

**ELEMENTS OF STRATEGIC PLAN FOR THE CARTAGENA PROTOCOL ON BIOSAFETY**

**VISION**

*Biological diversity is adequately protected from any adverse effects of living modified organisms*

**MISSION**

*To strengthen global, regional & national action and capacity in ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements*

<i>Strategic Objective</i>	<i>Expected Impacts</i>	<i>Operational Objectives</i>	<i>Outcomes</i>	<i>Indicators</i>
<p><b>Focal area 1:</b></p> <p><b>Facilitating the establishment and further development of effective biosafety systems for the implementation of the Protocol</b></p> <p>To put in place further tools and guidance necessary to make the Protocol fully operational</p>	<p>Full implementation of the Cartagena Protocol on Biosafety by Parties</p> <p>Enhanced performance by Parties towards the attainment of the overarching objectives of conservation and sustainable use of biological diversity</p>	<p>1.1 National Biosafety Frameworks</p> <p>To enable all Parties to have operational national biosafety frameworks in place for the implementation of the Protocol</p>	<ul style="list-style-type: none"> <li>• Decisions regarding the safety of a living modified organism are based on established regulatory and administrative rules consistent with the Protocol</li> <li>• Biosafety issues and the implementation of the Biosafety Protocol are integrated into the relevant sectors</li> </ul>	<ul style="list-style-type: none"> <li>• Number of Parties, in particular centers of origin, that have in place national biosafety legislation and implementing guidelines not more than 6 years after accession to/ratification of the Protocol</li> <li>• Percentage of the Parties that have in place administrative rules and procedures for handling notifications and requests for approval of imports of LMOs intended for direct use as food or feed, or for processing; contained use and for introduction into the environment</li> <li>• Percentage of Parties that have designated national focal points and competent national authorities</li> <li>• Percentage of Parties that have received notifications in accordance with Article 8 of the Protocol or appropriate domestic legislation.</li> <li>• Percentage of Parties that have taken import decisions in accordance with Article 10 of the Protocol or appropriate domestic legislation.</li> </ul>

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		<p>1.2 Coordination and support</p> <p>To put in place effective mechanisms for developing biosafety systems with the necessary coordination, financing and monitoring support</p>	<ul style="list-style-type: none"> <li>• Improved understanding of the capacity-building needs of developing country Parties and Parties with economies in transition</li> <li>• A cohesive approach and effective mechanisms established for biosafety capacity-building</li> <li>• Parties have adequate and predictable financial and technical resources to enable them to implement their obligations under the Protocol in an integrated and sustainable manner</li> <li>• National biosafety capacity-building strategies and action plans by each Party in place and implemented</li> <li>• Existing resources and opportunities leveraged and more effectively used</li> <li>• Improved coordination and collaboration between Parties and entities implementing or funding biosafety capacity-building efforts</li> <li>• Improved coordination and collaboration between LMO importing and exporting Parties</li> </ul>	<ul style="list-style-type: none"> <li>• Number of Parties that have assessed their capacity-building needs, including training and institutional needs, and submitted the information to the BCH not more than 3 years after accession to/ratification of the Protocol</li> <li>• Percentage of the Parties that have developed national biosafety capacity-building action plans for implementing the Protocol</li> <li>• Percentage of the Parties that have in place training programmes for personnel dealing with biosafety issues and for long-term training of biosafety professionals</li> <li>• Percentage of Parties that have in place national coordination mechanisms for biosafety capacity-building initiatives</li> <li>• Amount of new and additional financial resources mobilized for the implementation of the Protocol</li> <li>• Number of Parties that have predictable and reliable funding for strengthening their capacity in implementing the Protocol</li> <li>• Number of Parties reporting that their capacity-building needs have been met</li> <li>• Number of cooperative arrangements reported involving LMO exporting and importing Parties</li> </ul>

