improperly deferred the environmental evaluation of the viral coat proteins present in this GE papaya to the U.S. Environmental Protection Agency ("EPA"). (EA at 5). The Ninth Circuit Court of Appeals has long held, however, that "[t]he EPA registration process for herbicides under FIFRA is inadequate to address environmental concerns under NEPA."[72] The court has determined that "FIFRA does not require or even contemplate the same examination that [an agency] is required to undertake under NEPA."[73] It therefore made clear "that the registration and labeling of a substance under FIFRA does not exempt an agency from its obligations under [NEPA]."[74] Furthermore, the Coat Protein in X17-2 is not covered by EPA's 1997 Tolerance Exemption. Thus, AHPHIS must address the impacts associated with the viral coat protein for this new GE papaya deregulation.

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[71] SAP (2005). "Plant-Incorporated Protectants Based on Virus Coat Protein Genes: Science Issues Associated with the Proposed Rule," FIFRA Scientific Advisory Panel, SAP Report No. 2006-01, pp. 32-40, esp'ly pp. 38-39 (Attachment 26); and SAP (2004). "Issues Associated with Deployment of a Type of Plant-Incorporated Protectant (PIP), Specifically Those Based on Plant Viral Coat Proteins (PVCP-PIPS)," FIFRA Scientific Advisory Panel, SAP Report No. 2004-09, pp. 45-46 (Attachment 27).

[72] *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984).

[73] Id.; *See also Washington Toxics Coalition v. Environmental Prot. Agency*, 413 F.3d 1024, 1032 (9th Cir. 2005) (same).

[74] *Washington Toxics Coalition*, 413 F.3d 1024 at 1032. *See also Northwest Coalition for Alternatives to Pesticides v. Lyng*, 844 F.2d 588, 596 (9th Cir. 1998) ("EPA's registration of an herbicide under [FIFRA] is inadequate to address NEPA environmental concerns and therefore reliance alone on that registration process is improper."); *Save Our Ecosystems*, 747 F.2d at 1249 ("[An agency] cannot abdicate its [NEPA] responsibilities by relying on another agency. It must evaluate the impact of its own actions."); *Oregon Envt'l Council v. Kunzman*, 714 F.2d 901, 905 (9th Cir. 1983) ("One agency cannot rely on another's examination of environmental effects under NEPA.").

There are several scientifically-grounded concerns that APHIS must assess in an EIS prior to deregulating the GE papaya.

1. Potential Allergenicity of the Papaya Ringspot Virus Coat Protein

The X17-2 transgenic papaya contains undetermined levels of a modified papaya ringspot virus coat protein ("PRSV-CP"). University of Florida ("UF") had attempted to prevent X17-2 papaya from generating PRSV-CP by introducing a frameshift mutation in the CP transgene before engineering it into the papaya, but this attempt failed.[75] UF does not state why it tried to prevent generation of PSRV-CP in X17-2, which is apparently not needed for the papaya's virus-resistance.[76] But virus experts have proposed that transgenic virus-resistant plants not be allowed to produce viral coat proteins from concern over adverse agronomic and environmental impacts.[77] We address these issues below. Expert advisers consulted by the EPA likewise favor RNA-based transgenic virus protection (i.e. post-transcriptional gene silencing, or PTGS) that does ***not*** involve production of virus coat protein due to numerous potential hazards posed by the unnecessary presence of viral coat proteins in transgenic produce.[78]

One potential hazard posed by viral coat proteins is allergenicity. EPA's expert advisers extensively discuss this issue, and recommend exhaustive testing to help

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[75] Petition at 3: "…analyses indicate that the [frameshift] mutation was repaired and that the CP transgene in recent generations is both translatable and expressed." Petition at 11: "[T]he CP gene is translatable and not non-translatable ***as intended***, and western analyses, described below and in Figure 5, indicate that the CP gene is expressed,", emphasis added. Note that "translate" and "express" are terms that indicate generation of the CP protein from the CP transgene introduced into X17-2.

