



Introduction to and Overview of the Budapest Treaty

National Seminar on the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Virtual)

Uganda, Kampala, October 21, 2020

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Structure:

- Origin of the Budapest Treaty
- Main features of the Budapest Treaty
- Benefits of the Budapest Treaty



What is a microorganism?

- Budapest Treaty concerns « Microorganisms »
- Humans have been using microorganisms for millennia
- Microorganisms are microscopic organisms (e.g., bacteria, fungi, viruses and yeasts) used in the production of:
 - *Food* (e.g., yogurt, cheese, beer, wine)
 - *Medical field* (e.g. antibiotics, vaccines, insulin – and diagnostic tools)
 - *Agriculture* (high-yielding, resistant crop varieties)
 - and other products (e.g., washing powder, ethanol)



Patentability requirements

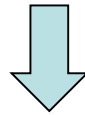
- High-risk research undertakings - patents are important for protection of biotechnological inventions
- Invention must comply with **patentability requirements**, incl.:
 - Novelty
 - Inventive step
 - Industrial applicability
- Sufficiency of disclosure
 - An invention must be described in sufficient detail to enable a person skilled in the art to carry it out



Important part of the social bargain between
the applicant and the society

Disclosure of microorganisms

- Disclosure is normally achieved by means of a written description (supplemented by drawings)
- How to disclose a microorganism?
 - Written description alone is generally not suffice

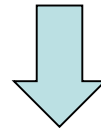


Written disclosure must be supplemented by the **deposit of the microorganism** in a recognized culture collection



Need for a Uniform International Deposit System

- By 1970s, many national laws required the deposit of microorganisms in culture collections
- However, there was no uniform system of recognition of deposit
 - no guidelines for patent offices, depositors, culture collections or third parties
 - variety of national laws
 - applicants deposited the same microorganism in several culture collections in different countries (complex and costly procedures)



Need for a streamlined and cost-effective international procedure for deposit of microorganisms

