Need for Harmonization: Lessons from Plant Biotechnology

Marcus Vinícius Segurado Coelho
Secretaria de Defesa Agropecuária
Ministério da Agricultura, Pecuária e Abastecimento

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Purpose of Regulations

- **Promote development**
  - **Organization of na activity/sector**
  - **Manage Risks/Address concerns**
    - Predictability
    - Legal certainty
    - Cost reduction
    - Increased efficiency and competitiveness

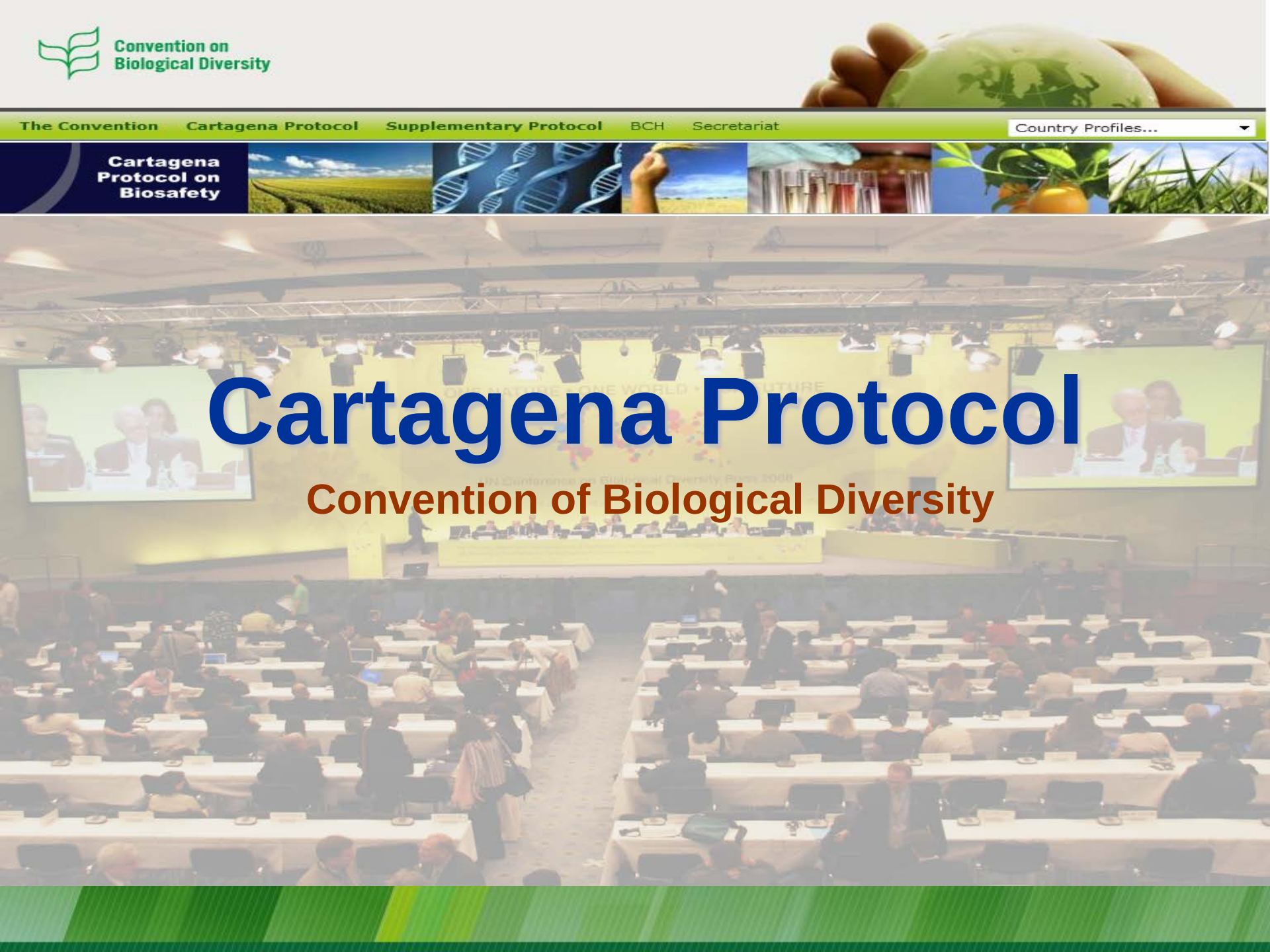
- **Legal basis and Policy**

International/Regional Harmonization

- **Benefits**
  - Exchange or transfer of knowledge
  - Financial Incentives
  - Reducing Barriers to Trade
  - Global development

