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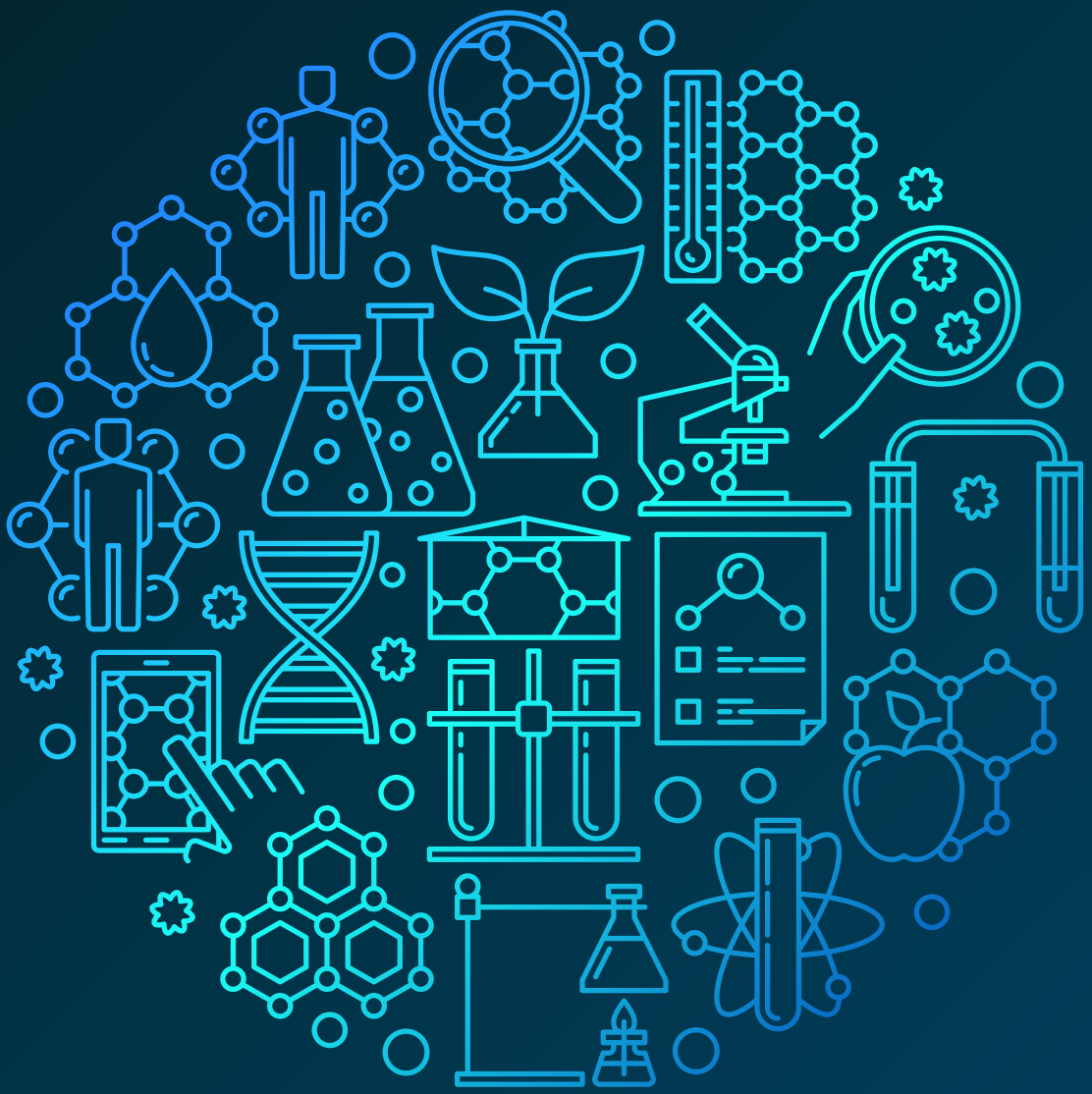
SYNTHETIC BIOLOGY AND ITS POTENTIAL IMPLICATIONS FOR BIOTRADE AND ACCESS AND BENEFIT-SHARING



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This publication has not been formally edited.

UNCTAD/DITC/TED/INF/2019/12

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Acknowledgements

This study was prepared by Mr. Frederic Perron-Welch, Access and Benefit-Sharing (ABS) Consultant for the BioTrade Initiative of the Trade, Environment, Climate Change and Sustainable Development Branch of UNCTAD.

