Biosafety Unit

ICGEB and its Biosafety Programmes

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Biosafety Unit

Developing knowledge

International Centre for Genetic Engineering and Biotechnology

A centre of excellence for research and training in genetic engineering and biotechnology with regard to the needs of developing world

Biosafety Unit

ICGEB

The **International Centre for Genetic Engineering & Biotechnology (ICGEB)** is an international organisation dedicated to advanced research and training in molecular biology and biotechnology, with special regard to the needs of the developing world

It comprises 3 components:

ICGEB - Trieste

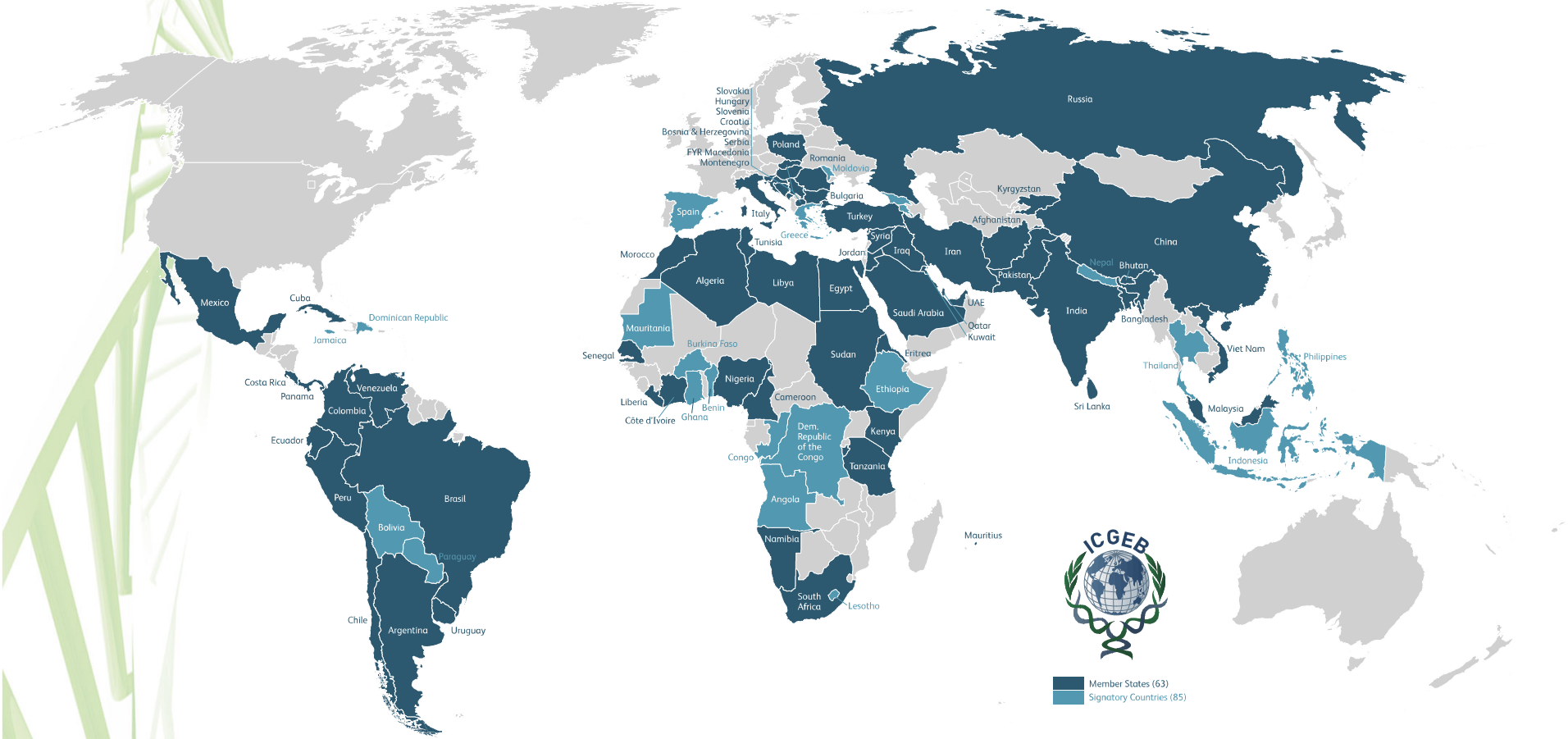
ICGEB – New Delhi

ICGEB – Cape Town

Biosafety Unit

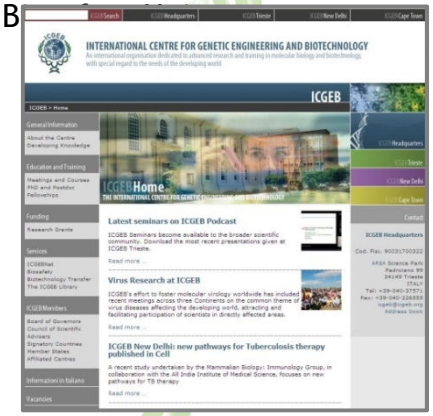
The ICGEB Constituency

63 Member States
85 Signatory Countries



One Centre: three Components and a Network of Affiliated Centres in Member States