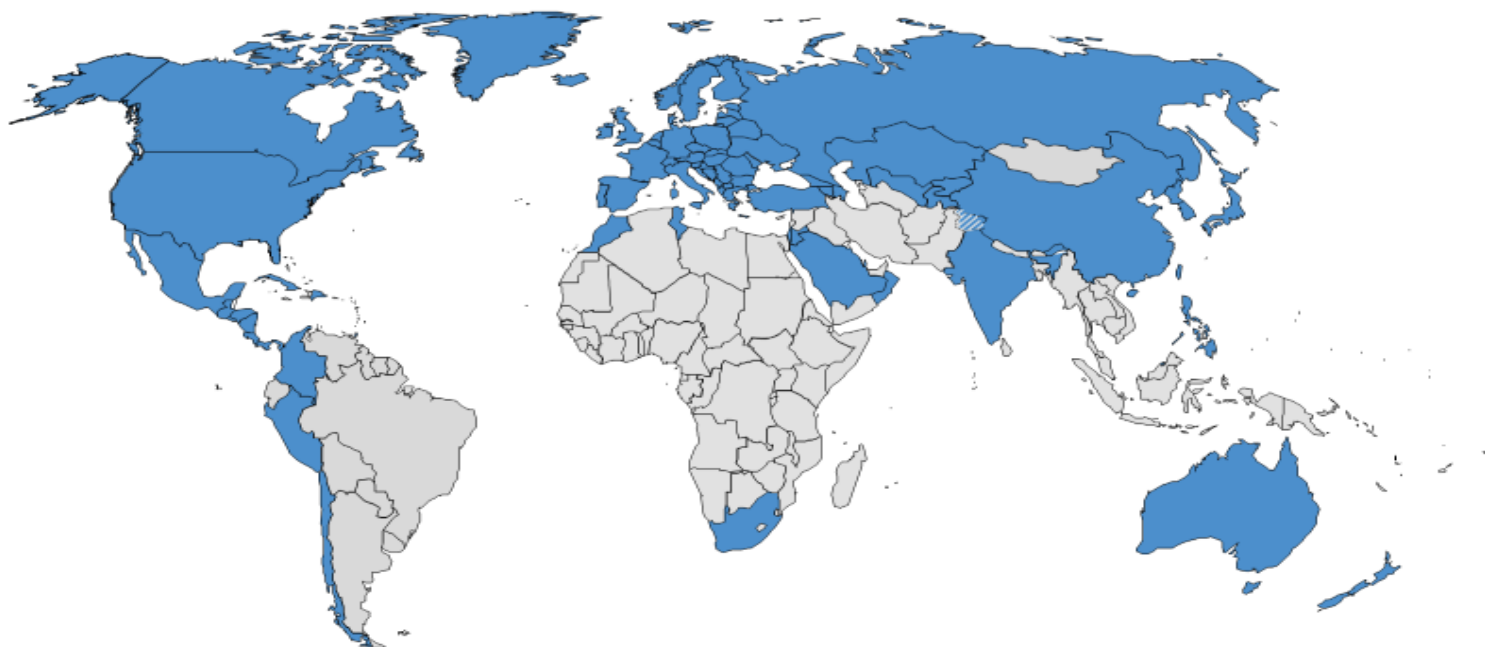
Committee of Experts

- Committee of Experts established in 1974
- The Committee
 - found that conclusion of a treaty was necessary
 - prepared a Draft Treaty and Draft Regulations for submission to a Diplomatic Conference
- Diplomatic Conference held in Budapest from April 14 to 28, 1977



The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

- Concluded in 1977
- Entered into force on August 19, 1980



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Contracting
States

Status on October 21, 2020

Main Features of the Budapest Treaty

- Under the Treaty, certain culture collections are recognized as “international depositary authorities” (IDAs).
- CP which allows or requires the deposit of microorganisms for the purposes of patent procedure **must recognize**, for such purposes, **the deposit of a microorganism with any IDA**, irrespective of whether such authority is on or outside the territory of the said State
- Any intergovernmental industrial property organization which files a formal declaration of acceptance must recognize a deposit made in any IDA
 - Declarations of acceptance have been deposited by EPO, EAPO and ARIPO

Main Features of the Budapest Treaty

Meaning of the Term “Microorganism”

- The term “microorganism” is not defined in the Treaty - may be interpreted in a broad sense
- It includes unicellular and multicellular organisms, bacteria, fungi, plant, animal and human cell cultures, murine embryos, plasmids, DNA sequences, enzymes, seeds, etc.
- Today, the term “biological material” is more commonly used