The study has greatly benefited from peer reviews and substantive inputs by: Ms. Lorena Jaramillo, Economic Affairs Officer, and Mr. David Vivas Eugui, Legal Officer, of the Trade, Environment, Climate Change and Sustainable Development Branch (TED) of UNCTAD; Ms. Anne Schick (Swiss State Secretariat for Economic Affairs SECO); Molly Bond (Bristol University); Dr. Marco D'Alessandro (Swiss Federal Institute of Intellectual Property (IPI)); Dr. Hartmut Meyer, (ABS Capacity Development Initiative); Ms. Maria Julia Oliva (Union for Ethical BioTrade (UEBT)); Dr. Balakrishna Pisupati (Forum for Law, Environment, Development and Governance (FLEDGE)); and Mr. Andrew Wilson (Helvetas Swiss Intercooperation). Desktop formatting was done by Mr. Rafe Dent of UNCTAD.

UNCTAD gratefully acknowledges the support of SECO in the development of this study under the Global BioTrade Programme: Linking trade, biodiversity and sustainable development.

2 October 2019

Abbreviations

ABS	Access and benefit-sharing
AHTEG-SB	Ad Hoc Technical Expert Group on Synthetic Biology
BBF	BioBricks Foundation
BioCAD	Computer-Aided Design software environments for biology
BLAST	Basic Local Alignment Search Tool
BPA	BioBrick Public Agreement
BT P&C	BioTrade Principles & Criteria
CAD	Computer-Aided Design
Cas9	CRISPR-Associated Protein 9
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COP	Conference of the Parties
COSMOS	COSMetic Organic Standard
CRISPR	Clustered regularly interspaced short palindromic repeats
DDBJ	DNA Data Bank of Japan
DNA	Deoxyribonucleic acid
DSI	Digital sequence information
ECSC	European Commission Scientific Committees
EFSA	European Food Safety Authority
EGGenTDurchfG	German Genetic Engineering Implementation Act
EMBL-EBI	European Bioinformatics Institute at the European Molecular Biology Laboratory
FAO	United Nations Food and Agriculture Organization
FDA	United States Food and Drug Administration
FCI	France Chirurgie Instrumentation S.A.S.
Gates Foundation	Bill & Melinda Gates Foundation
GMOs	Genetically modified organisms
GRAS	Generally recognized as safe
iGEM	International Genetically Engineered Machine Competition
IFF	International Flavors & Fragrances
INSDC	International Nucleotide Sequence Database
IUCN	International Union for Conservation of Nature
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LMOs	Living modified organisms
MAGE	Multiplex Automated Genome Engineering
MAT	Mutually agreed terms
NCBI	National Center for Biotechnology Information
NGS	Next generation sequencing
NIH	National Institutes of Health
OECD	Organisation for Economic Co-operation and Development
Online Forum	Open-ended Online Forum on Synthetic Biology
Open MTA	Open Material Transfer Agreement
PIC	Prior informed consent
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
SCCS	European Union Scientific Committee on Consumer Safety
SCENIHR	European Union Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	European Union Scientific Committee on Health and Environmental Risks
SDGs	Sustainable Development Goals
SSA	Semisynthetic artemisinin
SynBio	Synthetic biology
TALEN	Transcription Activator-Like Effector Nuclease
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
ZFN	Zinc-finger nuclease

EXECUTIVE SUMMARY

Synthetic biology was identified as an emerging issue meriting further research at the first meeting of the UNCTAD BioTrade Initiative Stakeholder Steering Committee meeting in 2018. This first study on the implications of synthetic biology for BioTrade was developed based on this request in order to provide guidance and further comprehension of the topic, especially its implications for BioTrade. BioTrade partners are expected to further support this line of work to enhance knowledge and provide practical experiences that enrich the findings in this study.

Although there is no universally agreed upon definition of the term 'synthetic biology', the 13th Conference of the Parties (COP) to the Convention on Biological Diversity acknowledged the following definition as a useful starting point for continued discussions: "a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems." As such, it falls within the scope of the Convention and its Protocols on biosafety and access and benefit-sharing (ABS).

