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Federal Department of the Environment,
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Federal Office for the Environment FOEN
Soil and Biotechnology Division

BioTrade and the Implementation of the Nagoya Protocol

Reflections by the Swiss Focal Point for the Nagoya Protocol

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Status of implementation

International level : Adopted 2010 at the 10th Conference of the Parties to the Convention on Biological Diversity → Today 68 Ratifications

National milestones :

14 May 2011: Switzerland signs the Nagoya Protocol.

21 March 2014: Parliament adopts the Nagoya Protocol and legal amendments in the Federal Act on the Protection of Nature and Cultural Heritage (NCHA).

11 July 2014: Switzerland ratifies the Nagoya Protocol (50th ratification).

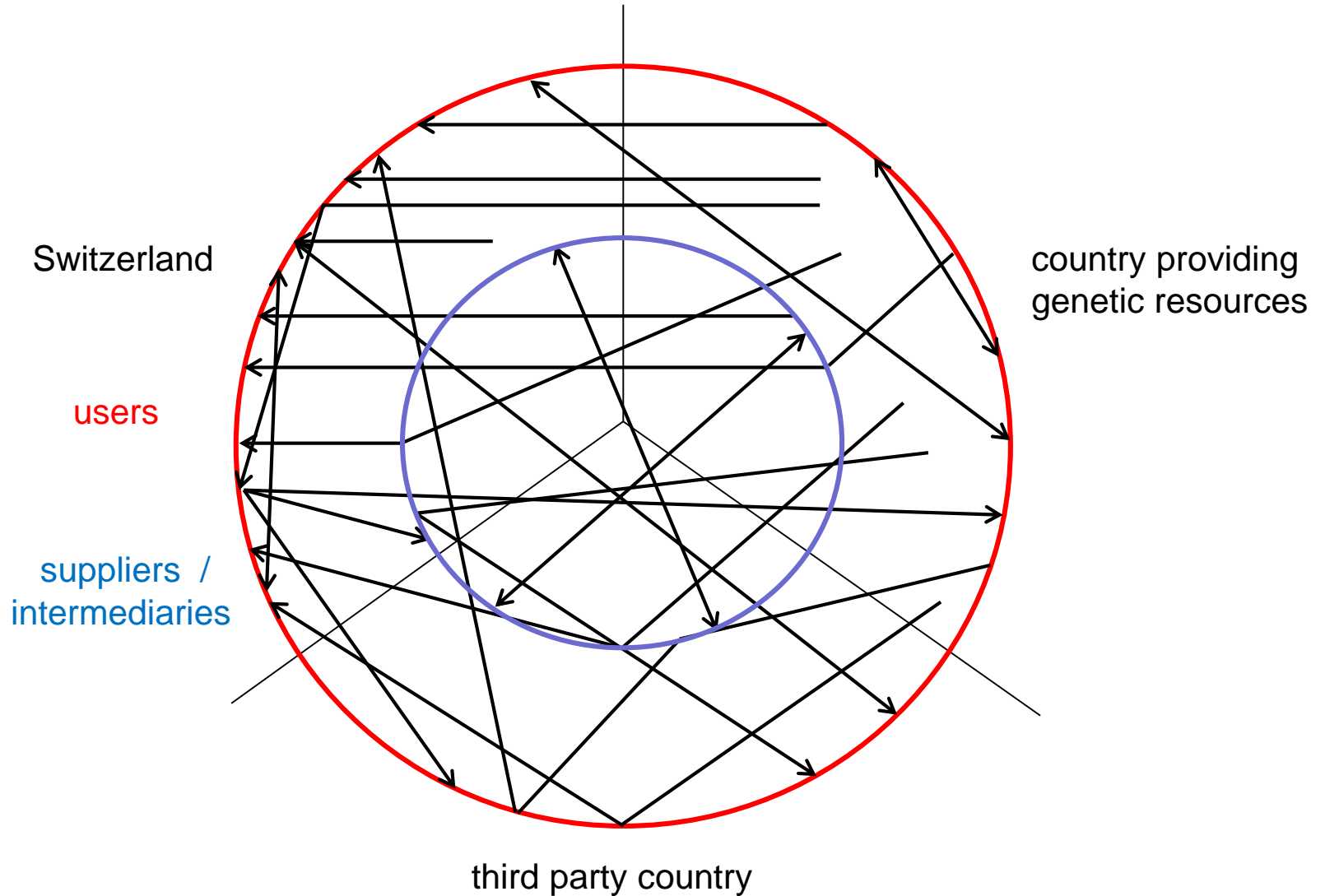
12 October 2014: The Nagoya-Protocol and the amendments in the NCHA enter into force.

