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

Seventy-fourth meeting of the Standing Committee
Lyon (France), 7 - 11 March 2022

Interpretation and implementation matters

Regulation of trade

SPECIMENS PRODUCED THROUGH BIOTECHNOLOGY: REPORT OF THE WORKING GROUP

1. This document has been submitted by China as Chair of the working group on Specimens produced through biotechnology.*

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

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* *The geographical designations employed in this document do not imply the expression of any opinion whatsoever on the part of the CITES Secretariat (or the United Nations Environment Programme) concerning the legal status of any country, territory, or area, or concerning the delimitation of its frontiers or boundaries. The responsibility for the contents of the document rests exclusively with its author.*

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.

Progress in the implementation of Decisions 18.149 and 18.150, paragraph b)

3. At its 72nd meeting, (Geneva, 2019), the Standing Committee established an intersessional working group on specimens produced through biotechnology with a mandate to:

   – *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; and*

   – *consider proposing appropriate revisions to existing resolutions or the development of a new resolution on trade in specimens produced from biotechnology.*

4. Members of the intersessional working group on specimens produced through biotechnology are as follows (12 Parties, 11 Observers): Canada, China (Chair), Cuba, the European Union, Germany, Indonesia, Japan, Malaysia, Senegal, the United Kingdom of Great Britain and Northern Ireland, the United Republic of Tanzania and the United States of America; the International Union for Conservation of Nature, Born Free Foundation, Center for Biological Diversity, International Fragrance Association, International Fund for Animal Welfare (IFAW), Lewis and Clark – International Environmental Law Project, Natural Resources

Defense Council (NRDC), San Diego Zoo, Wildlife Conservation Society (WCS), World Animal Protection and World Wildlife Fund.

5. In accordance with paragraph b) of Decision 18.150, the Secretariat issued a Notification to the Parties, No. 2020/062 of 14 October 2020, seeking information on Parties' experience relating to the issue of specimens produced through biotechnology.

6. In response to Notification to the Parties No. 2020/062, the Secretariat received replies from seven Parties (Austria, China, Germany, Pakistan, Slovakia, the United Kingdom, and the United States of America).

Application of the term "readily recognizable part or derivative"

7. These Parties' responses to the Notification No. 2020/062 provide a variety of regulated types of animal and plant products of biotechnology, including 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. Parties also provided cases of products that they did not consider to be regulated, such as paclitaxel and musk produced through total syntheses, and human cell lines with inserted cloned synthetical gene of primates.

8. From the answers to the Notification No. 2020/062, it appears that respondents (Austria, the United Kingdom and the United States of America) use Resolution Conf. 9.6 (Rev. CoP16) as a basis for determining whether a product produced through biotechnology is considered a 'readily recognizable part or derivative'. Pakistan reported no cases have been dealt with, but the definition of 'readily recognizable part or derivative' is based on, and closely follows the wording of Resolution Conf. 9.6 (Rev. CoP16). China and Slovakia explain the general process of the application and checking system. The information used to determine whether a product should be regulated mainly comes from the applicant.

9. Germany reported that it does not employ a general interpretation of the term 'readily recognizable' regarding specimens produced through biotechnology. It decides on case-by-case basis whether CITES documents are required or not. In determining whether a permit is needed, Germany uses three reference points:

    i) whether any DNA of the origin plant/animal is left in the specimen,

    ii) whether the specimen is produced completely synthetically,

    iii) whether it is apparent from accompanying documents, packaging, mark or label or any product description that cells or DNA/RNA of protected species are included.

Amendment of Resolution Conf. 9.6 (Rev. CoP16)

10. From the discussions that followed within the Working Group, two general conclusions emerged. The first is that most of the members who have responded agree that specimens produced through biotechnology should be regulated within the framework of the Convention, more specifically through Resolution Conf. 9.6 (Rev. CoP16). The second is that, given the complexity of biotechnology and the diverse paths of production, the members of the Working Group do not deem it fit to introduce new definitions into the Convention or to develop a new Resolution at this moment.

