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### *Biosafety legislation and the regulatory status of the products of precision breeding in the Latin America and the Caribbean region*

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## ***Plants, People, Planet Supporting information***

**Article title:** Biosafety legislation and the regulatory status of the products of precision breeding in the Latin America and the Caribbean region

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The following Supporting Information is available for this article:

**Table S1.** Survey form on regulatory matters on precision breeding in the LAC region.

**Table S2.** Survey form on research and development activities on precision breeding in the LAC region.

**Table S3.** List of institutions that responded the survey in regulatory matters on precision breeding in the LAC region.

**Table S4.** List of institutions that responded the survey in research and development activities on precision breeding in the LAC region.



	<p>If yes:</p> <p>3.2. who?</p> <p>3.3. Which of the following stakeholder groups are represented?</p> <p><input type="checkbox"/> National Competent Authorities</p> <p><input type="checkbox"/> Governmental agencies</p> <p><input type="checkbox"/> Academia</p> <p><input type="checkbox"/> Civil Society</p> <p><input type="checkbox"/> Farmers</p> <p><input type="checkbox"/> Other (Please specify):</p> <p>3.4. Is/did any external agency(ies)/organization(s) providing/provide advise and/or guidance in this process?</p> <p><input type="checkbox"/> No            <input type="checkbox"/> Yes</p> <p>3.5. If yes, which?</p> <p>3.6. Is/did the process considering alignment with any legal framework in other jurisdiction?</p> <p><input type="checkbox"/> No            <input type="checkbox"/> Yes</p> <p>3.7. If yes, which country?</p> <p>3.8. When is the new legal framework expected to be promulgated?</p>
	<p>4. Which is/will be trigger for the regulation?</p> <p><input type="checkbox"/> The use of emerging biotechnologies</p> <p><input type="checkbox"/> Being a product with certain properties</p> <p><input type="checkbox"/> A combination of both product and process</p> <p><input type="checkbox"/> Other (Please specify):</p>
<p>III: Regulatory aspects</p>	<p>5. Does/will your country consider any product derived from NPBTs have to be treated as Genetically Modified Organisms (GMOs)? *</p> <p><input type="checkbox"/> No            <input type="checkbox"/> Yes            <input type="checkbox"/> Still under discussion</p> <p>If yes:</p>

5.1. Which products derived from the following NPBTs should be treated as GMOs?

Products derived from:

- Genome editing techniques, such as: Oligonucleotide-directed mutagenesis (ODM) or Site-directed nucleases (SDNs)
- Epigenetic modification, such as RNA-directed DNA methylation (RdDM)
- Gene drive systems
- Agroinfiltration
- Cis-/intra-genesis
- Grafting
- Reverse breeding
- RNA interference
- Synthetic biology
- All of above
- Others (Please specify):

5.2. And why?

5.3. Which of the following provisions from your national biosafety regulatory system of GMOs will apply?

- Detection and identification
- Liability and redress
- Risk assessment (including environmental risk assessment, food and feed safety assessment)
- Risk management measures (monitoring and surveillance)
- Risk communication strategies (information sharing)
- Public participation
- Socio-economic considerations
- All of above
- Others (Please specify):

6. Does/will your country consider that NPBTs and/or its products that are not treated as GMOs will be subject to a new risk regulation? \*

No             Yes             Still under discussion

If yes:

6.1. Why?

6.2. How will this new risk regulation work?

7. Does/will your legal framework for NPBTs distinguish between different types of activities, such as for research and development (R&D) and commercial purposes? \*

No             Yes             Still under discussion

If yes:

7.1. Does/will the system regulate:

Contained use (Lab/greenhouse/glasshouse facilities)

Confined use (confined field trials)

Commercial-scale cultivation

Importation of products for food, feed or processing (FFPs)

Other (please specify):

8. Are there any institutions (governmental or private) authorized to use NPBTs and/or its products in your country? \*

No             Yes

If yes:

8.1. Please indicate their name

8.2. Event(s) of which crop categories is/are being authorized?

If possible, provide examples.

Cereals:

Pulses:

Oil crops:

Root and tuber crops:

Forage crops:

Fruit and berry crops:

Fiber crops:

Other (Please specify):

8.3. Which activity/-ies are being authorized?

Contained use (Lab/greenhouse/glasshouse facilities)

Confined use (confined field trials)

Commercial-scale cultivation

Importation of products for FFPs

Other (please specify):

**Table S2.** Survey form on research and development activities on precision breeding in the LAC region.

Sections	Questions
I: Identification [ <i>This section will be kept confidential</i> ]	Country:
	Institution:
	Name of interviewee:
	Position held:
	Date:
II: Technical aspects	1. Does your institution deal with research and development activities on NPBTs? <input type="checkbox"/> No <input type="checkbox"/> Yes  If yes:  1.1. Which of the following NPBTs are being used in your institution?  <input type="checkbox"/> Genome editing techniques, such as: Oligonucleotide-directed mutagenesis (ODM) or Site-directed nucleases (SDNs)  <input type="checkbox"/> Epigenetic modification, such as RNA-directed DNA methylation (RdDM)  <input type="checkbox"/> Gene drive systems  <input type="checkbox"/> Agroinfiltration  <input type="checkbox"/> Cis-/intra-genesis  <input type="checkbox"/> Grafting  <input type="checkbox"/> Reverse breeding  <input type="checkbox"/> RNA interference  <input type="checkbox"/> Synthetic biology  <input type="checkbox"/> All of above  <input type="checkbox"/> Others (Please specify):
	2. Event(s) of which crop categories are being used?  If possible, provide examples.  <input type="checkbox"/> Cereals:



	<p><input type="checkbox"/> Pulses:</p> <p><input type="checkbox"/> Oil crops:</p> <p><input type="checkbox"/> Root and tuber crops:</p> <p><input type="checkbox"/> Forage crops:</p> <p><input type="checkbox"/> Fruit and berry crops:</p> <p><input type="checkbox"/> Fiber crops:</p> <p><input type="checkbox"/> Other (Please specify):</p> <hr/> <p>3. Under which level of confinement is your research being carried out?</p> <p><input type="checkbox"/> Contained use (Lab/greenhouse/glasshouse facilities)</p> <p><input type="checkbox"/> Confined use (confined field trials)</p> <p><input type="checkbox"/> Others (Please specify):</p>
<p>III:      Regulatory aspects</p>	<p>4. Are you aware of any existing legal framework to regulate the use of NPBTs and/or its products in your country?</p> <p><input type="checkbox"/> No                      <input type="checkbox"/> Yes</p> <p>If yes,</p> <p>4.1. Which?</p> <hr/> <p>5. Are you aware of any proposal of legal framework for NPBTs currently under development in your country?</p> <p><input type="checkbox"/> No                      <input type="checkbox"/> Yes</p> <p>If yes:</p> <p>5.1. Are you member of any advisory committee or group of experts where these discussions take place?</p> <p><input type="checkbox"/> No                      <input type="checkbox"/> Yes</p> <p>5.2. If yes, which?</p> <hr/> <p>6. Did you receive any authorization from a National Authority (if any) to use NPBTs in your facilities?</p> <p><input type="checkbox"/> No                      <input type="checkbox"/> Yes</p>

If yes,

6.1. Who granted to you this authorization?

7. Do you consider any product derived from NPBTs have to be treated as Genetically Modified Organisms (GMOs)?

No             Yes             Still under discussion

If yes:

7.1. Which of the following products derived from NPBTs should be treated as GMOs?

Products derived from:

Genome editing techniques, such as: Oligonucleotide-directed mutagenesis (ODM) or Site-directed nucleases (SDNs)

Epigenetic modification, such as RNA-directed DNA methylation (RdDM)

Gene drive systems

Agroinfiltration

Cis-/intra-genesis

Grafting

Reverse breeding

RNA interference

Synthetic biology

All of above

Others (Please specify):

None

7.2. And why?

**Table S3.** List of institutions that responded the survey in regulatory matters on precision breeding in the LAC region.

<b>Country</b>	<b>National Competent Authority, Governmental Agency or Biosafety National Commission</b>
Antigua and Barbuda	Ministry of Agriculture, Fisheries and Barbuda Affairs (MAFBA)
Brazil	National Technical Commission on Biosafety (CTNBio)
Colombia	Alexander von Humboldt Research Institute of Biological Resources
Costa Rica	National Office of Seeds (ONS)
Cuba	Office of Environmental Regulation and Safety (ORSA)
Dominican Republic	Ministry of Environment and Natural Resources (MIMARENA)
Ecuador	Ministry of Environment, Water and Ecological Transition (MAATE)
El Salvador	Ministry of Environment and Natural Resources (MARN)
Grenada	Ministry of Agriculture, Lands, Forestry and Fisheries
Honduras	National Academy of Sciences
Mexico	National Commission for the Knowledge and Use of Biodiversity (CONABIO)
Mexico	Inter-secretarial Commission of Biosafety of GMOs (CIBIOGEM)
Panama	Ministry of Environment (MiAMBIENTE)
Paraguay	Ministry of Agriculture and Livestock (MAG)
Peru	Ministry of Environment (MINAM)
Saint Kitts and Nevis	Ministry of Agriculture, Marine Resources, Cooperatives, Environment and Human Settlement
Saint Lucia	Ministry of Education, Innovation, Gender Relations and Sustainable Development
Suriname	Foundation for National Rice Research (SNRI)
Venezuela	Ministry of Popular Power and Eco-socialism (MINEC)

**Table S4.** List of institutions that responded the survey in research and development activities on precision breeding in the LAC region.

<b>Country</b>	<b>University, National Research Center or International Research Organization</b>
Argentina	National Institute of Agricultural Technology (INTA)
Argentina	University of Buenos Aires (UBA)
Brazil	Federal University of Pernambuco (UFPE)
Chile	Agricultural Research Institute (INIA)
Colombia	National University of Colombia (UNAL)
Colombia	Pontifical Xavierian University
Colombia	EAFIT University (EAFIT)
Colombia	International Center for Tropical Agriculture (CIAT)
Costa Rica	University of Costa Rica (UCR)
Cuba	Institute of Plant Biotechnology (IBP)
Cuba	Center of Genetic Engineering and Biotechnology (CIGB)
Ecuador	University of San Francisco of Quito (USFQ)
Ecuador	Armed Forces University (ESPE)
El Salvador	National Center for Agricultural Technology and Forestry (CENTA)
Honduras	Autonomous National University of Honduras (UNAH)
Paraguay	Paraguayan Institute of Agrarian Technology (IPTA)
Paraguay	National University of Asuncion (UNA)
Peru	National Institute of Agricultural Innovation (INIA)
Uruguay	University of the Republic (UDELAR)
Venezuela	Foundation Institute of Advanced Studies (IDEA)