ICGEB



www.icgeb.org

The **ICGEB** strengthens the research capability of its members through training and funding programmes and advisory services, and represents a comprehensive approach to promoting biotechnology internationally

ICGEB promotes the safe use of biotechnology

Research and Development Focus

Human Health

Basic and applied research in infectious diseases and the genetic component of tumors and cardiovascular pathologies

Crop improvement

Biotic and abiotic stress, plant transformation, insect resistance, biopesticides

Biosafety risk assessment

Technology development and transfer

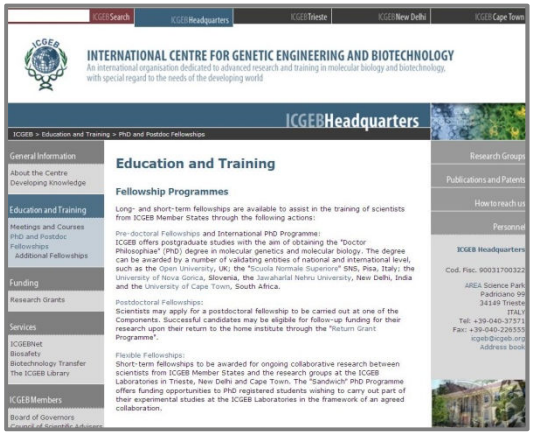
Cooperation with other UN bodies

How does ICGEB develop knowledge?

Biosafety Unit

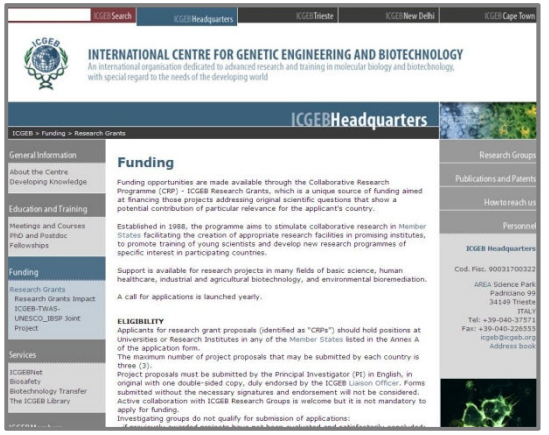
http://www.icgeb.org/research-groups.html

http://www.icgeb.org/fellowships.html



- Research projects
- Long term training
- Short term training
- Collaborative research programme
- Cooperation with industrial sector
- Scientific services
- Institutional services

http://www.icgeb.org/meetings-and-courses.html



http://www.icgeb.org/research-grants.html

Biosafety Unit

ICGEB Biosafety Unit (BU)

www.icgeb.org/biosafety

Formed in 1997, the role of the **ICGEB Biosafety Unit** is to:

- **disseminate** as widely as possible **significant information** related to the biosafety issues raised through the use of products derived from modern biotechnology,

- as well as to **assist its Member States in their capacity** to identify, regulate, manage, and monitor those products within their own Countries

How is this carried out?

Biosafety Unit

Strengthening the Role of Science in the Decision-making of Biotech Products

www.icgeb.org/biosafety

The activities of the ICGEB Biosafety Unit are a fully inter-locking package:

- *Providing greater access to current scientific information* **(dissemination of information)**,
- *Providing training in how to make best use of these data* **(capacity building - personnel)**, *and*
- *Assisting the identification of local gaps in information [required by the regulatory process but not already addressed by the scientific community] and help fill them* **(capacity building - local assistance)**

Biosafety Unit

Dissemination of information

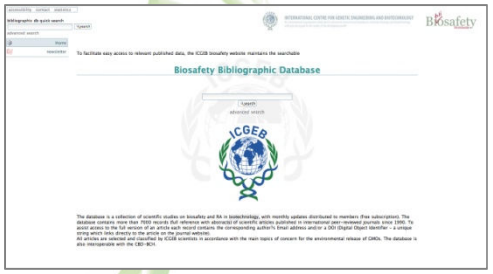
www.icgeb.org/biosafety

Biosafety Webpages

- Offer access to ICGEB publications and ICGEB databases, as well as useful biosafety information and links
- Undergoing an up-date…