25 March 2015: Public consultation for the Nagoya Ordinance to further implement the legal amendments of the NCHA and the Nagoya Protocol.

End of 2015 ? : Adoption of the Nagoya Ordinance.



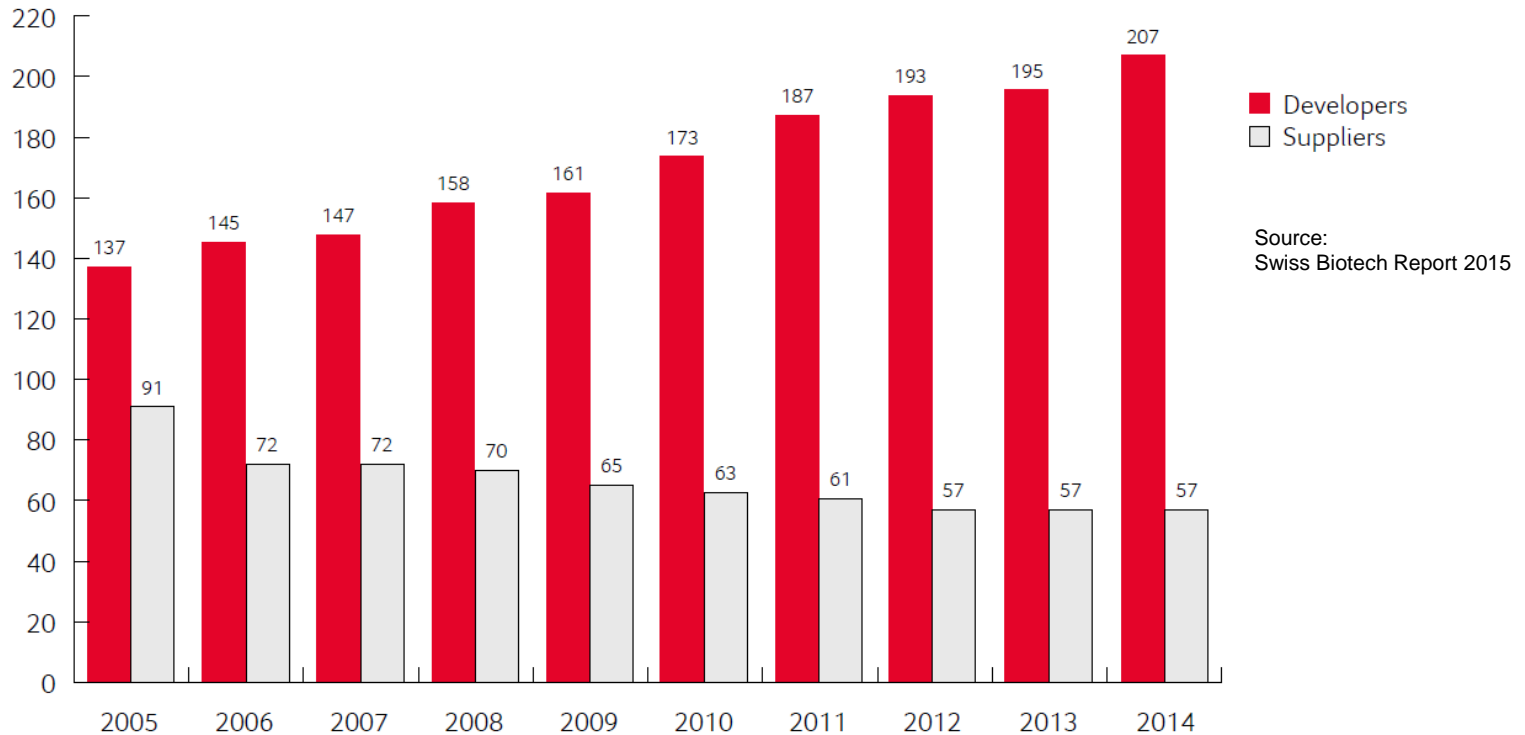
The utilization of genetic resources





Biotech companies

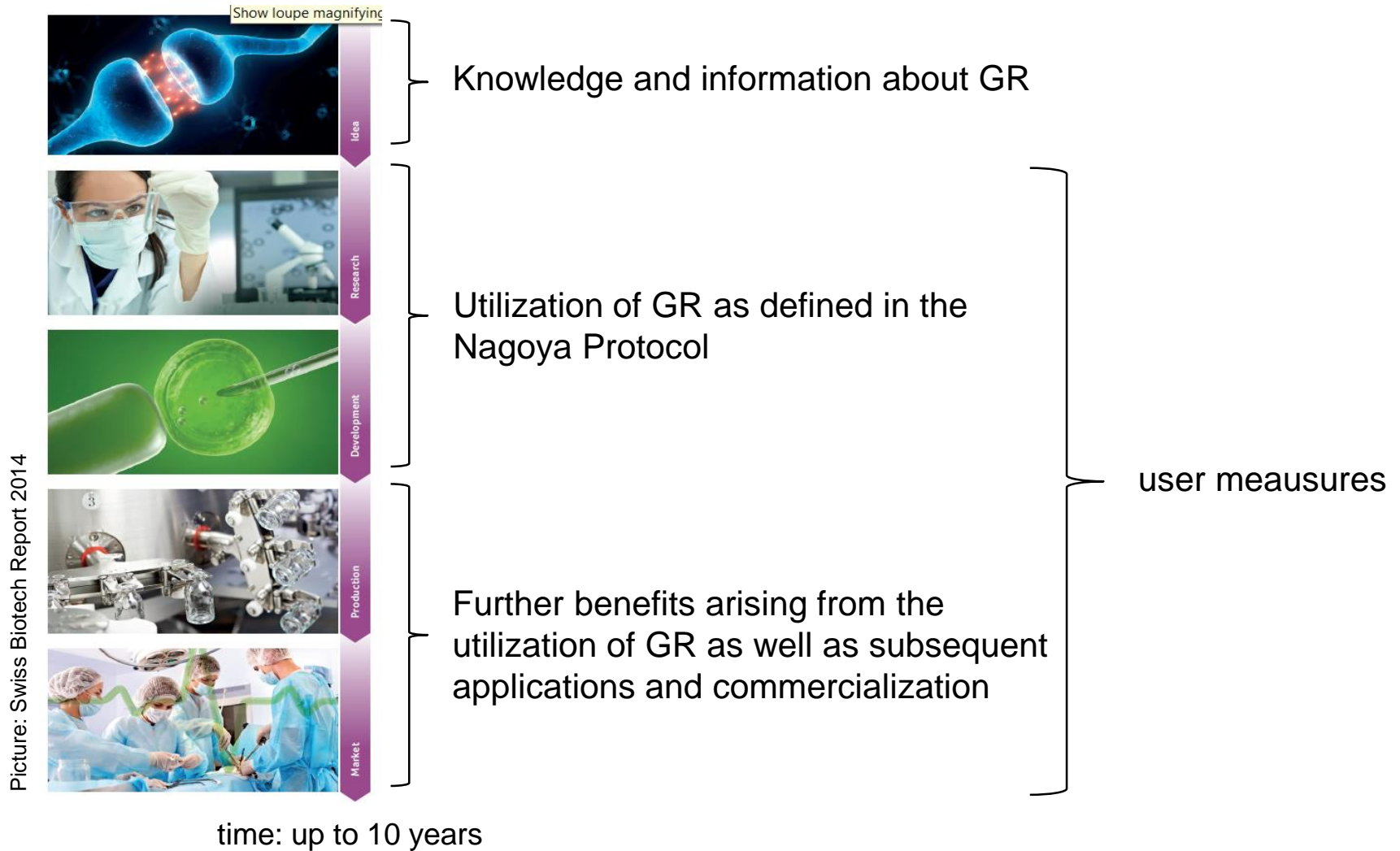
Number of biotech companies in Switzerland



- ❑ Some companies are developers and suppliers
- ❑ Not all of the developers are utilizing genetic resources
- ❑ Not all suppliers provide GR for their utilization but as traded commodities.



The biotech value chain





ABS user compliance measures

Federal Act on the Protection of Nature and Cultural Heritage (NCHA):

1. Due diligence obligation (Art. 23n)

Any person that utilizes a GR or that directly benefits from its utilization (users) shall apply due diligence to ensure that:

- access to GR took place in accordance with the domestic ABS regulatory requirements of the Party that provided the GR; and that
- Mutually Agreed Terms for the fair and equitable benefit-sharing have been established.

