





Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA) BCH-RA-CZ-115675-1 LAST UPDATED: 11 AUG 2020 **General information** Country **Czech Republic** PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY **ENTRY INTO FORCE: 11 SEP 2003** Title of the risk assessment Risk assessment of GM barley producing LL-37 peptide EN Date of the risk assessment 28 Jan 2019 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-115698-1Barley modified for the production of LL-37 peptide | Palacky UniversityOlomouc Production of medical or pharmaceutical compounds (human or animal) Resistance to
antibiotics - Hygromycin Selectable marker genes and reporter genesBCH-LMO-SCBD-115700-1Barley modified for the production of LL-37 peptide | Palacky UniversityOlomouc Production of medical or pharmaceutical compounds (human or animal) Protein
purification Resistance to antibiotics - Hygromycin Selectable marker genes and reporter genesShow detection method(s)BCH-LMO-SCBD-115699-1Barley modified for the production of LL-37 peptide | Palacky UniversityOlomouc Production of medical or pharmaceutical compounds (human or animal) Protein
purification Resistance to antibiotics - Hygromycin Selectable marker genes and reporter genes
Show detection method(s)BCH-LMO-SCBD-115699-1Barley modified for the production of LL-37 peptide | Palacky University
Olomouc Production of medical or pharmaceutical compounds (human or animal) Resistance to

antibiotics - Hygromycin Selectable marker genes and reporter genes

Scope of the risk assessment

LMOs for introduction into the environment field trial

Risk assessment report / summary

? CZ-RA_GMO-barley-LL37.pdf (English)

Methodology and points to consider

Estimation of the overall risk

The transgenic plants producing the LL-37 peptide (T1-T3 generation) were grown in a closed phytotron and in greenhouses of the Palacký University (Department of Molecular Biology) in Olomouc within contained GMO use management. No selective advantages or disadvantages, nor any interactions with control plants or other organisms were observed for the selected modifications (UBI:LL-37, bHOR:LL-37 and bHOR:MBPLL-37). The modified spring barley does not pose any risks to the environment, nor to any risks to human health or animal health.

Receiving environment(s) considered

Czech Republic, region Olomouc, Cadastral teritory Mohelnice

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

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

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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 413 rue Saint-Jacques, suite 800 Montreal, Québec, H2Y 1N9 Canada Fax: +1 514 288-6588 Email: secretariat@cbd.int