

Record of Categorical Exclusion Determination for an Extension to a Determination of Nonregulated Status for Non-Browning Arctic® apple Event PG451 (20-213-01ext)

Brief History and Description of Proposed Action

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), is proposing to extend a determination of nonregulated status to non-browning arctic PG451 apple (20-213-01ext) from Okanagan Specialty Fruits Inc. (OSF).

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering which are Plant Pests or Which there is Reason to Believe are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms (GE) and products are considered "regulated organisms."

Pursuant to the terms set forth in the regulations, any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an organism developed using genetic engineering (modified organism) should not be regulated under 7 CFR part 340¹, or that APHIS extend a determination of nonregulated status to other organisms. Such an extension request must include information to establish the similarity of the antecedent organism and the modified organism in question

The PG451 apple event was produced by the *Agrobacterium*-mediated transformation of the apple cultivar Gala (PG) with the binary vector GEN-03. Therefore, the PG451 Arctic Gala apple event meets the definition of a regulated organism under APHIS regulations at 7 CFR part 340.

July 31, 2020, OSF submitted an extension request (20-213-01ext) to APHIS seeking a determination that PG451 Arctic Gala apple is unlikely to pose a plant pest risk and, therefore, should no longer be regulated pursuant to regulations at 7 CFR part 340 (OSF 2020). APHIS reviewed and analyzed the information submitted in the extension request by OSF and has concluded that PG451 apple is similar to the antecedent organisms GD743 Arctic Golden apple and GS784 Arctic Granny apple (GD743 and GS784 apples, 16-215-01p). Therefore, based on PG451 apple Plant Pest Risk Similarity Assessment (PPRSA), APHIS has concluded that PG451 apple is unlikely to pose a plant pest risk (USDA APHIS 2020).

¹ The petition for nonregulated status described in this PPRSA is being evaluated under the version of the regulations effective at the time that it was created. Animal and Plant Inspection Service (APHIS) issued a final rule published in the Federal Register on May 18, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034), revising 7 CFR part 340; however, the final rule is being implemented in phases. The new Regulatory Status Review (RSR) process, which replaces petition for determination of nonregulated status process, became effective on April 5, 2021 for corn, soybean, cotton, potato, tomato, and alfalfa. The RSR process is effective for all crops as of October 1, 2021. However, "[u]ntil RSR is available for a particular crop, APHIS will continue to receive petitions for determination of nonregulated status for the crop in accordance with the [legacy] regulations at 7 CFR § 340.6." (85 FR 29815). This petition for a determination of nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020) as it was received by APHIS on 9/30/2020.

Number and Title of Categorical Exclusion Applied

The proposed action is within the class of actions which have been subject to categorical exclusion under APHIS' NEPA Implementing Procedures (7 CFR § 372.5(c)), specifically (4) *Extending deregulations for genetically engineered organisms. Extension of nonregulated status under part 340 of this chapter to organisms similar to those already deregulated.*

Regulatory Requirements

The proposed action is to extend a determination of nonregulated status under 7 CFR part 340 to PG451 apple is based upon APHIS' determination of nonregulated status of its similar antecedents GD743 and GS784 apples (10-161-01p). Notice of the antecedent organisms' non-regulated status was published in the Federal Register on February 18, 2015 (USDA-APHIS 2015). The same genetic construct GEN-03 used to transform the OSF antecedent apple events GD743 and GS784 apples with non-browning characteristics, was used to transform and generate the PG451 apple event. The comparison of characteristics of PG451 apple to the antecedent GD743 and GS784 apples indicates that the non-browning cassette inserted into PG451 apple and the antecedent GD743 and GS784 apples was the same, except with a different 3' untranslated region (USDA APHIS 2020). PG451 apple was transformed using the same binary vector as events GD743 and GS784, yielding the same non-browning phenotype. Unlike GD743 and GS784 apples, a full copy of the vector backbone was transferred into PG451 apple genome. PG451 apple vector backbone comprises a number of prokaryotic elements that will not be expressed in *planta* and do not affect the safety assessment.

APHIS reviewed and analyzed the information submitted in the extension request by OSF (OSF 2020), and has concluded that PG451 apple is similar to GD743 and GS784 apples. Based on its PPRSA for PG451 apple, APHIS has concluded that PG451 apple is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived (USDA APHIS 2020). The comparison of characteristics of PG451 apple to the antecedents GD743 and GS784 apples, indicates that the phenotype and traits of PG451 apple and the antecedents GD743 and GS 784 apples are the same. The conclusions of the molecular, assessments indicate PG451 apple has the same non-browning characteristics upon injury and the same mode of action for suppression of polyphenol oxidases (PPO) as GD743 and GS784 apples (USDA APHIS 2014a, 2020). Therefore, PG451 apple does not exhibit any additional phenotypic traits beyond those that are expressed in the antecedent apples (OSF 2020; USDA APHIS 2020).