11. The Working Group discussed possible revisions to the Resolution Conf. 9.6 (Rev. CoP16), for the purpose of providing clarification that existing definitions and guidance are applicable to specimens produced through biotechnology. There is, however, no agreement yet on the exact shape such amendment should take.

12. A first proposal is that put forward by the United States of America, revised by China (Chair), and supported by Canada, Germany, and the United Kingdom, to insert a new sub-paragraph to paragraph 2 of Resolution Conf. 9.6 (Rev. CoP16) to endorse the existing criteria in paragraph 1 of said Resolution, as follows:

    1. AGREES that the term 'readily recognizable part or derivative', as used in the Convention, shall be interpreted to include any specimen which appears from an accompanying document, the packaging or a mark or label, or from any other circumstances, to be a part or derivative of an animal or plant of a species included in the Appendices, unless such part or derivative is specifically exempted from the provisions of the Convention;

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*

   […]

13. The above proposal raised the concern of observers that it will introduce an undefined term, i.e., "biotechnology". The Center for Biological Diversity, Lewis & Clark Law School, and NRDC suggest the following alternate amendment, which is supported by Born Free, IFAW and WCS, but is opposed by some party members (the United States of America, the United Kingdom, Canada, and Germany):

    1. *AGREES that the term 'readily recognizable part or derivative', as used in the Convention, shall be interpreted to include any specimen which appears from an accompanying document, the packaging or a mark or label, or from any other circumstances, to be a part or derivative of an animal or plant of a species included in the Appendices, unless such part or derivative is specifically exempted from the provisions of the Convention. This includes:*

       a) *products that contain DNA of species included in the Appendices and are not otherwise expressly exempted under this Resolution; and*

       b) *products that, although they do not contain actual DNA, appear from a visual, physical, scientific, or forensic examination, test, or any other inspection to be specimens of CITES-listed species.*

Additional issues to be considered

14. In addition to the questions addressed above, the Working Group, through its discussions, identified a number of further questions that merit exploration and discussion. These include the following:

    a) 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;

    b) What proof should be required for issuing CITES documents for specimens produced through biotechnology;

    c) How the legality of the species origin of the source material is established;

    d) Whether there should be an exception for specimens that were entirely synthetically produced;

    e) Whether the current source codes are suitable or whether a new source code is needed;

    f) 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;

    g) 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;

    h) The estimated caseload and administrative burden;

    i) Whether regulation is necessary at this stage. 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; and

j) Whether biotechnology issues concerning animals and plants should be addressed distinctly.

15. The Chair of the Working Group relayed the above issues identified under paragraph 14, and some emerging cases that were not considered in the report AC31 Doc. 17/PC25 Doc. 20, such as hirudin and squalene, which might potentially affect the international trade and enforcement, to the focal points of Animals and Plants Committees by e-mail.

16. Some members of the Working Group noted that the issues outlined in paragraphs 14-15 might need further refinement. Because of time constraints and the fact that the above issues do not all clearly fall within the mandate of the Working Group, the Working Group did not have an in-depth discussion on these questions. However, the Working Group does consider that these questions merit attention, including in some cases by the Animals and Plants Committees, and suggest discussing these in the next intersessional period.

Recommendations

17. The Standing Committee is invited to:

a) Review the progress made by the Working Group and offer its comments and recommendations to CoP19, in particular with respect to the proposed amendments to Resolution Conf 9.6 (Rev. CoP16) described in paragraphs 10-13;

b) Review and refine the issues identified under paragraphs 14 and 15 for consideration by the Animals and Plants Committees in the next intersessional period for further advice and guidance; and

c) Consider revising and updating the relevant Decisions to incorporate, *inter alia*, the considerations outlined in paragraphs 17 b) of the present document and propose them for adoption to the 19th meeting of the Conference of the Parties.