Internacional/Regional Harmonization

- **Difficulties**
  - Distinct technological and economic levels
  - Asymmetric regulatory framework
  - Distinct domestic and geopolitical interests



Cartagena Protocol

Convention of Biological Diversity

Cartagena Protocoal – Key points

- **Transbondary movement (import and export)**
- **Advanced Informed Agreement – previously to any GMO movement**
- **Risk Assessment**
- **Documentation and Identification (grains, seeds, animals, research material)**
- **Cooperation**

- 1999. Ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology
- **CAC/GL 44-2003 - Principles for the Risk Analysis of Foods Derived from Modern Biotechnology**
- CAC/GL 45-2003 Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- **CAC/GL 68-2008 Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals**
- Codex Committee on Food Labelling (CCFL)

Working Group on Harmonization of Regulatory Oversight in Biotechnology

Consensus Documents

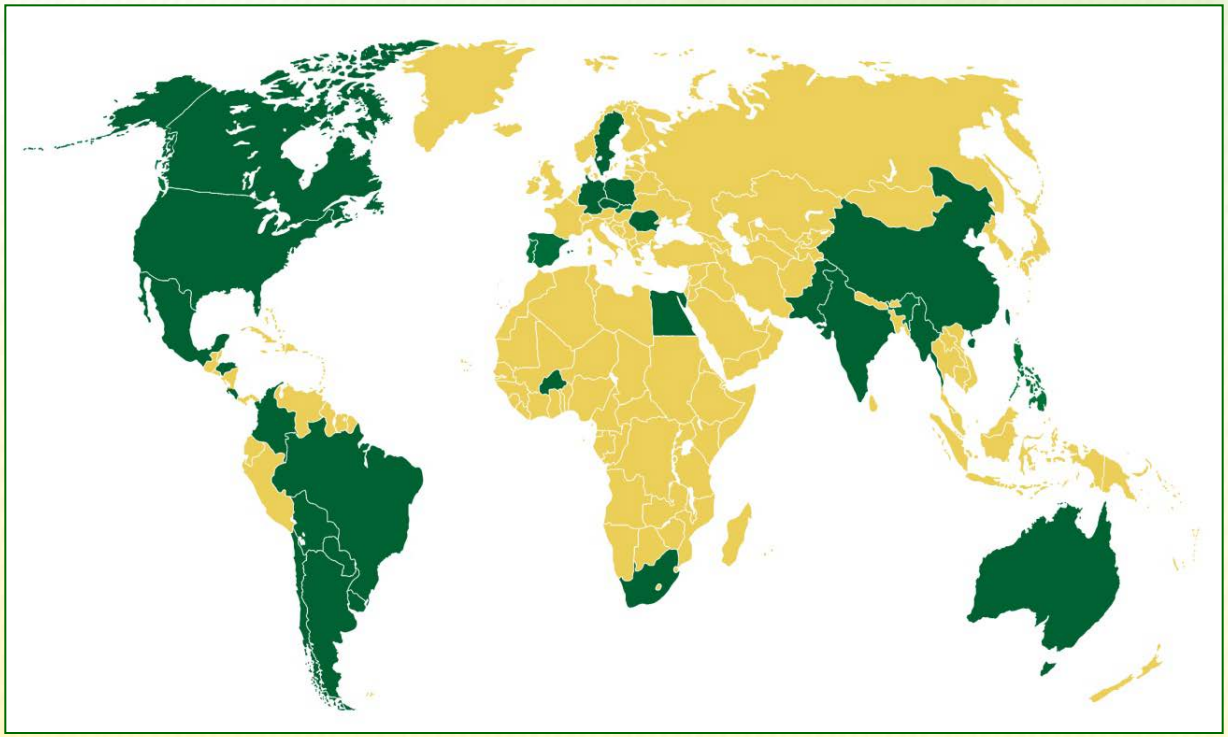
(Reference Materials)

