

## Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-US-114100-1

LAST UPDATED: 13 DEC 2018

## General information

Country

United States of America

NON-PARTY

Title of the risk assessment

Biotechnology Consultation Note to the File BNF No. 000042

EN

Competent National Authority(ies) responsible for the risk assessment

- **COMPETENT NATIONAL AUTHORITY:** BCH-CNA-US-6392-2 | [BCH-CNA-US-6392-2](#)**COMPETENT NATIONAL AUTHORITY**

U.S. Food and Drug Administration  
DHHS/FDA/CFSAN 5100 Paint Branch Parkway  
College Park, MD  
20740, USA  
Email: [biotechfood@fda.gov](mailto:biotechfood@fda.gov)

- **COMPETENT NATIONAL AUTHORITY:** BCH-CNA-US-6413-3 | [BCH-CNA-US-6413-3](#)**COMPETENT NATIONAL AUTHORITY**

U.S. Environmental Protection Agency  
U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances,  
Code 7101 1200 Pennsylvania Ave, NW  
Washington, DC  
20460, USA  
Email: [biotech.reg@epa.gov](mailto:biotech.reg@epa.gov)  
Website: <http://www.epa.gov/pesticides/biopesticides/>, <http://www.epa.gov/scipoly/oscpbiotech.htm>, <http://www.epa.gov/opptintr/biotech/>

- **COMPETENT NATIONAL AUTHORITY:** BCH-CNA-US-6391-2 | [BCH-CNA-US-6391-2](#)**COMPETENT NATIONAL AUTHORITY**

U.S. Department of Agriculture  
USDA, APHIS, BRS 4700 River Road, Unit 133  
Riverdale, MD

20737-1236, USA

Email: [usbiotechregs@aphis.usda.gov](mailto:usbiotechregs@aphis.usda.gov)

Website: [www.aphis.usda.gov](http://www.aphis.usda.gov)

## Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-40294-8](#) | CUH-CP551-8 - Papaya resistant to papaya ringspot virus | Cornell University and University of Hawaii | Resistance to antibiotics (Kanamycin), Resistance to diseases and pests (Viruses, Papaya ringspot virus (PRV)), Selectable marker genes and reporter genes  
[Show detection method\(s\)](#)

[BCH-LMO-SCBD-40296-11](#) | CUH-CP631-7 - Papaya resistant to papaya ringspot virus | Cornell University | Resistance to antibiotics (Kanamycin), Resistance to diseases and pests (Viruses, Papaya ringspot virus (PRV)), Selectable marker genes and reporter genes  
[Show detection method\(s\)](#)

Scope of the risk assessment

LMOs for introduction into the environment

LMOs for direct use as food

LMOs for direct use as feed

Risk assessment report / summary

? [U.S. Food and Drug Administration](#) ( English )

## Information sharing with other databases

Is this risk assessment related to an LMO for commercial use?

No

Should this risk assessment be forwarded to the OECD Secretariat for possible inclusion in the [BioTrack Product Database](#)?

No

Is this risk assessment related to food safety?

No

Was it conducted in accordance with the Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*?

No

Should this information be forwarded to the Secretariat of the [FAO GM Foods Platform](#)?

No

## Further Information

Questions about the Cartagena Protocol on Biosafety or the operation of the Biosafety Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

**Secretariat of the Convention  
on Biological Diversity**

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Montreal, Québec, H2Y 1N9  
Canada

Fax: +1 514 288-6588

Email: [secretariat@cbd.int](mailto:secretariat@cbd.int)