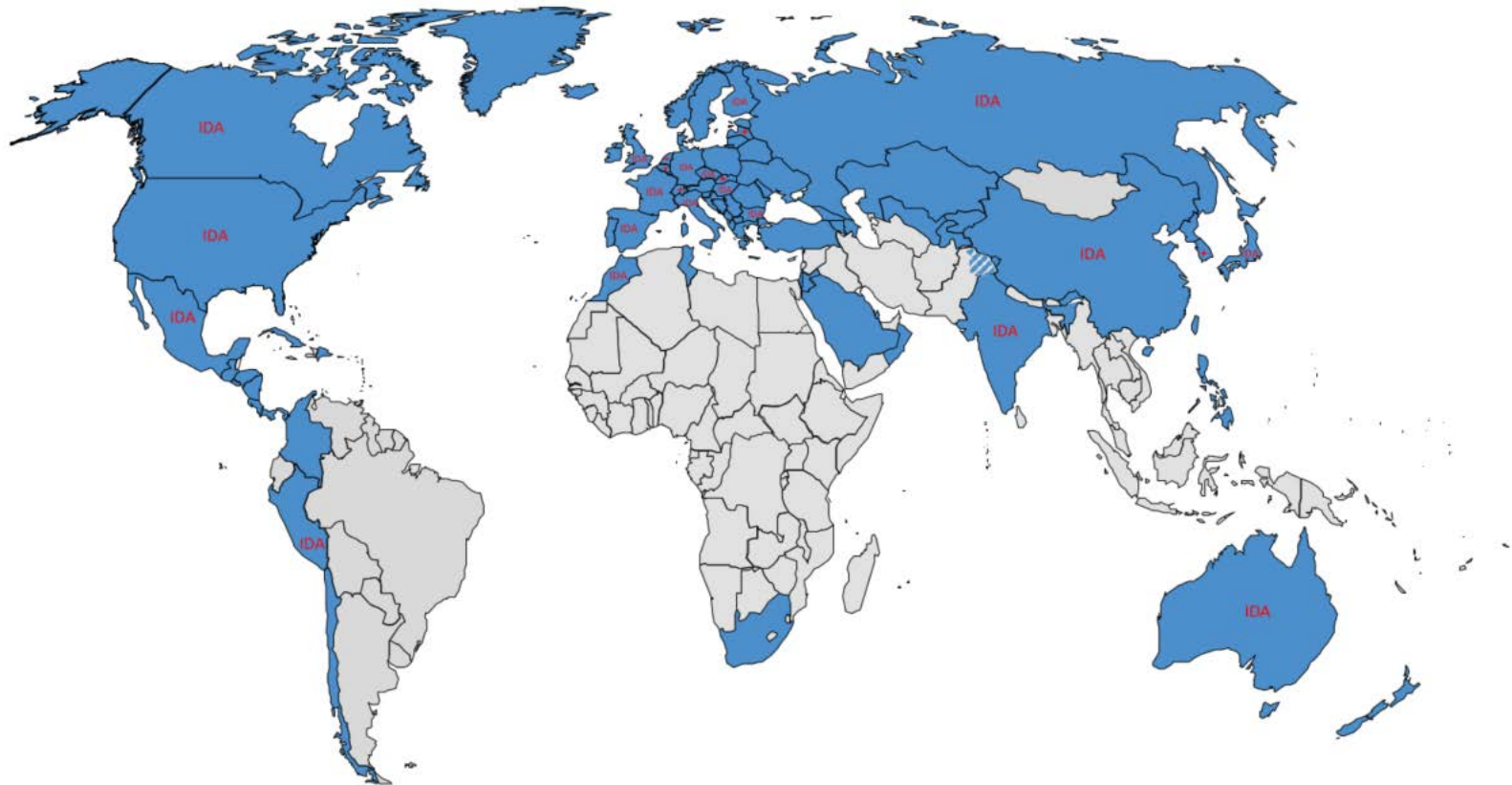
Main Features of the Budapest Treaty

International depositary authority (IDA)

- Any culture collection can become an IDA
 - **formal nomination** by the Contracting State on whose territory it is located
 - **assurances** that the institution complies and will continue to comply with the requirements of the Treaty and the Regulations (Art.7)
 - assurances may be furnished also by an intergovernmental industrial property organization - culture collection must be located on the territory of one of its member States