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		<p>1.3 Risk assessment and risk management</p> <p>To further develop and support implementation of scientific tools on common approaches to risk assessment and risk management for Parties</p>	<ul style="list-style-type: none"> <li>• Guidance on risk assessment and risk management including guidance on new developments in modern biotechnology</li> <li>• Common approaches to risk assessment and risk management established and adopted by Parties and other Governments, as appropriate</li> </ul>	<ul style="list-style-type: none"> <li>• Percentage of Parties adopting and using guidance documents on risk assessment and risk management for the purpose of:                             <ul style="list-style-type: none"> <li>○ Performing their own risk assessment and risk management;</li> <li>○ Evaluating risk assessment reports submitted by notifiers.</li> </ul> </li> <li>• Percentage of Parties adopting common approaches to risk assessment and risk management</li> <li>• Percentage of Parties that undertake actual risk assessment pursuant to the Protocol.</li> </ul>
		<p>1.4 LMOs or traits that may have adverse effects</p> <p>To develop modalities for cooperation and guidance in identifying LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health</p>	<ul style="list-style-type: none"> <li>• Modalities developed and put in place</li> <li>• Parties enabled to identify, assess, and monitor LMOs or specific traits that may have adverse effects</li> </ul>	<ul style="list-style-type: none"> <li>• Guidance on living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, developed by Parties and available</li> <li>• Number of Parties that have the capacity to identify, assess and monitor living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.</li> </ul>

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		<p>1.5 Liability and Redress</p> <p>To adopt and implement the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.</p>	<ul style="list-style-type: none"> <li>Each Party takes administrative and legal measures necessary to implement the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety at the domestic level</li> </ul>	<ul style="list-style-type: none"> <li>Entry into force of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety prior to the seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol</li> <li>Percentage of Parties to the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety having in place national administrative and legal frameworks incorporating rules and procedures on liability and redress for damage caused by living modified organisms</li> </ul>
		<p>1.6 Handling, transport, packaging and identification</p> <p>To enable Parties to implement the requirements of the Protocol and COP-MOP decisions on identification and documentation requirements for living modified organisms</p>	<ul style="list-style-type: none"> <li>All shipments of living modified organisms intended for direct use as food or feed, or for processing, contained use or intentional introduction into the environment are identified through accompanying documentation in accordance with the requirements of the Protocol and COP-MOP</li> </ul>	<ul style="list-style-type: none"> <li>Percentage of Parties that put in place documentation requirements for living modified organisms intended for direct use as food or feed, or for processing</li> <li>Percentage of Parties that put in place documentation requirements for living modified organisms for contained use and for intentional introduction into the environment</li> <li>Number of Parties with access to tools that</li> </ul>

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			<p>decisions</p> <ul style="list-style-type: none"> <li>• Easy to use and reliable technical tools for the detection of unauthorized LMOs are developed and made available</li> <li>• Existing guidance for handling, transport and packaging of LMOs is used</li> </ul>	<p>are capable of detecting unauthorized LMOs.</p> <ul style="list-style-type: none"> <li>• Number of Parties using guidance developed for the handling, transport and packaging of LMOs</li> </ul>
		<p>1.7 Socio-economic considerations</p> <p>To, on the basis of research and information exchange, provide relevant guidance on socio-economic considerations that may be taken into account in reaching decisions on the import of living modified organisms</p>	<ul style="list-style-type: none"> <li>• Peer reviewed research relevant to socio-economic considerations, taking into account the modality of peer review as specified in section E, Annex III of decision VIII/10</li> <li>• Guidelines regarding socio-economic considerations of living modified organisms developed and used, as appropriate, by Parties</li> <li>• Socio-economic considerations applied, where appropriate, by Parties</li> </ul>	<ul style="list-style-type: none"> <li>• Number of peer reviewed research papers published, made available and used by Parties in considering socio-economic impacts of LMOs</li> <li>• Number of Parties reporting on their approaches to taking socioeconomic considerations into account</li> <li>• Number of Parties reporting on their experiences in taking socio-economic considerations into account in reaching decisions on import of living modified organisms</li> <li>• Number of Parties using guidelines on socio-economic considerations</li> </ul>

