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

Seventieth meeting of the Standing Committee
Rosa Khutor, Sochi (Russian Federation), 1-5 October 2018

Interpretation and implementation matters

Trade control and traceability

SPECIMENS PRODUCED FROM SYNTHETIC AND CULTURED DNA: REPORT OF THE SECRETARIAT AND OF THE WORKING GROUP CHAIR

1. This document has been prepared jointly by the Secretariat and Chair of the intersessional working group on synthetic and cultured DNA (Mexico).

Background

2. At its 17th meeting (CoP17, Johannesburg, 2016), the Conference of the Parties adopted Decisions 17.89 to 17.91 on *Specimens produced from synthetic or cultured DNA*, as follows:

Directed to the Secretariat

17.89 The Secretariat, subject to external funding, is requested to:

a) undertake a review of relevant CITES provisions, resolutions and decisions, including Resolution Conf. 9.6 (Rev. CoP16) on Trade in readily recognizable parts and derivatives, to examine how Parties have applied the interpretation of Resolution Conf. 9.6 (Rev. CoP16) to wildlife products produced from synthetic or cultured DNA, under what circumstances wildlife products produced from synthetic or cultured DNA meet the current interpretation, and whether any revisions should be considered, with a view to ensuring that such trade does not pose a threat to the survival of CITES-listed species; and

b) report the findings and recommendations of this study to the 29th meeting of the Animals Committee, the 23rd meeting of the Plants Committee, and the 69th meeting of the Standing Committee.

Directed to the Animals and Plants Committees

17.90 At the 29th meeting of the Animals Committee and the 23rd meeting of the Plants Committee, the Animals and Plants Committees are requested to review the findings and recommendations of the Secretariat's report in Decision 17.89 and make recommendations for consideration at the 69th meeting of the Standing Committee, including appropriate revisions to existing resolutions.

Directed to the Standing Committee

17.91 At its 69th meeting, the Standing Committee is requested to review the findings and recommendations of the Secretariat's report in Decision 17.89 and the recommendations of the Animals and Plants Committees, and make recommendations for consideration at the 18th

meeting of the Conference of the Parties, including appropriate revisions to existing resolutions.

3. The Standing Committee, at its 69th meeting (SC69; Geneva, November 2017) reviewed the Secretariat's report (see document SC69 Doc. 35) on the progress made and provided further inputs into the terms of reference for the study. The Standing Committee also invited Parties and observers to provide relevant information on the issue of specimens produced from synthetic or cultured DNA to the Secretariat, including existing reports and literature, examples of specimens produced from synthetic or cultured DNA, etc.

4. Furthermore, the Standing Committee established an intersessional working group (chaired by Mexico) on synthetic or cultured DNA (see SC69 summary record, item 35) with a mandate to:

   a) review the findings and recommendations of the Secretariat's report in Decision 17.89 and the recommendations of the Animals and Plants Committees, and

   b) make recommendations for consideration at the 70th meeting of the Standing Committee, including appropriate revisions to existing resolutions.

Progress Since SC69

5. Once the terms of reference (Annex 2) were finalized in December 2017, the Secretariat recruited a consultant to conduct the study in accordance with the United Nations rules and regulations, and pursuant to Decision 17.89, paragraph a). The Secretariat also issued Notification to the Parties No. 2018/013 on 29 January 2018 to collect information on cases where they have issued (or not issued) CITES permits and certificates for bioengineered specimens. As seen in the summary found in Annex 3 to the present document, out of the seven Parties (and one observer) that responded, one Party has reported to have issued permits deemed to be related to bioengineering, and one Party expressed it did not determine whether permits had been issued for specimens based on bio-engineered, synthetic, or cultured DNA. Others confirmed that no permits have been issued for bioengineered specimens.

6. The study has taken longer than expected to complete, due in part to the time taken for the recruitment process for the consultant and in part to the complexity of the topic when placed in the context of the Convention. As directed in Decision 17.89, paragraph, b), a partial draft of the study was shared with the Animals and Plants Committees for their consideration at the joint session of the 30th meeting of the Animals Committee and 24th meeting of the Plants Committee (AC30/PC24, Geneva, July 2018),[1] along with the Secretariat's summary of the findings. This draft contained the sections focusing on the technological and scientific elements, which correspond to the "first part of the study" and "third part of the study" found in the terms of reference.