International Depository Authorities

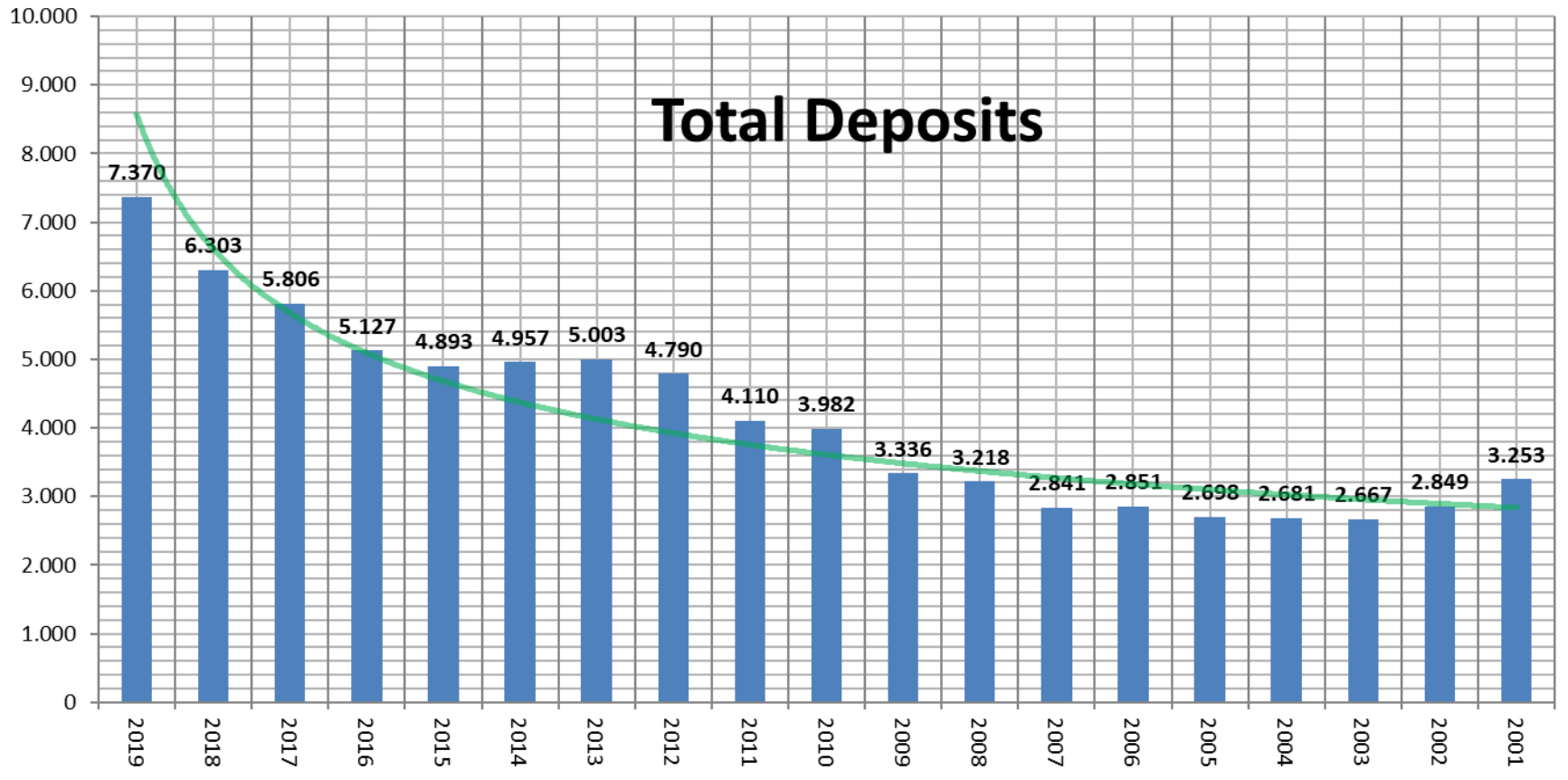


— Contracting Parties to the Budapest Treaty
+ / IDA Contracting Parties in which one or more International Depository Authorities are located

