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Global Agricultural Information Network

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Japan approved GM papaya

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Report Highlights:
On December 1, 2011, Rainbow Papaya from Hawaii will be fully approved for commercial shipments to Japan. This announcement marks the end of a long and tedious approval process which started in 1999, and the beginning of a new chapter for Hawaiian papaya growers. The approval of biotech papaya is significant because it is the first horticultural product, and the first direct-to-consumer food product to gain regulatory approval in Japan. The degree of acceptance of this product at the consumer level will serve as a leading indicator for numerous biotech products that are in the developmental and regulatory pipeline.

General Information:

Historical Background

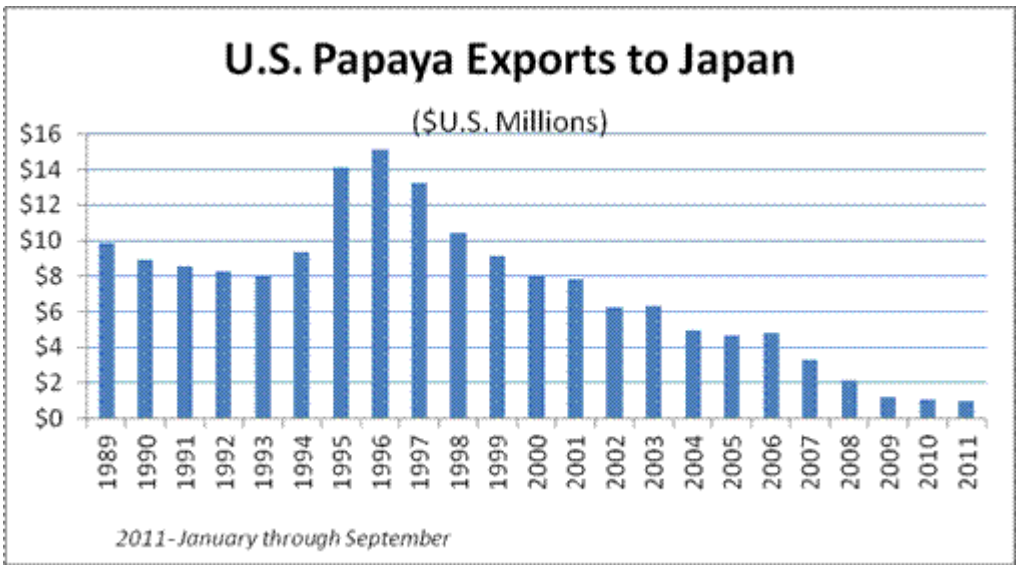
In 1911 Dr. Garritt P. Wilder, a botanist at the Bishop Museum, introduced the Solo papaya from Barbados and Jamaica to Hawaii. This introduction led to a complete transformation of the Hawaiian papaya industry and over the next century, Hawaiian papaya growers perfected their production practices and developed markets, in the United States and around the world. In 1984, papaya production in Hawaii reached a record 80.5 million pounds.

In 1945, PRSV was discovered on the Hawaiian island of Oahu and devastated the papaya production in the 1950's. PRSV is transmitted by aphids and there is no natural resistance to PRSV in any conventional papaya cultivars. This led to the relocation of main papaya production to Puna area of Hawaii Island in early 1960s. Though Puna was free from PRSV at the time, the virus had been observed on Hawaii Island, only 19 miles from Puna area. It was only a matter of time before the papaya in Puna became infected and in the early 1990's, PRSV was discovered in Puna area, and from that point started to spread rapidly, threatening the entire industry. The devastation was so acute that by 1997 Papaya production in the State of Hawaii decreased to 38.8 million pounds, less than a half of its peak in 1984.