7. At AC30/PC24, the Animals and Plants Committees agreed that the title of this subject matter should be changed from "specimens produced from synthetic or cultured DNA" to "specimens produced through biotechnology" in order to encompass the wider range of techniques and technologies that need to be considered. However, the Committees refrained from making any specific recommendations on the content of the study for consideration by the Standing Committee. Instead, they agreed that decisions should be drafted and submitted to the Conference of the Parties at its 18th meeting so that the study on specimens produced through biotechnology could be presented to the Animals and Plants Committees at their next joint session in 2020.

8. The Standing Committee's intersessional working group reviewed the draft study and the Secretariat's summary described in paragraph 6 above in May and June 2018, and a number of its members provided detailed feedback. The working group also provided inputs in the form of additional documents of relevance for the consideration of the consultant, as well as information on other international fora that are currently discussing similar concepts and technologies. Furthermore, the working group supported the work of the Secretariat by encouraging Parties to respond to the Notification to Parties No. 2018/013 and reviewed the responses received.

9. The working group has been informed that the consultant was ready to share the completed study, which takes on board the relevant feedback of the intersessional working group members and includes a section on *elements that may be considered from a legal and regulatory perspective* (which corresponds to the "second part of the study" according to the terms of reference). The Secretariat revised its summary of

[1] *See AC30 Doc. 14/PC24 Doc. 14 (Rev. 1) Annex 5 for the partial draft of the study.*

findings accordingly. The Secretariat's summary can be found in Annexes 4 and 5 of the present document, while the revised study is attached to the present document as Annex 6.

10. At the time of writing (early August 2018), the working group had yet to review the findings and recommendations of the Secretariat's study in its completed form, which are contained in this document, particularly with regard to the section on *elements that may be considered from a legal and regulatory perspective*. Adding to the fact that the Animals and Plants Committees refrained from making any specific recommendations at AC30/PC24 for consideration by the Standing Committee, the working group was not able to submit specific recommendations on the Secretariat's findings and recommendations (summarized below) to the Standing Committee in writing.

11. It is possible that the working group members would have examined and discussed the findings and recommendations of the Secretariat, based on the complete study, between August and October. The Chair of the working group may therefore wish to provide an oral report at SC70 regarding the working group's review of the findings and recommendations of the Secretariat (below).

Secretariat's findings and recommendations from the study

12. Four techniques/technologies were covered in this study: DNA synthesis, DNA modification, cell culture, and tissue culture. Since the details of the technologies and their relevance may be difficult to grasp for non-specialists, the Secretariat has prepared a brief overview of the technologies as well as examples of their current and future applications (Annex 4) in an attempt to aid the readers.

13. The study highlights that these biotechnologies, individually or together, may allow the engineering of organisms at organ, cellular, molecular and genetic levels for the synthetic production of almost any CITES-listed specimens. Although only a few applications are commercially available or known today, many others are possible, both currently and in the future, at least in theoretical terms. Furthermore, combining these biotechnologies with other technological tools such as three-dimensional printing would allow even further possibilities for making synthetic specimens that closely mimic the physical appearance of their wildlife counterparts. The multitude of processes and the range of technologies, as well as the scientific potential for future production seem to indicate that the technologies are evolving constantly, and will pose an increasingly complex landscape to identify, let alone regulate. A close monitoring of the technological developments and their applications by the Secretariat may therefore be necessary.

14. The study notes that some of the specimens may be extremely difficult to determine, by visual or analytical means whether they are produced through biotechnology or derived from wild fauna and flora (Annex 5). In cases where they are indistinguishable, the study suggests that all specimens be regulated as if they were from the wild. Even in cases where they can be differentiated, the study suggests that some form of regulation may be necessary. In these cases, the synthetic specimens produced through biotechnology may be considered to fit into the operational definition of the term for 'part' in Resolution Conf. 9.6 (Rev. CoP16) on *Trade in readily recognizable parts and derivatives*.

