

CONVENTION ON INTERNATIONAL TRADE IN ENDANGERED SPECIES
OF WILD FAUNA AND FLORA



Nineteenth meeting of the Conference of the Parties
Panama City (Panama), 14 – 25 November 2022

Interpretation and implementation matters

Regulation of trade

SPECIMENS PRODUCED THROUGH BIOTECHNOLOGY

1. This document has been prepared by the Standing Committee and the Secretariat.
2. At its 18th meeting (CoP18, Geneva, 2019), the Conference of the Parties adopted Decisions 18.147 to 18.150 on *Specimens produced through biotechnology* as follows:

18.147 Directed to the Parties

Parties are invited to provide information to the Secretariat regarding:

- a) *cases where they have issued, or received requests to issue, CITES permits and certificates for specimens produced through biotechnology;*
- b) *other situations when they have applied the interpretation of Resolution Conf. 9.6 (Rev. CoP16) on Trade in readily recognizable parts and derivatives to fauna and flora products produced through biotechnology; and;*
- c) *technological developments and applications taking place, particularly in their jurisdiction, that may result in the manufacture of specimens produced through biotechnology that may have impact on the interpretation and implementation of the Convention.*

18.148 Directed to the Animals and Plants Committees

The Animals and Plants Committees shall:

- a) *review the complete study on “Wildlife products produced from synthetic or cultured DNA”, monitor the most recent scientific and technological advancements and applications that may lead to the synthetic production of specimens of CITES-listed species, and make recommendations for consideration by the Standing Committee, including appropriate revisions to existing resolutions; and*
- b) *provide any relevant scientific advice and guidance on matters relevant to international trade in specimens produced through biotechnology and communicate it to the Standing Committee, as appropriate.*

18.149 Directed to the Standing Committee

The Standing Committee shall:

- a) *discuss whether and how to apply the term “readily recognizable part or derivative” to trade in products of biotechnology, which might potentially affect international trade in*

CITES-listed specimens in a way that would threaten their survival, including enforcement of CITES provisions;

- b) communicate to the Animals and Plants Committees any matters that may require scientific advice and guidance, as appropriate; and*
- c) make recommendations for consideration at the 19th meeting of the Conference of the Parties, including appropriate revisions to existing resolutions or the development of a new resolution on trade in specimens produced from biotechnology.*

18.150 Directed to the Secretariat

The Secretariat shall:

- a) present the study on “Wildlife products produced from synthetic or cultured DNA”, along with the Secretariat’s findings and recommendations, to the Animals and Plants Committees;*
- b) collate information received from Parties in relation to Decision 18.147, as well as any other information received from Parties, governmental, intergovernmental and nongovernmental organizations and other entities related to the issue of specimens produced through biotechnology;*
- c) communicate with the Secretariat of the Convention on Biological Diversity (CBD), the Food and Agricultural Organization of the United Nations (FAO), the International Union for Conservation of Nature (IUCN) and other relevant organizations as appropriate, to keep abreast of the discussions taking place on other fora on issues that may be relevant to specimens produced through biotechnology; and*
- d) share the information collated under paragraphs b) and c) and report progress on the implementation of this Decision to the Animals and Plants Committees, and the Standing Committee, as appropriate.*

3. China, as Chair of the working group on *Specimens produced through biotechnology*, informed the Standing Committee at its 74th meeting (SC74, Lyon, March 2022) about progress in the implementation of Decision 18.149 in document [SC74 Doc. 49](#).
4. Based on the Parties’ response to Notification No. 202/062 that provided a variety of regulated types of animal and plant products of biotechnology¹, as well as cases of products that Parties did not consider to be regulated², it appeared Parties used Resolution Conf. 9.6 (Rev. CoP16) on *Trade in readily recognizable parts and derivatives* as a basis for determining whether a product produced through biotechnology is considered a ‘readily recognizable part or derivative’.
5. The working group reported to the Standing Committee the following two conclusions:
 - a) specimens produced through biotechnology should be regulated within the framework of the Convention, more specifically through Resolution Conf. 9.6 (Rev. CoP16); and
 - b) given the complexity of biotechnology and the diverse paths of production, it was too early to introduce new definitions into the Convention or to develop a new Resolution at this moment.
6. The working group proposed to the Standing Committee an amendment to Resolution Conf. 9.6 (Rev. CoP16) that endorsed the existing criteria in paragraph 1 of said Resolution. The Committee considered the report of the Chair of the working group and agreed to submit to CoP19 the amendment to Resolution Conf. 9.6 (Rev. CoP16), contained in Annex 1 to the present document.