[76] There are two major mechanisms for transgenic virus protection: RNA-based post-transcriptional gene silencing (PTGS) and protein-mediated virus protection. The first mechanism involves production by the plant of RNA from the inserted gene, but not protein. The latter mechanism involves production of both RNA and viral coat protein. By attempting to engineer the transgene to prevent viral coat protein production as detailed above, UF's ***intent*** was virus protection via PTGS; since UF failed to prevent coat protein production, it is unclear which mechanism is involved in X17-2. See EA at 10: "The mechanisms for cross protection have been ***determined*** to be ***either*** RNA-based [PTGS] or protein-mediated" (emphasis added). APHIS's statement is misleading in that these are the only two currently applied mechanisms of transgenic virus protection; hence, nothing has been "determined."

[77] Latham, JR and AK Wilson (2007). "Transcomplementation and synergism in plants: implications for viral transgenes?" *Molecular Plant Pathology* 9(1):85-103 (Attachment 28). See also the authors' non-technical summary of this paper: "Rethinking the Risks of Viral Transgenes," Bioscience Resource Project Commentaries, Nov. 30, 2007 (Attachment 29).

[78] SAP (2005). "Plant-Incorporated Protectants Based on Virus Coat Protein Genes: Science Issues Associated with the Proposed Rule," FIFRA Scientific Advisory Panel, SAP Report No. 2006-01, p. 13 (Attachment 26): "PTGS is a highly desirable transgenic resistance strategy for virus resistance because 1) it is based on a natural plant defense mechanism against viruses themselves, 2) ***transgenes can be designed to produce only RNA, not protein***, and 3) PTGS gives stronger resistance than protein methods," emphasis added. See also: SAP (2004). "Issues Associated with Deployment of a Type of Plant-Incorporated Protectant (PIP), Specifically Those Based on Plant Viral Coat Proteins (PVCP-PIPS)," FIFRA Scientific Advisory Panel, SAP Report No. 2004-09, p. 41 (Attachment 27). Here, the SAP responds to a question from EPA regarding potentially hazardous environmental impacts from novel viral interactions in transgenic plants modified with viral coat proteins such as PSRV-CP: "If one really wishes to eliminate novel interactions, then resistance based on post-transcriptional gene silencing is an obvious solution. However, the Panel was aware that this approach was not a subject for consideration."

determine whether viral coat proteins expressed in transgenic plants could cause allergies.[79]

While the EPA's expert advisers discuss the allergenic potential of viral coat proteins in general, an important 2002 study[80] conducted at Europe's leading center for GM food safety research (RIKILT in Wageningen, The Netherlands) has identified PRSV-CP as a potential allergen.[81] The authors of this study, Kleter and Peijnenburg, conducted an exhaustive analysis of the transgenic proteins expressed in GE food crops for their potential to cause allergies upon exposure (e.g. when consumed). Of the 33 transgenic proteins they assessed, PRSV-CP was one of only four identified as potential allergens, based on its structural (i.e. amino acid sequence) similarity to the known nematode allergen, ABA-1. The RIKILT scientists recommend further investigations to determine whether PSRV-CP will cause allergies in those who consume X17-2 papaya.

Neither UF nor APHIS provides any assessment of allergenicity, and neither even mentions this potential health threat to those who consume X17-2 papaya. APHIS notes that EPA granted a tolerance exemption for the coat protein of papaya ringspot virus in 1997,[82] but APHIS cannot rely on this 11-year old decision. Under NEPA, APHIS is not permitted to defer its statutory duty to assess X17-2 papaya for impacts on the "human environment," which includes human health as well as environmental impacts, to another federal agency. Such deferral is even less appropriate given the fact that EPA granted this exemption before publication of the 2002 study cited above showing that PRSV-CP is a potential allergen that requires further investigation.

