

Biosafety Clearing-House (BCH)

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC)

BCH-DEC-DE-111587-3

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DE

LAST UPDATED: 05 NOV 2020

Amendment

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

No

General information

Country

Germany

PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY

ENTRY INTO FORCE: 18 FEB 2004

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

- [COMPETENT NATIONAL AUTHORITY: BCH-CNA-DE-12096-6](#) | [BCH-CNA-DE-12096-6](#)

COMPETENT NATIONAL AUTHORITY

Federal Office of Consumer Protection and Food Safety

Mauerstrasse 39-42

Berlin

10117, Germany

Phone: +49-(0)3018-445-6500

Fax: +49-(0)3018-445-6099

Email: german_bch@bvl.bund.de

Website: http://biosicherheit-bch.de/BCH/EN/Home/home_node.html,

<http://www.biosicherheit-bch.de>, http://www.bvl.bund.de/EN/Home/homepage_node.html,

<http://www.bvl.bund.de>

Title / Reference number of the decision or communication

6786-01-0130 (adv. 42010.0130); Decision regarding the risk assessment of a deliberate release (field trial) of genetically modified potato (*Solanum tuberosum* L.), Alc-GUS-22, Alc-GUS-37, Alc-GUS-45, issued by the German Competent Authority

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Date of the decision

13 Jun 2002

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 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?

No

Applicant's contact details

- **ORGANIZATION:** INSTITUT FÜR PFLANZENGENETIK UND KULTURPFLANZENFORSCHUNG |
BCH-CON-DE-49376-1

ORGANIZATION

Institut für Pflanzengenetik und Kulturpflanzenforschung

Corrensstrasse 3

Gatersleben

06466 , Germany

Phone: +49 (0)39482 5-0

Fax: +49 (0) 39482 5139

Email: info@ipk-gatersleben.de

Website: <http://www.ipk-gatersleben.de>

Does the decision involve field trials?

Yes

Does the decision involve commercial release?

No

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

No

Result of the decision

Result of the decision

Approval of the import and/or use of the LMO(s) with conditions

Conditions

- Fertile plant material has to be transported and stored in closed and clearly labelled repositories at any time outside the release site and laboratory and has to be kept separately

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from non transgenic plant material.

- All remaining fertile plant material has to be destroyed by disruption of their germination capacity.
- After harvest and in the following year, the first 15-20 cm of upper soil of the release site have to be loosened up. Potato tubers that emerge during that procedure have to be manually collected, removed, and destroyed by disruption of their germination capacity.
- After the end of the field trial no plant species must be cultivated on the release site that impairs the detection of transgenic potato volunteers.

Reasons

To comply with requirements of Directive 2001/18/EC, Gentechnikgesetz (German Gene Technology Act): reduce possibility of GMO spread/establishment.

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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-111454-1](#) LIVING MODIFIED ORGANISM | POTATO MODIFIED WITH AN ETHANOL-INDUCIBLE GUS REPORTER SYSTEM |

Institut für Pflanzengenetik und Kulturpflanzenforschung | Resistance to antibiotics (Kanamycin), Selectable marker genes and reporter genes

Risk assessment

[BCH-RA-DE-111586-3](#) RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS | 6786-01-0130 (ADV. 42010.0130); SUMMARY OF THE RISK ASSESSMENT OF A DELIBERATE RELEASE (FIELD TRIAL) OF GENETICALLY MODIFIED POTATO (SOLANUM TUBEROSUM L.), ALC-GUS-22, ALC-GUS-37, ALC-GUS-45, ISSUED BY THE GERMAN COMPETENT AUTHORITY |

Potato modified with an ethanol-inducible GUS reporter system | Resistance to antibiotics, Selectable marker genes and reporter genes

Document on the decision, communication, notification or declaration

? [BVL database on field trials in Germany \(German language only\)](#) (*English*)

? [BVL-Datenbank zu Freisetzungsvorhaben in Deutschland](#) ()

Additional Information

- type of decision: field trial
- 3 independent lines
- legal basis: Directive 2001/18/EC, Gentechnikgesetz (German Gene Technology Act)
- scope: test of field performance of LMO
- authorization valid from 13 June 2001 to 31 December 2002
- locations: 1 experimental field located in 1 village in Germany, for details refer to the German LMO/GMO location register (https://apps2.bvl.bund.de/stareg_web/localeSwitch.do?language=en&page=/showflaechen.do?)
- size: 600 m²/site/year
- max. 450 LMO/site/year

- There is no Summary Notification Information Format available on the Internet (WebSNIF) forB/DE/01/130

The decision on this deliberate release was made by the Robert Koch Institute (RKI).

The RKI was the competent national authority for the German Gene Technology Act before the competences were transferred to the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL) on April 1st 2004. Deliberate releases that were authorized by the RKI prior to this date are now handled by the BVL.

Other relevant website addresses and/or attached documents

? [BVL german LMO/GMO location register](#) (*English*)

? [Deutsches GMO-Standortregister des BVL](#) ()

? [6786-01-0130 \(bzw. 42010.0130\); Zusammenfassung der Risikobewertung eines Freisetzungsvorhabens \(Feldversuch\) mit gentechnisch veränderten Kartoffelpflanzen \(Solanum tuberosum L.\), Alc-GUS-22, Alc-GUS-37, Alc-GUS-45, erstellt durch die deutsche zuständige Behörde](#) ()

? [6786-01-0130 \(adv. 42010.0130\); Summary of the risk assessment of a deliberate release \(field trial\) of genetically modified potato \(Solanum tuberosum L.\), Alc-GUS-22, Alc-GUS-37, Alc-GUS-45, issued by the German Competent Authority \(courtesy translation; only the German text is authentic\)](#) (*English*)

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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