Regional Arrangements

Examples:

- Grupo Ad hoc de Biotecnologia Agropecuária do Mercosul (GAHBA)/Mercosul
- **Conselho Agropecuário do Sul – Grupo de Trabalho nº 05**
- **North American Biotechnology Initiative – NABI**

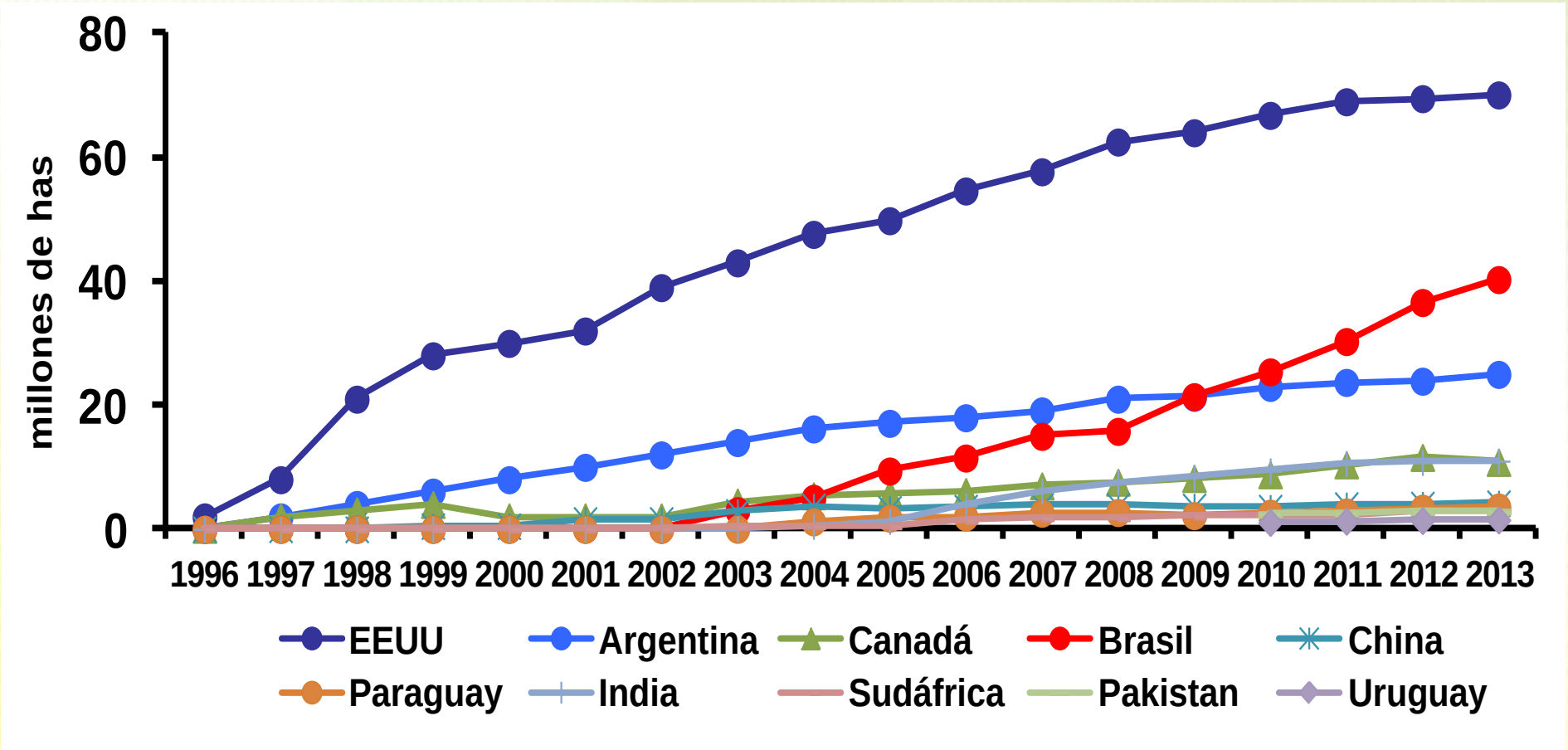
GM Crops in the World



Soybean – corn – cotton – canola - others

- **29 countries cultivating GM Plants**
- **170 million hectares**

Evolução da superfície cultivada com OGM, por país



Fuente: ISAAA, 2013

Biotecnology Regulation in Brazil

- **Law nº 8.974/95 (1st Law of GMO Biosafety)**
- **Law nº 11.105/05 (2nd Law of GMO Biosafety)**
- **Decree nº 6.041/2007 – National Policy for Biotechnology Development**

GM crops Approved (37)

Maize (19)
T25 – Liberty Link
MON 810 - YieldGard
Bt11
NK 603 - Roundup Ready 2
GA21
TC 1507 - Herculex
MIR162 - Viptera
MON 810 x NK603 – YieldGard/RR2
Bt11 x GA21
MON 89034 – YieldGard VT Pro
TC1507 x NK603
MON 89034 x NK 603 – YieldGard VT Pro
Bt 11 x MIR 162 x GA21
MON 88017 - YieldGard VT Rootworm/RR2
MON 89034 x TC 1507 x NK 603
TC 1507 x MON 810 x NK 603
TC 1507 x MON 810
MON 89034 x MON 88017
TC1507 x DAS-59122-7
Beans (1)
EMBRAPA 5.1

Cotton (12)
MON 531 - Bolgard I
LLCOTTON25 – Liberty Link
MON 1445 – Roundup Ready
281-24-236/3006-210-23 Widestrike
MON 15985 - Bolgard II
MON 531 x MON 1445