Through this study, particularly the case studies, UNCTAD aims to show the potential implications of synthetic biology for BioTrade and ABS. From the research carried out, it appears that synthetic biology will not have direct impacts on all BioTrade sectors, as existing technologies mainly target specific market sectors such as the cosmetics sector, food and fragrances sector, and pharma/phytopharmaceutical sector. The most foreseeable consequence for BioTrade is the displacement of naturally sourced ingredients with ingredients produced through the use of synthetic biology. However, displacement in the BioTrade sector may be limited, as consumers purchasing products with BioTrade ingredients are likely looking to purchase products produced in line with economic, social and environmental sustainability criteria and are less likely to be influenced by cost savings resulting from the use of synthetic biology ingredients. This trend is especially strong with younger consumers.

Many of the implications of synthetic biology for BioTrade remain prospective because most synthetic biology companies are not yet producing economically competitive products. Given this, it is an opportune time for BioTrade actors to take a proactive approach to this matter. Based on the analysis conducted in the study, several recommendations for BioTrade can be made. These recommendations offer different possible approaches to addressing synthetic biology in the revised BioTrade Principles and Criteria (BT P&C), and addressing its implications for the sustainable use of biodiversity more broadly.

Recommendations:

1. Provider countries may want to consider conducting socioeconomic impact assessments for nationally important value chains when a synthetic biology alternative appears on the market in order to determine its potential impact on jobs and livelihoods.
2. Where there is a significant risk to jobs and livelihoods, it may be appropriate for provider countries to assist producers to transition to different BioTrade value chains to prevent the impact on livelihoods and biodiversity that would result from a shift away from the existing value chain.
3. Consider the need and potential implications of defining "natural product" or "goods and services derived from native biodiversity" in the context of BioTrade. This would be a challenging undertaking and it may be preferable to leave this to national decision makers and standard-setting bodies.
4. Consider addressing how the BioTrade Principles and Criteria address specific types of technologies or products falling under the broad scope of synthetic biology. This may include the question of whether a broad approach is preferable, or whether a case-by-case approach based on sustainability criteria is appropriate.
5. Consider whether a case-by-case approach to the use of products fabricated with genetically modified/synthetic biology organisms in BioTrade products is appropriate where they are demonstrably more sustainable than their naturally derived counterparts (e.g. where there is a trade ban under CITES, listed on the International Union for Conservation of Nature (IUCN) Red List).
6. If a case-by-case approach is adopted, consider the development of a traceability mechanism for ingredients that are derived from CITES-listed species to prove that they have been fabricated using SynBio processes and not directly from these species.

SECTION 1: INTRODUCTION TO BIOTRADE, SYNTHETIC BIOLOGY AND SYNTHETIZATION

This emerging issues study on the implications of synthetic biology (SynBio) for BioTrade was developed at the request of BioTrade Initiative partners, who requested further guidance and understanding of the topic of SynBio and its potential implications for BioTrade. This section addresses the concept of BioTrade, the field of SynBio, and the differences between chemical synthesis and biosynthesis.

1. BioTrade

BioTrade involves the collection, production, transformation and commercialization of goods and services derived from native biodiversity (species and ecosystems) under environmental, social and economic sustainability criteria—the BioTrade Principles and Criteria (BT P&C). The underlying premise of BioTrade is that biodiversity based products — if sourced and elaborated with respect for equity, fairness and sustainability principles — can also provide a strong basis for local livelihoods, respect for traditional practices and values, and the conservation and sustainable use of biodiversity. A distinction must be drawn between BioTrade that takes place in line with the BT P&C, and the broader trade in biodiversity-based products, as not all commercial use of biological resources is sustainable.[1]

BioTrade is being implemented in sectors such as personal care, pharmaceutical (phytopharma); food; fashion; ornamental flora and fauna; handicrafts; textiles and natural fibres; sustainable tourism; and forestry-based carbon credit activities.[2] Specific examples of BioTrade products are provided in the Table 1 (page 2).

Although not relevant to all BioTrade sectors, synthetic biology (SynBio) products could have an impact on BioTrade value chains in the following sectors: personal care; pharmaceutical (phytopharma); food; fashion; and textiles/natural fibres. Case studies on existing and emerging SynBio products in the cosmetics and flavourings and fragrance sectors will be presented in this report in order to demonstrate the potential for impacts on BioTrade value chains, as they are the most developed and have the greatest potential impact.

