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Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety
Twelfth meeting
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Item 16 of the provisional agenda*
National legislation, regulations and guidelines on new developments in modern biotechnology

Information on national legislation, regulations and guidelines on new developments in modern biotechnology

Note by the Secretariat

I. Introduction

1. In its decision CP-11/1 C, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety encouraged Parties to submit information regarding national legislation, regulations and guidelines on new developments in modern biotechnology that were relevant to the Cartagena Protocol and not published on the Biosafety Clearing-House.

2. The Conference of the Parties serving as the meeting of the Parties to the Protocol requested the Executive Secretary of the Convention on Biological Diversity to compile information contained on the Biosafety Clearing-House and other sources regarding current national legislation, regulations and guidelines on new developments in modern biotechnology.

3. The Executive Secretary was also requested to submit the information shared by Parties and the information compiled by the Executive Secretary for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its twelfth meeting.

4. The present note has been prepared pursuant to those requests to facilitate the consideration of the matter by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its twelfth meeting.

II. New developments in biotechnology: a basic introduction

5. In recent years, new tools and techniques have emerged for altering the genome of an organism. Those tools and techniques go beyond the insertion of foreign DNA into the host genome, which is known as transgenesis, to include genome editing, transgrafting, cisgenesis, intragenesis and transient modification, among other techniques. Depending on how those techniques are applied, varying levels of change are possible within the host genome. The aim in the present section is to provide an overview of the different techniques so as to facilitate an understanding of the approaches

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to regulating the organisms produced through the use of those techniques, as described in section III below.

6. For certain types of techniques (for example, genome editing, oligonucleotide mutagenesis and base editing), the final modification differs from the non-modified genome by one or a few changes (additions, deletions or base pair conversions). Those changes can consequently resemble mutations produced through traditional breeding techniques or natural spontaneous mutations. In some cases, there are no other changes to the host genome that could provide an indication of how the mutation was produced.[1]

7. In the case of cisgenic and intragenic organisms, the techniques used to create transgenic organisms are also used to transform recipient organisms in these cases. The genetic material introduced (for example, genetic elements, genes or gene cassettes) is sourced, however, from the same or a closely related, sexually compatible species: the incorporated sequences contain either exact copies of genes (cisgenesis) or gene cassettes assembled from different endogenous genes (intragenesis). The resulting modification, which contains additional endogenous genes without involving the introduction of foreign genetic material, could potentially be similar to conventionally bred products, particularly in the case of cisgenic organisms.[2]

8. Both transient modification and transgrafting rely on transgenesis but the considerations are different. In transient modification, only somatic (non-reproductive) cells are transformed and express transgenic products and therefore, despite the presence of transgenes in some tissues, there is no intended inheritance by offspring. In transgrafting, only the rootstock (or the "scion") is modified, while the other component remains unmodified. Since the transgenic scion exchanges gene products with the grafted component without the insertion of transgenes into the genome, the grafted component remains similar to a non-modified or conventionally bred counterpart.[3]

9. A variety of analytical techniques have the capacity to enable detection and identification of transgenic organisms and tissues. However, when changes introduced into the genome – such as those produced through genome editing – are minute, current analytical techniques can enable the detection of the genomic change (through the use of sequencing, probes or specialized polymerase chain reactions) but not the identification of the process that caused the mutation. A priori knowledge (for example, concerning the sequencing of information related to the genome edit) may be required for proper implementation of analytical testing. Research is nevertheless active with respect to the detection, identification and quantification of organisms produced through new biotechnological techniques.[4]

10. An overview of genetic modification techniques and additional bibliographic references for further reading are provided in information document CBD/CP/MOP/12/INF/6.

[1] See Jorge Martínez-Fortún, Dylan W. Phillips and Huw D. Jones, "Natural and artificial sources of genetic variation used in crop breeding: a baseline comparator for genome editing", *Frontiers in Genome Editing*, vol. 4 (2022).
[2] See European Food Safety Authority Panel on Genetically Modified Organisms, "Updated scientific opinion on plants developed through cisgenesis and intragenesis", *EFSA Journal*, vol. 20, No. 10 (2022); and S. N. Vasudevan and others, "Cisgenics and intragenics: boon or bane for crop improvement", *Frontiers in Plant Science*, vol. 14 (2023).
[3] See Esra Seyran and Wendy Craig, "New breeding techniques and their possible regulation", *AgBioForum*, vol. 21, No. 1 (2018).
[4] See Patrick Guertler and others, "Detection of commercialized plant products derived from new genomic techniques (NGT): practical examples and current perspectives", *Food Control*, vol. 152 (October 2023); Caroline Bedin Zanatta and others, "Specificity testing for NGT PCR-based detection methods in the context of the EU GMO regulations", *Foods*, vol. 12, No. 23 (2023); and Alexandra Ribarits and others, "Detection methods fit-for-purpose in enforcement control of genetically modified plants produced with novel genomic techniques (NGTs), *Agronomy*, vol. 11, No. 1 (2021).