Biosafety Unit

Dissemination of information



http://bibliosafety.icgeb.org

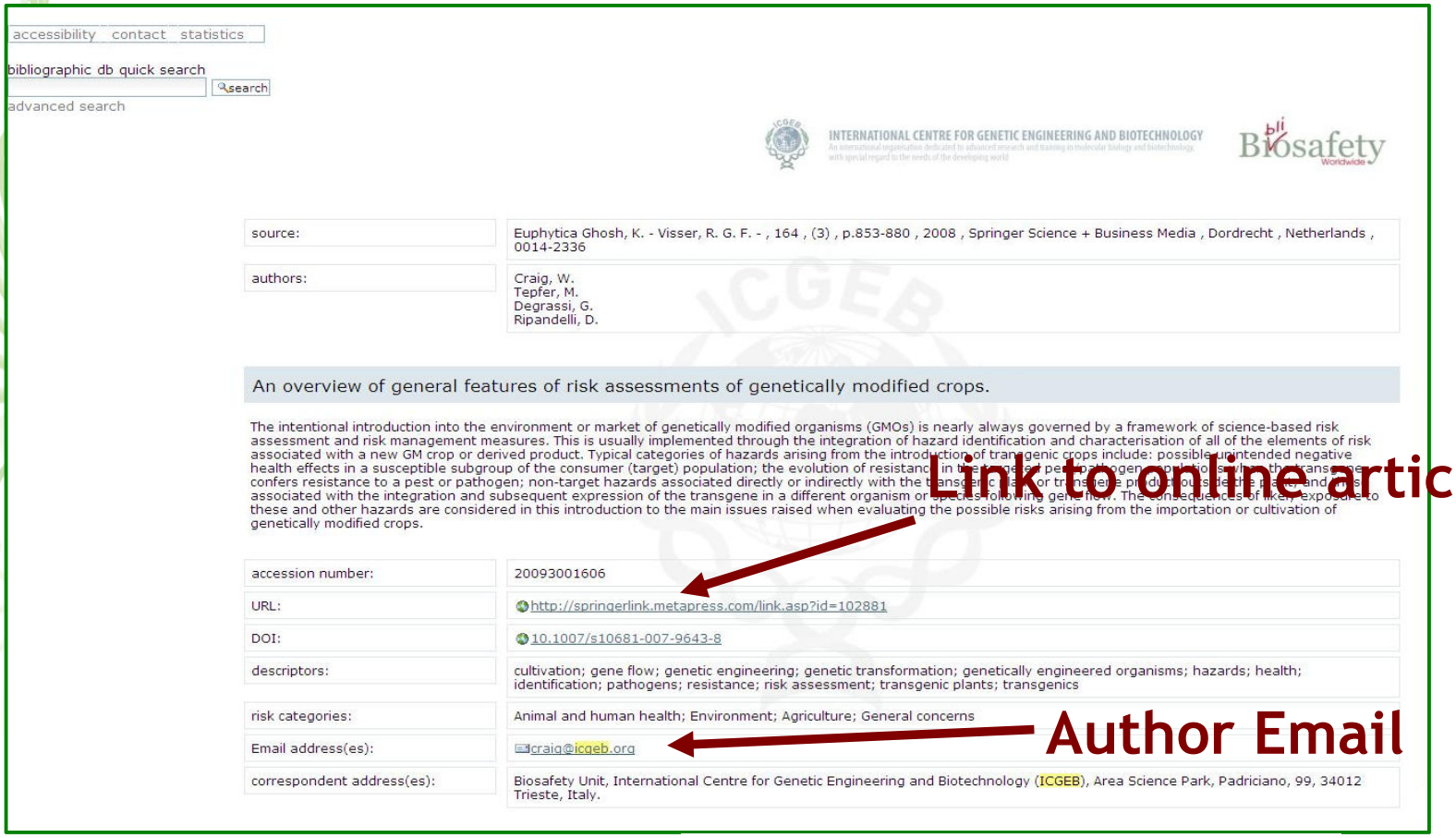
Bi[bli]osafety – The Biosafety Bibliographic Database

- Also used as a training tool
- Covers scientific and technical topics underpinning GMO decision-making
- Inter-operable with the CBD central portal

To receive free monthly up-dates, Email…

Biosafety-data-join@icgeb.org

Biosafety Unit



accessibility contact statistics

bibliographic db quick search

search

advanced search

INTERNATIONAL CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY

Biosafety

source:	Euphytica Ghosh, K. - Visser, R. G. F. - , 164 , (3) , p.853-880 , 2008 , Springer Science + Business Media , Dordrecht , Netherlands , 0014-2336
authors:	Craig, W. Tepfer, M. Degrassi, G. Ripandelli, D.

An overview of general features of risk assessments of genetically modified crops.

The intentional introduction into the environment or market of genetically modified organisms (GMOs) is nearly always governed by a framework of science-based risk assessment and risk management measures. This is usually implemented through the integration of hazard identification and characterisation of all of the elements of risk associated with a new GM crop or derived product. Typical categories of hazards arising from the introduction of transgenic crops include: possible unintended negative health effects in a susceptible subgroup of the consumer (target) population; the evolution of resistance in target pests to a pesticide produced by the transgene that confers resistance to a pest or pathogen; non-target hazards associated directly or indirectly with the transgenic plant or transgene product produced in the plant; hazards associated with the integration and subsequent expression of the transgene in a different organism or species following gene flow. The consequences of likely exposure to these and other hazards are considered in this introduction to the main issues raised when evaluating the possible risks arising from the importation or cultivation of genetically modified crops.

accession number:	20093001606
URL:	http://springerlink.metapress.com/link.asp?id=102881
DOI:	10.1007/s10681-007-9643-8
descriptors:	cultivation; gene flow; genetic engineering; genetic transformation; genetically engineered organisms; hazards; health; identification; pathogens; resistance; risk assessment; transgenic plants; transgenics
risk categories:	Animal and human health; Environment; Agriculture; General concerns
Email address(es):	craig@icgeb.org
correspondent address(es):	Biosafety Unit, International Centre for Genetic Engineering and Biotechnology (ICGEB), Area Science Park, Padriciano, 99, 34012 Trieste, Italy.

