

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-BR-261535-1

LAST UPDATED: 01 SEP 2022

General Information

Country

Brazil

Title of the risk assessment

Risck assessment of cotton, event MON1445 - Technical Opinion No. 1598/2008.

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Date of the risk assessment

18 Sep 2008

Competent National Authority(ies) responsible for the risk assessment

- **COMPETENT NATIONAL AUTHORITY:** | [BCH-CNA-BR-45556-3](#)

COMPETENT NATIONAL AUTHORITY:

National Technical Biosafety Commission
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Contact details of the main responsible risk assessor

- **ORGANIZATION:** MONSANTO DO BRASIL LTDA | [BCH-CON-BR-244799-1](#)

ORGANIZATION:

Monsanto do Brasil Ltda
Private sector (business and industry)
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Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-14880-14](#) | MON-Ø1445-2 - Roundup Ready™ cotton | Resistance to antibiotics - Kanamycin, Streptomycin Resistance to herbicides - Glyphosate
[Show detection method\(s\)](#)

Scope of the risk assessment

LMOs for introduction into the environment
LMOs for contained use
LMOs for direct use as food
LMOs for direct use as feed
LMOs for processing

Risk assessment report / summary

[Commercial release 1598-2008.pdf](#) [Portuguese]

Roundup Ready Cotton event MON 1445 was genetically modified from the transformation of the commercial variety Coker 312 with the plasmid PVGHGT07, through the system mediated by *A. tumefaciens*. The transformation inserted the cp4 epsps, nptII, gox and aad genes into the genome of this cotton variety (75). The strain resulting from the transformation expresses the enzyme CP4 EPSPS (CP4 5-enolpyruvylshikimate-3-phosphate synthase) from *Agrobacterium* sp. strain CP4, which is naturally tolerant to glyphosate, the active ingredient in Roundup herbicide. This strain also expresses the NPTII protein (neomycin phosphotransferase type II), which confers resistance to aminoglycosylated antibiotics, enabling the selection of cells transformed with the cp4 epsps gene in a culture medium containing the antibiotic kanamycin in the in vitro phases of the transformation process. The third gene introduced, aad, encodes the protein AAD (3''(9)-O-aminoglycoside adenyltransferase). This gene is not expressed in plant tissue because it is under the control of a prokaryotic promoter.

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Methodology and points to consider

Potential adverse effects identified in the risk assessment

Roundup Ready Cotton, event MON 1445, shows genetic stability in several environmental conditions determined in several generations of strains obtained by backcross with elite cultivars, including a variety adapted for cultivation in the Brazil.

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Likelihood that the potential adverse effects will be realized

During the 2002/2003 harvest, the phenotypic, morphological and agronomic parameters were again evaluated and expanded. The experiments were carried out in two locations (Santa Cruz das Palmeiras - SP and Santa Helena de Goiás - GO). These experiments

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compared the development of Roundup Ready Cotton event MON 1445 cultivar DP50RR, conventional cotton DP50 and eight commercial cultivars, four at each location. The plots planted with Roundup Ready Cotton event MON 1445 cultivar DP50RR were treated with 1.5 Kg/ha of Roundup herbicide (MON14445 formulation) in foliar application at the V4 stage and complemented with 1.0 Kg/ha with directed application between rows of the same formulation 20 days after the first application. For the other cultivars, all plots were treated equally with fertilizers and agrochemicals to control diseases and insects, using the same products and doses and following conventional agronomic practices, typically used in each region. Comparisons between genetically modified cotton and conventional varieties were carried out during the harvest for the following parameters: plant vigor, flowering cycle, plant height, early maturation, cycle to harvest, retention of the plume by the boll after dehiscence, weight of boll, average weight of 1000 seeds, percentage of fibers, susceptibility to diseases and pests (*Colletotrichum* sp., *Ramularia* sp., Disease Azul, Vermelhão and *Alternaria* sp.), productivity and fiber quality. No significant differences were observed between the genetically modified cultivar, with or without glyphosate application, and its conventional recurrent parent in the phenotypic, morphological and agronomic parameters evaluated.

Possible consequences

Whereas Roundup Ready Cotton event MON 1445 belongs to the specieswell-characterized (*Gossypium hirsutum*) and with a solid safety record for usehuman and that the cp4 epsps gene introduced into this strain does not encode a toxic protein, being harmless to humans.

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Estimation of the overall risk

The evaluations of the phenotypic and agronomic characteristics of Roundup Ready Cotton, event MON 1445, cultivar DP50RR, carried out in Brazil have results similar to those found in other regions of the world in experimental and commercial planting.

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

The evaluations of the phenotypic characteristics and crops of Roundup Ready Cotton event MON 1445 cultivar DP50RR carried out in the Brazil have similar results to those found in other regions of the world in planting experimental and commercial. With the exception of tolerance to the herbicide glyphosate, resulting from cp4 epsps gene expression, the Roundup Ready Cotton event MON 1445 demonstrates phenotypic and agronomic characteristics equivalent to the pattern of parental lines conventional and commercial cultivars of conventional cotton.

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Need(s) for further information on specific issues of concern

The commercial release of the Roundup Ready Cotton MON event 1445 is not potentially harmful to human and animal health, nor of significant environmental degradation.

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Receiving environment(s) considered

The MON 1445 event has already been approved in several countries, such as USA, Canada, Japan, Australia, Mexico, South Africa, Argentina, China, European Union, Philippines, Colombia and Korea, having been commercially cultivated in some of these, without showing

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negative for human, animal or environmental health.

LMO detection and identification methods proposed

Molecular traditional methods.

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Information sharing with other databases

Is this risk assessment related to an LMO for commercial use?

Yes

Should this risk assessment be forwarded to the OECD Secretariat for possible inclusion in the [BioTrack Product Database](#)?

Yes

Is this risk assessment related to food safety?

Yes

Was it conducted in accordance with the Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*?

Yes

Should this information be forwarded to the Secretariat of the [FAO GM Foods Platform](#)?

Yes

[BCH-RA-BR-261535-1](#)

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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