

NATIONAL POLICIES TO ADDRESS LLP: COLOMBIA'S APPROACH

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Disclaimer

The opinions expressed are those of the presenter, and do not reflect those of the National Food and Drug Surveillance Institute – INVIMA or the Colombian Government.

Colombia's Biosafety Story

- Several types of authorization:

- Food  Ministry of Health and Social Protection

- Feed  Ministry of Agriculture

- Field trials  Ministry of Agriculture

- Seed  Ministry of Agriculture

- Environmental  Ministry of Environment

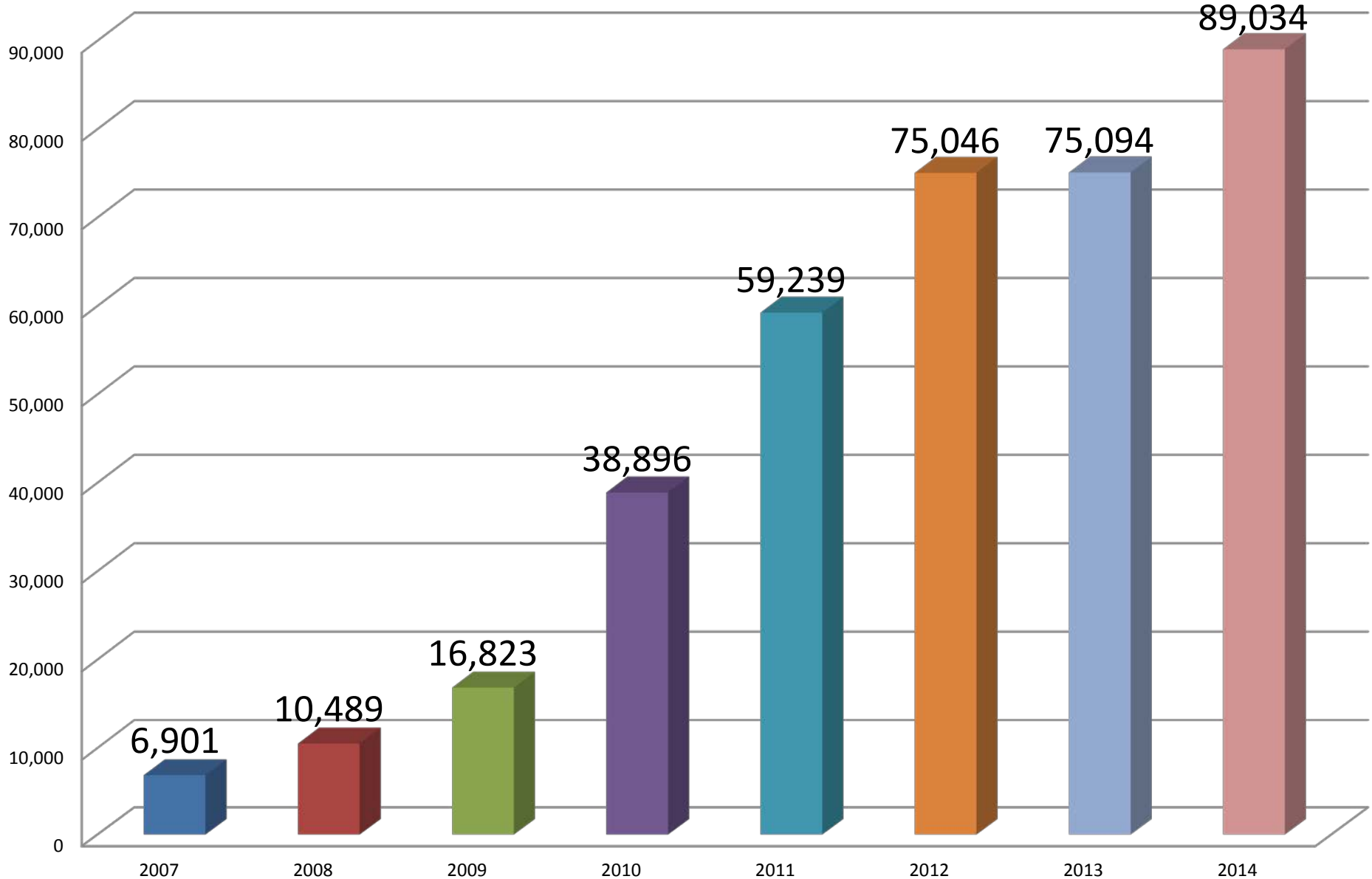
- * They may be independent or the same event may have several approvals