2. Notification obligation (Art. 23o)

- Compliance with the due diligence shall be notified to a centralized checkpoint at the Federal Office for the Environment (FOEN) by the time of market authorization or commercialization of a product developed on the basis of a utilized GR.
- Legal basis to transfer information to the Party that provided the GR and to the ABS Clearing-House and for the publication of some information related to the utilized GR.
- Designation of further “checkpoints” in existing procedures to check whether a notification to FOEN has been made (e.g. in the authorization procedure for pharmaceuticals).



ABS users compliance measures

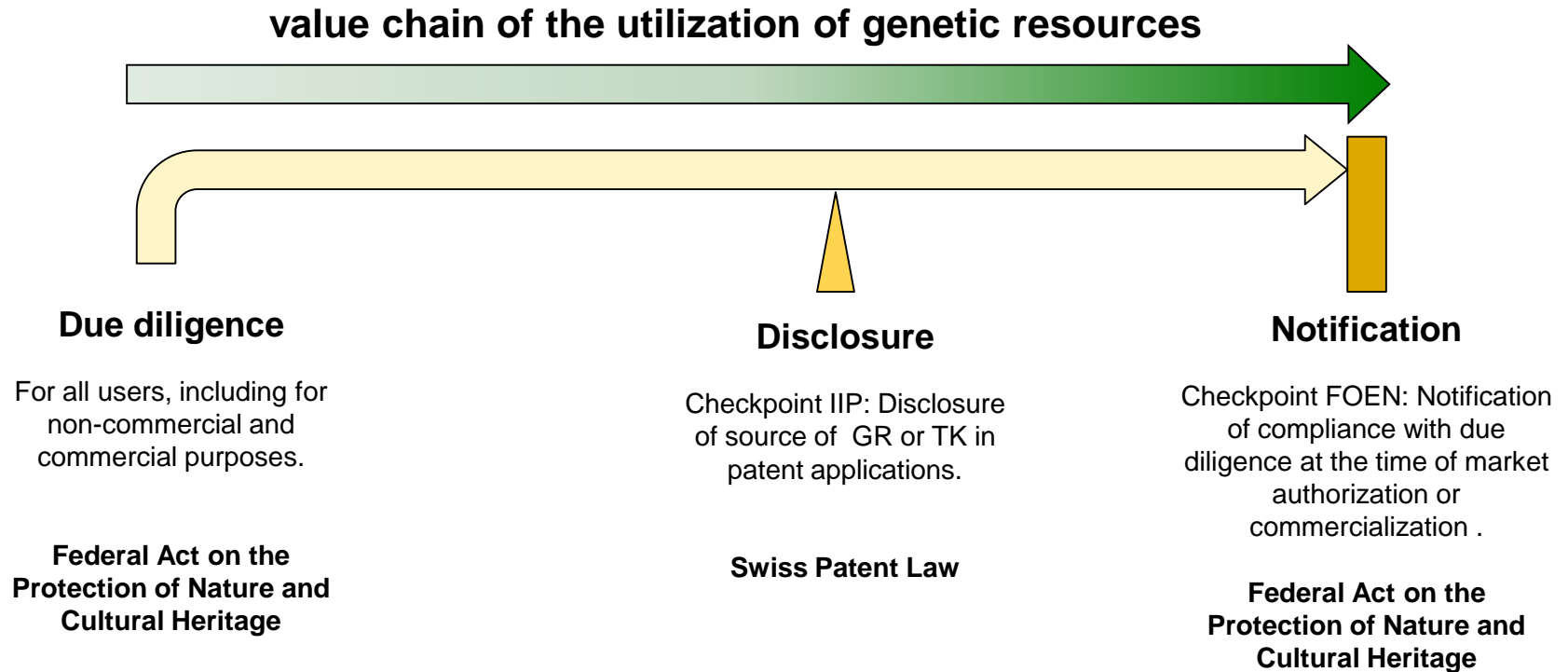
- **Sanctions and administrative measures:**
 - A fine of up to 100'000 Swiss Francs for those that provide no or wrong information
 - No authorization of products developed on the basis of utilized genetic resources if the notification to the centralized checkpoint has not been made by the time of market authorization.
 - Possibility to take administrative measures in cases of violation of the due diligence obligation (An administrative order can go as far as prohibiting the use of a GR).

- The measures will also apply to the utilization of **traditional knowledge associated with genetic resources**, unless it is already freely available to the public (Art. 23p).