15. Should a need arise to create exemptions or simplified procedures to demonstrate that the specimen was produced through biotechnology the study suggests a number of options may be used to make them 'readily recognisable', including:

    a) Requirement of scientific measures, where possible, such as insertion of a genetic "kite-mark", markers, or biological barcode during the manufacturing process – these would allow for some synthetic specimens to be 'readily recognizable' through scientific analysis;

    b) Register of persons and bodies (laboratories and factories), as well as the specimens they produce; and

    c) Use of a new source code and other additional information to be used for CITES permits and certificates.

16. The study does not make any conclusive remark on which options should be suitable, or precisely what should be regulated, and how - which would require careful consideration by Parties. In particular, there are existing CITES-listed specimens that use similar procedures to some of the above-mentioned options, which could be useful to investigate further and consider whether comparisons could be drawn for specimens produced through biotechnology.

17. There are a number of topics that arose or were referred to in the study, which may benefit from further investigation and consideration as they may affect the legal interpretation and implementation of the regulation of specimens produced from biotechnology. Thorough examination, including assessing the need for additional research, may be useful in one or more of these areas:

    a) Specimens produced through biotechnology using 'naturally excreted waste products': While Resolution Conf. 9.6 (Rev. CoP16) excludes coral sand and coral fragments, urine, faeces and ambergris from the provisions of the Convention, they could theoretically be used for producing CITES-listed specimens, including parts and derivatives. Parties may need to consider regulatory implications for specimens that are produced through biotechnology using products exempted under Resolution Conf. 9.6 (Rev. CoP16) paragraph 3 b).

    b) Harmonising with the discussion on the definition of the term 'artificially propagated' [Decision 17.175-17.177, 16.156 (Rev. CoP17)]: The Plants Committee is currently exploring the possibility of a further elaboration on the definition of 'artificial propagation' and a possible new source code to address some challenges. Some of these developments may overlap with, or impact significantly on the discussion of how to regulate specimens produced through biotechnology.

    c) Application of Article II paragraph 2 b) of the Convention and Resolution Conf. 9.24 (Rev. CoP17) on *Criteria for amendment of Appendices I and II*: Referred to in the study as the treatment of 'look-alike' species, Article II paragraph 2 b) refers to the inclusion in CITES Appendix II *"other species which must be subject to regulation in order that trade in specimens of certain species referred to in sub-paragraph (a) of this paragraph may be brought under effective control"*.

    d) Previous cases and discussions: One Party has reported to have issued permits deemed to be related to bioengineering, and one Party expressed it did not determine whether permits had been issued for specimens based on bio-engineered, synthetic, or cultured DNA. These cases may need to be examined further to see the state of play with the current practice. In addition, it may be useful to investigate further whether there are any other Parties with similar experiences.

       The study also mentions the example of proposal CoP12 Prop.1 which was submitted by Switzerland as Depositary Government at the request of the Standing Committee to CoP12 (Santiago, 2002). While the study does not elaborate the matter further, there was intense discussion on this proposal, which was later withdrawn. Two different versions of the proposal were taken up at CoP13,[2] (Bangkok, 2004), both of which were also withdrawn afterwards. The history of these discussions at the CoPs and at the intersessional meetings may need to be captured into the current debate.

    e) Other potential cases: the study poses the question on how to regulate whether CITES-listed specimens produced through biotechnology using non-CITES-listed species. There may be other potential applications that may need to be considered.

18. In addition, the following issues were raised by members of the Standing Committee working group and/or during the discussion at the joint session of AC30/PC24. These topics were deemed outside of the terms of reference for this study, but may be of topic for future discussion:

    a) Conservation effects of the use and release into the environment of CITES-listed specimens produced through biotechnology;

    b) Socioeconomic implications, including the likelihood of potential market opportunity for both legal and illicit traders, and how to apply a "precautionary approach".

