



THE ABS CAPACITY DEVELOPMENT INITIATIVE

L'INITIATIVE DE

RENFORCEMENT

DES CAPACITES

POUR L'APA

## Digital Sequence Information on Genetic Resources: New Studies on Potential Approaches to Access and Benefit Sharing

**Global Webinar** 

23 February 2022, 13:00-15:00 CET

funded by





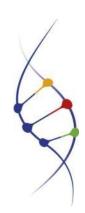
Schweizerische Eidgenossenschaf Confédération suisse Confederazione Svizzera Confederaziun svizra

Confederazione Svizzera Confederaziun svizra Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER State Secretariat for Economic Affairs SECO implemented b







#### • Gaute Voigt-Hanssen Ministry of Climate and Environment, Norway

#### • Simon Malete

Department of Forestry, Fisheries and the Environment, South Africa

#### Andreas Gettkant

ABS Capacity Development Initiative, Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)

erview	
Background and context of the webinar	Suhel al-Janabi
Key elements of three new studies	Timothy Hodges
<ul> <li>National ABS Approaches to DSI: Perspectives, Options and Limits</li> <li>Digital Sequence Information (DSI): lessons from multilateral mechanisms</li> <li>"Just" Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good</li> </ul>	
flection panel with Q&A	
Kick-off exchange among panelists	Timothy Hodges
Initial reflections	Henry de Novion
	Margo Bagley
	Chloe Johnson
	Facilitation: ABS Initiative
<ul> <li>Q&amp;A and discussion between floor and panel</li> </ul>	

### **Questions and Answers**

- Please type your comments and questions in the chat
- Colleagues from the ABS Initiative will screen the chat and compile aggregated questions and comments
- ABS Initiative will present questions and comments to the panelists, who will endeavor to address them
- (Remaining) questions and comments will inform topics and orientations of future webinars and dialogues







2020 UN BIODIVERSITY CONFERENCE C O P 1 5 - C P / M O P 1 0 - N P / M O P 4 Ecological Civilization-Building a Shared Future for All Life on Earth KUNMING · CHINA



- **COP 14** acknowledged the divergence of views among Parties on benefit-sharing from the use of DSI, and Parties committed to working towards resolving this divergence through a science- and policy-based process and further consultations.
- ABS Initiative to continue activities on DSI in the context of the Norwegian South African Environmental Cooperation Program.
- So far: webinars, Global Dialogue on DSI brought together govt' experts / negotiators, stakeholders from various sectors, IPLC representatives.
- Objective: support for an informed exchange on DSI during OEWG 3 in the context of the future post-2020 Global Biodiversity Framework
- Formal intersessional process preparing for OEWG 3: informed by submissions on DSI; further analyses of the policy approaches, options and modalities; Co-Chairs Informal Advisory Group on DSI, report by Co-Leads.
- As contribution to the informal intersessional process, the ABS Initiative will focus on informing / discussing key documents, topics and processes related to DSI discussion – guided by Co-Leads of the contact group on DSI of the OEWG 3.1.

#### 6. Performance matrix

# Background Currently at stake

oPEN.ENDED WORKING CHOLP ON THE FOST-2000 CLOBAL BIODVERSITY FRAMEWORK Thad meeting (resumed) Venue and dates to be determined Agenda item 5 COLLEADS' REFORT ON THE WORK OF THE INFORMAL CO-CHAIRS' ADVISORY GROUP ON BIGHTAL SEQUENCE INFORMATION ON GENETIC RESOURCES Note by the co-leads of the Informal Co-Chairs' Advicory Group on digital aquarce information on genetic resources I. INTROVICTION A Background 1. Af the farst part of the fluid meeting of the Open-eaded Working Group on the Fost-2020 Global Biodiversity Framework, held variably form 24 Aquats to 3 Softenber 2021, the Co-chains, Mr. Basile van Monte Status and the fluid meeting of the Open-eaded Working Group on the Fost-2020 Global Biodiversity Framework, held variably form 24 Aquats to 3 Softenber 2021, the Co-chains, Mr. Basile van Monte Status and Advices and the open-eaded Working Group on the Fost-2020 Global Biodiversity framework, held variably form 24 Aquats to 4 Softenber 2021, the Co-chains, Mr. Basile van Monte Status and the fluid meeting of the Open-eaded Working Group on the Fost-2020 Global Monte Status and Advices and Mr. Basile experiments and the Advices and Mr. Basile experiments and the Advices and Mr. Basile experiments and the Advices and Mr. Advices and Mr. Basile experiments and the Advi