Box 1: Sample BioTrade case

In 2009, Weleda, a Swiss-based company producing natural and organic beauty products and anthroposophic medicines, and a [Union for Ethical BioTrade] member, launched a project for the organic and sustainable cultivation of sandalwood in Sri Lanka. Sandalwood is used as an essential oil and fragrance for a range of Weleda products… For Weleda, it is fundamental that the sandalwood oil used not only comes from organic and sustainable sources, but also contributes to increasing the number of sandalwood trees in Sri Lanka and to the livelihoods of local communities.

In this context, Weleda formed a partnership with a local family-owned company. Together, they found an old, abandoned tea plantation in the highlands of Sri Lanka. There, next to 100-year-old tea bushes, grew almost 1000 sandalwood trees, including young saplings. The trees had spread naturally thanks to birds carrying seeds and had thrived on the steep terrain protected by the wide root systems of the tea bushes. With the support of Weleda, the company invested in the land and techniques for organic and sustainable harvesting of sandalwood…

In line with the Ethical BioTrade Standard – based on BT P&C – the Weleda sandalwood project also has a strong social component. Weleda signed an agreement committing to the project and to sourcing exclusively from this company for a number of years. It has also supported the creation of a plant nursery and a training and education centre for the collectors. This centre focuses not only on sandalwood, but also on the cultivation of vegetables, tea and cinnamon trees. This is to ensure that a variety of crops is cultivated – key to local food security and to diversifying local incomes. For example, the local company now independently harvests and commercializes other crops, with an organic certification.

Source: 20 Years of BioTrade: Connecting People, the Planet and Markets, pp. 24-5.

Table 1: BioTrade sectors prioritized by countries and partners

Sector	Type of product
Personal care	Essential oils, natural dyes, soaps, cream and butters, cosmetics, etc.
Pharmaceutical (phytopharma)	Extracts, capsules and infusions from medicinal plants, etc
Food	Fruit pulps, juices, jams, biscuits, sauces, spices, nuts, tubers, snacks, food supplements, meat from caiman and fish, etc.
Fashion	Skin and belts, bags from Caiman yacare, etc.
Ornamental flora and fauna	Heliconias, orchids, butterflies, etc
Handicrafts	Jewellery, decorative objects based on native species, garments, etc
Textiles and natural fibres	Furniture and decorative objects based on natural fibres, bags, shoes, etc.
Sustainable tourism	Ecotourism, nature-based tourism, community-based tourism, etc.
Forestry-based carbon credit activities	Reducing Emissions from Deforestation and Forest Degradation, conservation, sustainable management of forests and enhancement of forest carbon stocks (REDD+), greenhouse gas (GHG) emissions mitigation strategies for specific value chains, etc.

Source: L Jaramillo & B Onguglo, "BioTrade — harmonizing trade, biodiversity and livelihoods" in 20 Years of BioTrade: Connecting People, the Planet and Markets, United Nations Doc. UNCTAD/DITC/TED/2016/4, 3.

2. Defining synthetic biology

SynBio is a rapidly developing field which emerged from developments in genetic engineering in recent decades.[3] It builds on advances in molecular biology, genetic engineering and microbiology,[4] while also moving beyond these fields through the embrace of "techniques and ideas from biology, engineering, chemistry and materials sciences."[5] SynBio uses all available genetic engineering technologies, but aims at a faster and easier process.[6] As such, it is best understood as "an umbrella term … that gathers a set of activities that ranges from the basic sciences to innovative technology, rather than as a new scientific paradigm."[7] It is "a toolbox, not an end in itself."[8] The activities taking place in the field of SynBio are not so distinct from earlier technologies as to fall outside the broad definition of biotechnology provided for in the Convention on Biological Diversity (CBD),[9] namely: "any technological application that uses biological systems,

early signs of potentially important developments through a systematic examination of potential threats and opportunities, with emphasis on new technology and its effects on the issue at hand."[11]

In the past decade, SynBio has become "a key part of 21st century bioscience and biotechnology."[12] Advances in reading DNA (sequencing) and writing DNA (synthesis) have "have led to the development of ground-breaking technologies for the design, assembly, and manipulation of DNA encoded genes, materials, circuits, and metabolic pathways, which are allowing for an ever greater manipulation of biological systems and even entire organisms."[13] Next generation sequencing (NGS) technologies and DNA synthesis technologies "form the two foundational technologies driving synthetic biology efforts and will eventually instill the predictability and reliability to engineered biological systems that chemical engineering has brought to chemical systems."[14] Due to NGS technologies, there