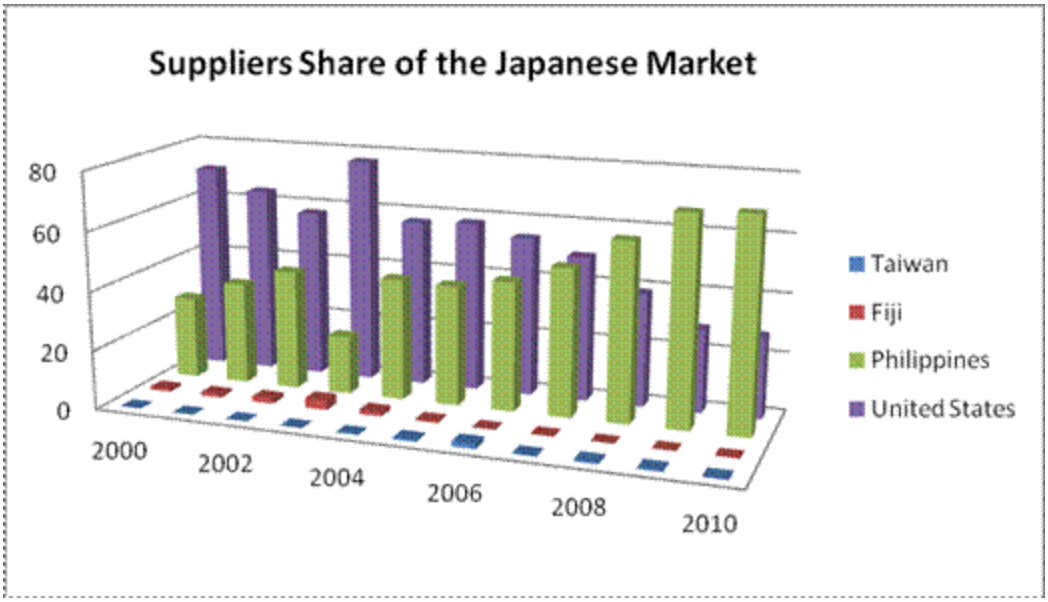
The agricultural community was well aware of how devastating PRSV would be to the Hawaiian papaya industry when it attacked the main production region of Puna. To address this threat, in the late 1980s a group of researchers started to develop a papaya that was resistant to PRSV by using biotechnology. The first field trial of biotech papaya in Hawaii was performed in 1992, and the developers initiated the process to gain regulatory approval for commercial production of biotech papaya in 1996. Following USDA approval, the first seeds for biotech papaya were distributed in May of 1998. Since that first distribution of biotech papaya seed in 1998, papaya production has recovered remarkably, reaching 55.0 million pounds in 2001. As of today, roughly 85% of papaya grown in the State of Hawaii is biotech.

Hawaiian Papaya in Japan

For years, Japanese tourists have enjoyed the incomparable taste of papaya in Hawaii, and demand for papaya in Japan began to build. The United States began shipping papaya to Japan in 1989. At its height in 1996, the Hawaiian papaya industry shipped nearly $15 million worth of papaya to the Japanese market. However, as Hawaiian farmers adopted biotech papaya varieties, they lost access to the Japanese market, as those varieties were not approved by Government of Japan. From 1996 to 2010, U.S. papaya exports to Japan shrank to approximately $1 million a year.



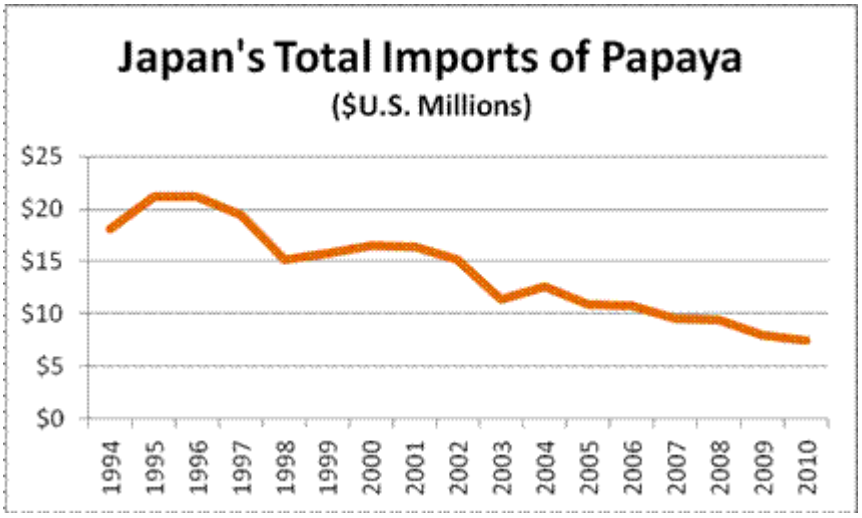
The Japanese Market for Papaya:



According to Japanese trade statistics since 2000, Japanese world imports of papaya averaged about $11.6 million annually. Prior to 2007, exports of U.S. papaya dominated the Japanese market. However, from 1999, the inability to ship biotech papaya to Japan began eroding U.S. market share as other strong suppliers, such as the Philippines, were able to continue shipping non-biotech varieties. Since 2007 the Philippines share of the Japanese papaya market has held steady at around 63 percent followed by U.S. papaya with 36 percent. Other relevant papaya suppliers are Fiji and Taiwan but Mexico and Belize have also been active on and off throughout the years.

Japanese world imports of papaya have steadily declined, dropping by 65 percent in 2010 compared to peak levels in 1996. Overall per-household consumption of fruit in Japan, including papaya, remains

on a downward trend. Unit prices for Philippine papaya are more competitive than those for Hawaiian papaya, which are only air-shipped to Japan and hence, more expensive. However, the quality and taste of Hawaiian papaya is considered among traders the best. The good reputation of Hawaiian papaya will provide exporters an edge to take advantage of GOJ's recent approval and hopefully restore U.S. share of Japan's papaya market.



Hawaiian Biotech Papaya in Japan:

In 1999 the Hawaii Papaya Industry Association applied for regulatory approval biotech papaya in Japan with a formal submission to the Ministry of Health Labor and Welfare, and the Ministry of Agriculture, Forestry and Fisheries. This process required an evaluation of the environmental impact, a full food-safety evaluation, and an approval of HPIA's identity preservation procedures. After nearly 12 years of navigating the Government of Japan's biotechnology regulatory system, full approval of biotech papaya from GOJ was granted on September 1, 2011, and commercial imports into Japan were permitted starting December 1, 2011.

Timeline:

- October 29, 1999 - Submission to Ministry of Health and Welfare (former MHLW) and MAFF
- July 1, 2003 - Establishment of Food Safety Commission
- August 18, 2004 - Re-submission of the environmental safety review under Cartagena Law to MAFF/MOE.
- October 6, 2005 - First discussion in Expert Subcommittee group of MAFF/MOE
- January 26, 2006 - Re-submission to MHLW. Food safety review by FSC started.
- February 27, 2006 - First review by FSC's GM Food Expert Group at 37th meeting.
- March 17, 2008 - Second review by the expert group at 60th meeting
- May 19, 2009 - Final review by the expert group at 70th meeting and safety approved.
- May 28, 2009 - Draft review report from FSC.
- May 28 – June 26, 2009 - Public comment (one comment was sent).

