





Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-CZ-104303-3

LAST UPDATED: 24 OCT 2012

General information

Country

Czech Republic PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY ENTRY INTO FORCE: 11 SEP 2003

Title of the risk assessment

Decision on a small-scaled field trial with GM flax

ΕN

Date of the risk assessment

26 Apr 2007

Competent National Authority(ies) responsible for the risk assessment

- COMPETENT NATIONAL AUTHORITY: BCH-CNA-CZ-160-8 | BCH-CNA-CZ-160-8

COMPETENT NATIONAL AUTHORITY

Ministry of the Environment

Vrsovicka 65

Prague

10010, Czech Republic

Phone: +420 267 122 066 Fax: +420 267 310 013 Email: gmo@mzp.cz

Website: http://www.env.cz

Risk assessment details

Living modified organism(s)

BCH-LMO-SCBD-104317-1 | Flax modified for tolerance to fungal diseases and/or insect pests | Agritec Plant Research Resistance to antibiotics - Kanamycin Resistance to diseases and pests - Bacteria, Fungi

BCH-LMO-SCBD-104316-1 | Flax modified for herbicide tolerance | Agritec Plant Research Resistance to antibiotics - Kanamycin Resistance to herbicides - Glufosinate

BCH-LMO-SCBD-104315-1 | Flax modified for insertional mutagenesis | Agritec Plant Research Resistance to antibiotics - Hygromycin Selectable marker genes and reporter genes

BCH-LMO-SCBD-104318-1 | Flax modified for improved ability to bind heavy metals | Agritec Plant Research Resistance to antibiotics - Kanamycin Use in industrial applications - Bioremediation

BCH-LMO-SCBD-104320-1 | Flax modified for improved ability to bind heavy metals | Agritec Plant Research Resistance to antibiotics - Kanamycin Use in industrial applications - Bioremediation

Scope of the risk assessment

LMOs for introduction into the environment

Risk assessment report / summary

? Decision_GM flax.pdf (English)

Methodology and points to consider

Estimation of the overall risk

Analysis of the characteristics of transgenic flax lines has shown that the risk for potential adverse effects on human and animal health and the receiving environment, resulting from the planned field trials with GM flax and linseed lines, is consistently negligible: Cultivation of flax depends to a great deal on human care because its competetivness is very low. Current flax and linseed cultivars are not able to withstand winter under condition of mid Europe both on field areas and in natural environments either as seeds of plants. Under cold and wet conditions flax plants are immediately attacked by numerous fungal and bacterial pathogenes and crop has to be chemically protected against harm. Flax propagates using the seed exclusively.

The risk of the introduced traits in flax to be the cause of any competitive advantage or disadvantage in natural environments is also negligible. Like for any other conventional flax, the likelihood of these GM flax and linseed lines to spread into non-agronomic environments is negligible. Moreover, there is no potential for gene transfer from GM flax to any wild plant species. There is a limited number of wild flax species common in Europe, which are sexually compatible to cultivated flax but their natural habitats in CZ do not correspond to areas of flax cultivation. Even our attempts to obtain hybrids through artificial crossings with L. flavum were unsuccessful (Tejklová 2005).

GM flax lines pose negligible risk for adverse environmental effects through their interactions with target organisms. The ecological interactions of GM lines derived from insertion mutagenesis were not different from traditional flax. Based on target genes characteristics the same is expected for other modified lines.

Recommendation(s) on whether the risks are acceptable/manageable and any management strategies

The distance from the nearest cultivation of unmodified flax will be at least 300 m. At least 3 m-wide separating distance of other crops will be kept to decrease dissemination of seeds and to monitor effects of GM organism on field flora and fauna closed to experimental plots too. Sowing and harvesting machinery will be cleaned on site to prevent the dispersal of GM seed. Harvested material and seed will be transported from the site in closed and labelled containers to the laboratories for analyses. Remaining seed which will not be used in following seasons will be inactivated as well as vegetative plant material. The area will be controlled for volunteers for a period of 1 consecutive year. During the next 6 years time there will be no conventional flax cultivation, which equals conventional crop rotation practice. Volunteers will be treated using conventional agricultural practices. During the release the project leader and trained personnel will monitor the trial site at defined intervals.

ΕN

ΕN

Receiving environment(s) considered

Czech Republic, Olomoucky Region

ΕN

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

Additional Information

Other relevant website addresses and/or attached documents

? Czech National Node of the BCH (<code>English</code>)

? Joint Research Centre - Deliberate Release and Placing on the EU Market of GMOs (${\it English}$)

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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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