2. The Coat Protein in X17-2 is not Covered by EPA's 1997 Tolerance Exemption

Modifications to the PRSV-CP in X17-2 (relative to natural PRSV coat protein) present additional concerns that this coat protein may cause allergies or otherwise have toxic effects. These modifications also make EPA's 1997 tolerance exemption for PRSV-CP, as cited by APHIS, inapplicable. Appendix II of UF's petition shows the expected versus observed nucleotide sequence of the PRSV-CP gene in X17-2, which comprises 1009 nucleotides from #3352 to #4360 of the T-DNA PRC fragment depicted in Appendix II. The expected sequence represents that of the natural gene encoding PRSV-CP in isolate H1K (except for an inserted thymidine), which was the sequence in the transformation vector used to engineer X17-2. The observed sequence represents the differing nucleotide sequence of the PRSV-CP gene that is actually found in a fifth generation (R_5) X17-2 papaya. The observed sequence has six changes relative to the expected sequence. One change is the loss of a thymidine residue inserted to create a

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79 SAP (2005), pp. 32-40; SAP (2004), pp. 44-45.

80 Kleter, GA and AD ACM Peijnenburg (2002). "Screening of transgenic proteins expressed in transgenic food crops for the presence of short amino acid sequences identical to potential, IgE-binding linear epitopes of allergens," *BMC Structural Biology* 2002, 2:8: 1-11 (Attachment 30).

81 An allergen is a substance, usually a protein that is responsible for inducing allergic sensitization and reactions in allergy-prone individuals. An allergen can act via inhalation (inhalational allergen), via ingestion (food allergen), or less commonly, via dermal contact.

82 EA at 6, citing EPA (1997). Coat Protein of Papaya Ringspot Virus and the Genetic Material Necessary for its Production; Exemption From the Requirement of a Tolerance, 62 FR 44572.

frameshift mutation to generate a stop codon and so prevent translation of the PRSV-CP protein; as noted above, UF states that this mutation was repaired, leading to the unintended presence of PRSV-CP in X17-2 papaya. The five remaining changes were all point mutations (single nucleotide changes): the two at 3511 and 3961 resulted in synonymous codons (i.e. no change in the amino acid translated vis-à-vis the expected codon). The other three resulted in amino acid alterations: cytosine → adenine at 3902 resulted in translation of threonine rather than the expected proline; thymine → adenine at 4309 gave isoleucine instead of phenylalanine; and guanine → cytosine at 4360 changed a stop codon to one encoding tyrosine, resulting in an additional amino acid at the end of the protein.

These structural changes may confer new, different and potentially hazardous changes on the PRSV-CP actually found in X17-2 relative to the expected, natural sequence encoded by the transformation vector. These changes represent an additional risk factor beyond that identified by RIKILT scientists in the 2002 study noted above, changes that may render the PRSV-CP in X17-2 (more) allergenic or toxic relative to its unmodified form. Subsequent to its 1997 tolerance exemption for PRSV-CP, EPA continued to study and refine its policies for viral coat proteins in transgenic plants as a class, resulting in a proposal to categorically exempt viral coat proteins in transgenic plants from the requirement of a tolerance, but only when such viral coat proteins are either identical in sequence to naturally occurring viral coat proteins, or are "virtually modified when compared to an entire unmodified coat protein..."[83] EPA has not finalized this proposed rule, but based on EPA's discussion in the above-cited supplemental rule, the modified PRSV-CP in X17-2 would not qualify for the categorical exemption of virus coat proteins (or virtually unmodified versions thereof) from the requirement of a tolerance, for two reasons. First, EPA's proposed definition of "virtually unmodified" is limited to coat proteins that are identical to the natural version with the exception of one or two amino acid additions or deletions at either end of the protein.[84] Of the three amino acid alterations noted above, two occur in the midst of the protein, only one at an end of the protein. Thus, the PRSV-CP in X17-2 is not "virtually unmodified" and does not qualify for the categorical exemption.