CBD

the Co-Chairs in conducting informal consultations on the matter during the intersessional period.
2. As stated in its terms of reference,<sup>1</sup> the advisory group was established to provide advice and feedback to the Co-Chairs and the Executive Secretary on the following elements in advance of the second part of the faird meeting of the Working Group:

(a) The undertaking of an assessment of consequences of digital sequence and mains for benefits in this gaining from the uniliantics of digital sequence and mains on genetic resource (DSI), based on the report of the first part of the third meeting of the Working Group, including CBD WG2003/CRP1, anseens II and III of document CBD WG2003/4, and submissions received by 30 September 2012);

(b) Areas of potential convergence and areas of divergence based on the summary prepared b the co-leads, annexed to the report on the first part of the third meeting of the Working Group;

(c) Areas of additional work on DSI that may be required in the period between the third meeting of the Working Group and the fifteenth meeting of the Conference of Parties.

<sup>1</sup> See the Appendix to annex V of the report of the meeting CBD/WG2020/3/5.

Criteria and sub-criteria	Scoring 10=high- performing; 0=non- performing; 1=low- performing; N/A=do not know/not applicable. OR pass/fail	Option 0	Option 1	Opt	ion 2	Opt	ion 3	Option 4	Option 5	Option 6
		Status Quo	DSI treated as GR	Countr y MAT	Global MAT	Payment for access to DSI	Other contributi ons	Enhanced TSC and CB	No benefit sharing from DSI	1% levy on retail sales of GR
A. Effective in achieving policy goals										
1. Potential to deliver predictable monetary benefits										
2. Potential to deliver predictable non-monetary benefits										
3. Access to public databases remains open										
4. Does not hinder research and innovation										
5. Potential to contribute to the conservation and sustainable use of biodiversity										
B. Efficient and feasible to implement										
6. Technically feasible										
7. Legally feasible										
8. Legally clear and certain to implement										
9. Administratively simple										
10. Implementable in an efficient and timely manner										
11. Enables distinction between commercial and non- commercial use of DSI										
12. Cost of set-up and implementation										
C. Enables good governance										
13. Easy to understand by providers and users										
14. Easily enforceable by providers										
15. Ease of compliance for users										
16. Does result in jurisdiction shopping										
17. Facilitates the sharing of benefits with IPLCs										
D. Coherent and adaptable										
18. Coherence with other forums considering DSI										
19. Agile and adaptable to future technological and scientific development										

From: CBD/WG2020/3/INF/8, 18 November 2021. Co-leads' Report on the Work of the Informal Co-chairs' Advisory Group on Digital Sequence Information on Genetic Resources



CBD Executive Secretary

Co-chairs van Havre and Ogwal

OEWG 3 13.3-29.3.2022

Informal Co-chairs advisory group 22.9-3.11.2021 Overview Presentation for Webinar on "Digital Sequence Information on Genetic Resources: New Studies on Potential Approaches to Access and Benefit Sharing" Wednesday 23 February 2022

Selected highlights and findings

**Timothy J Hodges** 

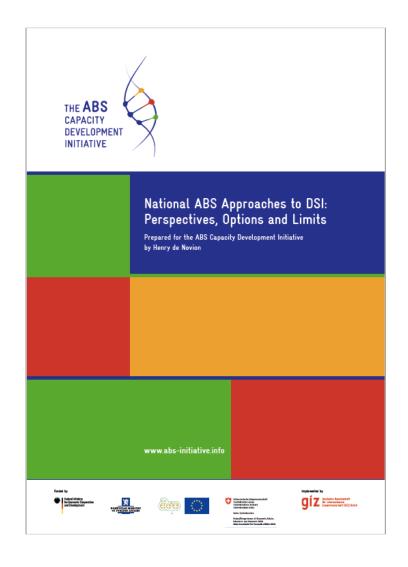


## **Three New Studies**

- National ABS Approaches to DSI: Perspectives, Options and Limits prepared for the ABS Initiative by Henry de Novion
- **Digital Sequence Information (DSI): lessons from multilateral mechanisms** prepared for DEFRA (UK) by Natalie Clare and Mar Maestre of ICF Consulting Services Ltd
- "Just" Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good

prepared by Margo Bagley







- An assessment of three approaches ("scenarios") to regulation of DSI in national ABS regimes
- Assessed through the potential impacts of the three scenarios, from three perspectives:
- Evaluated on the basis of Sirakaya's (desirable) characteristics of an effective ABS



