

# Questions and Answers: Arctic Apple Deregulation

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) deregulated apples that are genetically engineered (GE) to resist browning. This action is based on a final plant pest risk assessment (PPRA) that finds the GE apples are unlikely to pose a plant pest risk to agriculture or other plants in the United States, as well as an environmental assessment prepared consistent with the National Environmental Policy Act (NEPA) and regulatory provisions. If APHIS finds through its rigorous scientific review that a new GE plant is unlikely to pose a plant pest risk, then under the law and its regulations, it is required to deregulate the GE plant. These apples, developed by Okanagan Specialty Fruits Inc. (OSF), will be marketed as Arctic® apples.

## **Q: How are Arctic® apples different from traditional apples?**

**A:** Arctic® apples will, over time, age, turn brown, and rot just like any other fruit. However, Arctic® apples are genetically engineered to produce less of the substance that causes browning. When these apples are sliced or bruised, the apple flesh retains its original color longer instead of turning brown.

## **Q: Has Arctic® apple been field tested in the U.S.?**

**A:** Yes. Arctic® apple has been field tested in Washington and New York States. All field tests that have occurred in the United States were under permits granted by APHIS. The field trials were overseen and inspected by APHIS.

## **Q. What is APHIS authority to make the decision to deregulate?**

**A:** Pursuant to the Plant Protection Act (PPA), under APHIS' regulations, the Agency is specifically required to evaluate if the apple variety is a plant pest risk to agricultural crops or other plants or plant products. The Act defines a plant pest as organisms, such as bacteria, fungi, or insects that can cause harm to agricultural crops or other plants or plant products. If APHIS finds that a new GE plant is unlikely to pose a plant pest risk, it must deregulate the GE plant.

## **Q: How was the public involved in APHIS' decision?**

**A:** APHIS solicited comments on OSF's petition for deregulation. After those comments were evaluated, APHIS completed a draft EA and PPRA. Both were made available through the publication of a Federal Register notice with a request for comments. APHIS carefully reviewed all of the comments received and, when appropriate, addressed them in its final assessments of these GE apples.

## **Q: What kind of comments did APHIS receive through the review process?**

**A:** When APHIS published its draft analyses on this GE apple for public review, the Agency received many comments. The majority of those comments did not raise any specific disagreement with APHIS' analysis of the pest risk of this GE apple; rather, they expressed general opposition to GE organisms or GE apples.

APHIS also received comments regarding concerns about the safety of this GE apple for human consumption, as well as concerns regarding potential impacts to exports of U.S. apples abroad. APHIS carefully reviewed all of the comments received and, when appropriate, addressed them in its final assessments of this GE apple.

However, under the Plant Protection Act and the Agency's regulations, APHIS' final decision can only be based on its analysis of the potential for the GE plant to pose a plant pest risk to agriculture or other plants in the United States.

## **Q. Why did APHIS prepare an EA rather than an Environmental Impact Statement?**

**A:** APHIS pursued the EA because after carefully analyzing OSF's petition for deregulation, as well as public comments received on the petition, APHIS determined that its regulatory decision regarding this GE apple would not have a significant impact on the human environment. Therefore, APHIS prepared and finalized an EA to fulfill its requirements under National Environmental Policy Act (NEPA). Through its EA, APHIS was able to reach a finding of no significant impact regarding its regulatory decision for this GE apple. With this finding, under NEPA, APHIS does not need to pursue preparation of an EIS.

## **Q: What were some of the main issues the EA and PPRA focused on?**

**A:** APHIS examined a number of issues in the EA including potential cross-pollination with other apple varieties (including native crabapples), effect on

the physical environment, effects on biological organisms including threatened and endangered species, the potential for weakened plant defenses and increased susceptibility to disease or infection, and potential economic impacts on the U.S. apple industry and market. The PPRA focused on a variety of issues needed to determine whether the Arctic® apples represented a risk as a plant pest.

**Q: What is FDA's role in this action?**

**A:** Responsibility for food safety of apples and apple products resides with FDA, which conducts food safety consultations on new products such as the Arctic® apple.

**Q: When might this apple be available for purchase in the marketplace?**

**A:** The company that petitioned would be in a better position to answer this, but it is reasonable to believe it is several years away from making this product available in stores.

**Q: What is the next step in the process for the Arctic apple?**

**A:** After USDA deregulates, OSF is free to market their trait to apple growers. Most likely, budwood with the GE trait, or budwood grafted to rootstock (existing apple trees) will be sold to growers. The trees will then produce apple fruit with the desired trait within 3-5 years.

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