





Biosafety Clearing-House (BCH)

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC)

BCH-DEC-DE-103567-3 EN DE



LAST UPDATED: 31 JUL 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

6786-01-0169 (adv. 42010.0169); Decision regarding the deliberate release (field trial) of genetically modified maize (Zea mays) hybrid lines MON810, MON88017 and MON88017 x MON810, issued by the German Competent Authority

ΕN

Date of the decision

28 Oct 2005

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

No

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: MONSANTO AGRAR DEUTSCHLAND GMBH | BCH-CON-DE-103566-2

PERSON

Monsanto Agrar Deutschland GmbH

Vogelsanger Weg 91

Düsseldorf

40470, Germany

Phone: + 49 (0) 211 - 36 75-0 Fax: + 49 (0) 2 11 - 36 75-333 Email: mon@monsanto.de

Website: http://www.monsanto.de/, http://www.monsanto.de/

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

repositories at any time outside the release site and biogas plants. Flowering plants and plant material including blossoms have to be transported in containers that prevent the distribution of pollen from the plant material. Genetically modified maize and wild type maize has to be stored separately at any time.

- Repositories and containers for transport, seed drills, crop chopper and machines used for inactivation of the germination capacity of corn need to be thoroughly cleaned after usage to prevent accidental transfer of genetically modified seeds.
- The release site of the genetically modified maize has to be in the distance of at least 200 m to other maize cultivation areas or maize that is cultivated closer to the genetically modified maize has not to be used as food and feed and needs to be destroyed for instance within a biogas plant.
- After completion of the field trial, maize must not be cultivated on the release site for one year. During this period, the release site, the area where shelter crops were planted and further 10 m of surrounding area have to be inspected for transgenic maize volunteers. Volunteers have to be removed and disposed prior to inflorescence.
- Maize plants that are not transported to genetic engineering facilities have to be destroyed by destroying the germination capacity of corn kernels, inactivating plant material of the genetically modified maize and shelter crops through appropriate land management (chaffing of plant material and subsequent covering with soil) or by disposal in biogas plants (efficient inactivation needs to be assured) or by composting of all non-fertile plant material (leaves, petioles, cobs, bracts, silage maize) on the release site; this is also permitted for corn kernels that were inactivated through mechanical procedures.
- Inspection of release site on unexpected biological traits of the LMO and reciprocal effects between LMO and other organisms has to be accomplished weekly during the experimental release and sufficient risk measures have to be performed.

Reasons

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

ΕN

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?

Nο

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?

LMO identification & risk assessment

LMO identification

BCH-LMO-SCBD-14750-19 LIVING MODIFIED ORGANISM | MON-ØØ81Ø-6 - YIELDGARD™ MAIZE

Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths)

BCH-LMO-SCBD-15106-10 LIVING MODIFIED ORGANISM | MON-88Ø17-3 - YIELDGARD™ VT™ ROOTWORM/RR2™ MAIZE |

Resistance to diseases and pests - Insects - Coleoptera (beetles) Resistance to herbicides - Glyphosate

BCH-LMO-SCBD-15374-8 LIVING MODIFIED ORGANISM | MON-88Ø17-3 X MON-ØØ81Ø-6 - YIELDGARD™ VT TRIPLE |

Resistance to diseases and pests - Insects - Coleoptera (beetles), Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate

Risk assessment

BCH-RA-DE-103565-4 RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS | 6786-01-0169 (ADV. 42010.0169); SUMMARY OF THE RISK ASSESSMENT OF A DELIBERATE RELEASE (FIELD TRIAL) OF GENETICALLY MODIFIED MAIZE (ZEA MAYS) HYBRID LINES MON810, MON88017 AND MON88017 X MON810, ISSUED BY THE GERMAN COMPETENT AUTHORITY

MON-ØØ81Ø-6 - YieldGard[™] maize | Resistance to diseases and pests | MON-88Ø17-3 - YieldGard[™] VT[™] Rootworm/ RR2[™] Maize | Resistance to diseases and pests, Resistance to herbicides | MON-88Ø17-3 x MON-ØØ81Ø-6 - YieldGard[™] VT Triple | Resistance to diseases and pests, Resistance to herbicides

Document on the decision, communication, notification or declaration

? BVL database on field trials in Germany (German language only) (<code>English</code>)

? BVL-Datenbank zu Freisetzungsvorhaben in Deutschland ()

Additional Information

- type of decision: field trial
- LMO: hybride lines of MON810, MON88017 and MON88017 x MON810,
- legal basis: Directive 2001/18/EC, Gentechnikgesetz (German Gene Technology Act)
- scope: test of field performance of LMO
- authorization valid within the vegetation periods of the years 2006 to 2010
- locations: 5 experimental fields located in 5 different villages in Germany; for details see German LMO/GMO location register (http://apps2.bvl.bund.de/stareg_web/

localeSwitch.do?language=en&page=/showflaechen.do?)

- size: release site 1: 5 ha, release site 2: 20 ha, release site 3: 29 ha, release site 4: 3.1 ha, release site 5: 9.2 ha

max. 100,000 LMO/site

- related publications:

De Schrijver A, Devos Y, Van den Bulcke M, Cadot P, De Loose M, Reheul D, Sneyers M (2007) Risk assessment of GM stacked events obtained from crosses between GM events, Trends in Food

Science & Technology, 18, 2, 101-109

Taylor ML, Hartnell G, Nemeth M, Karunanandaa K, George B (2005) Comparison of Broiler Performance When Fed Diets Containing Corn Grain with Insect-Protected (Corn Rootworm and European Corn Borer) and Herbicide-Tolerant (Glyphosate) Traits, Control Corn, or Commercial Reference Corn—Revisited, Poultry Science, 84, 1893–1899

Other relevant website addresses and/or attached documents

- ? Summary Notification Information Format available on the Internet (WebSNIF) (English)
- ? Summary Notification Information Format available on the Internet (WebSNIF) ()
- ? BVL german LMO/GMO location register (<code>English</code>)
- ? Deutsches GMO-Standortregister des BVL ()
- ? 6786-01-0169 (adv. 42010.0169); Summary of the risk assessment of a deliberate release (field trial) of genetically modified maize (Zea mays) hybrid lines MON810, MON88017 and MON88017 x MON810, issued by the German Competent Authority (courtesy translation; only the German text is authentic) (English)
- ? 6786-01-0169 (bzw. 42010.0169); Zusammenfassung der Risikobewertung eines Freisetzungsvorhabens (Feldversuch) mit gentechnisch veränderten Mais (Zea mays) Hybride von MON810, MON88017 und MON88017 x MON810, erstellt durch die deutsche zuständige Behörde ()

BCH-DEC-DE-103567-3

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

413 rue Saint-Jacques, suite 800 Montreal, Québec, H2Y 1N9

Canada

Fax: +1 514 288-6588 Email: secretariat@cbd.int