- July 9, 2009 - Dossier was returned back to MHLW (risk management body)*.
- September 1, 2009 - Consumer Affairs Agency (CAA) established. The authority of food labeling was transferred from MHLW/MAFF to CAA.
- September 3, 2009 - Second discussion in Expert Subcommittee group of MAFF/MOE
- January 26, 2010 - Third discussion in Expert Subcommittee group of MAFF/MOE
- February 19, 2010 - Fourth discussion in Expert Subcommittee group of MAFF/MOE. Discussion in Expert Subcommittee concluded.
- March 23, 2010 - Discussion by Expert Group in CAA at First Meeting of Consumer Agency's Food Labeling Committee. The "relevance" and scope of labeling for Rainbow papaya was discussed.
- March 24, 2010 - MAFF/MOE General Committee for Cartagena Law agreed for public comment
- April 19 – May 19, 2010 - Public comment period for Type 1 Use permission (import and cultivation) under Cartagena Law by MAFF/MOE. As three other events (a soybean and two corn events), most comments were not specific to event but general about concern on the application of modern biotechnology to agricultural crops, such as possible out-crossing with wild species. No wild plant in Japan can be crossed with papaya as replied to the comment (http://www.bch.biodic.go.jp/download/lmo/public_comment/public42.pdf).
- May 24, 2010 - Discussion by Expert Group in CAA at Second Meeting of Consumer Agency's Food Labeling Committee. The members agreed on the labeling for papaya and the establishment of detection method for processed products of papaya.
- May 28-June 4, 2010 - Inter-Ministerial discussion with MHLW based on Food Sanitation Law Article 65, Section 2-2.
- May 28-Dec 7, 2010 - Inter-Ministerial discussion with MAFF based on JAS Law Article 19, Section 13-5.
- October 4, 2010 - Discussion by Expert Group in CAA at Fourth Meeting of Consumer Agency's Food Labeling Committee.