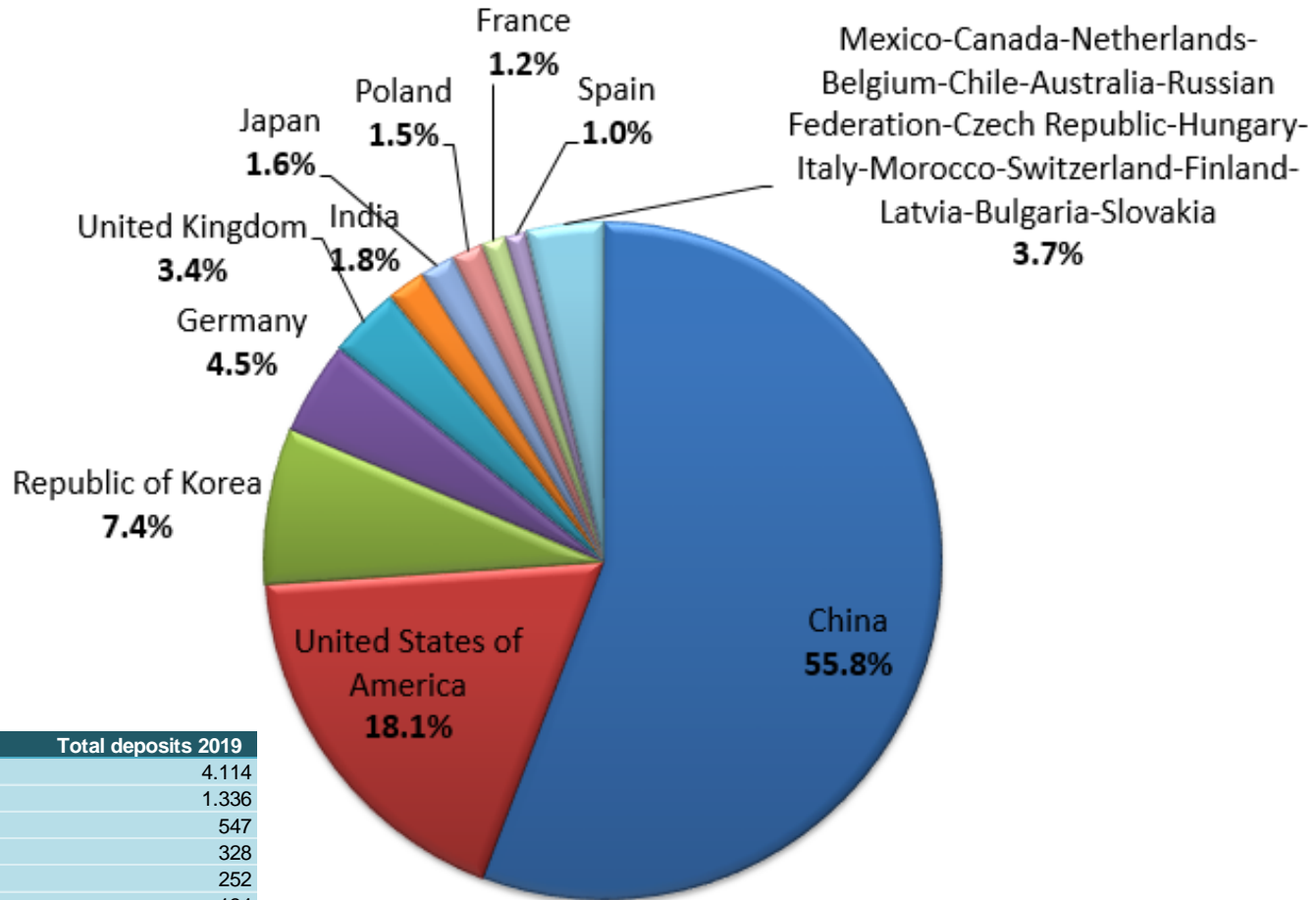
■ 48 IDAs

■ 122,446 microorganisms deposited by the end of 2019

Total Deposits



Total deposits 2019



Country	Total deposits 2019
China	4.114
United States of America	1.336
Republic of Korea	547
Germany	328
United Kingdom	252
India	134
Japan	121
Poland	109
France	85
Spain	73
Mexico-Canada-Netherlands-Belgium-Chile-Australia-Russian Federation-Czech Republic-Hungary-Italy-Morocco-Switzerland-Finland-Latvia-Bulgaria-Slovakia	271
Total	7.370

Main Features of the Budapest Treaty

The depositary institution must, in its capacity of IDA (Article 6(2):

- have a continuous existence;
- have the necessary staff and facilities, as prescribed in the Regulations, to perform its scientific and administrative tasks under this Treaty;
- be impartial and objective;
- be available, for the purposes of deposit, to any depositor under the same conditions;
- accept for deposit any or certain kinds of microorganisms, examine their viability and store them, as prescribed in the Regulations;
- issue a receipt to the depositor, and any required viability statement, as prescribed in the Regulations;
- comply, in respect of the deposited microorganisms, with the requirement of secrecy, as prescribed in the Regulations;
- furnish samples of any deposited microorganism under the conditions and in conformity with the procedure prescribed in the Regulations.

Main Features of the Budapest Treaty

Safeguard of Deposit

- IDA must have the expertise and facilities necessary to keep the microorganism **viable and uncontaminated** (R.2.2)
- IDA must provide for sufficient **safety measures to minimize the risk of losing** deposited **Mo** (R.2.2)
- **New deposit-** if IDA cannot furnish samples of the deposited Mo (Art.4)
- **Transfer** of deposited Mo to another IDA- if IDA ceases to function (R.5.1)

Main Features of the Budapest Treaty

■ Duration of storage of deposited Mo:

- At least five years after the most recent request for the furnishing of a sample of the deposited Mo was received by the IDA and, in any case, for a period of at least 30 years after the date of the deposit (R.9.1)

- (time limit for deposit is not addressed- depends on the national law)