GHB 614 – GlyTol
GHB 119 x T 304-40 – TwinLink
MON 88913
GlyTol x TwinLink
GlyTol x LibertyLink
MON 15985 X MON 88913
Soybean (5)
GTS-40-3-2 – Roundup Ready
BSP-CV127-9 - Cultivance
A-2704-12 - Liberty Link
A 5547-127 – Liberty Link
MON 87701 x MON 89788 – Intacta RR2 PRO™

Source: CTNBio, May , 2014

GM crops currently on the Market in Brazil

Maize (16) Event / Commercial Name
MON 810 – YieldGard®
Bt11 – Agrisure TL®
NK 603 – Milho RR2®
GA21 – GA21®-TG
Herculex I® – TC 1507
MIR 162 – Agrisure Viptera
MON 810 x NK 603 – YieldGard RR2®
Bt11 x GA21 – Agrisure TL/TG®
MON 89034 – YieldGard VT PRO®
TC1507 x NK603 – Herculex I RR (HR)®
MON89034 x NK603 – YieldGard VT PRO 2®
Bt11 x MIR162 x GA21 – Viptera TL/TG®
MON89034 x TC1507 x NK603 – VT PRO MAX/ Powercore®
MON810 x TC1507 x NK603 – YieldGard Herculex I RR (YHR) ®
TC1507 x MON810 – YieldGard Herculex I (YH)®
MON89034 x MON88017 – YieldGard VT PRO 3®

Cotton (10) Event / Commercial Name
MON 531 – Bollgard I®
LLCOTTON25 – Liberty Link
MON 1445 – Roundup Ready
281-24-236/3006-210-23 – Widestrike
MON 15985 – Bolgad II
MON 531 X MON 1445 – Bollgard®/RR
MON 88913 – Roudup Ready Flex®
GHB614 x T604-40 x GHB119 – Algodão Glytol x TwinLink
GHB614 x LLCOTTON25 – Algodão Glytol x Liberty Link
MON15985 x MON88913 – Bollgard® II RR Flex (B2RF)

