

Biosafety Clearing-House (BCH)

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC)

BCH-DEC-US-6585-5

LAST UPDATED: 13 DEC 2018

Amendment

Is this an amendment to a decision or communication already published on the BCH?

No

General information

Country

[United States of America](#)

NON-PARTY

Competent National Authority(ies) responsible for the decision or communication

- [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
Website: www.aphis.usda.gov

- [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

Title / Reference number of the decision or communication

Agency Response Letter Re: FMF 526 and Docket No. 91A-0330

EN

Date of the decision

17 May 1994

Is the decision taken prior to entry into force of the Protocol?

Yes

Subject of the decision, notification, communication or declaration

Decision on LMOs for direct use as food or feed, or for processing (Article 11, LMOs-FFP)
Decision on LMOs for intentional introduction into the environment (according to Article 10 or domestic regulatory framework)

LMOs for intentional introduction into the environment

Was the decision triggered by a request for a transboundary movement of LMOs into your country?

No

Does the decision apply to transboundary movements of LMO(s) into the country?

Yes

Applicant's contact details

- **ORGANIZATION:** CALGENE INC. | [BCH-CON-US-6580-1](#)

ORGANIZATION

Calgene Inc.

Does the decision involve field trials?

Yes

Does the decision involve commercial release?

Yes

Will the decision apply to subsequent introductions of the same LMO(s) into the environment?

Yes

LMOs for direct use as food or feed, or for processing (LMOs-FFP)

Use(s) of LMO

LMOs for direct use as food
LMOs for direct use as feed

Has the decision been taken in the absence of a domestic regulatory framework and in accordance with Article 11.6?

No

Result of the decision

Result of the decision

Approval of the import and/or use of the LMO(s) without conditions

Information sharing with other databases

Is this decision related to an LMO for commercial use?

No

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

No

Is this decision 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

LMO identification & risk assessment

LMO identification

[BCH-LMO-SCBD-14867-12](#) LIVING MODIFIED ORGANISM | CGN-89564-2 - FLAVR SAVR™ TOMATO |
Changes in physiology and/or production (Ripening), Resistance to antibiotics (Kanamycin)

Risk assessment

[BCH-RA-US-114125-2](#) RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS | AGENCY RESPONSE
LETTER RE: FMF 526 AND DOCKET NO. 91A-0330 |
CGN-89564-2 - FLAVR SAVR™ tomato | Resistance to antibiotics, Changes in physiology and/or production

Document on the decision, communication, notification or declaration

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

[BCH-DEC-US-6585-5](#)

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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