

#### The ABS Management Tool Updated for the Nagoya Protocol

Panel on Access and Benefit-Sharing Third Meeting of the Global Partnership for Business and Biodiversity

October 2, 2013

Strategies to Sustainability

# **ABS** MANAGEMENT TOOL

#### Best Practice Standard and Handbook

#### Implementing Genetic Resource Access and Benefit-Sharing Activities

– for \_\_\_\_\_

Developed by Stratos Inc. in cooperation with Geoff Burton and Jorge Cabrera

Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs FDEA State Secretariat for Economic Affairs SECO Updated May 2012

# Volume 1 The ABS Best Practice Standard

**VOLUME 1 - THE ABS BEST PRACTICE STANDARD** 

### Volume 2 - The Handbook

Part 1: Good Practice Guidance for each Standard

#### Part 2: Supporting Tools

- Roadmap of interaction with national legal frameworks
- ABS agreement matrix for GR users
- Material transfer agreements
- Model contract outline
- Guidance on negotiating strategies
- Links to sector-specific guidelines (See hand out)

#### Part 3: Case Studies

#### What the ABS – MT Provides:

Guidance for legal certainty

A fair, equitable, structured process for Users and Providers to assist deal making

Support to governments for NP compliant domestic ABS systems - implementation

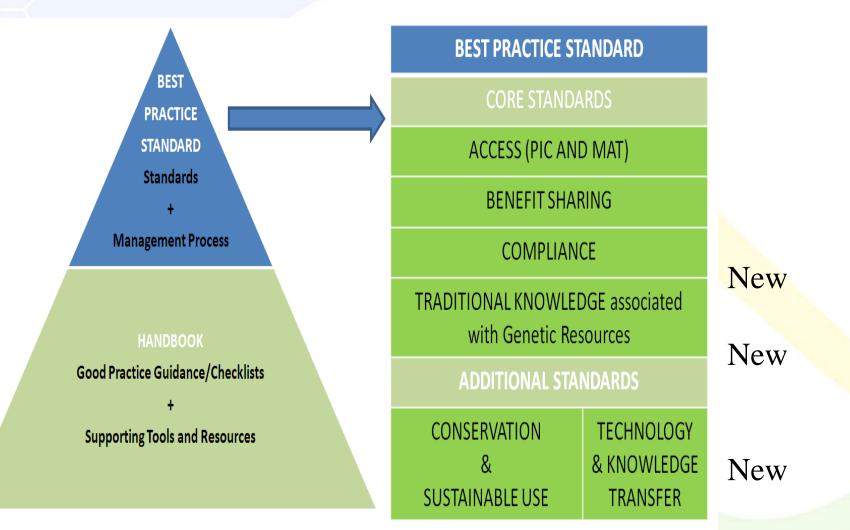
#### Application of the ABS – MT

- The ABS-MT applies to all stages of genetic resource activity:
  - Prior to access
  - Access (collection and bio-discovery)
  - Academic research
  - Research and development
  - Commercialization and commercial use

#### The ABS-MT is relevant to many sectors:

- Pharmaceuticals
- Cosmetic
- Botanicals + Neutraceuticals
- Biotechnology including for environmental remediation
- Horticulture including ornamentals
- Agriculture (except where the FAO ITGRFA applies)

# **UPDATED ABS MT**



### Standard 1.0 - Access

**1.1 PIC** is prior, informed and consented in intent and practice.

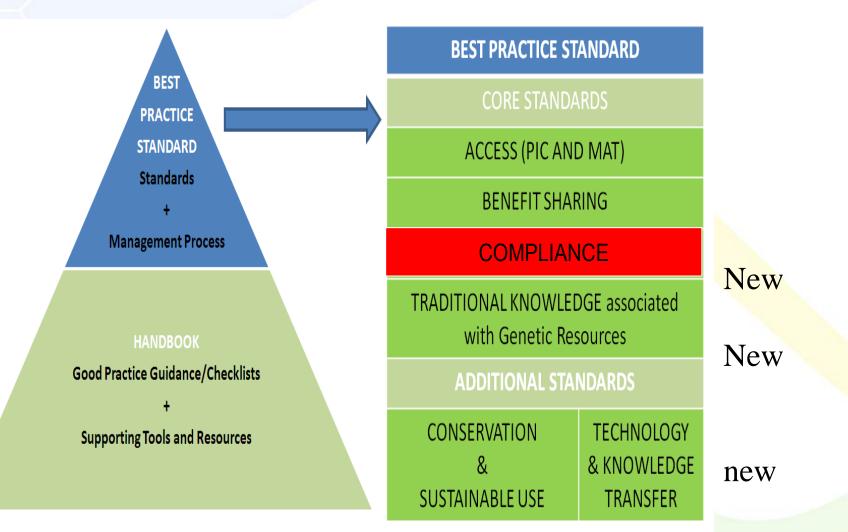
**1.2 PIC** is obtained in writing from the competent government authority, and from the relevant stakeholders, including local communities and indigenous peoples who are the owners, managers or custodians of genetic resources, or traditional knowledge associated with genetic resources.