Way forward

19. Considering that this is an emerging, and yet rapidly developing field, the full extent of the scientific, environmental and regulatory implications of the specimens produced through biotechnology is difficult to predict. Moreover, the subject matter seems to overlap with, or have potential effect on a few existing CITES provisions, processes, and discussions. The study provided the Secretariat with a basis from which relevant

[2] *See CoP 13 Prop.1 (https://www.cites.org/sites/default/files/eng/cop/13/prop/E13-P01.pdf) and CoP13 Prop.2 (https://www.cites.org/sites/default/files/eng/cop/13/prop/E13-P02.pdf)*

issues regarding the potential applications of the technologies and the ramifications on existing regulatory regimes could be extracted and considered further in the context of the Convention.

20. Evidence from other ongoing processes (such as the Convention on Biological Diversity and the Food and Agriculture Organization) as well as past CITES negotiations for CoP12 Prop.1, CoP13 Prop. 1 and Prop. 2 suggest that this is a difficult topic, and the discussion could become very complicated. It is therefore necessary for Parties to avoid straying into marginal issues and remain focused on the main objective, which is to consider whether and how to regulate products produced through biotechnology that are based on, linked to, or mimic specimens of CITES-listed species, in order to achieve the Convention's objectives, which is to ensure that the international trade in specimens of CITES-listed species do not threaten their survival in the wild.

21. The Working Group Chair and the Secretariat are of the view that it may be premature to recommend to the Conference of the Parties at its 18th meeting to adopt a new source code or other regulatory solutions, since it has not had sufficient time to consider the Secretariat's findings and recommendations of the study, nor has it received the recommendations from the Animals and Plants Committees. There are also some pertinent issues that merits further investigation, such as those mentioned in paragraphs 17 and 18 above. The Standing Committee may wish to examine implications of any potential regulatory solutions carefully, while maintaining the momentum of the progress made so far. This includes close observation of the technological developments and their applications, particularly on technological advancements that result in products that mimic specimens of Appendix-I-listed species, where a precautionary approach may need to be exercised.

22. In mirroring the recommendations from AC30/PC24, the Standing Committee may also wish to recommend that decisions be submitted to the Conference of the Parties at its 18th meeting so that the Standing Committee may make recommendations at its next session.

Recommendations

23. The Standing Committee is invited to:

    a) take note this report;

    b) use the expression "specimens produced through biotechnology" instead of "specimens produced from synthetic or cultured DNA" for the title of this subject matter as recommended by Animals and Plants Committees;

    c) analyse the need and implications of creating a new source code for specimens produced through biotechnology; and

    d) revise the draft decisions on specimens produced through biotechnology contained in Annex 1.

DRAFT DECISIONS OF THE CONFERENCE OF THE PARTIES

Specimens produced through biotechnology

Directed to Parties

18.AA 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 wildlife 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.AB In implementing Decision 18.AA above, Parties are requested to pay particular attention to technological developments and applications that result in products that may be recognised as specimens of Appendix-I listed species.

Directed to the Animals and Plants Committees

18.BB The Animals and Plants Committees shall:

a) review the complete study on Wildlife products produced from synthetic or cultured DNA, 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.

Directed to the Standing Committee

18.CC The Standing Committees shall:

a) consider the study on wildlife products produced from synthetic or cultured DNA, as well as the Animals and Plants Committee's recommendations, pursuant to Decision 18.BB, and;

b) propose other issues that may require further examination or assessment, if any;

c) communicate to the Animals and Plants Committees any matters that may require scientific advice and guidance, as appropriate; and

d) make recommendations for consideration at the 19th meeting of the Conference of the Parties, including appropriate revisions to existing resolutions related to new regulatory measures, such as the operational definition of the term 'part or derivative' and the pertinence and usefulness of creating a new source code for specimens produced through biotechnology.

Directed to the Secretariat

18.DD 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 and the Standing Committee;

b) collate information received from Parties in relation to Decision 18.AA, 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 United Nations Food and Agricultural Organization (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) report progress to the Animals and Plants Committees, and the Standing Committee, as appropriate.