- The user measures will only apply to GR provided by **other Parties to the Nagoya Protocol that have ABS regulations in place** as well as to access situations that occurred after the new provisions have come into force (**no retroactivity!**)
 - an incentive for others to ratify and implement the Nagoya Protocol !



Overview of the ABS user measures



- **International Treaty for Plant Genetic Resources for Food and Agriculture:** Federal Act on Agriculture and a new Ordinance (2016) → standard Material Transfer Agreement of the Multilateral Benefits-sharing System for PGRFA in the national gene bank



The Draft Nagoya Ordinance (NagO)

General approach:

- Enhancing legal certainty and facilitating the application of the new obligations while maintaining sufficient flexibility to cope with sectorial differences as well as with the various ABS regulatory requirements of other Parties to the Nagoya Protocol.
- As far as possible and where useful harmonisation with the EU-Ordinance 511/2014.

Main elements of the Ordinance:

- Use of terms: Same terms as in the Nagoya Protocol and in the CBD → Three additional terms: “User”, “commercialisation”, and “international recognized certificate of compliance”
- Information, which has to be recorded, stored and transferred to subsequent users in the context of the due diligence requirement.
- Specifies the notification obligation, in particular the designation of other authorities in marked authorisation procedures that will check whether a notification to FOEN has been made.
- Further elements: Recognition of collections and best practice tools, emergency situations, traditional knowledge, role of authorities, etc.
- Access regulation for genetic resources in Switzerland (Art. 23q NCHA)



No PIC and MAT requirement but a **documentation for accessing GR in Switzerland and a notification requirement by the time of commercialization.**





Important user compliance provisions in the context of (Bio)Trade

Art. 23n NCHA

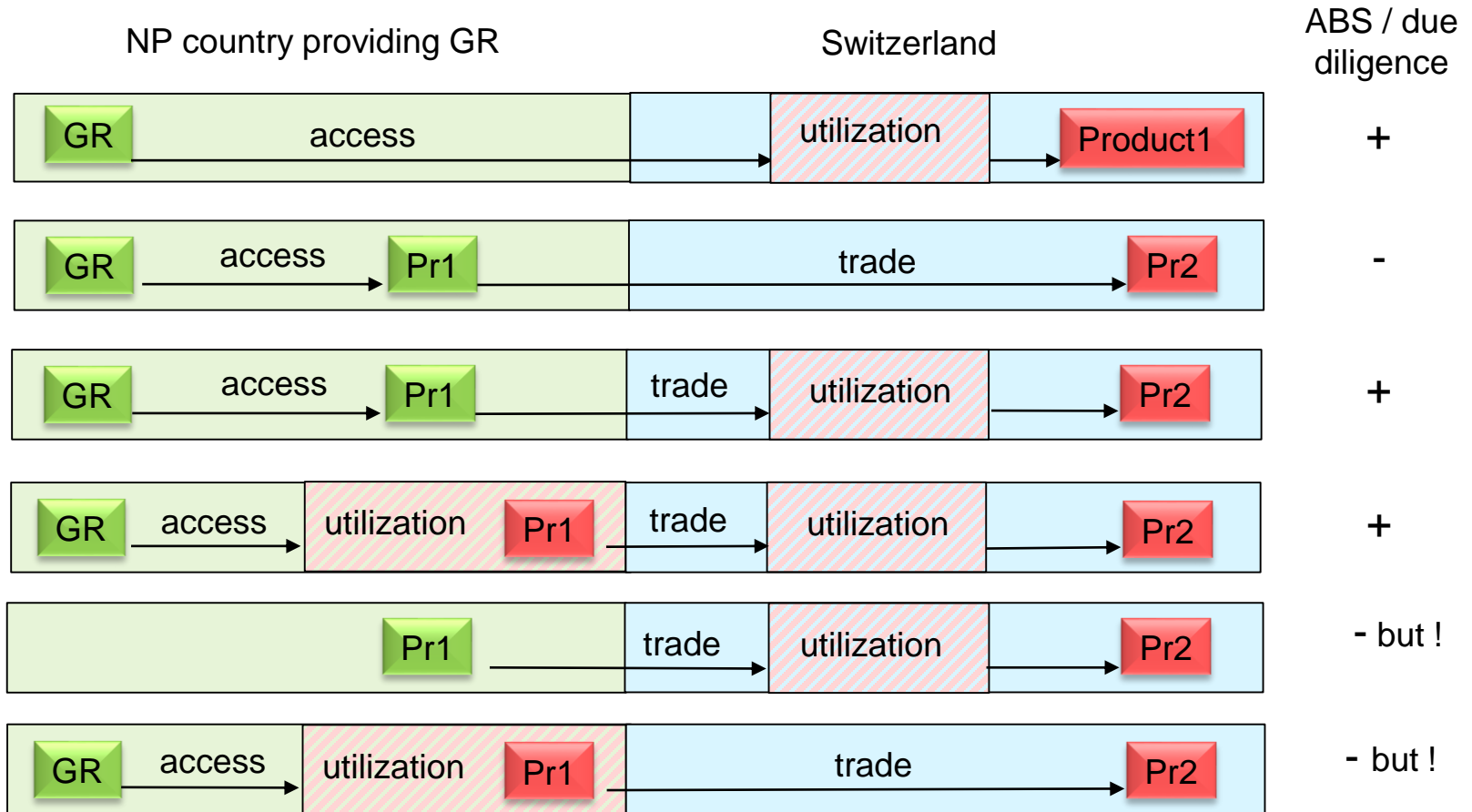
- Para. 1: Any person who in accordance with the Nagoya Protocol utilises genetic resources or directly benefits from their utilisation (users) shall apply due diligence appropriate to the circumstances to ensure that
- Para. 2: Genetic resources are not subject to the due diligence requirement if they:
.....
 - f. as commodities or goods in trade are not utilised as genetic resources in terms of the Nagoya Protocol.
- Para. 3: Utilisation of genetic resources in terms of paragraph 1 means to conduct research and development on the genetic or biochemical composition of genetic resources, including through the application of biotechnology.