- March 9, 2011 - Discussion by Expert Group in CAA at 8th Meeting of Consumer Agency's Food Labeling Committee. Improvement in detection method was reported.
- April 7 – May 6, 2011 - Consumer Affairs Agency held domestic public comment regarding the labeling of fresh and processed products of biotech papaya.
- April 14 – June 13, 2011 - Consumer Affairs Agency notified WTO-SPS for the labeling of fresh and processed products of biotech papaya (G/SPS/N/JPN/276).
- April 26 – June 26, 2011 - Consumer Affairs Agency notified WTO-TBT for the labeling of fresh and processed products of biotech papaya (G/TBT/N/JPN/355).
- July 27, 2011 - Discussion by Expert Group in CAA at 12th Meeting of Consumer Agency's Food Labeling Committee. Committee members agreed on the proposal of biotech papaya labeling.
- August 31, 2011 - CAA released the official notification of labeling for biotech papaya based on JAS (http://www.caa.go.jp/foods/pdf/syokuhin697.pdf). Also three comments given to during

domestic public comment period (from April 7 to May 6, 2011) were released to public (http://www.caa.go.jp/foods/pdf/syokuhin698.pdf).

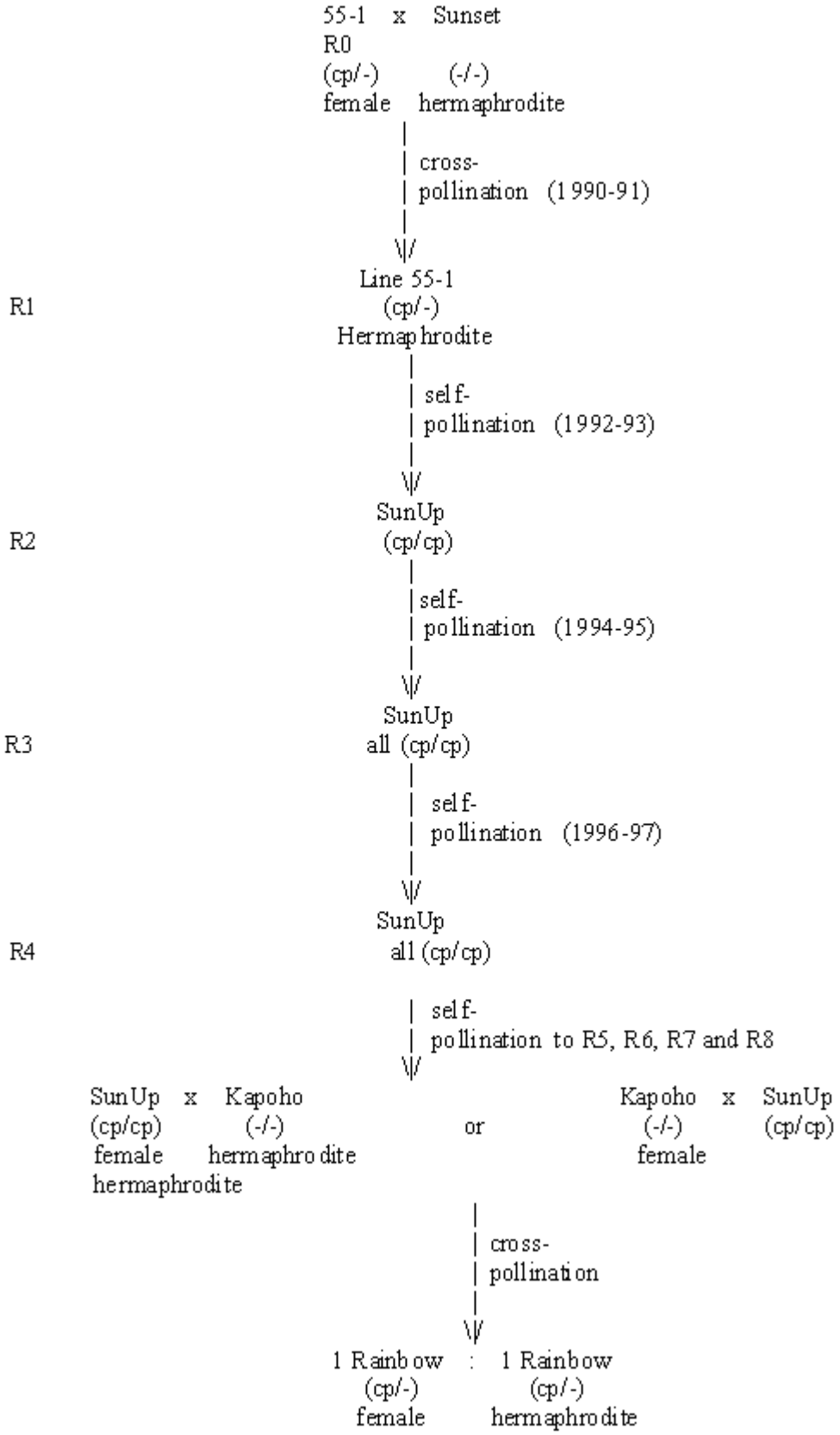
- December 1, 2011 – MAFF released the notification that the environmental review of rainbow papaya completed. MHLW also lifted the sanction to rainbow papaya and released the notification of food safety completed which has been used as green sign for the commercial import and distribution of biotech crops for Japanese public.
    - MAFF's announcement of the environmental review completed http://www.maff.go.jp/j/syouan/nouan/carta/c_list/pdf/list01_20111201.pdf
    - MHLW's announcement of the sanction to biotech papaya lifted http://www.mhlw.go.jp/topics/yunyu/kensa/2011/dl/111201-2.pdf
    - MHLW's notification of the food safety review of biotech papaya completed http://www.maff.go.jp/j/syouan/nouan/carta/c_list/pdf/list01_20111201.pdf