III. Compilation of information

A. Submissions received

11. In notification No. 2025-136, issued on 31 October 2025 pursuant to decision CP-11/1 C, Parties were invited to submit information regarding national legislation, regulations and guidelines on new developments in modern biotechnology that were relevant to the Protocol and not published on the Biosafety Clearing-House.

12. Submissions were received from seven Parties.[5] A number of those Parties (Brazil, European Union and its member States, Niger and Philippines) submitted legislation, or references to legislation, accompanied by explanations, while others (Ecuador and Uruguay) submitted only the text of the legislation. One Party (Bosnia and Herzegovina) submitted a publication on genetically modified organisms in agriculture and forestry.

13. In one submission, a legal instrument ("normative resolution") was described, which established, inter alia, a procedure for determining whether certain products generated through "innovative precision breeding techniques" fell under the regular biosafety legislation applying to living modified organisms or were exempt from that legislation. The framework set out procedural steps, documentation requirements and decision criteria and clarified the institutional roles associated with the determination.

14. Outlined in another submission were the features of a ministerial instrument that provided technical guidance for determining whether certain seeds or crops developed through precision breeding techniques could be registered or commercialized as conventional organisms or were subject to biosafety legislation. The instrument defined institutional responsibilities and detailed the analytical process for case-by-case determinations. Forms to be used in that process were annexed to the instrument.

15. In one submission, an overview was provided of the legal framework applying to genetically modified organisms that currently existed. A legislative proposal that applied to plants produced through certain new genomic techniques, such as targeted mutagenesis and cisgenesis, was described in that submission. The proposal set out specific rules for the deliberate release into the environment and marketing of such plants and their products.

16. In another submission, a detailed overview was provided of the national biosafety framework comprising primary legislation and implementing decrees, as well as policy instruments and guidance documents. The framework established the legal, institutional and procedural basis for the safe development, handling, use and transboundary movement of living modified organisms, including those resulting from new developments in biotechnology. In its submission, the Party indicated that the operationalization of the existing legal and institutional framework was challenging in the context of limited resources.

17. In one submission, a description was provided of the legal instruments that applied to plant and plant products derived from plant breeding innovations or new breeding techniques. The instruments established criteria for determining whether specific plants or plant products should be considered genetically modified organisms or not. Products from plant breeding innovations would be classified as genetically modified organisms if they contained a "novel combination" of genetic material obtained through the use of modern biotechnology that could not have been obtained through conventional breeding. Products from plant breeding innovations would be classified as non-genetically modified organisms or conventional products if they did not contain a novel combination of genetic material. Only genetically modified plants and plant products derived from plant breeding innovations would be regulated under the biosafety legislation, while non-genetically modified plants

[5] Bosnia and Herzegovina, Brazil, Ecuador, European Union and its members States, Niger, Philippines and Uruguay. The submissions are available at https://bch.cbd.int/en/submissions-to-notifications?currentPage=1&schema=submission&notification=2025-136.

and plant products derived from plant breeding innovations would not be so regulated. A structured decision-making tool guided authorities through that determination process.

18. In another submission, a legal instrument was described that established a mechanism for determining whether organisms or products developed through new breeding techniques – covering plants, animals and microorganisms for use in agriculture, aquaculture or forestry – were subject to or exempt from legislation applicable to living modified organisms. The decree established procedural steps and criteria for making that determination.

19. Through one submission, a publication was shared on genetically modified organisms in agriculture and forestry. The publication addressed, among other subjects, the history of genetic modifications; gene editing methods; genetically modified plants, trees and animals and the application of genetically modified microorganisms in agriculture; risk assessment; and detection and identification of living modified organisms, as well as future trends and legislation as related to genetically modified organisms.

B. Relevant information published on the Biosafety Clearing-House

20. The Biosafety Clearing-House contains several records with relevance for the topic, both as national records and as reference records.