Link to online article

Author Email

Risks for animal and human health:
toxicity & food/feed quality/safety; allergies; pathogen drug resistance (antibiotic resistance), impact of selectable marker

Risks for the environment:
persistency of gene or transgene (volunteers, increased fitness of GM crop, invasiveness) or of transgene products (accumulative effects); susceptibility of non-target organisms; change in use of chemicals in agriculture; unpredictable gene expression or transgene instability (gene silencing); environmentally-induced (abiotic) changes in transgene expression; ecological fitness; changes to biodiversity (interference of tri-trophic interactions); impact on soil fertility/soil degradation of organic material

Horizontal gene transfer:
genetic pollution through pollen or seed dispersal & horizontal gene transfer (transgene or promoter dispersion); transfer of foreign gene to micro-organisms (DNA uptake) or generation of new live viruses by recombination (transcapsidation, complementation, etc.)

Risks for agriculture:
resistance/tolerance of target organisms; weeds or superweeds; alteration of nutritional value (attractiveness of the organism to pests); change in cost of agriculture; pest/weed management; unpredictable variation in active product availability; loss of familiarity/changes in agricultural practise

General concerns:
detection and analytical methods; ethical issues (eg. labelling); substantial equivalence; risk assessment/ risk management; general biosafety; public attitudes, perception; legislation (incl. liability & redress); monitoring; socio-economics (eg. situation of poor farmers in developing countries); IPR (Intellectual Property Rights); GM traceability / commodity segregation

Risk categories

Finding Information
- National Contacts
- Laws and Regulations
- Country's Decisions and other Communications
- Roster of Experts
- LMOs, Genes or Organisms
- National Reports
- Capacity-Building
- Organizations
- The BCH Virtual Library
- -- Advanced Search --

Compiled Information
- National Contacts
- LMO Registry
- Organism Registry
- Gene Registry

Welcome to the BC

The Biosafety Clearing-House (BCH) ...gena Protocol on Biosafety to facilitate the exchange of information on Living M... the Parties to better comply with their obligations under the Protocol. Global access to ...ronmental, legal and capacity building information is provided in all 6 of the UN languag...

BCH account holders can create and ...ng in through the Management Centre (*Registering Information*) section.

Latest news

2012-04-07 Malaysia - 3rd National Bio... (BCH) Training Workshop, ... April 2012...
2012-04-03 Primer Taller de Capacitaci... Panamá – UNEP-GEF...
2012-03-30 Panama - Oficina del IICA-... videoconferencia....
2012-03-30 Panama - Traspaso de la Presidencia de la Comisión Nacional de Bioseguridad de Panamá...
2012-03-26 Central African Republic - Les ateliers de formation BCH en République centrafricaine...

More news...

Additions [More additions...]

-10 Trinidad and Tobago - National Focal Point
-10 Malaysia - Country's Decision or any other Communication
-10 Malaysia - Country's Decision or any other Communication
-10 Malaysia - Risk Assessment
2012-04-10 Malaysia - Risk Assessment

Latest updates

2012-04-10 Papua New Guinea - National Focal Point
2012-04-10 Spain - Law, Regulation or Guideline
2012-04-10 Spain - Country's Decision or any other Communication
2012-04-10 Malta - Law, Regulation or Guideline
2012-04-10 Viet Nam - Law, Regulation or Guideline

Second National Report on the Implementation of the Cartagena Protocol —RESULTS—

Open-ended Online Expert Forum on Risk Assessment and Risk Management

Online Forum on Capacity-Building

DETECTION & IDENTIFICATION LABORATORY NETWORK

Biosafety

Follow us: Listserver | BCH | CPB | Twitter | Facebook | BCH Channel

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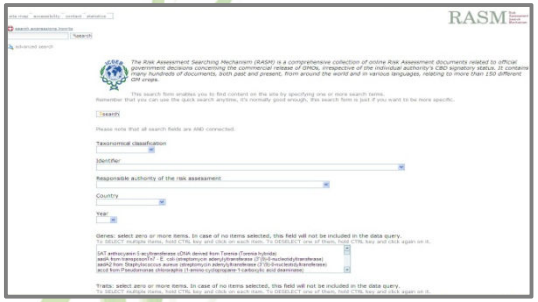
Dissemination of information



Risk Assessment Search Mechanism (RASM)

