verinomics

Verinomics, Inc.
5 Science Park
New Haven, CT 06511
203-823-9308

Dr. Donna Lalli
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98
Riverdale, MD 20737

December 5, 2025

Contains Confidential Business Information

Dear Dr. Lalli:

Verinomics, an agricultural biotechnology company based in New Haven, Connecticut, USA, has used Plant Breeding Innovations, specifically CRISPR-CAS technology, to modify key agronomic traits in *Prunus dulcis*. The trait developed through this technology is self-pollination capability. Verinomics has established a protocol to confirm the absence of any foreign DNA in the improved almond plants. Verinomics requests formal confirmation that the edited plants and any plants propagated from them are not a "regulated article" subject to APHIS oversight under 7 CFR part 340 due to the lack of any inserted genetic material from a plant pest and no DNA from the editing process remains in the final product. This request is submitted pursuant to the "Am I Regulated" process under 7 CFR part 340 and in accordance with the USDA-APHIS Biotechnology Regulatory Services Guidance (2025). Additionally, neither *Prunus dulcis* nor any sexually compatible relative species are listed in the Federal Noxious Weeds and as such there is no basis to believe that the edited product could become a plant pest.

The following letter describes our approach to producing the edits in the targeted gene sequence, the methods used to screen for the edits, and the techniques for validating the absence of any material regulated under 7 CFR Part 340.

Thank you for your attention to this request.

Sincerely,

Giovanni Scalzo
Chief Operating Officer
Verinomics, Inc.
5 Science Park, New Haven, CT 06511
Phone: 203-823-9308
Email: gio@verinomics.com

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CBI Justification

Verinomics submits this document to USDA-APHIS for "Am I Regulated" review pursuant to 7 C.F.R. § 340.4. In accordance with 7 C.F.R. § 1.8, Verinomics has designated information in this document that is trade secret or confidential commercial information ("protected information") and therefore not subject to public disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(4)), Federal Trade Secrets Act (18 U.S.C. § 1905), and USDA's implementing regulations codified at 7 C.F.R. part 1, subpart A. See also Food Mktg Inst. v. Argus Leader Media, 139 S. Ct. 2356 (2019) (holding that where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is "confidential" within the meaning of FOIA).

Verinomics claims portions of the accompanying letter are CBI. Specifically, the CBI in the letter consists of novel methods, processes, procedures, or safeguards that are used in the creation of the gene-edited product. The confidential business information in this letter includes the genes being edited, the editing protocol used to generate transgene-free edits, the construct used to create transgene-free edits and the description of its components, and some of the methods used to screen for transgene-free edits. Public release of any of this information could be damaging to the business and result in substantial competitive and financial harm.

Pursuant to USDA regulations, Verinomics understands that USDA will promptly notify the company if the Agency determines that any protected information, in whole or in part, may be subject to public disclosure and will describe the protected information that has been requested or include a copy of the requested records, and provide the company advance notice and a reasonable period within which to object to such disclosure in accordance with 7 CFR § 1.8.

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Developer name and contact information party:

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Gio Scalzo
Chief Operating Officer
gio@verinomics.com
203-823-9308

Taxonomic description of the organism

Kingdom: Plantae

Family: Rosaceae

Genus: Prunus

Species: Prunus dulcis

Description of Intended phenotype(s)

Almond plants with self-pollination capability.

Description of intended activity

Conduct greenhouse and field trials followed by propagation and commercial release.

Description of intended genetic change in the final product

Deletions were generated in the coding sequence of target genes resulting in frameshifts that disrupt downstream function. The final product may contain these deletions in one or both alleles of the target gene. The target gene is the [

CBI deleted

]

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Description of vector or vector agent used to induce genetic change in the organism

A [CBI deleted
] to plant cells. This [CBI deleted] expresses a [ ] gene to confirm
successful transformation. The [CBI deleted] also expresses the molecular
components necessary to produce indel edits at the target gene, namely a [CBI deleted]
gene to produce the Cas protein and a guide RNA.

[CBI deleted
] and successful editing has occurred. [CBI deleted

] Note that many of our references CBI deleted
use a [CBI deleted
A description of how CBI deleted
these plants are identified as having edits and tested for [ ] is CBI deleted
provided in the relevant section below.

Name of construct

The construct used for editing has internal designation [CBI deleted]. A description of the
components of this construct is provided in the section below.

Description of construct

The construct used to generate the edited almond plant is a [CBI deleted
]. The constitutive components of this construct are provided CBI deleted
in Table 1:

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Table 1: Constitutive Components of Construct [ ] CBI deleted

Element Type	Element Name	Source Organism	Description
[			
			CBI deleted
			]

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Description of the scientific methodology to confirm the desired genetic changes and they do not retain DNA sourced from a plant pest

The primary methodology for identifying plants with the desired genetic changes is PCR and short read sequencing. DNA is extracted from regenerated shoots and then the editing site is amplified via PCR. These PCR products undergo short read sequencing to directly identify any editing events occurring in one or both alleles of interest. Sequencing is further used to confirm that the editing event is a [CBI deleted
] CBI deleted

[ ], PCR, and next generation sequencing CBI deleted
[ ] Initial screening [CBI deleted

], two PCR reactions to amplify CBI deleted
sequences specific to the [CBI deleted
] necessary for editing. When these PCR CBI deleted
reactions [ ], primarily validation using deep CBI deleted
whole genome sequencing is performed.

Deep whole-genome sequencing [CBI deleted

] as measured by PCR and the [CBI deleted

] CBI deleted

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Conclusion

The information presented demonstrates that almond with self-pollination capability developed by Verinomics does not meet the USDA-APHIS definition of a "regulated article" as the final organism does not retain any genetic material from a donor organism, recipient organism, or vector or vector agent that belongs to any genera or taxa designated in 7 CFR Part 340.2 that meets the definition of a plant pest. Therefore, Verinomics requests confirmation that the almond with self-pollination capability developed by Verinomics with the described Plant Breeding Innovation is not regulated under 7 CFR Part 340. [**CBI deleted**] genes that regulate [**CBI deleted**] using the same Plant Breeding Innovation described above. [**CBI deleted**] nor are they plant pests and therefore **CBI deleted** do not meet the definition of a "regulated article" under 7 CFR Part 340.1. Only plants that do not qualify as "regulated articles" under 7 CFR Part 340.1 will be advanced to commercialization.

We look forward to your response. Do not hesitate to contact us if you have questions or need additional information.

Sincerely,

Giovanni Scalzo
Chief Operating Officer
Verinomics, Inc.

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Cited References

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CBI deleted

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