1. National records

21. Through a search within the national records published by Parties and non-Parties under "biosafety laws, regulations, guidelines and agreements", 16 relevant records from a total of 14 Parties[6] and one non-Party[7] were identified. Two of those Parties also made a submission.[8] In its search, the Secretariat looked for records containing terms such as "new genomic techniques", "NGT", "genome editing", "gene editing", "new breeding techniques", "NBT" and "precision breeding" and their equivalents in French and Spanish. It is possible that other national records of relevance to the topic are available in the Clearing-House, especially if they were described using a different terminology or in languages other than English, French or Spanish.

22. Four of the records available on the Biosafety Clearing-House were linked to legislation and eight, to guidelines or other guidance documents. The pieces of legislation were adopted in the period 2018–2023, while most of the guidelines were adopted in the period 2020–2025.

23. In most of those instruments, procedures and rules are set out that enable decision makers to exempt certain organisms from the scope of application of the biosafety legislation under which living modified organisms are regulated. The instruments show that the determination whether an organism would fall under a country's biosafety legislation or not is generally made on a case-by-case basis. Some instruments apply specifically to organisms developed using genome editing technology and some instruments are limited in application to plants only.

24. Across the documents, a feature common to most is the establishment of an administrative process through which developers may request a determination of the regulatory status of organisms produced using genome editing or other new genomic techniques. The approaches differ, however, in the extent to which they specify the substantive criteria for making that determination. Some countries set out detailed criteria for identifying categories of organisms that fall outside the scope of existing legislation on genetically modified organisms or living modified organisms. Examples of such criteria include "no foreign genetic material is present" or "the genetic changes could arise also through conventional breeding". Other countries establish the determination process without prescribing detailed exclusion criteria, thereby leaving the competent authority with greater

[6] Brazil, Burkina Faso, Costa Rica, Ethiopia, European Union, Germany, Ghana, Kenya, Malawi, Nigeria, Paraguay, Peru, Zambia and Zimbabwe.
[7] Argentina.
[8] Brazil and European Union.

discretion to decide, on a case-by-case basis, whether an organism is subject to the existing biosafety framework.

25. The regulatory approaches to organisms developed through new genomic techniques described in those records are similar to the regulatory approaches outlined in the submissions.

26. A list of national records is provided in information document CBD/CP/MOP/12/INF/6.

2. Reference records

27. The Biosafety Clearing-House contains several reference records linked to articles that are relevant for the topic at hand.[9] Roughly summarized, the articles discuss the regulatory treatment of new breeding techniques and genome editing, with a particular focus on the implications of regulatory uncertainty and differing legal approaches. An overview of the reference records on the Biosafety Clearing-House is provided in information document CBD/CP/MOP/12/INF/6.

C. Information from other sources

28. A myriad of information is available on regulatory approaches related to living modified organisms developed through certain new genomic technology. A search conducted by the Secretariat resulted in the retrieval of various types of materials, including national legislation, guidance documents and publications focused on developments in national legislation. Many of those materials are published by national Governments or government agencies, while others are published by entities including academia, research institutes and intergovernmental organizations. Furthermore, a few databases have been created for the purpose of keeping track of developments in legislation relating to organisms produced through certain new genomic technology, with many of those databases having global coverage. A list of references relating to those materials is provided in information document CBD/CP/MOP/12/INF/6 and brief descriptions of the different types of materials are provided in the present section.

1. National legislation and guidance documents

29. Several Parties and non-Parties have published statutory texts, implementing regulations, guidance documents or standard operating procedures relating to, among other issues, the regulatory framework applying to certain genome edited organisms. Several of those documents set out information similar to that provided in many of the submissions described in section III.A above, including on procedural requirements for developers and regulators, and address issues such as exemptions, triggers for regulation and categorization of modified organisms. In other documents, it is indicated that certain organisms are or can be exempted from legislation applying to living modified organisms or genetically modified organisms.

2. Articles and other documentation

30. Several articles are available concerning developments in the regulation of genome edited organisms by different countries. In many of those articles, proposed changes to the regulation of certain organisms are explained and some articles focus on the implications of such changes. Certain publications describe proposals for legislative reform relating to specific jurisdictions.