■ Obligation of secrecy

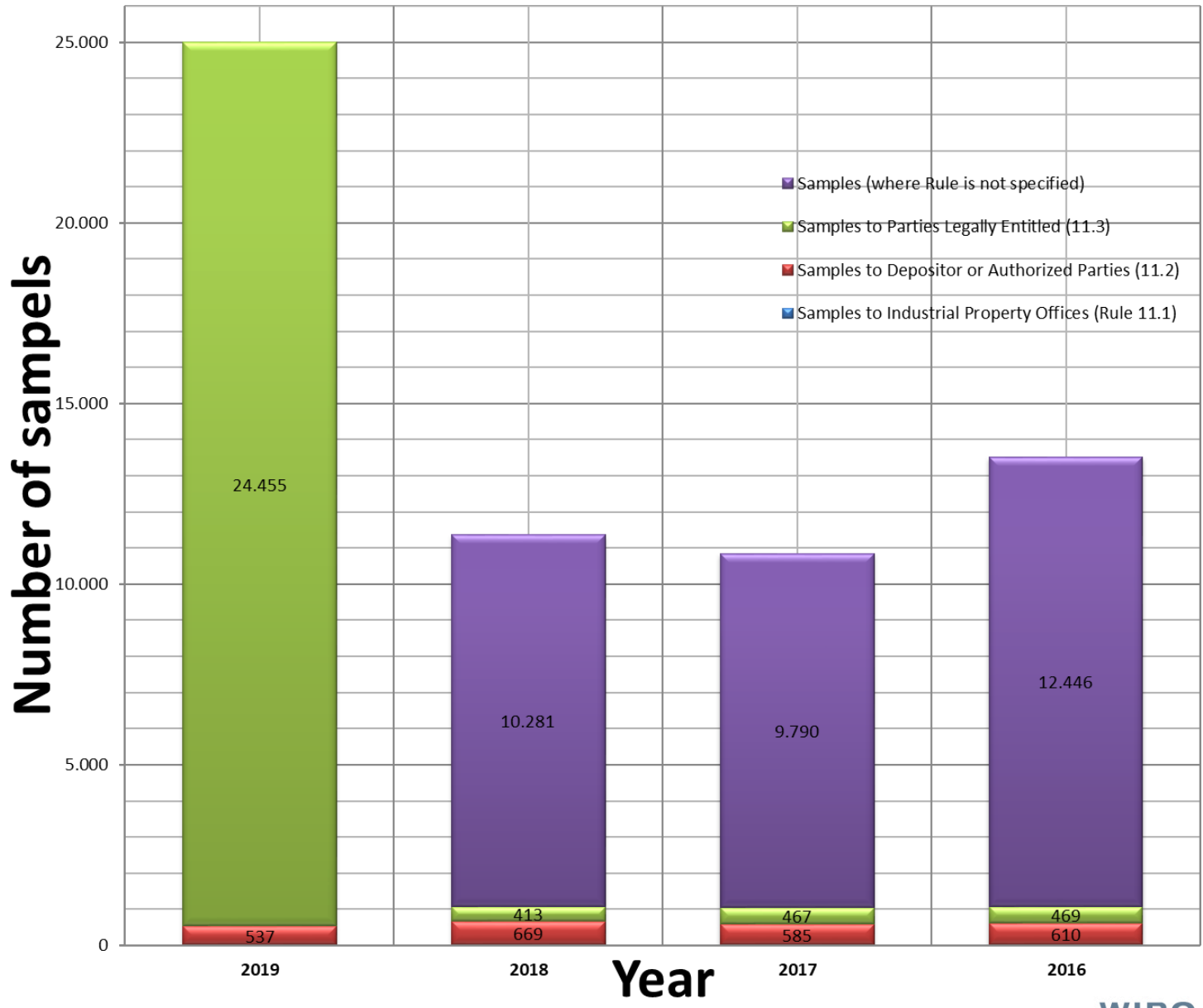
- IDA shall not give any information to anyone concerning any Mo, except to an authority, natural person or legal entity which is entitled to obtain a sample under Rule 11 (R.9.2)

Main Features of the Budapest Treaty

Furnishing of Samples

Furnishing of Samples

- **Any interested industrial property office** of a Contracting State or an intergovernmental industrial property organization (R.11.1)
 - “interested” office - either processing a patent application or has granted a patent in respect of the deposited Mo.
 - sample can be used for patent procedures only
- **The depositor or third parties** authorized by the depositor (R.11.2)
- **Any parties legally entitled** under the applicable legislation, request is made on a prescribed form and certified by the IP office (R.11.3)
 - application referring to Mo is being processed by office
 - the certified party has a right to a sample under the law