EPA also proposes an "exemption conditional on Agency determination."[85] In this case, the EPA would consider various information about the PRSV-CP to determine whether it qualifies as "minimally modified" relative to its natural form, and hence exempt from the requirement of a tolerance. EPA cites a 2005 Scientific Advisory Panel (SAP) report discussing criteria to consider in determining whether a PRSV-CP is "minimally modified." Among the changes that the SAP cites as disqualifying a protein as "minimally modified" because of potentially hazardous changes thereby induced is: "the addition or removal of proline residues that act as secondary structure 'break

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[83] EPA (2007). Exemption from the Requirement of a Tolerance under the Federal Food, Drug, and Cosmetic Act for Residues of Plant Virus Coat Proteins that are Part of a Plant-Incorporated Protectant (PVC-Proteins); Supplemental Proposal," Federal Register, Vol. 72, No. 74, April 18, 2007: 19646.
[84] Id., Section IV.E.1 at 19646.
[85] Id., Section IV.E.2, at 19649.

point,'..."[86] As noted above, one change in the PRSV-CP in X17-2 is the substitution of a threonine residue for the expected proline residue, which represents a removal of proline and hence an amino acid alteration with the potential to change the secondary structure of the PRSV-CP. Structural alterations of this sort can affect a protein's allergenicity. This unexpected threonine residue presents additional allergenicity concerns as an amino acid that possesses a reactive side chain that can serve as a site for post-translational modifications such as glycosylation, which can make a protein allergenic.[87]

In sum, there are numerous reasons to be concerned that the modified PRSV-CP in X17-2 papaya may cause allergies in those who consume or are otherwise exposed to it (e.g. inhalation of pollen). APHIS must thoroughly assess this potential impact on the human environment in a NEPA-compliant EIS. Alternately, APHIS should deny the petition for non-regulated status based on the unintended presence of modified PSRV-CP coat protein and the allergenicity concerns it raises.

3. Potential for X17-2 Transgenic Papaya to Contain Increased and Hazardous Levels of Toxins that Occur Naturally in Conventional Papaya

Genetic engineering has the potential to increase levels of toxic compounds that naturally occur at low, unobjectionable levels in food crops. Papayas contain many biologically active compounds, some of which have medicinal uses, and some of which appear to have toxicity.[88] Therefore, APHIS should conduct a thorough assessment of the levels of (potentially) toxic compounds in X17-2 transgenic papaya, grown in a variety of different climatic and soil conditions, in comparison to levels found in the closest conventional papaya relative. This analysis should include both unripe green fruit as well as ripe fruit, because green fruit has been reported to contain higher levels of certain hazardous compounds (see below), green papaya is often consumed in raw or cooked form,[89] APHIS explicitly states that Florida is the source of "green cooking type papayas,"[90] and UF states that: "Varieties are being developed with characteristics suitable for the green fruit and/or fresh fruit markets."[91]

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[86] Id. at 19649.
[87] Id. at 19646. "EPA has identified cysteine, asparagine, serine, and threonine as the amino acids containing side chains that could promote cross-linking or serve as sites for post-translational modifications. EPA therefore excludes the addition of these amino acids from the proposed definition of virtually unmodified." See also: SAP (2005). "Plant-Incorporated Protectants Based on Virus Coat Protein Genes: Science Issues Associated with the Proposed Rule," FIFRA Scientific Advisory Panel, SAP Report No. 2006-01, p. 44. In answer to a question about which changes to a viral coat protein could increase its toxicity or allergenicity: "The addition of other amino acids containing reactive side chains that can serve as sites for post-translational modifications may be significant and should be evaluated on a cases-by-case basis."
[88] "Treating Livestock with Medicinal Plants: Beneficial or Toxic? Carica papaya," Cornell University, Department of Animal Science, available at http://www.ansci.cornell.edu/plants/medicinal/papaya.html (Attachment 32).
[89] Petition at 4.
[90] EA at 18.
[91] Petition at 3.

Such an analysis is completely lacking in the EA and in UF's petition. UF's petition contains only a crude nutritional comparison of X17-2 and various conventional papaya varieties, but provides no analysis of the levels of (potentially) hazardous compounds.