- * Stacked events also have individual authorizations

Colombia's Biosafety Story

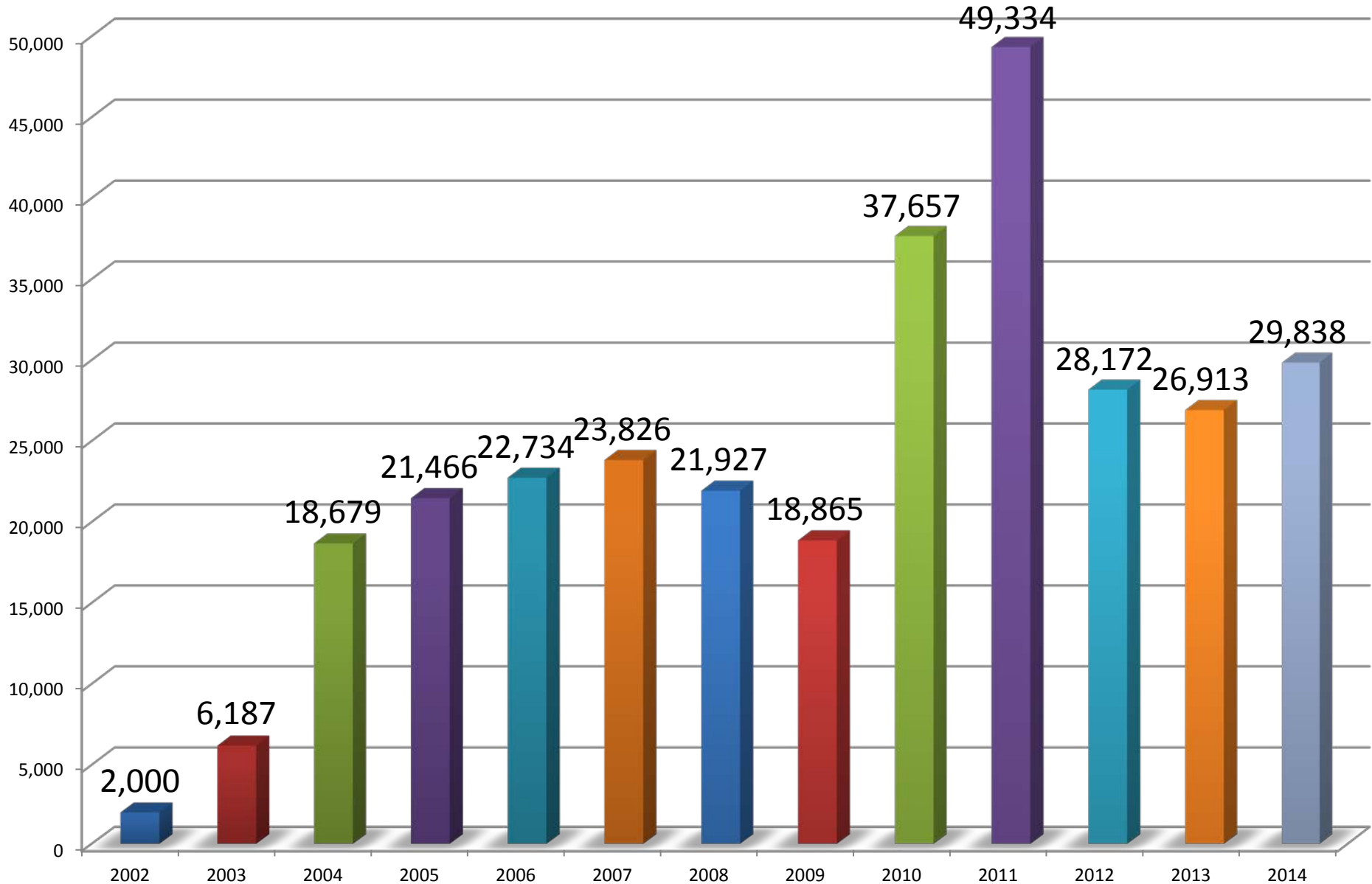
- Research: Coffee, Cassava, Sugarcane, Potato
- Food approvals (August 2015):
 - 34 single events
 - 29 stacked events
 - 21 pending authorization resolution
 - 12 events under study