Based on the prior Environmental Assessment (APHIS-USDA 2014b) and Finding of No Significant Impact (FONSI) for GD743 and GS784 apples and similarity of GD743 and GS784 apples and PG451 apple, the proposed action will not affect the quality of the human environment, including the health of U.S. crops. PG451 apple is similar to the nonregulated antecedent organism GD743 and GS784 apples (10-161-01p), so it's presumed to interact with the environment in the same way as the antecedent. A determination of nonregulated status of PG451 apple is not expected to directly cause an increase in agricultural acreage devoted to apple production, or those apple acres devoted to modified apple cultivation. The availability of PG451 apple will not change cultivation areas for apple in the United States and there are no anticipated changes to the availability of apple produced through genetic engineering and apple produced using organic methods or specialty systems varieties on the market.

A determination of nonregulated status of PG451 apple is not expected to change the market demands for modified apple, or apple produced using organic methods or specialty systems. APHIS has concluded that the availability of PG451 apple would not alter the current agronomic practices such as planting, tillage, fertilizer application or use, irrigation, pesticide application use, or volunteer control. The impact of PG451 apple on wildlife or biodiversity is no different than that of other apple varieties currently grown in the United States.

The proposed action does not affect unique characteristics of a geographical area such as waterfalls or bogs because PG451 apple will be deployed on agricultural land currently suitable for production of apples. It is also not expected to cause an increase in agricultural acreage devoted to apple production. The common agricultural practices that would be carried out under the proposed action are the same as those used for the antecedent GD743 and GS784 apples. The long history of apple production in the United States is a strong indicator that any potential effects on the quality for the human environment are not highly controversial, are not highly uncertain, or do not involve unique or unknown risks. The proposed action does not establish precedent or represent a decision in principle about a future consideration. This is because APHIS handles each determination of nonregulated status on a case-by-case basis.

Based on the prior EA and FONSI for GD743 and GS784 apples and similarity of PG451 apple to GD743 and GS784 apples, APHIS has concluded that extending a determination of nonregulated status to PG451 apple would have no effect on species listed as threatened or endangered under the Endangered Species Act (ESA) or on any species proposed for such listing. Therefore, PG451 apple would not affect designated critical habitat or habitat proposed for designation under the Act.

The incremental impact of this proposed action, when added to other past, present, and reasonably foreseeable future actions, does not have the potential to impact the human environment. This is because common agricultural practices that would be carried out under the proposed action are the same as those used for the antecedent GD743 and GS784 apples.

The proposed action has not been found to be inconsistent with any Federal, State, or local laws, other environmental review requirements, or administrative determinations. The proposed action will not occur on or near any districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places (NRHP), and it will not cause the loss or destruction of scientific, cultural, or historical resources.

The exceptions for an action subject to a categorical exclusion identified in 7 CFR 372.5(d), do not apply to the proposed action because there is no use of a previously licensed or approved biologics, or new issues raised by organism developed using genetic engineering or novel modifications. Additionally, there are no cumulative impacts with other related actions anticipated that might result in impacts on the human environment. This is because APHIS evaluates each determination of nonregulated status on a case-by-case basis and examines information provided by applicants to assess whether the regulated organism in question raises new issues meriting a separate review under the petition process.

Determination

I have determined that extending a determination of nonregulated status to PG451 apple will not result in an impact to the environment based upon my review of the available information. The proposed action meets the regulatory requirements set forth above for categorical exclusions. Further NEPA review is not required for this action.

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services, APHIS, USDA

Date

References

- OSF. 2020. *Request for an Extension of Determination of Nonregulated Status for Non-Browning Arctic® Apple Event PG451*.
- USDA APHIS. 2014a. *Plant Pest Risk Assessment for Okanagan Specialty Fruits Inc. 's Petition (10-161-01p) for Determination of Nonregulated Status for Non-browning Arctic Apple Events GD743 and GS784*. Retrieved from https://www.aphis.usda.gov/brs/aphisdocs/10_16101p_fprra.pdf
- USDA APHIS. 2014b. *Environmental Assessment for Okanagan Specialty Fruits Petition (10-161-01p) for Determination of Non-regulated Status of Arctic™ Apple Events GD743 and GS784*. Retrieved from https://www.aphis.usda.gov/brs/aphisdocs/10_16101p_fea.pdf
- USDA APHIS. 2020. *Plant Pest Risk Assessment for Determination for an Extension to a Determination of Nonregulated Status for Non-Browning Arctic® Apple Event PG451 (20-213-01ext)*.