Technical Background

The mechanism for the resistance to biotech papaya is called RNA interference, or RNAi. RNAi is naturally existing phenomena of post-translational gene expression (i.e., epigenetic) control. In short, two types of RNA strands (which are the direct products of genes) bind to each other and control the gene activity, for example, preventing viral mRNA from producing protein (http://www.nature.com/focus/rnai/animations/index.html).

In the case of biotech papaya (event name, 55-1), a short sequence of the PRSV's coat protein (protein at the surface of virus membrane) was combined with a marker and other necessary genes, and then inserted into papaya genome through the use of a 'gene gun', a device used to transform plants by injecting cells with particles of heavy metal coated with new genetic materials. For the development of PRSV resistant papaya, Sunset, a solo type papaya was used as the host plant. The first generation of recombinant papaya was named 55-1 and subjected to regulatory review in the United States and Japan. 'Rainbow' papaya, a commercial biotech papaya resistant to PRSV, is developed by conventional breeding of 55-1 and non-biotech solo type papaya. The generation diagram shown below details this development.

Generation diagram



As Rainbow papaya is F1, the seeds of Rainbow are F2 generation showing non-uniform characteristics.

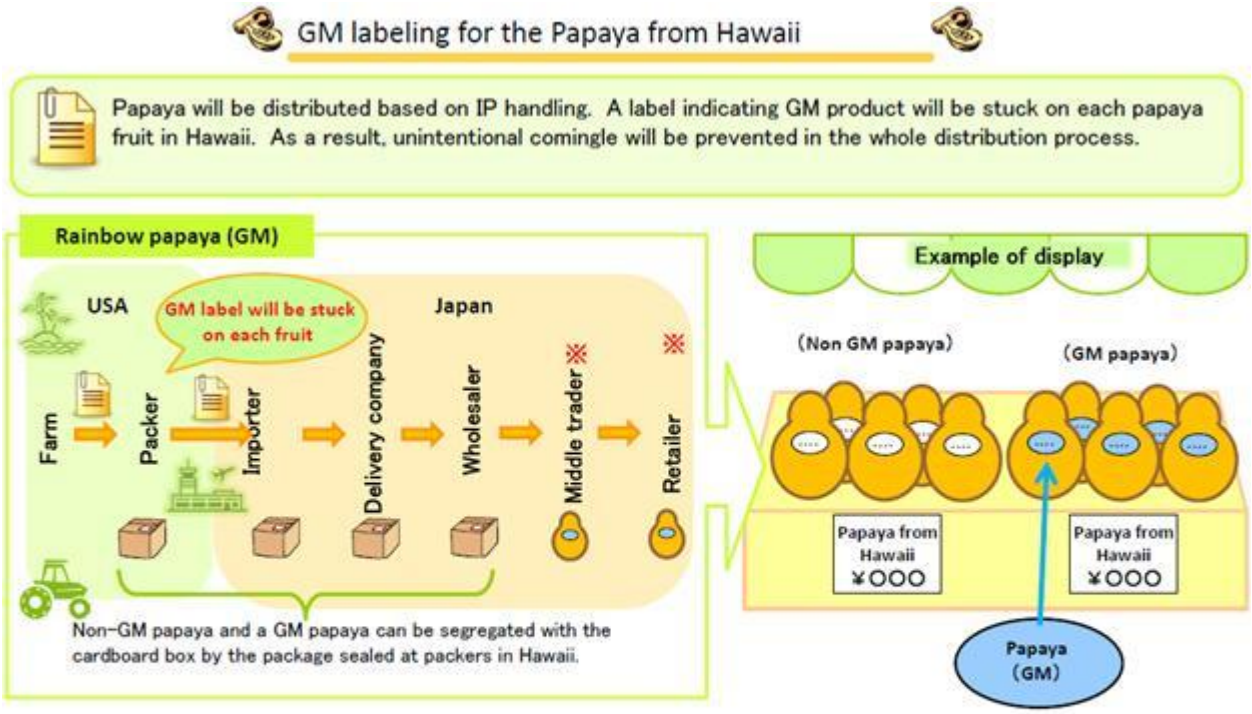
Labeling and Identity Preservation

Japan mandates the labeling of all biotech-derived products. At the same time, to claim the products are non-biotech, the identity of the product has to be preserved throughout the process, from the beginning (farm) to the end (retail shelf), even though the labeling as non-biotech is not mandatory. All biotech food crops approved in Japan, except biotech papaya 55-1, are bulk commodities such as corn and soybean and the documentation to guarantee the source of products as non-biotech (or biotech) is necessary with each shipment lot. In case of biotech papaya, the product is a consumer-ready fruit. For shipment, several fruit will be packed into a box and the volume of trade will be significantly smaller compared with bulk products. In addition, the scale of specialty crop production is much smaller than grains, and it may be a financial burden for the industry to practice IPP of non-biotech and biotech papaya based on laborious documentation. As the result of close communication between Japan's Consumer Affairs Agency, the Hawaii Papaya Industry Association, the Hawaii Department of Agriculture, and FAS Tokyo, the industry agreed to apply labeling to individual fruit. By placing labels to indicate biotech or non-biotech throughout the process, the label on individual fruit functions as IPP, preserving its identity. Therefore, the industry does not have to use other resources to prepare documentation for each shipment.

An example of biotech labeling. Japanese language indicates 'Hawaii Papaya (Geneteically Modified).

It is important to note that the labeling of biotech and non-biotech fruit is done voluntarily by the Hawaii papaya industry and unique to Hawaiian papaya. The industry agreed on the use of individual fruit labeling instead of IPP paperwork. As such, this case must not be considered as general labeling practice applicable to other biotech specialty crops which may be released in future.