¹ For instance, whole plants, tissues and extracts derived from *in vitro* techniques, cell cultures/lines of primates, virus/bacteria cultivated from cell cultures of primates, testing kit for detection for antibody samples consisting of cells of different tissues, and tissue, serum and other reagents derived from animals listed in Appendices.

² For instance, paclitaxel and musk produced through total syntheses, and human cell lines with inserted cloned synthetic gene of primates.

7. The Committee furthermore requested the Secretariat to work with the Standing Committee Chair to draft new decisions to submit to CoP19 in order to continue the work on specimens produced through biotechnology, taking into account the proposal in paragraph 13 of document SC74 Doc. 49, the issues addressed in paragraphs 14 and 15 of the same document, the need for general guidance and the need to identify which issue, if any would warrant further discussion.
8. In preparing the new decisions as directed by the Standing Committee, the Secretariat noted the complexity of the issues merit focused attention and proposed to convene and organize a meeting of concerned Parties and relevant organizations to facilitate the discussions and develop guidance on the implementation of the amendment to Resolution Conf. 9.6 (Rev. CoP16) on *Trade in readily recognizable parts and derivatives*.
9. Pursuant to paragraph c) of Decision 18.150, the Secretariat communicated with the Secretariat of the Convention on Biological Diversity (CBD), the Food and Agriculture Organization of the United Nations (FAO), the International Union for Conservation of Nature (IUCN) and other relevant organizations on this matter. As part of the consultations, the Secretariat participated in a webinar organized by the CBD Secretariat on 1 November 2021 and exchanged information with colleagues from the Biological Weapons Convention (BWC), the United Nations Conference on Trade and Development (UNCTAD), the World Health Organization (WHO) and IUCN. The information about the work of those organizations in relation to synthetic biology was published by the CBD Secretariat in its Technical Series No.100 on synthetic biology, available at <https://www.cbd.int/doc/publications/cbd-ts-100-en.pdf>.
10. Pursuant to the Committee's recommendation, the Standing Committee Chair and the Secretariat drafted the decisions contained in Annex 2 to the present document, for consideration by the Conference of the Parties.
11. The Secretariat considers that Decisions 18.147 to 18.150 have been implemented and can be deleted.

Recommendations

12. The Conference of the Parties is invited to:
 - a) adopt the amendments to Resolution Conf. 9.6 (Rev. CoP16) on *Trade in readily recognizable parts and derivatives* contained in Annex 1 to the present document;
 - b) adopt the draft decisions on *Specimens produced through biotechnology* in Annex 2 to the present document; and
 - c) consequently, agree to delete Decisions 18.147 to 18.150.

PROPOSED AMENDMENT TO RESOLUTION CONF. 9.6 (REV. COP16)
ON *TRADE IN READILY RECOGNIZABLE PARTS AND DERIVATIVES*

[...]

2. RECOMMENDS that:

- a) Parties consider all products of ranching operations to be readily recognizable; and
- b) Parties consider all specimens produced through biotechnology that meet the criteria in paragraph 1 to be readily recognisable unless specifically exempted from the provisions of the Convention; and

[...]

DRAFT DECISIONS ON *SPECIMENS PRODUCED THROUGH BIOTECHNOLOGY*

Directed to the Standing Committee

19.AA The Standing Committee shall:

- a) continue to discuss trade in products of biotechnology, which might potentially affect international trade in CITES-listed specimens in a way that would threaten their survival, including enforcement of CITES provisions. The Committee's discussion shall take into account the need for general guidance and the need to identify which issue, if any would warrant further discussion and shall include consideration of:
 - i) how to define the term "biotechnology", taking into account the language proposed in paragraph 13 of document SC74 Doc. 49;
 - ii) whether CITES documents should be required for all specimens produced through biotechnology or whether certain products/specimens should benefit from special provisions, such as simplified procedures;
 - iii) what proof should be required for issuing CITES documents for specimens produced through biotechnology;
 - iv) how the legality of the species origin of the source material is established;
 - v) whether there should be an exception for specimens that were entirely synthetically produced;
 - vi) whether the current source codes are suitable or whether a new source code is needed;
 - vii) how to address the risk of natural specimens of illegal origin being passed as synthetic and thereby entering the market with a valid CITES permit;
 - viii) how to ensure a clear link (e.g., marking, other means of identification) between a specimen produced through biotechnology and CITES documentation in order to prevent misuse;
 - ix) the estimated caseload and administrative burden;
 - x) whether regulation is necessary at this stage; and in this regard take into consideration that it appears that, in the context of the Convention, currently mainly cell lines, few extracts and artificially propagated plants are traded. Cell lines and plants are already covered by Resolution Conf. 9.6 (Rev.CoP16) and Resolution Conf. 11.11 (Rev. CoP18). For extracts and chemicals, the general approach of whether material from a natural organism of origin is still present within the specimen seems to be implemented by some Parties. Substances that are produced entirely synthetically as a "synthetic reproduction" of the natural substance (e.g., musk) do not seem to be considered as a CITES specimen by the Parties;
 - xi) whether biotechnology issues concerning animals and plants should be addressed distinctly;
 - xii) any emerging issues or cases not considered in the document AC31 Doc.17/PC25 Doc.20, such as hirudin and squalene.
- b) communicate to the Animals and Plants Committees any matters that may require scientific advice and guidance, as appropriate; and
- c) make recommendations for consideration at the 20th meeting of the Conference of the Parties, including appropriate revisions to existing resolutions or the development of a new resolution on trade in specimens produced from biotechnology.

Directed to the Animals and Plants Committees

- 19.BB The Animals and Plants Committees shall provide any relevant scientific advice and guidance on matters relevant to international trade in specimens produced through biotechnology and communicate it to the Standing Committee, as appropriate.

Directed to the Secretariat

- 19.CC Subject to the availability of external funds, the Secretariat shall convene and organize a meeting to facilitate the discussions mentioned in Decision 19.AA and develop guidance on the implementation of the amendment to Resolution Conf. 9.6 (Rev. CoP16) on *Trade in readily recognizable parts and derivatives*. The Secretariat shall extend invitations to concerned Parties as well as relevant entities, including the Biological Weapons Convention (BWC), the Secretariat of the Convention on Biological Diversity (CBD), the Food and Agriculture Organization of the United Nations (FAO), the International Union for Conservation of Nature (IUCN), the United Nations Conference on Trade and Development (UNCTAD), the World Health Organization (WHO) and other relevant organizations as appropriate.

**TENTATIVE BUDGET AND SOURCE OF FUNDING
FOR THE IMPLEMENTATION OF DRAFT RESOLUTIONS OR DECISIONS**

According to Resolution Conf. 4.6 (Rev. CoP18) on *Submission of draft resolutions, draft decisions and other documents for meetings of the Conference of the Parties*, the Conference of the Parties decided that any draft resolutions or decisions submitted for consideration at a meeting of the Conference of the Parties that have budgetary and workload implications for the Secretariat or permanent committees must contain or be accompanied by a budget for the work involved and an indication of the source of funding. The Secretariat proposes the following tentative budget and source of funding.

Decision	Activity	Cost implications (USD)	Source of external funding
19.CC	Subject to the availability of external funds, the Secretariat shall convene and organize a meeting to facilitate the discussions mentioned in Decision 19.AA and develop guidance on the implementation of the new amendments to Resolution Conf. 9.6 (Rev. CoP16) on <i>Trade in readily recognizable parts and derivatives</i> . The Secretariat shall extend invitations to concerned Parties as well as relevant entities, including the Secretariat of the Convention on Biological Diversity (CBD), the Food and Agriculture Organization of the United Nations (FAO), the International Union for Conservation of Nature (IUCN) and other relevant organizations as appropriate.	<ul style="list-style-type: none"> • USD 80,000 for a meeting 	Not identified