- Provides on-line access to scientific risk assessment documentation relevant to the commercialisation of GM crops world-wide
- Currently contains ~1200 records of 160 transgenic events and 21 plant species

http://rasm.icgeb.org

site map | accessibility | contact | statistics

RASM Risk Assessment Search Mechanism

search expressions how-to

search

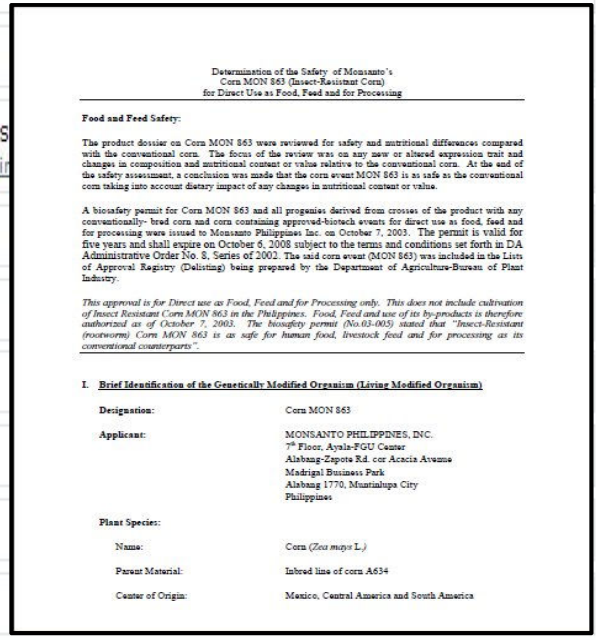
advanced search

Determination of the Safety of Monsanto's Corn MON 863 (Insect-Resistant Corn) for Direct Use as Food, Feed and for Processing

Go to document

ICGEB identifier:	853
Organism:	Corn / Maize
Trait:	Coleopteran insect resistance (Bt-toxin)
Gene(s):	cry3Bb1 from Bacillus thuringiensis subsp. kumamotoens npt II (neomycin phosphotransferase II) from E. coli li
Unique identifier:	MON-00863-5 link
Developer:	Monsanto
Product code:	MON 863
Document author:	Philippines Bureau of Plant Industry
Country:	Philippines
Year:	2008

Link to RA Document



Determination of the Safety of Monsanto's
Corn MON 863 (Insect-Resistant Corn)
for Direct Use as Food, Feed and for Processing

Food and Feed Safety:

The product dossier on Corn MON 863 were reviewed for safety and nutritional differences compared with the conventional corn. The focus of the review was on any new or altered expression trait and changes in composition and nutritional content or value relative to the conventional corn. At the end of the safety assessment, a conclusion was made that the corn event MON 863 is as safe as the conventional corn taking into account dietary impact of any changes in nutritional content or value.

A biosafety permit for Corn MON 863 and all progenies derived from crosses of the product with any conventionally- bred corn and corn containing approved-biotech events for direct use as food, feed and for processing were issued to Monsanto Philippines Inc. on October 7, 2003. The permit is valid for five years and shall expire on October 6, 2008 subject to the terms and conditions set forth in DA Administrative Order No. 8, Series of 2002. The said corn event (MON 863) was included in the Lists of Approval Registry (Delisting) being prepared by the Department of Agriculture-Bureau of Plant Industry.

This approval is for Direct use as Food, Feed and for Processing only. This does not include cultivation of Insect Resistant Corn MON 863 in the Philippines. Food, Feed and use of its by-products is therefore authorized as of October 7, 2003. The biosafety permit (No.03-005) stated that "Insect-Resistant (rootworm) Corn MON 863 is as safe for human food, livestock feed and for processing as its conventional counterparts".

I. Brief Identification of the Genetically Modified Organism (Living Modified Organism)

Designation: Corn MON 863

Applicant: MONSANTO PHILIPPINES, INC.
7th Floor, Ayala-FGU Center
Alabang-Zapote Rd. cor Acacia Avenue
Madrigal Business Park
Alabang 1770, Muntinlupa City
Philippines

Plant Species:

Name: Corn (*Zea mays* L.)

Parent Material: Inbred line of corn A634

Center of Origin: Mexico, Central America and South America

site map accessibility contact statistics

RASM Risk Assessment Search Mechanism

search expressions how-to

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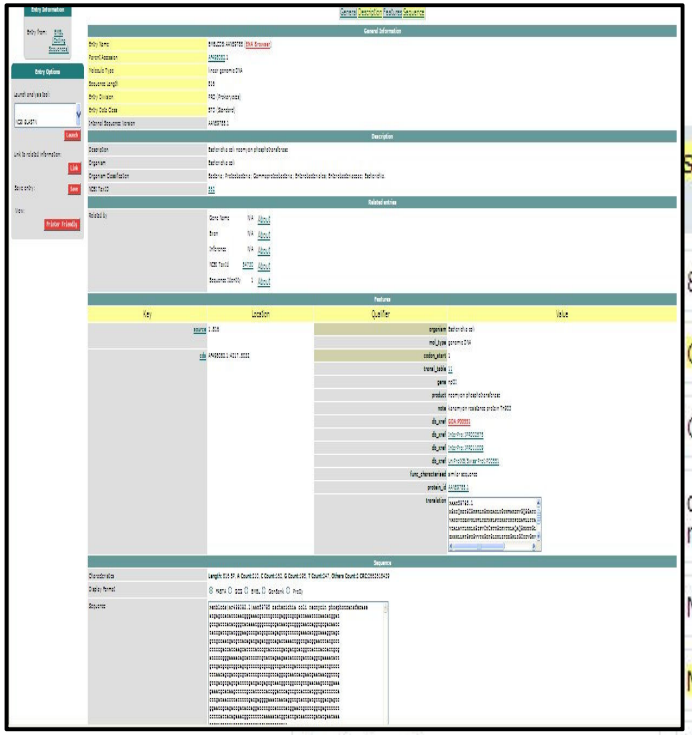