Soybean (2) Event / Commercial Name
GTS40-3-2 (MON 04032-6) – Soja RR
MON 87701 x MON 89788 – Soja Intacta RR2 Pro

Source: CTNBio, May 19th

Production of GM crops in Brazil

(in millions of tonnes)

Soybean 89,94

1. Mato Grosso 26,03
2. Paraná 14,22
3. Rio Grande do Sul 12,38

Maize 78,38

1. Mato Grosso 18,73
2. Paraná 16,33
3. Mato Grosso do Sul 7,73

Cotton 1,73

1. Mato Grosso 0,92
2. Bahia 0,54
3. Mato Grosso do Sul 0,07

Source: Céleres. Informativo Biotecnologia, april 2014

Adoption rate of GM crops in Brasil

(by area)

Soybean
91,8%

In millions of hectares:
Conventional
2,45
GM
27,41
TOTAL
29,86

Maize
81,6%

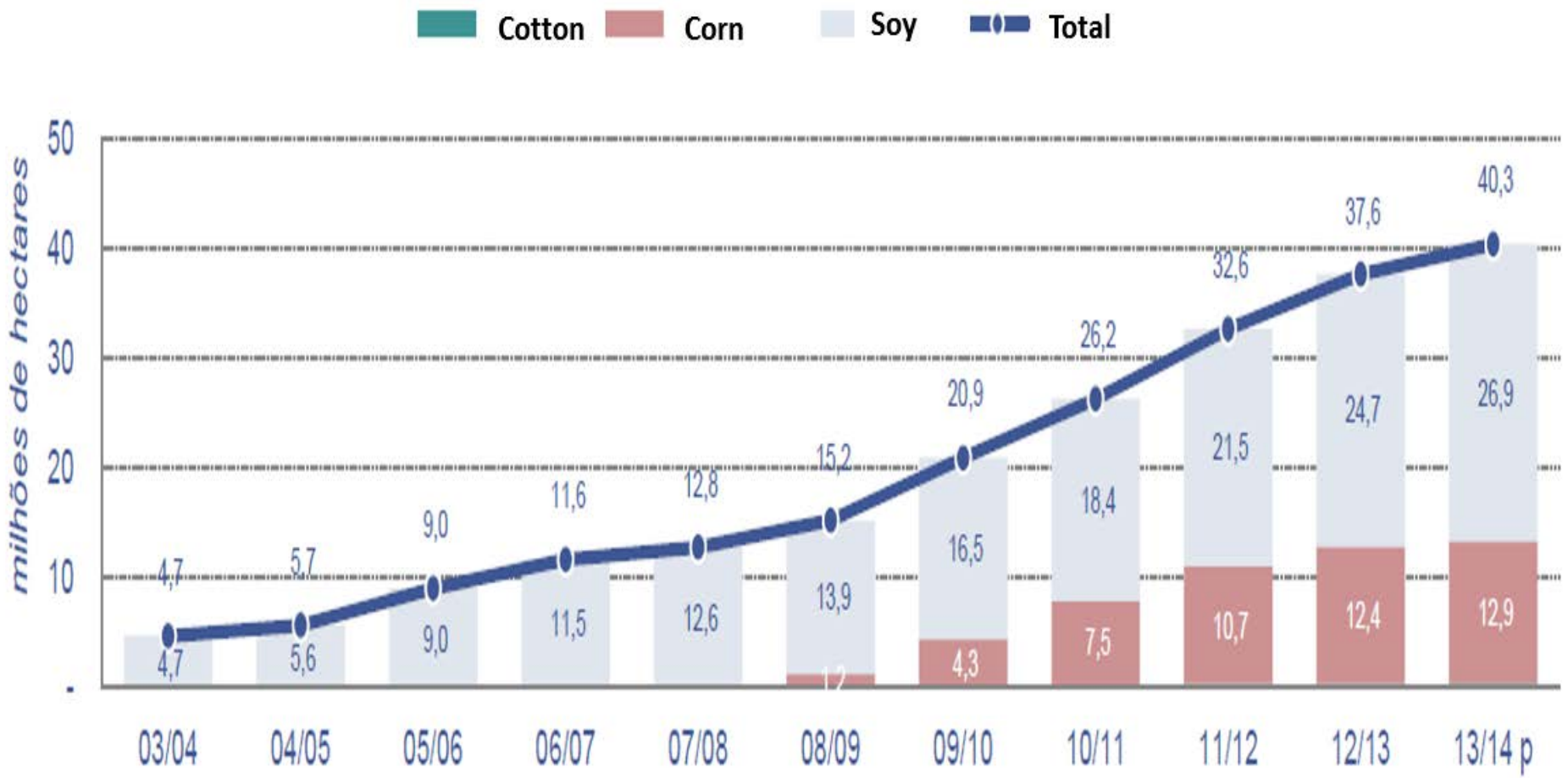
Conventional
2,82
GM
12,45
TOTAL
15,27

Cotton
65%

Conventional
0,39
GM
0,71
TOTAL
1,10

Source: Céleres. Informativo Biotecnologia, abril 2014

Biotechnology Adoption in Brazil
(million hectares)



Source: CÉLERES

Low Level Presence

Presence of traces of GMOs that are authorized in the exporting country but is not yet authorized in the importing country

LLP – Regulatory Options

Zero Tolerance Policy

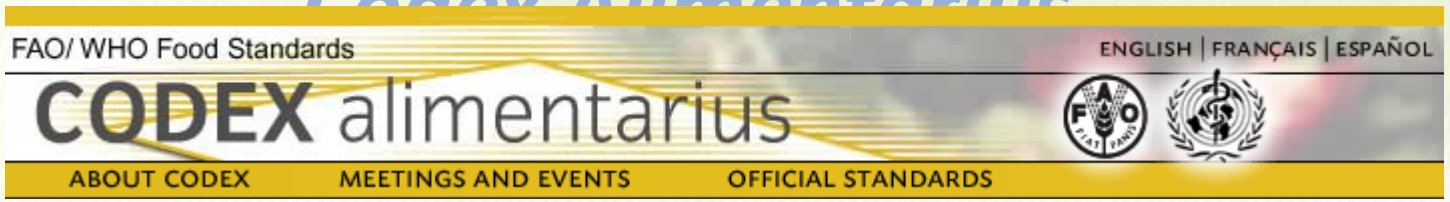
X

Threshold Policy

X

Functional Regulatory Systems (full authorization)

Low Level Presence



Complementary Guideline for LLP

Guidelines for GMO Detection

“Global Initiative on LLP”

- **Argentina, Australia, Brasil, Canada, Chile, Costa Rica, Indonesia, México, África do Sul, EUA, Rússia, Uruguay e Vietnam**
- **Observers: China e UE**
- **Objective: To discuss regulatory options to manage globally the issue of LLP in agricultural products**

Lessons from Harmonization process in Plant Biotechnology

- **Harmonization x Feasibility**: Complex and difficult, but it must be pursued. In the immediate impossibility, regional or bilateral group for exchange of legal framework / experiences / solutions is extremely useful.

- **Harmonization x Time**: anticipation of relevant issues is beneficial and distinction between scientific and political aspects highly relevant

- **Harmonization x Scope**: prevent attempts to harmonize legislation as a whole. Focus on objective technical aspects (risk assessment, eg.)

Lessons from Harmonization process in Plant Biotechnology

- **Harmonization and Stakeholders**: support of independent experts, academia and industry contributes heavily.

- **Harmonization x Institutionality**: strengthen discussion and commitments in international fora

- **Harmonization x Context**: establish a regulatory/internal policy before pursuing international harmonization

Technical Topics that might be useful to have some Harmonization

- **Environmental Risk Assessment**
- **Characterization of the Events**
- **Detection**
- **Approach for labeling**

Obrigado!

Coordenação de Biossegurança/SDA/MAPA

cbio@agricultura.gov.br
Fone: 55 – 61- 3218-2320