**Three national ABS regulatory scenarios** 

- 1. Absence of ABS regulation
- 2. ABS regulation requiring PIC/MAT
- 3. Open access, under terms and conditions



Evaluated on basis of Sirakaya's characteristics of an effective ABS system

- legal certainty
- sustainable use
- cost effectiveness
- low transaction costs
- predictable conditions
- fairness and equity
- transparency



Assessed through potential impacts of the three scenarios, from 3 perspectives

- Providers
- Users
- Databanks



### Scenario 1: Absence of ABS Regulation

Cha	Perspectives racteristics	Providers	Users	Databanks	
•	Legal certainty	none	none	none	
•	Sustainable use	lowest	lowest	lowest	
•	Cost-effectiveness	lowest	lowest	lowest	
•	Transaction costs	highest	highest	rather high	
•	Predictability	none	lowest	lowest	
•	Fairness and equity lowest		lowest	lowest	
•	Transparency	lowest	lowest	lowest	
Ren	narks	Monitoring compliance may lead to high technical/ administrative burden and costs, which are likely to outweigh benefits.	Proving compliance may lead to high technical/ administrative burden and costs, which are likely to outweigh benefits.	Expectations that databanks will include private data access and use agreements may lead to high technical burden and costs.	



Henry de Novion, National ABS Approaches to DSI: Perspectives, Options and Limits (2022)

### Scenario 2: ABS Regulation Requiring PIC/MAT

Cha	Perspectives racteristics	Providers	Users	Databanks	
•	Legal certainty	intermediate	intermediate	intermediate	
•	Sustainable use	Sustainable use low		low	
•	Cost-effectiveness	st-effectiveness rather low		rather low	
•	Transaction costs rather high		rather high	rather high	
•	Predictability	rather low	rather low	rather low	
•	Fairness and equity	low	rather low	rather low	
•	Transparency	rather low	rather low	rather low	
Remarks		Technical complexity of monitoring DSI use may be beyond the capacity of most provider countries.	Legal uncertainty due to the complexity of different ABS rules in different countries.	Expectations on databanks to include IRCC (PIC/MAT) may lead to high technical burden and costs. Low predictability due to uncertainty about the legal implications of sharing DSI.	



Henry de Novion, National ABS Approaches to DSI: Perspectives, Options and Limits (2022)

## Study #1: *National ABS Approaches to DSI* Scenario 3: Open Access, Under Terms & Conditions

Perspectives Providers		Users	Databanks	
Characteristics				
Legal certainty	highest	highest	high	
Sustainable use	highest	rather high	highest	
Cost-effectiveness	highest	rather high	highest	
Transaction costs	lowest	rather low lowest		
Predictability	rather high	highest	highest	
• Fairness and equity	Fairness and equity intermediate		high	
Transparency	intermediate	highest	rather high	
Remarks	Transparency is key, but depends on willingness of all stakeholders to comply. Low control over DSI use. High benefit sharing compliance costs and dependence on third parties. High cost of creating and maintaining an ABS online registration system is likely to outweigh the benefits for most provider countries.	Pre-set terms and conditions allow users to acknowledge their rights and obligations before deciding to start DSI use/description, clarifying costs and risks beforehand. Bulk DSI use will require more complex and burdensome compliance efforts, in which case benefit-sharing and compliance may increase transaction costs, reducing cost-effectiveness.	Instead of requiring PIC/MAT for DSI use/description, databanks would have to require the IRCC/ certificate of registration prior to the depositing of the DSI – not as a condition of use, but as a condition for the deposit of the sequence. Political pressure to create such fields may lead to technical burden and costs for databanks, while users may be reluctant to accept this change.	