GM Maize adoption 2007-2014 (Ha/Year)



Data from the Colombian Agropecuary Institute -ICA

GM Cotton adoption 2007-2014 (Ha/Year)



Data from the Colombian Agropecuary Institute -ICA

Labelling and identification approach

- Why was this needed?
 - PUBLIC INTEREST LAWSUIT

Against:

- Ministry Of Health and Social Protection
- Ministry of Agriculture
- Ministry of Commerce
- Colombian Agropecuary Institute – ICA
- National Food and Drug Surveillance Institute –INVIMA

Labelling and identification approach

- Resolution 4254 of 2011 → Labelling is compulsory when, due to the genetic modification, at least one of this conditions occurs:
 - No substantial equivalence
 - Storage, preparation or cooking of the food differs
 - Presence of an allergen not expected
 - Organoleptic differences

Resolution 4254 of 2011

- Not permitted declarations:
 - “GMO free”
 - “No GMO’s”
- Unless the manufacturer can demonstrate that his declaration is true and not misleading through laboratory analysis and traceability.
- Identification of raw materials – Grains
 - May Contain

Not required by the court but in compliance with the Cartagena Protocol decisions

Definition: Low Level Presence

Low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline on the Conduct of Food Safety Assessment of Food from Recombinant-DNA Plants (CAC/GL 45-2003) may be present in food in countries, but may on occasion be present in food in countries in which the food safety of the relevant recombinant-DNA plants has not been determined

TRANSITORY MEASURE

Background: Maize certification

ITEM	BASIC	CERTIFIED
Pure seed (minimum) %	98	98
Inert Material (maximum) %	2	2
Seed out of type/kg (maximum)	1	4
Other crops seed/kg (maximum)	0	1
Weed seeds/kg	0	0
Humidity (maximum)	14	14
Germination (minimum) %	90	90

Ministry of Agriculture Regulation 397 (Oct. 31/1974)

Draft of the Technical Annex of the Resolution 4254 of 2011

- List of events ~~the shipment~~
- May contain
- Industry demanded a threshold
 - Only ~~Seed regulation of~~ certification of maize ~~is~~



Low Level Presence

- Seed: Current legislation 2% for approved maize seed certification. For unapproved events no LLP is established.
 - Currently in the process of revision
- Food: Proposal of a threshold
- Feed: No LLP established, proposal to be the same threshold as for food.

The "Technical Annex"

~~27% of the population~~

~~37% of the population~~

Authorized by another country using the *Codex guideline* that the trait has been previously **been assessed by the committee with satisfactory recommendation.**

The “Technical Annex”

- Identification of shipments:
 - This shipment of grains contains GMOs destined for food
 - when the identity is known
 - This shipment is not destined for its intentional release into the environment
 - when not authorized for cultivation or GMOs present are unknown

The “Technical Annex”

- <5% threshold for the detection of the single events:
 - The event doesn't have a negative recommendation by the Biosafety Committee
 - The event has been authorized in another country using the *Codex alimentarius* guidelines
 - Cumulative for the individual detection of the parental events

Main concerns:

- How to support and provide scientific evidence for the 5% threshold on LLP for food and feed?
- If >5% is detected, what action should be taken?
Codex annex?
- Reference material for quantification of unauthorized events.
- Costs of monitoring and implementing de LLP policy
- Cumulative
- Breeding Stacks
- Is dilution permitted?