Diagram of labeling procedure to individual papaya fruit (prepared by CAA after consultation with HPIA and HDOA)



- In case of sticker peels off (at middle trader or retailer)
·When they handle only GM papaya, they still need to confirm identity of GM by documents to put sticker again.
·If they handle both GM and Non-GM papaya, they can still put a GM sticker again only when they can confirm a fruit is GM by checking a copy of a certificate in each stage of entire distribution.
·Distributing GM papaya without re-attach GM sticker might become a violation.
·It is violation to peel off the GM stickers deliberately and distribute GM papaya as Non GM papaya.

Marketing of Rainbow Papaya in Japan

To commemorate the Government of Japan's announcement that Rainbow papaya had received full regulatory approval, Dr. Dennis Gonsalves, the chief researcher who developed the biotech papaya, traveled to Japan to promote the product, and explain the technology. Dr. Gonsalves gave presentations on biotech papaya in Fukuoka and Osaka at symposiums co-sponsored by the Japanese Society for Plant Cell and Molecular Biology. He also gave talks at two seminars in Tokyo, which were sponsored by FAS/Japan.

One of the seminars was held at U.S. Ambassador John Roos' residence to celebrate the approval of biotech papaya for commercial sale in Japan. The event, attended by more than 100 traders, importers, end users, and media representatives, featured a cooking demonstration using Rainbow papaya by Mr. Sam Choy, renowned Hawaiian restaurateur. After the demonstration, dishes incorporating papaya were served to the attendees. A second seminar focused on technical aspects of the Rainbow papaya was attended by government officials, biotech companies, food safety experts, and consumer and media representatives. Besides a presentation by Dr. Gonsalves, this seminar featured also a presentation by

an official in charge of food labeling issues at the Consumer Affairs Agency who explained about the labeling requirements for Rainbow papaya. The two presentations were followed by a Q&A and tasting session, including a lively discussion regarding marketing ideas for the Rainbow papaya.

A total of approximately 700 people attended all the seminars and symposiums. The media participants of both national and trade media reported about Dr. Gonsalves' presentations in their newspapers or journals including those on the web. The reports, estimated to reach approximately 4 million readers and viewers, were favorable and/or fair in tone and helped raise public awareness about the virus resistant Hawaiian biotech papaya and the fact that Japan approved the papaya for import after December 1, 2011.

FAS Japan received permission to receive samples of biotech papaya for diplomatic events before the official commercial import date. The samples were displayed and served for tasting at the events in Tokyo and Osaka. Participants were eager to see the actual biotech papaya and found the papaya delicious, with a flavor and texture that outshone its competitors. These demonstrations certainly helped reduce the level of concern about biotech foods among the attendees.

Sam Choy Cooking Demonstration Event – One of the key constraints to selling biotech papaya in Japan is the idea that Rainbow papaya may be somehow "different" than conventional papaya. The science café and reception event in the Ambassador's residence held on September 7, 2011, supported by QSP funds, featured a Sam Choy cooking demonstration. QSP funds were used to ship the GMO papaya from HI to Japan. Approximately 100 traders/wholesalers/HRI reps/and media attended. The papaya was prepared for tasting by the guests in the form of salads, pastries, confectionary, and meal condiments. Chef Choy and Dr. Gonsalves worked together to present the papaya recipes which included Curry Chicken and Shrimp Papaya salad.

On December 10, 2011, no more than 10 days after approval, Rainbow papaya went on sale in all 12 Costco Japan stores. No doubt that it will take time to redevelop the market for HI papaya, but the industry is well on its way.

Dr. Gonsalves Conducting the Technical Seminar at the Ambassador's Residence

The Papayas Arrive at the Ambassador's Residence

Chef Sam Choy Cooking Demo Start

Chef Choy Preparing the Papaya

The final product - Shrimp Papaya Salad

Reference

Hawaii Papaya Industry Association. http://www.hawaiipapaya.com

USDA National Agricultural Statistics Service. 2009. Hawaii Papaya acreage. http://www.nass.usda.gov/hi

Nature - RNAi focus from Nature Reviews: RNA interference – Animations, http://www.nature.com/focus/rnai/animations/index.html

Summary of PRSV resistant papaya (modified PRSV CP, uidA, nptII, Carica papaya L.)(55-1, OECD UI: CUH-CP551-8), http://www.bch.biodic.go.jp/download/lmo/public_comment/55_1ap.pdf (Japanese)