santo's Corn MON 863 (Insect-Resistant Corn) for Direct Use as Food, Feed and for Processing

	853
	Corn / Maize
	Coleopteran insect resistance (Bt-toxin)
	cry3Bb1 from Bacillus thuringiensis subsp. kumamotoensis npt II (neomycin phosphotransferase II) from E. coli link
	MON-00863-5 link
	Monsanto
Product code:	MON 863
Document author:	Philippines Bureau of Plant Industry
Country:	Philippines
Year:	2008

Link to EMBL Database

site map | accessibility | contact | statistics

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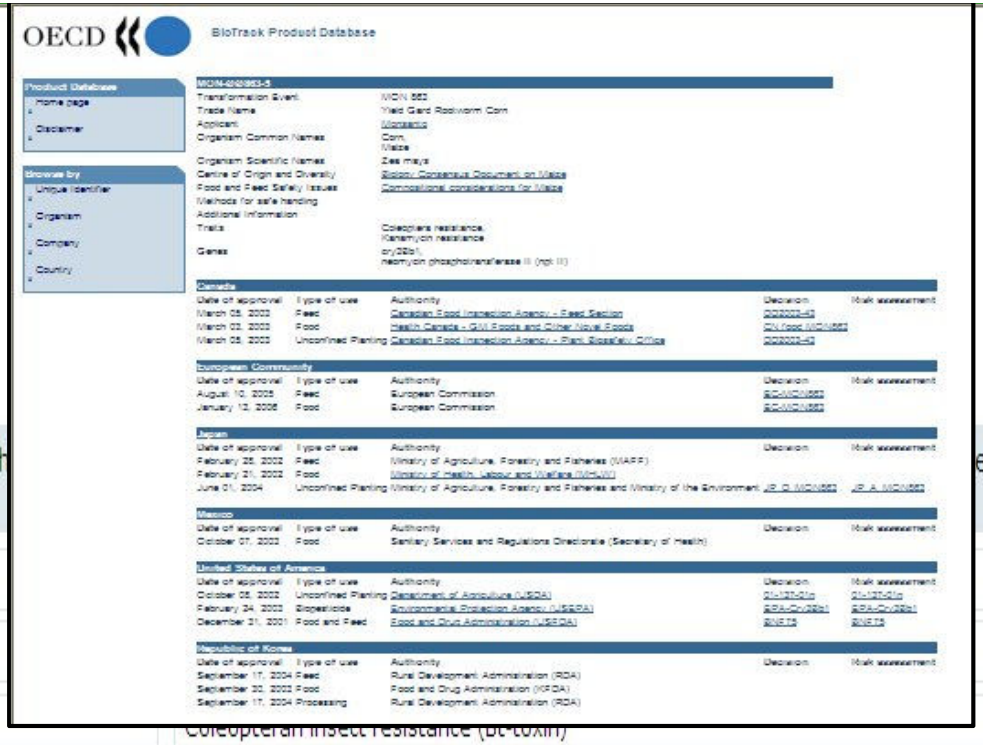
RASM Risk Assessment Search Mechanism



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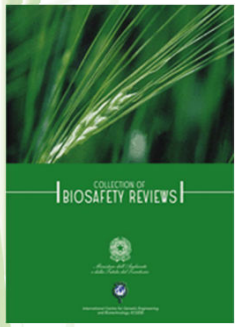
Product code:	MON 863
Document author:	Philippines Bureau of Plant Industry
Country:	Philippines
Year:	2008

Link to OECD recor

Biosafety Unit

Dissemination of information

Collection of Biosafety Reviews



- Annual compilation of scientific studies on biosafety and risk assessment, summarising the present status of specific fields of biosafety expertise
- Volume VIII just published, covering:
  - GMO Regulation
  - Problem Formulation in GM Food/Feed Evaluation
  - GMO Product Stewardship

www.icgeb.org/biosafety/publications/collections.html

Biosafety Unit

BIOSAFETY WEB PAGES

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34149 Trieste, Italy
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Fax: +39-040-226555
Email: biosafe@icgeb.org

Publications

Collection of Biosafety Reviews

The ICGEB Biosafety Unit, in the framework of its collaboration with the Italian Ministry for the Environment, publishes the "Collection of Biosafety Reviews", a compilation of scientific studies on areas of major interest for biosafety and risk assessment, prepared by internationally recognized scientists summarising the state of the art in their field of expertise.