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		<p>1.8 Transit, contained use, unintentional transboundary movements and emergency measures</p> <p>To develop tools and guidance that facilitate the implementation of the Protocol's provisions on transit, contained use, unintentional transboundary movements and emergency measures</p>	<ul style="list-style-type: none"> <li>• Parties enabled to manage LMOs in transit</li> <li>• Guidance developed to assist Parties to detect and take measures to respond to unintentional releases of living modified organisms</li> </ul>	<ul style="list-style-type: none"> <li>• Percentage of Parties having in place measures to manage LMOs in transit</li> <li>• Percentage of Parties having in place measures for contained use</li> <li>• Percentage of Parties using the guidance to detect occurrence of unintentional releases of living modified organisms and being able to take appropriate response measures</li> </ul>
<p><b>Focal area 2:</b></p> <p><b>Capacity building</b></p> <p>2. To further develop and strengthen the capacity of Parties to implement the Protocol</p>	<p>Increased safety in the transfer, handling and use of living modified organisms</p> <p>Effective and efficient regulatory, administrative and monitoring frameworks established by Parties for the implementation of the Protocol</p> <p>Necessary mechanisms put in place to enable</p>	<p>2.1 National Biosafety Frameworks</p> <p>To further support the development and implementation of national regulatory and administrative systems.</p>	<ul style="list-style-type: none"> <li>• National Biosafety Frameworks developed and implemented</li> </ul>	<ul style="list-style-type: none"> <li>• Number of Parties with operational regulatory frameworks</li> <li>• Number of Parties with functional administrative arrangements</li> </ul>

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	<p>Parties to make science-based risk assessments</p> <p>More transparent and expeditious decision-making</p> <p>Full use of information exchange systems</p>	<p>2.2 Risk assessment and risk management</p> <p>To enable Parties to evaluate, apply, share and carry out risk assessments and establish local science-based capacities to regulate, manage, monitor and control risks of LMOs</p>	<ul style="list-style-type: none"> <li>• Resources, including human resources required to assess risks of living modified organisms are available and administrative mechanisms are in place</li> <li>• Training materials and technical guidance on risk assessment and risk management developed and used by Parties</li> <li>• Infrastructure and administrative mechanisms established for the management of risks of living modified organisms at national, subregional or regional level</li> </ul>	<ul style="list-style-type: none"> <li>• Ratio of risk assessment summary reports as against number of decisions on LMOs on the BCH</li> <li>• Number of risk assessment summary reports in the BCH that are in compliance with the Protocol</li> <li>• Number of people trained on risk assessment, as well as in monitoring, management and control of LMOs</li> <li>• Number of Parties that have infrastructure, including laboratories for monitoring, management and control</li> <li>• Number of Parties that are using the developed training materials and technical guidance</li> <li>• Number of Parties that are of the opinion that the training materials and technical guidance are sufficient and effective</li> </ul>
		<p>2.3 Handling, transport, packaging and identification</p> <p>To develop capacity for handling, transport, packaging and identification of living modified organisms</p>	<ul style="list-style-type: none"> <li>• Customs/border officials are able to enforce the implementation of the Protocol's requirements related to handling, transport, packaging and identification of living modified organisms</li> <li>• Personnel are trained and equipped for sampling, detection and identification of LMOs</li> </ul>	<ul style="list-style-type: none"> <li>• Number of customs officers and laboratory personnel trained</li> <li>• Percentage of Parties that have established or have reliable access to detection laboratories</li> <li>• National and regional laboratories certified with the capacity to detect LMOs</li> <li>• Number of certified laboratories in operation</li> </ul>

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		<p>2.4 Liability and Redress</p> <p>To assist Parties to the Protocol in their efforts to establish and apply the rules and procedures on liability and redress for damage resulting from the transboundary movements of living modified organisms</p>	<ul style="list-style-type: none"> <li>• An institutional mechanism or process identified or established to facilitate the implementation of the international rules and procedures on liability and redress at the national level</li> </ul>	<ul style="list-style-type: none"> <li>• Number of eligible Parties that received capacity building support in the area of liability and redress involving living modified organisms</li> <li>• Number of domestic administrative or legal instruments identified, amended or newly enacted that fulfill the objective of the international rules and procedures in the field of liability and redress</li> </ul>
		<p>2.5 Public awareness, education and participation</p> <p>To enhance capacity at the national, regional and international levels that would facilitate efforts to raise public awareness, and promote education and participation concerning the safe transfer, handling and use of LMOs</p>	<ul style="list-style-type: none"> <li>• Parties have access to guidance and training materials on public awareness, education and participation concerning the safe transfer, handling and use of LMOs</li> <li>• Parties are enabled to promote and facilitate public awareness, education and participation in biosafety</li> </ul>	<ul style="list-style-type: none"> <li>• Percentage of Parties having in place mechanisms for ensuring public participation in decision-making concerning LMOs not later than 6 years after accession to/ratification of the Protocol</li> <li>• Percentage of Parties that inform their public about existing modalities for participation</li> <li>• Number of Parties having in place national websites and searchable archives, national resource centres or sections in existing national libraries dedicated to biosafety educational materials</li> </ul>