Terms of reference for the study on wildlife products produced from synthetic or cultured DNA

Pursuant to Decision 17.89 and drawing upon document CoP17 Doc. 27 (paragraphs 21 to 26) and other relevant documentation submitted by Parties and observers, the study should review relevant CITES provisions, Resolutions and Decisions, including Resolution Conf. 9.6 (Rev. CoP16) on *Trade in readily recognizable parts and derivatives* and taking into consideration past discussions on specimens covered by the Convention, e.g. ambergris, etc. to examine:

– Part I – How Parties have applied the interpretation of Resolution Conf. 9.6 (Rev. CoP16) to wildlife products produced from synthetic or cultured DNA;

– Part II – Under what circumstances wildlife products produced from synthetic or cultured DNA meet the current interpretation; and

– Part III – Whether any revisions should be considered, with a view to ensuring that such trade does not pose a threat to the survival of CITES-listed species.

First part of the study

Describe in a very concise manner the different ways that DNA can be synthesized, cultured or otherwise produced artificially, and how wildlife products can be produced from synthetic or cultured DNA in the context of CITES.

Summarize cases where specimens of CITES-listed species are being produced from synthetic or cultured DNA, e.g. rhino horn, ivory, pangolin scales, medicinal plants, fragrances, etc.

The Secretariat shall issue a Notification to Parties asking for information on cases where they have issued (or not issued) CITES permits and certificates for bioengineered specimens, and the study shall collate this information and include it in the study report.

Second part of the study

Identify and analyse relevant legal/regulatory/enforcement and scientific/technological inter-related elements that should be considered by the Standing Committee and the joint meeting of the Animals and Plants Committees.

Elements that may be considered from a legal/regulatory/enforcement perspective:

a) Resolution Conf. 9.6 (Rev. CoP16) interprets the term ‘readily recognizable’ but does not provide an operational definition for the term ‘part or derivative’. The study shall explore the pertinence and relevance of including an operational definition of the term ‘part or derivative’ in Resolution Conf. 9.6 (Rev. CoP16) in this context; and

b) The pertinence and usefulness of creating a new source code for “bioengineered” wildlife products derived from synthetic or cultured DNA as a separate category of specimens.

Third part of the study

Elements to be considered from a scientific/technological perspective:

c) Information on existing or potential tools to distinguish between wildlife products derived from synthetic and cultured DNA;

d) Information on technological developments that can be used to produce specimens of CITES-listed species within the field of synthetic biology; and

e) Information on relevant risk management measures and best practices which can be used to help ensure that trade in wildlife products derived from synthetic and cultured DNA does not pose a threat to the survival of CITES-listed species.

To ensure consistency and to avoid duplication, the consultant shall – in undertaking these tasks – take into account ongoing discussions and work carried out by other relevant international organizations, including the Convention on Biological Diversity and its protocols.

Responses to Notification to the Parties No. 2018/013
(as at 24 April 2018)

Party	Issued permits or assessed permit applications ?	Any other information
Australia	**NO**	According to the national law, the Management Authority expects that it would require CITES permits in the event that a bioengineered CITES specimen was to enter/exit Australia.
China	**YES**	Issued 5 permits deemed to be related to bioengineering, including paclitaxel (582.9kg) and docetaxel (4kg) from *Taxus chinensis* and cultured cells of *Chlorocebus aethiops* 2 projects of synthetic biology, using plant-derived compounds in microbial cell cultures (taxol and ginseng)[3,4] Few projects launched recently on plant synthetic biology and mammalian cell synthetic biology[5]
European Union	**NO**	Germany would like to flag that the CITES community may consider creating rules for specimens produced from synthetic or cultured DNA because the demand for those specimens could lead to an increase in the demand for (illegal) real specimens (e.g. rhino horn) and because these specimens could be mixed with (illegal) real specimens. It could be detrimental to the aims of CITES (to protect species in the wild) if those specimens (continue to?) simply fall out of the scope of CITES. This new field reminds us of challenges with look-alike species in the case of listing proposals.
Switzerland	**NOT SURE**	Switzerland exports regularly medicinal products or research material derived from research on primates. However, to determine whether these products are based on bio-engineered or synthetic or cultured DNA has not been required or possible to date. Database where examples of synthetic bioengineered products are listed[6] Website created by the Swiss Natural Science Foundation specifically devoted to the topic of synthetic biology[7] FAO CGRFA study *"Digital sequence information" on genetic resources for food and agriculture* (CGRFA-17 Bureau 2/18/4)[8] *A Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol (CBD/DSI/AHTEG/2018/1/3)*