**1.4** A new **Prior Informed Consent** is given for any use that differs in type or scope from that originally outlined. An agreement is concluded with the provider that reflects the terms and conditions of PIC including, *inter alia*, terms and conditions regarding benefit-sharing. (see Vol 1 page 21)

**1.6 MATs** are negotiated in a manner that builds confidence and a relationship of trust between the providers of genetic resources (holders, owners, managers, and custodians) and the users. Negotiations establish the basis for a long-term, transparent, and respectful relationship and communication between them. MATs are established in writing.

**1.7 MATs** are negotiated in good faith by users and providers, respecting the terms and understanding of prior informed consent, allowing benefits to flow to the holders, owners, managers, or custodians of the genetic resource, and facilitating access.

# **UPDATED ABS MT**



#### **Nagoya Protocol - Compliance**

#### **National Compliance obligations:**

- ensure imported genetic resources are lawfully obtained
- ensure Benefit-sharing Agreements (contracts) are honoured
- establish 'checkpoints' where information about utilisation of genetic resources is obtained, and
- Support establishment of model contract clauses, standards and best practices

#### The Internationally Recognized Certificates of Compliance

- Permit issuing country places a copy (or certain minimum information) with the ABS Clearing House Mechanism
- This then becomes an Internationally Recognised Certificate of Compliance
- The information on the ABS CHM is public & allows for electronic verification of Permits and provenance
- Certificates verify imported material lawfully obtained

### **Standard 3.0 - Compliance**

Compliance means meeting the requirements and obligations of national (domestic) ABS legislative, administrative or policy measures on access to genetic resources and traditional knowledge associated with genetic resources. Similarly, compliance means meeting the requirements of national (domestic) laws and administrative or policy measures of the **country** in which genetic resources and associated traditional knowledge are **utilized.** 

In both cases compliance also means meeting the requirements and obligations documented in mutually agreed terms.

### Standard 3.0 – Compliance

**3.1** The legal framework existing in the country(ies) to which the genetic resources are to be used (or going to be sent) is disclosed to the provider of the genetic resource and to relevant governmental organizations by the user. Such disclosure includes any measures existing to support compliance with national ABS legislation or measures of the providing country; mechanisms in place to cooperate in cases of non-compliance; options for access to justice in such country(ies); and possibilities for recognition of foreign court arbitral awards, among others. (While not explicitly required by the Protocol, such action builds trust and supports the implementation by governments of their arrangements to discharge the Protocol's compliance and monitoring provisions.)

**3.2** Users and providers respond in a timely manner and in writing to any allegations of noncompliance with the national ABS legislation or measures as well as non-compliance with

MATs and PIC, and seek – in good faith – to remedy or solve any situation of noncompliance, if existing.

### Standard 3.0 – Compliance

**3.3** All relevant information regarding PIC, MATs, compliance with national legislation, and utilization of genetic resources and associated traditional knowledge, is disclosed to the appropriate checkpoints existing in the country of the provider or user country as the case may be. Any internationally recognized certificate of compliance is disclosed. If there are no officially designated checkpoints, information on the appropriate offices dealing with regulatory approvals, intellectual property rights, publications, and research and other funding, among others, are disclosed by the user – to the extent feasible and on a case-by-case basis.

**3.4** National monitoring mechanisms for the use of genetic resources and associated traditional knowledge are complied with by the user to support compliance and enhance transparency, including through the ABS Clearing-House Mechanism and Internationally Recognized Certificates of Compliance where feasible.

**3.5** Users report their compliance with ABS legislation or measures of the country where the genetic resources are accessed as required by the country in which they are used. Reporting includes any non-confidential information on any third-party.

# **Compliance Guidance**

STANDARD 3.0: COMPLIANCE	For Provider	For User
<ul> <li>Facilitate information regarding legal mechanisms existent on access to justice, cooperation between the providing country and the country in which the material is utilized, recognition and enforcement of foreign awards, and of legal remedies available in cases of non-compliance with the contract in countries where the genetic resources will be sent upon request of the provider.</li> </ul>		x
<ul> <li>Ensure the user of the material has an Internationally Recognized Certificate of Compliance.</li> </ul>		
<ul> <li>Disclose relevant information on prior informed consent, mutually agreed terms, utilization of genetic resources and associated traditional knowledge, and compliance with national ABS measures in the country where the resources were accessed to the checkpoints established in the country where the material is utilized – where these exist.</li> </ul>		x
<ul> <li>If checkpoints do not exist, provide relevant information, where appropriate, on the above matters to institutions such as IPR offices, product register, journals, and funding institutions, others on a case-by-case basis.</li> </ul>		x

## The ABS MT Supports NP Compliance

- Importance of legal certainty to meeting compliance requirements and managing risk
- Companies able to demonstrate legal provenance will avoid regulatory, investment, partnership, obstacles and reputational risk
- Will apply to companies in NP ratifying and nonmember countries
- Universities and Research institutes and spun out start-up companies are now the predominant source of bio-discoveries for the Majors – so supply chain matters



Stratos http://www.stratos-sts.com

The updated ABS-MT can be viewed and downloaded from the following locations:

From the Government of Switzerland's ABS Clearing House: http://www.sib.admin.ch/en/nagoya-protocol/abs-management-tool/index.html

The Convention on Biological Diversity website: <a href="http://www.cbd.int/abs/instruments/">http://www.cbd.int/abs/instruments/</a>