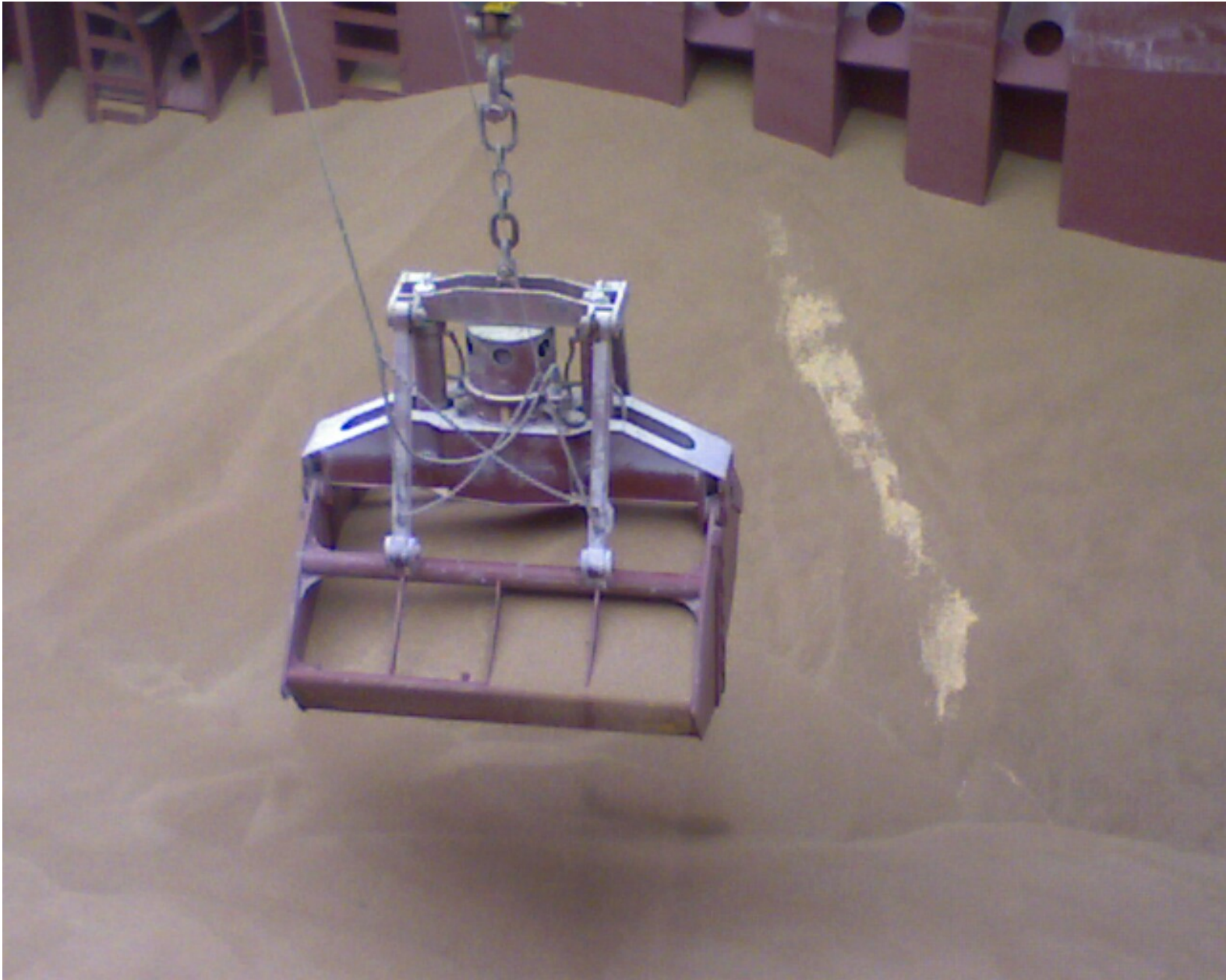
Challenges:

- Bureaucracy
- Being very proactive
- Lawsuits
- Trade with partners, exportation of processed food
- Health sector promoting the establishment of the LLP – feed/seed

New Challenges

- Ruling of the Constitutional court: Sentence C-580/15 (September 8th, 2015)
- The court determined that the minimum information that should be given to the consumer should specify if it contains GMO's or the percentage of GMO in its components that it contains, and orders the congress to generate a law within two years.

Colombia's reality



THANK YOU

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