### **Selected Conclusions**

- Feasibility of tracking/tracing DSI description and use under a purely bilateral approach extremely costly and entangled
- Without DSI use, benefits will hardly be generated
- Frequency of use should be fostered and not regarded as a transaction cost, as is the case in all three scenarios



### **Take-home Messages**

- "DSI description and use regularization could perhaps be better addressed through a multilateral governance structure, to be subsequently implemented on a national level."
- "However, timidity does not help solve global issues. Bold thinking that moves outside the box or reconceptualises the box can assist with identifying effective workable solutions." Paul Oldham







- DEFRA commissioned ICF Consulting Services to conduct "a rapid case study review of multilateral mechanisms in a range of fields to draw out lessons which could support international discussions on possible modalities for a DSI access and benefit sharing mechanism ahead of CBD COP15"
- Seeks to contribute to the wider evidence base available to the Parties to the CBD, including the UK
- Does not represent the view of the UK Government



### Aim to develop understanding for each mechanism on

- Operational models and governance structures
- Resources (e.g., money, skills/personnel, time) required for mechanism set up and ongoing operation, including potential funding sources to support this
- Technical rules, requirements and associated processes governing decisions on and disbursement of funds, as well as obligations on fund recipients
- Lessons and implications of each mechanism, which are relevant for further discussion



### Four case studies chosen for analysis

- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
- Pandemic Influenza Preparedness Framework (PIP Framework)
- Lion's Share Fund
- Global Environment Facility (GEF)



### Lessons from case studies re funding mechanism

- In nearly all cases funding remains reliant on just <u>one</u> source most commonly public sector contributions not directly linked to utilisation of genetic material/use of the resources
- A stable funding stream is important to support long term planning and operational activities
- Private sector contributions require right type of incentives to remain stable; payment upon commercialization may not generate meaningful levels of benefit sharing, and voluntary contributions can be unstable
- Payments can be linked to commercial benefits, so long as the link is not overly direct, Nonmonetary benefit sharing hard to establish, track and enforce



### Lessons from case studies re <u>distribution of benefits</u>

- Recipients of benefits in the mechanism do not need to also be the providers
- Mechanisms use criteria-based approaches to allocate benefits, where the criteria are linked to the priorities of the mechanism.
- Monetary benefits are typically shared through the funding of projects
- Monitoring and evaluation is a core function, providing assurance and accountability for monetary benefit sharing



### Lessons from the case studies re governance structure

- There are core components to a benefit sharing governance structure including:
  - A secretariat or governing body to manage and govern the mechanism
  - An evaluation team, either as an independent office or as a team within the mechanism
  - An external advisory group, to oversee the mechanisms and guarantee its accountability and transparency
- The administrative costs of mechanism governance may be in the region of 10% or more of a mechanism's total funds



"Just" Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good (Forthcoming, 63 HARVARD INTERNATIONAL LAW JOURNAL (2022))

Margo A. Bagley

#### Abstract

Genome sequence information is being used to develop improvements in diverse product areas from agriculture to therapeutics. In fact, the rapid development of COVID-19 vaccines required access to the genome sequence of the virus. Beyond the COVID-19 context, however, vast amounts of what is being called digital sequence information (DSI) are being used, and patented, without permission from the countries that own the genetic resources from which the sequences are derived. This issue is stymieting negotiations in several international fora, including the UN Convention on Biological Diversity (CBD) and its Nagoya Protocol. These reaties obligate users of genetic resources to share the benefits of resource utilization with the resource providers. But parties disagree profoundly on whether these obligations extend to DSI. And as DSI often obviates the need for access to tangible material, monetary benefits are likely to decline even further.

This Article identifies challenges to and opportunities for achieving "just" sharing outcomes on DSI under the CBD and Nagoya Protocol and argues for the development of a global multilateral benefit sharing mechanism as a more just and efficient vehicle for compliance with benefit-sharing obligations while retaining open access to sequence information. The prime benefit-sharing beneficiaries are intended to be the indigenous peoples and local communities who conserve and safeguard global biodiversity, yet who often are the most socioeconomically deprived among us. As such, this Article also situates the DSI benefit-sharing controversy within the larger societal moments focused on justice for the vulnerable and climate change mitigation.

