

Biosafety Clearing-House (BCH)

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC)

BCH-DEC-DE-111113-3

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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

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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

6786-01-0127 (adv. 42010.0127); Decision regarding the risk assessment of a deliberate release (field trial) of genetically modified potato (*Solanum tuberosum* L.), lines VR/T18; VR/T21; VR/T23 and amf/T85; amf/T103; amf/T121, issued by the German Competent Authority

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Date of the decision

18 Sep 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

- **PERSON:** MPIPZ | [BCH-CON-SCBD-111079-2](#)

PERSON

MPIPZ

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RELATED ORGANIZATION

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

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repositories at any time outside the release site and laboratory and has to keep separately from non transgenic plant material.

- The field site needs to be labeled, stating that this potato is unfit for consumption.
- All remaining fertile plant material has to be destroyed by disruption of their germination capacity.
- All machines that have been used on the release site have to be thoroughly cleaned on the release site.
- 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.
- Following the deliberate release, the release site must be inspected for transgenic volunteer potatoes at least once every four weeks. The inspection period has to be extended for another year if potato volunteers were observed. 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-111084-1](#) LIVING MODIFIED ORGANISM | POTATO MODIFIED FOR POTATO LEAF ROLL VIRUS RESISTANCE |

MPIPZ Resistance to antibiotics - Kanamycin Resistance to diseases and pests - Viruses - Potato leaf roll virus (PLRV), Potato virus Y (PVY)

BCH-LMO-SCBD-111080-1 LIVING MODIFIED ORGANISM | POTATO MODIFIED FOR ALTERED AMYLOSE CONTENT |

MPIPZ altered carbohydrate composition: increased amylopectin content Resistance to antibiotics - Kanamycin

Risk assessment

BCH-RA-DE-111112-3 RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS | 6786-01-0127

(ADV. 42010.0127); SUMMARY OF THE RISK ASSESSMENT OF A DELIBERATE RELEASE (FIELD TRIAL) OF GENETICALLY MODIFIED POTATO (SOLANUM TUBEROSUM L.), LINES VR/T18; VR/T21; VR/T23 AND AMF/T85; AMF/T103; AMF/T121, ISSUED BY THE GERMAN COMPETENT AUTHORITY |

Potato modified for altered amylose content | Resistance to antibiotics, Changes in quality and/or metabolite content |

Potato modified for Potato Leaf Roll Virus resistance | Resistance to diseases and pests, Resistance to antibiotics

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
- LMO: lines VR/T18; VR/T21; VR/T23 and amf/T85; amf/T103; amf/T121
- legal basis: Directive 2001/18/EC, Gentechnikgesetz (German Gene Technology Act)
- scope: test of field performance of LMO
- authorization valid from 18 September 2002 to 31 December 2003
- 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: 5000 m²/site/year
- max. 1500 LMO/site/year

- There is no Summary Notification Information Format available on the Internet (WebSNIF) for B/DE/01/127

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](#) ()

? [6786-01-0127 \(bzw. 42010.0127\); Zusammenfassung der Risikobewertung eines Freisetzungsvorhabens \(Feldversuch\) mit gentechnisch veränderten Kartoffelpflanzen \(Solanum](#)

tuberosum L.), Linien VR/T18; VR/T21; VR/T23 und amf/T85; amf/T103; amf/T121, erstellt durch die deutsche zuständige Behörde ()

? 6786-01-0127 (adv. 42010.0127); Summary of the risk assessment of a deliberate release (field trial) of genetically modified potato (*Solanum tuberosum* L.), lines VR/T18; VR/T21; VR/T23 and amf/T85; amf/T103; amf/T121, issued by the German Competent Authority (*English*)

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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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