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		<p>2.6 Information sharing</p> <p>To ensure that the BCH is easily accessed by all established stakeholders, in particular in developing countries and countries with economies in transition</p>	<ul style="list-style-type: none"> <li>• Increased access to information in the BCH and sharing of information through the BCH by users in developing countries and countries with economies in transition</li> <li>• Tools to facilitate implementation of the Protocol are easily accessible through the BCH</li> <li>• Information on the BCH is easily accessible to stakeholders including the general public</li> </ul>	<ul style="list-style-type: none"> <li>• Number of submissions to the BCH from developing countries and countries with economies in transition</li> <li>• Amount of traffic from users to the BCH from developing countries and countries with economies in transition</li> </ul>
		<p>2.7 Biosafety education and training</p> <p>To promote education and training of biosafety professionals through greater coordination and collaboration among academic institutions and relevant organizations</p>	<ul style="list-style-type: none"> <li>• A sustainable pool of biosafety professionals with various competencies available at national/international levels</li> <li>• Improved biosafety education and training programmes</li> <li>• Increased exchange of information, training materials and staff and students exchange programmes among academic institutions and relevant organizations</li> </ul>	<ul style="list-style-type: none"> <li>• Number of academic institutions by region offering biosafety education and training courses and programmes</li> <li>• Number of biosafety training materials and online modules available</li> </ul>

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<p><b>Focal area 3:</b> <b>Compliance and review</b> To achieve compliance with and effectiveness of the Protocol</p>	<p>Parties are in compliance with the requirements of the Protocol</p>	<p>3.1 Compliance with the Protocol To strengthen the mechanisms for achieving compliance</p>	<ul style="list-style-type: none"> <li>• Each Party fully implements its obligations and regularly monitors the implementation of its obligations under the Protocol</li> <li>• Improved reporting by Parties including by submitting complete and timely national reports</li> <li>• All Parties able to enforce their regulatory frameworks and decisions</li> <li>• Sufficient financial resources are allocated to compliance</li> <li>• The Compliance Committee is able to thoroughly review the implementation of obligations by Parties and to propose appropriate measures</li> <li>• Supportive role of the Compliance Committee is improved</li> </ul>	<ul style="list-style-type: none"> <li>• Number of Parties that have identified and addressed their non-compliance issues</li> <li>• Number of Parties having approved and functional national legal, administrative and other measures to implement the Protocol</li> <li>• Percentage of Parties that designated all National Focal Points</li> <li>• Number of Parties having in place a system for handling requests including for Advance Informed Agreement</li> <li>• Percentage of Parties that published all mandatory information via the BCH</li> <li>• Number of Parties having in place a monitoring and enforcement system</li> <li>• Number of national reports received under each reporting cycle</li> <li>• Number of Parties able to access financial resources to fulfill their obligations under the Protocol</li> </ul>

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		<p>3.2 Assessment and review</p> <p>To improve the effectiveness of the Protocol, including through regular assessment and review processes</p>	<ul style="list-style-type: none"> <li>• Assessment and review of the Protocol, including its procedures and annexes, are undertaken on a regular basis</li> <li>• The Protocol, including its procedures and annexes, is adapted if new challenges are brought about by new developments in the field of modern biotechnology or to adapt to challenges of implementation</li> </ul>	<ul style="list-style-type: none"> <li>• Number of assessment reports submitted and reviews published</li> <li>• Number of Parties modifying their national biosafety frameworks to correspond with amendments to the Protocol adopted to address new challenges</li> </ul>
<p><b>Focal area 4:</b></p> <p><b>Information sharing</b></p> <p>To enhance the availability and exchange of relevant information</p>	<p>Transparency in the development and use of LMOs</p> <p>Increased compliance with national and international requirements</p> <p>Informed decision-making</p> <p>Enhanced public awareness of biosafety</p>	<p>4.1 BCH effectiveness</p> <p>To increase the amount and quality of information submitted to and retrieved from the BCH</p>	<ul style="list-style-type: none"> <li>• The BCH is recognized as the most authoritative repository of information on biosafety</li> <li>• Information submitted to the BCH is accurate, complete and timely</li> <li>• A larger number of countries submit and retrieve information</li> <li>• Risk assessment reports are shared in a timely manner through the BCH</li> <li>• Facilitated access to resources and experiences related to biosafety</li> </ul>	<ul style="list-style-type: none"> <li>• Ratio of risk assessment summary reports as against number of decisions on LMOs</li> <li>• Number of publications contained in the Biosafety Information Resource Centre</li> <li>• Amount of traffic from users to the BCH</li> <li>• Number of references to the BCH</li> <li>• Number of countries with focal points registered on the BCH</li> <li>• Number of countries/regions having published biosafety laws and or regulations on the BCH</li> <li>• Number of AIA/domestic decisions available through BCH</li> <li>• Number of users of the BCH requesting improvement on accuracy, completeness or timeliness of information</li> </ul>