#### INTRODUCTION

"When we're not hungry for justice, it's usually because we're too full with privilege." Carlos A. Rodriguez

What do the World Health Organization, the Convention on Biological Diversity, the Convention on the Law of the Sea, and the Food and Agriculture Organization have in common? In addition



<sup>&</sup>lt;sup>1</sup> Asa Griggs Candler Professor of Law, Emory University School of Law, Special thanks to Bob Friedmann, Tim Holbrook, Marcel Jaspar, Todd Kunken, Ruth Okcelij, Jake Sherkow, Amber Scholz, Daniel Turulio, Mark Wu, and participants in the Harvard Law School International Economic Law workshop; the Genetic Engineering and Society Colloquium at North Carolina State University; the 4:04 Airoon Biosecurity Workshop at Atricano State University; the 4:04 Airoon Biosecurity Workshop at Atricano State University; the 3:04 Airoon Biosecurity Workshop at Atricano State University; School at Law, The University of the Pacific McGeorge School of Law, the University School of Law, The University of the Pacific McGeorge School of Law, the University of Queensland, and a side event at the 14th Conference of the Parties to the Convention on Biological Diversity, Sharm El-Shekh, Bergyt, for helpful comments on this project. Thanks also to Dina Awshah, Eric Boyer, Morgan Gobel, Elizabeth Hemann, With Le, Candace Walther, Demetrius Williams, Cong Zhou, and the Emory McMillan Law Librarians for stellar research support.

- A review and exploration of the DSI issue in the CBD, and well beyond
- An example of real-world relevant scholarship



Introduction

- Reviews the successful development of the Ebola drug Inmazeb
- Poster child for the 'problem' or 'opportunity' known as DSI
- DSI an example of domestic and international law/policy playing catch-up with technological advances



### What's at Stake?

"Much as the digitization of music and movies facilitated a flood of online peerto-peer copying that threatened the prime revenue streams of the music and movie industries, the monetary benefits that developing countries were expecting to flow from the Access and Benefit Sharing ("ABS") regime instituted through the Nagoya Protocol are seemingly being threatened by the declining need for researchers to seek access to tangible genetic resources once sequence information from those resources has been made publicly accessible."



Key characterization of contending positions

Users say:

"'What's Yours is Mine and What's Mine is Mine':

I can use your resources (DSI) and not share any monetary benefits I generate from them with you."

Providers say:

"What's Mine is Mine and What's Yours Is Mine':

We own the DSI, and you need our permission to use it and must share with us significant monetary benefits from whatever you create using it no matter the size of the actual DSI contribution."



What's needed?

"Monetary benefit-sharing...is just and necessary both to fulfill all three objectives of the CBD and perhaps even to basic human flourishing. Without monetary benefit-sharing, necessary investments of financial and human resources to conserve biodiversity (which benefits us all) and aid in socioeconomic development for the most vulnerable among us are unlikely to occur...."



### Part I: Background on CBD and Nagoya Protocol

- Background on CBD and Nagoya Protocol implementation issues affecting DSI ABS discussions in treaty negotiations
  - Sub-section on DSI and Scope provides clarity



### Part II: DSI, CBD, Nagoya Protocol

- Examines definitional and scope issues raised by DSI re domestic ABS regimes and the complexity of DSI use scenarios that threaten benefit-sharing goals
- Unpacks three main sets of view on DSI
  - DSI is not within the definition of "genetic resources" but may result from utilization of GRS and can be addressed in MAT
  - CBD/Nagoya Protocol definition of "genetic resources" should be interpreted to include DSI
  - DSI is not within the definition of "genetic resources," but does result from utilization of genetic resources and monetary benefits should be shared from commercial uses



Part III: Need for a new approach

- Benefit sharing matters
- IPLCs matter
- Current framework inadequate to deal with DSI
- But possible to improve current system from within to deal with both tangible GRs <u>and</u> DSI



### Ways forward

- Guiding principles needed for DSI approaches:
  - Open access
  - Simplicity and certainty
  - Viability
  - Flexibility (for use of funds from multilateral benefit sharing)
  - Differential benefit sharing obligations for non-commercial and commercial research
  - Maintaining bilateral approach for tangible GRs and ATK
  - Interest convergence



### Some conclusions

- A global benefit sharing mechanism (Article 10) could ensure open access while providing meaningful benefits for biodiversity conservation, sustainable use, and economic development
- This can happen through
  - political will
  - less greed from users and providers
  - recognizing we are pivotal moment for the health of our planet