The Budapest Treaty: Benefits

- **Advantages to the depositor** if he/she is an applicant for patents in several contracting States-
 - **Efficient, streamlined and cost-effective** means of meeting the disclosure requirements associated with patenting Mo
 - **Reduced costs** - instead of depositing the microorganism in each and every contracting State in which he/she files a patent application, he/she will deposit it only once, with one depositary authority
 - **Increased security** of the depositor - because it establishes a uniform system of deposit, recognition and furnishing of samples of microorganisms
- **Advantageous for Contracting States:**
 - **No substantial changes** to the national/regional **patent laws** needed
 - **No financial obligations** are imposed on a Contracting Party
 - **No obligation to establish an IDA** in their own territory
 - **Promotion of R&D** in biotechnology sector

The Budapest Treaty

Becoming Party to the Treaty

- Any State member of the Paris Union for the Protection of Industrial Property may become party to this Treaty by:
 - (i) signature followed by the deposit of an instrument of ratification, or
 - (ii) deposit of an instrument of accession.

- Instruments of ratification or accession shall be deposited with the Director General.

The Budapest Treaty

Where to find more information?

https://www.wipo.int/treaties/en/registration/budapest/

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Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

Adopted in 1977, the Budapest Treaty concerns a specific topic in the international [patent](#) process: microorganisms.

All states party to the Treaty are obliged to recognize microorganisms deposited as a part of the patent procedure, irrespective of where the depository authority is located.

In practice this means that the requirement to submit microorganisms to each and every national authority in which patent protection is sought no longer exists.

- [Summary of the Budapest Treaty](#)

Members

- [Contracting parties](#) [PDF](#)
- [Members of the Budapest Union Assembly](#)
- International depository authorities (IDAs)
 - [List of IDAs](#) [PDF](#)
 - [Information on Kinds of Microorganisms Accepted and Amount of Fees Charged by IDAs](#) [PDF](#)

Additional information

- [Guide to the Deposit of Microorganisms under the Budapest Treaty](#)
- [Note by the Secretariat on the Budapest Treaty \(WO/INF/12\)](#) [PDF](#)
- [Statistics on Microorganisms: Number of deposits/samples furnished under Rule 11 of the regulations of the Budapest Treaty - based on information requested by WIPO from international depository authorities in annual surveys.](#) [XLS](#)

<https://www.wipo.int/treaties/en/registration/budapest/>

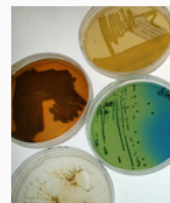
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Budapest – The International Microorganism Deposit System

The Budapest System provides a practical business solution when pursuing patents involving biological material in some 80 countries through the recognition of one international recognized deposit with an international depositary authority (IDA).

Adopted in 1977, the [Budapest Treaty](#) concerns a specific topic in the international patent process: inventions involving microorganisms. All states party to the Treaty are obliged to recognize microorganisms deposited as a part of the patent disclosure procedure with an IDA, irrespective of where the depositary authority is located. In practice this means that the requirement to submit microorganisms to each and every national authority in which patent protection is sought no longer exists.



The Budapest Treaty provides a simple and cost-effective means of meeting the international requirements associated with depositing microorganisms. (Photo)

Find out more

- [How the Budapest Treaty facilitates the disclosure of biotech inventions](#)
- [Budapest Treaty contracting parties](#)

[Contact us](#)

News

[Changes in the Schedule of Fees of the Colección Española de Cultivos Tipo \(CECT\)](#)

October 16, 2020

[Note By The Secretariat On The Budapest Treaty \(Document WO/INF/12\)](#)

October 6, 2020

<https://www.wipo.int/budapest/en/>

Guide to the Deposit of Microorganisms under the Budapest Treaty

(Status on October 8, 2020)

Note

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Part II: Specific requirements of individual international depository authorities and industrial property offices

Section D: Requirements of International Depository Authorities (IDAs)

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Section E: Requirements of Industrial Property Offices of States Party to the Budapest Treaty and of Intergovernmental Industrial Property Organizations

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Appendices

Appendix 1: Checklists of points to be attended to when depositing microorganisms and requesting samples under the Budapest Treaty

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Appendix 2: Text of the [Budapest Treaty](#) and of the [Regulations](#) under the Treaty

Appendix 3: Forms under the Budapest Treaty and Regulations

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Appendix 4: Editable version of Form BP/12

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Thank you!