[3] *Liu, W.C., T. Gong and P. Zhu, 2016. Advances in exploring alteranative Taxol sources. RSC Adv. 2016, 6-48800-48809.*

[4] *Zhuang, Y. et al. 2017. Biosynthesis of plant-derived ginsenoside Rh2 in yeast via repurposing a keypromiscuous microbial enzyme. Metabolic Engineering, 42:25-32.*

[5] *Chen, G. and Y. Wang, 2015. Progress in synthetic biology of "973 Funding Program" in China. Chinese Journal of Biotechnology 31 (6): 995-1008.*

[6] *http://www.synbioproject.org/cpi/*

[7] *https://naturwissenschaften.ch/topics/synbio*

[8] *This document is not yet available on the FAO Website.*

Thailand	**NO**	No other relevant information
United Kingdom	**NO**	Not aware of any records of applications for trade in CITES specimens derived from synthetic biology or from 'cultured DNA'
United States of America	**NO**	U.S. Fish and Wildlife Forensics Laboratory: "it is important to consider the differences between the protein products that arise from recombinant DNA and cultured cells and the products that are now being proposed by the biosynthetic tissue industry. One major difference is that proteins and antibodies produced from cultured cells are targeted products translated *in vitro* that do not require the presence of viable DNA molecules from the source organism for production or validation. Therefore, it appears that the biosynthetic tissues (for example, rhino horn) themselves would not require DNA for construction or translation, but that the value of the final product would likely be dependent upon the presence of rhino DNA to create the illusion that it is a real product. From a law enforcement perspective, there needs to be a method by which enforcement is able to discriminate between natural tissue and biosynthetic tissue, regardless of whether it's presented as a 3-D object (horn or tusk or carving) or a medicinal (powder or liquid). Without this detection ability, it is not possible to distinguish between genuine and fabricated items. The Laboratory was informed by an industry representative working with biosynthetic rhino horn that such a detection system would need to be proprietary in the event that a competitor wanted to exploit the fact that a product was synthetic, or to maintain the illusion that that biosynthetic product shares the same traditional characteristics of the natural product. Unfortunately, proprietary detection systems will not stand up in a court of law if we have to demonstrate that a product is real or biosynthetic as we would not be able to exclude a natural source. There are ways to "label" a biosynthetic product to prevent identification challenges for enforcement – a known DNA barcode could be incorporated into the DNA sample included in the synthesis of the final product, or an inert rare earth element could be added to the product that could be easily detected but not interfere with the commercial value of the product. For example, "biosynthetic" caviar can be distinguished from genuine fish eggs. These "eggs" are beads of a gelatinous substance made with flavor and color additives to resemble the properties of sturgeon roe. They do not contain DNA and the Laboratory has a method by which they can distinguish this product from real fish eggs, so there is no question that they are synthetic and are not real eggs. Synthetic DNA is a related topic, which is different from "biosynthetic products. " The Laboratory considers primers and polymerase chain reaction (peR) product to be "synthetic DNA" because it's an artificial copy of a DNA sequence, which is easily detected by the lack of methylated groups on the molecule. References for recombinant DNA can be found at: https://www.genome.gov/25520302/
Inputs from observers		
Lewis & Clark Law School and the Center for Biological Diversity	**NA**	Legal analysis regarding whether "products produced from synthetic or cultured DNA" are covered by CITES[9]

[9] *Revised version of CoP17 Inf. 22 submitted by the United States. The legal analysis has also been endorsed by WildAid and Natural Resources Defense Council*

Overview of different techniques/biotechnologies and their potential
Summary findings from the consultant's study on *Wildlife products produced from synthetic or cultured DNA (Revised 2 August 2018)*