APHIS's comparative assessment should include, but not be limited to, the compound benzyl-isothiocyanate (BITC), which the developers of a previous transgenic papaya resistant to ringspot virus identified as a potential abortifacient, and as occurring at much higher levels in the latex of immature (green, semi-ripe) fruit than in ripe fruit.[92] As noted above, Florida is a producer of green papaya. In addition, APHIS's assessment should include measurement of the BITC content of both the fruit and epicarp tissues of green and ripe papaya, given recent experimental findings showing that aqueous extracts of the epicarp of **ripe** papayas fed to pregnant mice induced embryonic resorption, an effect that was not observed with aqueous extracts of green papaya epicarp.[93] This finding suggests that ripe papaya may also have adverse effects on pregnant women.

In this case, APHIS' failure to take its own "hard look" at the impacts to the human environment of deregulating this GE papaya, which may cause adverse human health impacts associate with the viral coat protein and the potential increase of toxic compounds, violates NEPA. Therefore, APHIS must prepare an EIS to evaluate the significant impacts the human environment associate with this viral coat protein prior to deregulation.

Cumulative Impacts

The potential cumulative impacts associate with this new PRSV resistant GE papaya must be disclosed and analyzed in an EIS. APHIS briefly addresses cumulative impacts of the X17-2 papaya. (EA at 20). However, APHIS fails to address whatsoever that there are already 2 strains of PRSV resistant papaya varieties that have been approved, one of which has been grown extensively in Hawaii resulting in significant adverse effects to the non-GE papaya crops and farmers. APHIS merely concludes that because there is no effect on ecosystem from X17-2 generally that there can also be no cumulative impacts. This completely misses the point of NEPA's cumulative impacts analysis.

"NEPA requires an agency to consider the environmental impact that results from the incremental impact of the action when added to other past, present and reasonably foreseeable actions."[94] In 1998, APHIS deregulated a PRSV resistant GE papaya that has been widely planted in Hawaii. In considering the cumulative impacts, NEPA requires APHIS to consider any environmental impacts of this new GE papaya variety "when added to" the previous deregulation. APHIS may argue that this papaya is destined for

[92] FDA, "Note to File for BNF42," September 12, 1997 (Attachment 32).
[93] Anuar, NS et al (2008). "Effect of green and ripe Carica papaya epicarp extracts on wound healing and during pregnancy," Food Chem Toxicol. 46(7): 2384-2389.
[94] *Natural Resources Defense Council v. U.S. Forest Serv.*, 421 F.3d 797, 814 (9th Cir. 2005) (quoting 40 C.F.R. § 1508.7).

Florida alone, and therefore it need not consider the effects in relation to those impacts experienced by the planting and sale of the original GE papaya. (EA at 7). While the EA notes that this GE papaya is "only be useful for disease control in the Florida and Caribbean regions," it also establishes that "[t]he scope of a determination on X17-2 papaya, however, is considered to cover the entire U.S. and its territories." (EA at 7). Thus, APHIS cannot limit its analysis of impacts to Florida and the Caribbean.

The Hawaiian papaya industry is approximately ten times bigger than Florida (EA at 17), for example, and APHIS must consider the potential for X17-2 GE papaya to be grown in Hawaii and how that may contribute to the already significant biological contamination and interrelated adverse economic effects of GE papaya already established in Hawaii. APHIS must also consider cumulative impacts on the papaya market generally, considering all past adverse effects along with any present and future effects with this new GE papaya in consideration with all GE papaya varieties.

Thus, APHIS must prepare an EIS to evaluate the cumulative impacts related to the deregulation of GE papaya.

CONCLUSION

For the reasons stated herein and others that are raised in public comments on this proposed crop deregulation, the Center for Food Safety believes that the EA is both substantively and legally inadequate. CFS believes that a full EIS is necessary before any deregulation can occur.

Respectfully Submitted,

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