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		<p>4.2 BCH as a tool for online discussions and conferences</p> <p>To establish the BCH as a fully functional and effective platform for assisting countries in the implementation of the Protocol</p>	<ul style="list-style-type: none"> <li>• Countries are better equipped with tools made available through the BCH</li> <li>• The BCH principles of inclusiveness, transparency and equity are applied consistently</li> <li>• Protocol discussions and negotiating processes facilitated through the BCH</li> <li>• Increased awareness of the BCH in different stakeholder groups and regions</li> </ul>	<ul style="list-style-type: none"> <li>• Number of online discussions and real-time conferences carried out through the BCH platform</li> <li>• Percentage of Parties participating in online discussions and real-time conferences on the BCH</li> <li>• Number of participants in online discussions and conferences, their diversity and background</li> <li>• Number of capacity building activities aimed to increase the transparency, inclusiveness and equity of participation in the BCH</li> </ul>
		<p>4.3 Information sharing other than through the BCH</p> <p>To enhance understanding through other information exchange mechanisms</p>	<ul style="list-style-type: none"> <li>• Information sharing enhanced at regional, national and international biodiversity and biosafety meetings</li> <li>• Different modalities and opportunities used to share biosafety related information</li> </ul>	<ul style="list-style-type: none"> <li>• Number of events organized in relation to biosafety</li> <li>• Number of biosafety related publications shared</li> </ul>

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<p><b>Focal area : 5</b></p> <p><b>Outreach and cooperation</b></p> <p>To expand the reach of the Protocol and promote cooperation</p>	<p>Increased political support for the implementation of the Protocol</p> <p>Increased support from and collaboration with relevant organizations, conventions and initiatives for the implementation of the Protocol</p>	<p>5.1 Ratification of the Protocol</p> <p>To achieve global recognition of the Protocol</p>	<ul style="list-style-type: none"> <li>• All Parties to the Convention on Biological Diversity become Parties to the Protocol</li> </ul>	<ul style="list-style-type: none"> <li>• Percentage of Parties to the Convention on Biological Diversity that become Parties to the Protocol</li> </ul>
		<p>5.2 Cooperation</p> <p>To enhance international cooperation and collaboration in biosafety</p>	<ul style="list-style-type: none"> <li>• Official relationships established with secretariats of other conventions and organizations</li> <li>• Secretariat of the CBD invited as an observer to WTO SPS and TBT Committees</li> </ul>	<ul style="list-style-type: none"> <li>• Number of established relationships with other conventions as reflected in joint activities</li> </ul>
		<p>5.3 Communication and outreach</p> <p>To raise the profile of the Protocol</p>	<ul style="list-style-type: none"> <li>• Outreach services of the Protocol enhanced among relevant national and international stakeholders</li> <li>• All Parties have designed and implemented education and communication strategies</li> </ul>	<ul style="list-style-type: none"> <li>• Number of national awareness and outreach programmes on biosafety</li> <li>• Percentage of Parties that have in place national communication strategies on biosafety not later than 3 year after having adopted national biosafety laws</li> </ul>

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			<ul style="list-style-type: none"> <li>• Biosafety issues and Protocol activities are regularly covered by local as well as international media</li> <li>• Increased understanding of the relationship between the Protocol and the CBD and other biosafety-related agreements</li> </ul>	<ul style="list-style-type: none"> <li>• Percentage of Parties that have in place national biosafety websites, including national BCH nodes that are accessible to and searchable by the public</li> <li>• Number of Parties with awareness and educational materials on biosafety and the Protocol available and accessible to the public, including the diversity of these materials</li> </ul>