Volumes

Volume 1

Volume 2

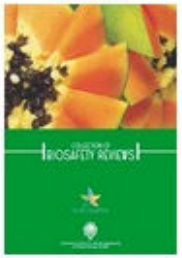
Volume 3

Volume 4

Volume 5

Volume 6

Volume 7



Volume 8

http://www.icgeb.org/biosafety/publications/collections.html

Biosafety Unit

Capacity building – Individual level

ICGEB supported workshops – 2012

- BSF-2012: Advanced biosafety course – ICGEB, Italy, April *"Problem Formulation: A Strategic Approach to Risk Assessment of GMOs"*
- Regional workshop: Colombo, Sri Lanka, May *"Biosafety of Genetically Engineered Crops: Best Practices from Laboratory to Farmer's Fields"*

ICGEB supported workshops – 2013

- Regional workshop: Doha, Qatar, January *"Detection of GMOs in Food and Agricultural Products"*
- BSF-2013: Advanced biosafety course – ICGEB, Italy, July *"Strategic Approaches in the Evaluation of the Science Underpinning GMO Regulatory Decision-making"*

Biosafety Fellowhips

- The BU has hosted a series of Biosafety Fellows over the years, providing them with vital *on the job* training. The current fellow started in Nov 2011.

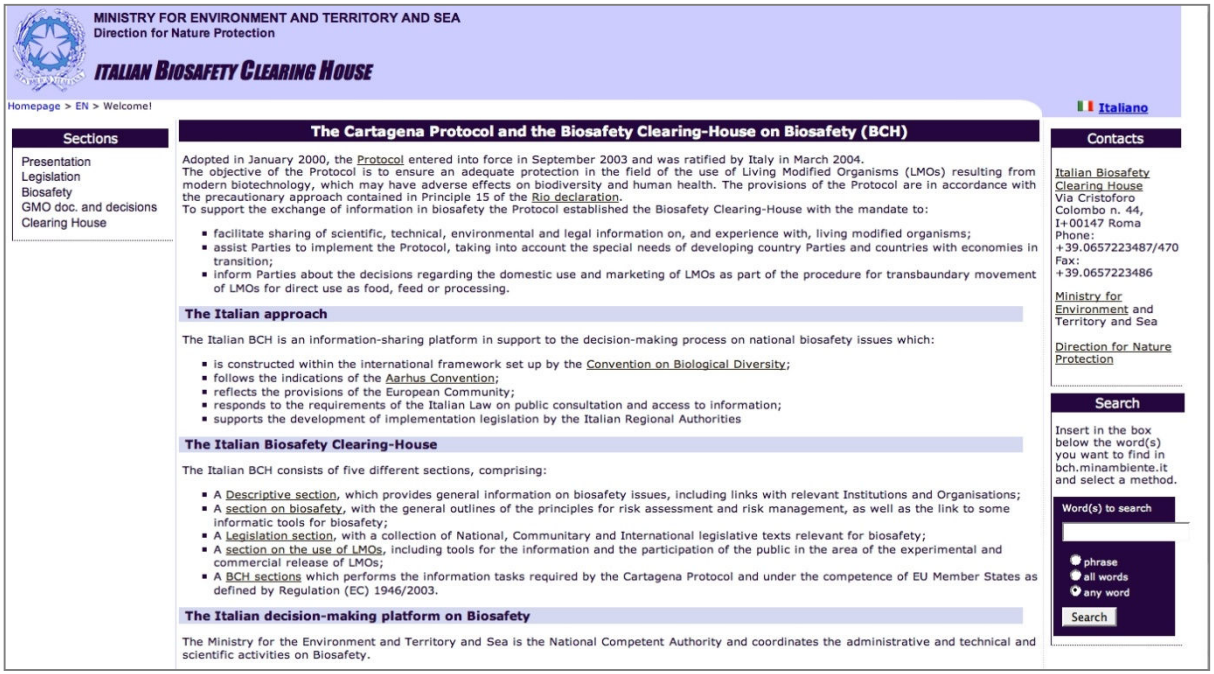
Biosafety Unit

Capacity building – Institutional level

- **Construction of Italian Biosafety Clearing House**

http://bch.minambiente.it/

❖ The Italian government is obliged to provide GMO information (eg via a BCH) to the public, under the Cartagena Protocol on Biosafety and EU Legislative Decree 224 (taking in Directive 2001/18/CE)