Techniques/ Technologies	Brief description of what it involves	Possible examples of current application	Potential and future application (theoretical; does not take into account economic factors)
DNA modification	Modify the DNA (and its expression) of both eukaryotic and prokaryotic organisms using a variety of genetic and molecular/cell biology techniques	Could theoretically be used to create "cell factories" that produce chemicals and proteins of other animals and plants	Can cause genetic variation in a given organism that may not be naturally inducible. Could result in significant changes in lifecycle, expression of proteins and other chemicals produced by the organism. Possible in most organisms already, and continuously being refined and made more precise.
DNA synthesis	Creating genetic elements (DNA molecules). Polymerase chain reaction (PCR) can be used to amplify the specific or targeted parts of a DNA sequence to generate thousands of copies.	This is currently primarily a research tool to make probes and copies of genes which may then be inserted into a genome	DNA synthesis is a powerful enabling technology and yet a limiting step due to the high costs involving DNA synthesis. This will become more and more important as the techniques are refined[10] and as the costs decrease, which will open new frontiers and project concepts.
Cell culture	Removal of cells from an animal or plant and their subsequent growth in a favorable artificial environment New genetic materials can be introduced into a cell before they are grown	Cells of rhino horn may be isolated, immortalized and grown in cell culture to produce a "rhino horn powder"	**Unicellular organisms** (e.g. bacteria) can be generated and grown over many 'generations' and is already a major tool in research and for commercial production of microorganisms or their metabolites in industries. Many whole **plants** can be generated from a single cell. Vegetative propagation allows production of a whole plat from tissue or cells (e.g. bananas). It is theoretically possible to isolate **animal** cells and culture them. Cell immortalization (a first step towards cloning of animals) is not as simple as for other organisms and remains primarily a research tool, this may change in the future.
Tissue (organ) culture	A number of different cell types are grown, often in some form of matrix (a layer of cells on gel or suspension of the cells in liquid culture) in order to	Muscle (meat) of animals can be created and commercial production has been researched. This	Organ/tissue from any organism can theoretically be synthesized using the techniques of modern biotechnology, including modifying the DNA in the tissue and/or using cell culture technology. However, each tissue/organ generated cannot be propagated further today; also, the reproducibility is low

[10] *see "'Minimal' cell raises stakes in race to harness synthetic life" in https://www.nature.com/news/minimal-cell-raises-stakes-in-race-to-harness-synthetic-life-1.19633*

	develop the characteristic structures in three dimensions (to aid self-assembly of cells)	may also be applied for CITES-listed animals	and remains difficult/expensive. The technology is constantly changing, however, and many applications may become possible in the future.
3d printing	Allows the creation of replicas (copies) of any product	Can create parts and derivatives that may be visually indistinguishable (e.g. rhino horn, elephant ivory, pangolin scales, etc.)	In combination with the tissue/organ culture, and with 3d printing it is likely to be a major technology in the near future.

Types of parts/derivatives that could be produced through biotechnology, identification/distinction and other scientific issues
Summary findings from the consultant's study on *Wildlife products produced from synthetic or cultured DNA (Revised 30 July 2018)*

Product type	**Examples of derivatives that may be produced from CITES-listed specimens using biotechnology**	**Ways in which the products can be distinguished from wild-sourced ones**	**Other scientific issues to consider**
Chemicals	Processed oils for fragrance (agarwood, sandalwood, civet/deer musk etc.), active ingredient of medicinal plants, shark oil, etc.	Difficult or impossible to distinguish, as the chemicals are purified and markers cannot be used. Impurities in the chemical extracts of natural-sourced products may distinguish them from synthetic ones, which may only contain the active (target) chemical compound.	Synthetic products could replace the natural-sourced materials
Complex compounds that include proteins	*Aloe vera*, orchid root powder Rhino horn powder, coral accessories, bear bile, caviar essence	Minor changes can deliberately be made to the protein sequence of the synthetically produced protein as a positive identification tool ("label")	
Cells, tissue, organisms	Plant tissue, wood products, timber, whole plants and trees Horns, bones, skin, fur, whole "synthetic" animals	Genetic markers could be inserted into the genome of the cultured products as a positive identification tool ("label") For some complex multi cellular products, the regularity of the cell structure may allow the distinction between synthetic and wild-based products	Synthetic tissue/organ culture is currently at early stages of development; development of whole animals and plants at the organism level is further ahead Epigenetic differences could theoretically be used to distinguish synthetic from natural, or even identify the source of the material