Art. 25d NCHA

- Articles 23n and 23o apply to circumstances relating to access to genetic resources that has occurred after the said provisions came into force → new access situations



Due diligence in the context of (Bio)Trade



- Whether ABS/due diligence applies has to be decided on a **case-by-case basis**, depending on:
 - whether **access to a GR** has taken place after the entering into force of the NP;
 - whether **utilization of GR** as defined in the NP is taking place;
 - **national ABS regulatory requirements** in user and provider countries, etc.



Reflections on the UNCTAD Scoping Study

Nagoya Protocol:

- ❑ Avoid (over)interpretations of specific provisions of the Nagoya Protocol (e.g. derivatives/biochemicals, BS triggered by the utilization of GR, user compliance measures only in industrialized countries, etc.).
- ❑ Include further provisions of the Nagoya Protocol that are relevant for the implementation of ABS (e.g. Art. 6 access to GR, Art. 8 special considerations, Art. 4 relationship with international agreements and instruments, Art. 15-18 on compliance, etc.).
- ❑ Further specify what is clearly outside of the scope of the Nagoya Protocol (e.g. Benefit-sharing without utilization of GR or for TK not associated with genetic resources).
- ❑ Refer to the ABS Clearing-House for finding further information on relevant domestic ABS legislations or regulatory requirements.



<https://absch.cbd.int>

National ABS regulatory requirements:

- ❑ Domestic ABS regulatory requirements in countries providing GR as well as in countries where GR are used are key for deciding whether a specific activity falls under ABS or not.
- ❑ Be more precise when including specific references to national ABS legislations or regulatory requirements.



Reflections on the UNCTAD Scoping Study

BioTrade:

- ❑ Further illustrate differences between BioTrade and “normal” trade with biological resources.
- ❑ Better indicate which BioTrade principles go beyond the Nagoya Protocol.
- ❑ Further illustrate the different sourcing practices and ways of using genetic and biological resources (as well as ATK) in the different sectors (e.g. pharmaceuticals, cosmetics, food and beverage, biotech, agriculture, etc.).
- ❑ Include possible approaches that would facilitate BioTrade and enhance legal certainty for companies that are only suppliers of GR but not users in the sense of the Nagoya Protocol:
 - Material transfer agreement that clearly specifies uses falling outside the scope of ABS regulations in a specific country.
 - Documentation requirements.
- ❑ Further elaborate on the approaches in chapter 9 which are not based on “legal ABS procedures” according to the NP but that are important to enhance the value and benefits of genetic and biological resources in countries providing GR :
 - technology transfer, collaboration and cooperation to utilize genetic resources in countries providing genetic resources
 - fair trade principles and other marketing strategies (e.g. certifications, labelling, etc.)
 - IP approaches
- ❑ Include further case studies and get feedback from users of GR and ATK in different sectors.