Biosafety Unit

ICGEB Capacity Building Project for sub-Saharan Africa

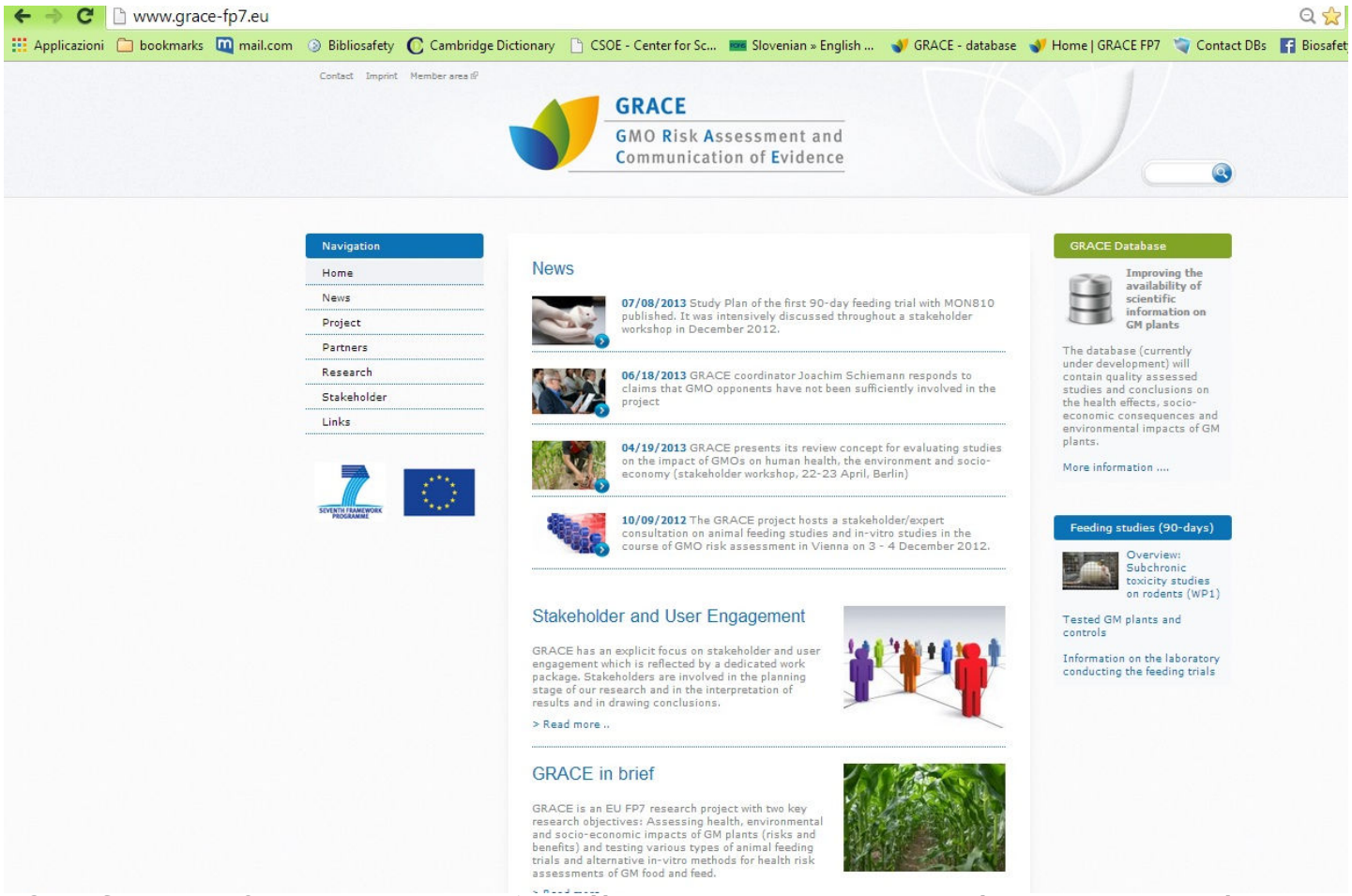
To support and expand ongoing efforts in helping governments in Sub-Saharan Africa to develop effective safety and regulatory systems in the field of modern biotechnology

A US$6 million 4-year second phase of an ambitious project focusing on improving training, information and other support to regionally-based specialists so that selected African countries have the opportunity to safely access scientific advances

BILL & MELINDA GATES foundation

Biosafety Unit

GRACE



GRACE is a 3.5 year, EUR 6 million, EU FP7 research project with two key research objectives:

- Assessing health, environmental and socio-economic impacts of GM plants (risks and benefits), and;
- testing various types of animal feeding trials and alternative in-vitro methods for health risk assessments of GM food and feed.

Biosafety Unit

13th ISBGMO

CAPE TOWN SOUTH AFRICA 2014

ISBR

9 - 13 November 2014

For more information on the 13th ISBGMO and **Sponsorship Opportunities**, please visit: http://isbr.info/ISBGMO13

Like our **Facebook Page** and stay on top of the latest developments: https://www.facebook.com/13thISBGMO

Follow us on **Twitter** @ISBGMO13

Questions? Pop us an e-mail at Hennie@biosafety.org.za

Biosafety Unit

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Head of Biosafety Unit

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Trieste
Wendy CRAIG
Francesca FAROLFI
Monica RACOVITA

New Delhi
Vanga Siva REDDY

Rome (Italian BCH)
Anna RUSSO

www.icgeb.org/biosafety