31. Ongoing developments related to the regulation of certain genome edited organisms have been documented by the Organisation for Economic Co-operation and Development (OECD). Two OECD working parties[10] serve as forums for the exchange of information on approaches and experiences in the context of environmental risk/safety assessments of organisms produced through modern biotechnology, with the aim being to improve mutual understanding and increase the efficiency of the assessments. The working parties have been following recent regulatory developments and have

[9] Reference records focusing on the scientific as opposed to the regulatory aspects of new genomic techniques are not included in the description.

[10] Working Party on the Harmonisation of Regulatory Oversight in Biotechnology and Working Party for the Safety of Novel Foods and Feeds.

exchanged information on new breeding techniques, the organisms derived from them and their applications and regulatory implications since 2022. Through a joint project of the working parties on enhanced information exchange on new breeding techniques, led by Japan, OECD aims towards collectively presenting comprehensive and accurate information on regional, national and local regulations related to new breeding techniques derived from an annual questionnaire. The information gathered is collated in periodic reports.[11]

32. Information on the regulation of certain genome edited organisms in countries globally has been documented through the DARWIN project funded by the European Union.[12] The aim of the DARWIN project is to develop a detection strategy for products obtained through new genomic techniques, as well as digital solutions. In the context of the project, a publication was prepared that addressed regulatory responses to new genomic breeding techniques in certain jurisdictions.[13]

33. Several organizations, including non-governmental organizations, have issued publications in that regard, as detailed in information document CBD/CP/MOP/12/INF/6.

3. Online databases and trackers

34. A few global online databases that provide information on national regulatory approaches and associated information concerning certain genome edited organisms have been developed by entities such as universities and research centres. The Institute for Molecular Physiology of the Heinrich Heine University Düsseldorf, for example, maintains a global database of regulations concerning genome editing in agriculture and the UK-CGIAR Centre developed a global "genome editing regulations tracker" which provides access to legislation of several jurisdictions and related publications. In the information accompanying the databases, the challenges in maintaining an overview that is up to date and complete are underlined.

D. Conclusions

35. In summary, the information submitted and collected indicates that numerous Parties are developing or have already adopted legal instruments that establish a procedure through which a determination can be made regarding whether a specific organism falls within the scope of biosafety legislation or is to be considered exempt from that legislation.

36. In many cases, institutional roles and responsibilities for making those determinations have been assigned and some countries have documentation and analytical requirements for making the determination, with varying degrees of specificity. In a few submissions, Parties confirmed that pending the adoption of specific legislation covering organisms developed through new genomic technology, those organisms remained regulated under the regular biosafety legislation.

37. Several initiatives exist that seek to keep track of the rapid developments in biotechnology and legislative responses in various jurisdictions.

[11] The report prepared on the basis of information provided through the 2025 survey is available athttps://one.oecd.org/document/ENV/CBC/MONO(2025)15/en/pdf. Moreover, the OECD Working Party for the Safety of Novel Foods and Feeds published a report that contained information on the legislative frameworks of several countries, including in relation to new breeding techniques, which is available at https://one.oecd.org/document/ENV/CBC/MONO(2025)14/en/pdf.

[12] Further information on the Darwin project is available at https://darwin-ngt.eu/.

[13] Available at https://darwin-ngt.eu/wp-content/uploads/2025/06/UNR_Worldwide-Regulation-report.pdf.

IV. Draft decision

38. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to adopt a decision along the following lines:

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol

1. *Welcomes* the information submitted by Parties regarding current national legislation, regulations and guidelines on new developments in modern biotechnology;

2. *Takes note* of the information regarding current national legislation, regulations and guidelines on new developments in modern biotechnology available through the Biosafety Clearing-House and in other sources, and acknowledges the ongoing efforts in various forums to track information on the development of legislation, regulations and guidelines concerning organisms developed through biotechnology;

3. *Recognizes* that modern biotechnology is developing rapidly and that regulatory responses have been developed or are under development in several countries;

4. *Invites* Parties, other Governments and relevant organizations to submit further information regarding national legislation, regulations and guidelines on new developments in modern biotechnology that are relevant to the Cartagena Protocol on Biosafety,[14] recognizing the usefulness of exchanging information to build understanding on ongoing developments in relation to legislation, regulations and guidelines and on new developments in modern biotechnology;

5. *Requests* the Executive Secretary to prepare an overview of the information submitted in response to the invitation contained in paragraph 4 above, for consideration at its thirteenth meeting.

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[14] United Nations, *Treaty Series*, vol. 2226, No. 30619.