### Take-away message

"... 'just' benefit-sharing can improve conservation and socioeconomic development while maintaining access and innovation, but getting there will require adjustments in mindset from 'mine' to 'ours' for both users and providers of physical genetic resources and DSI"



### **Panel Exchange**

#### • Timothy Hodges

Strategic Global Affairs, Institute for the Study of International Development, Mc Gill University, Montreal, Canada

#### Margo Bagley

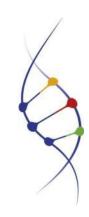
Asa Griggs Candler Professor of Law, Emory University School of Law, Atlanta, USA

#### Chloe Johnson

Dept. Convention on Biological Diversity Department for Environment, Food and Rural Affairs (Defra), UK

#### • Henry Novion

Advisor ABS Capacity Development Initiative formerly: Genetic Heritage Department, Ministry of the Environment, Brazil



### **Questions and Answers**

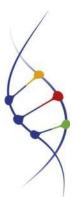
- Please type your comments and questions in the chat
- Colleagues from the ABS Initiative will screen the chat and compile aggregated questions and comments
- ABS Initiative will present questions and comments to the panelists, who will endeavor to address them
- (Remaining) questions and comments will inform topics and orientations of future webinars and dialogues

# New study on economic concepts for a DSI benefit-sharing framework



- Analysis of five policy options for DSI benefit-sharing based on economic concepts, uses four cases of utilizing organisms in R&D and commercialization to illuminate the advantages and disadvantages of alternative modalities to "Bilateral-Nagoya Protocol".
- A multilateral ABS regime must be informed by peer-reviewed literature ... Rather than a brokered policy riddled with gaps, loopholes and contradictions, the framework should address the two dozen issues identified and tabulated in this Report
- Two crucial questions need to be answered: Does probable cause exist that a given modality will cover the costs of implementation? Which modality will most likely achieve the first two objectives of the CBD?
- Only Modalities "Bounded openness over natural information" and "Open accesssubscription fee / levies" afford rents. The latter generates heavy excess burden.
- Ruiz Muller, Vogel, Angerer et al., 2021, <u>Study-Fairness-Equity-Efficiency-for-the-CBD-and-the-NP-2021.pdf (abs-biotrade.info)</u>

### New study on economic concepts for a DSI benefitsharing framework



6. "Material" in Article 2 of the CBD				
<b>Problem(s) rendering</b> <i>status quo</i> disadvantageous: Object of access for R&D is information. Evasion of ABS through disembodiment of genetic resource				
Modality 1: "Nagoya – Bilateral" Interpreted as tangible or physical matter				
Modality 2: "Open Access – Bilateral"	<u>Solution:</u> Interpretation of genetic resource as being information <u>Requirement:</u> "Tangible" interpretation is a foundational error. Precedent overturned by framework nature of CBD			
Modality 3-I: "Open Access – Multilateral": (Common pools)	Same as modality 2			
Modality 3-II: "Open Access – Multilateral": (Bounded openess)	<u>Solution:</u> Interpretation of genetic resource as biotic "natural information"			
	<u>Requirement:</u> Recognition that "tangible" interpretation is egregiously wrong. Precedent may be overturned			
Modality 4: "Open Access – Subscription fee / Levies"	Same as modality 2			
Modality 5: "Free Access – Capacity Development"	Nonissue			

### New publication on DSI policy options

### Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation

- 41 authors from 17 countries
- Hartmann Scholz et al., *Nature Communications*, Feb 2022
- <u>https://doi.org/10.1038/s41467-022-28594-0</u>
- https://www.nature.com/articles/s41467-022-28594-0
- members of the recently established DSI Scientific Network, providing a concrete framework for how DSI benefit-sharing could work
- <u>https://www.dsiscientificnetwork.org/</u>
- more information in the chat



### Thank you!



### Further information can be found on our website: <u>www.abs-biotrade.info</u>

ABS Capacity Development Initiative Division Climate Change, Environment & Infrastructure GloBe - Department Sector and Global Programmes Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH Postfach /P.O. Box 5180 65726 Eschborn Germany

The ABS Initiative is funded by







Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra

Swiss Confederation





Federal Department of Economic Affairs, Education and Research EAER State Secretariat for Economic Affairs SECO