

Union for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Union)

Assembly

**Forty-First (19th Extraordinary) Session
Geneva, July 9 to 17, 2024**

ACTIVITY REPORT ON THE OPERATION OF THE BUDAPEST SYSTEM

prepared by the International Bureau

1. This document contains information on the latest developments and activities relating to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty), since the Meeting of the Assembly of the Budapest Union held from July 14 to 22, 2022.

New Contracting States, Intergovernmental Industrial Property Organizations and International Depositary Authorities (IDAs)

2. Paraguay and Rwanda acceded to the Budapest Treaty on May 5, 2023 and September 4, 2023, respectively. As of April 12, 2024, the number of States party to the Budapest Treaty is 89. Table 1 shows the evolution of the number of Contracting States since the entry into force of the Budapest Treaty on August 19, 1980.

Table 1: Evolution of the number of Contracting States

	1980	1983	1993	2003	2013	2023
Number of Contracting States	6	14	28	58	78	89

3. In accordance with Article 9(1)(a) of the Budapest Treaty, any intergovernmental industrial property organization that meets the conditions set out in that provision may file a declaration that it accepts the obligations and effects stipulated in the Treaty and the Regulations under the Budapest Treaty (Regulations). The African Intellectual Property Organization (OAPI) made such a declaration on December 15, 2022. Consequently, as of April 12, 2024, there are four intergovernmental industrial property organizations that made the declaration under Article 9(1)(a), namely the OAPI, the African Regional Intellectual Property Organization (ARIPO), the Eurasian Patent Organization (EAPO) and the European Patent Organisation (EPO).

4. With respect to the International Depositary Authorities (IDAs), on January 26, 2023, the Collection of Plasmids and Microorganisms (KPD), located in Poland and, on April 25, 2024, the University of Coimbra Bacteria Culture Collection (UCCCB), located in Portugal, each acquired the status of an International Depositary Authority (IDA), becoming the 49th and 50th IDAs, respectively. Table 2 shows the evolution of the number of IDAs.

Table 2: Evolution of the number of IDAs

	1980	1983	1993	2003	2013	2023	2024
Number of IDAs	0	11	26	34	42	49	50

Currently, IDAs are located in the following Groups: Africa (one¹), Asia and Pacific (seven²), Central Asian, Caucasus and Eastern European Countries (two³), Central European and Baltic States (eight⁴), China (three), Group B (twenty-seven⁵) and Latin America and the Caribbean (two⁶).

5. It should be noted that both the membership of Treaty and the locations of the IDAs show more geographical diversity over time. A list of the Budapest Treaty Contracting States and IDAs is available on the [Budapest Treaty website](#).

¹ In Morocco.

² In India (3) and the Republic of Korea (4).

³ In the Russian Federation (2).

⁴ In Bulgaria (1), the Czech Republic (1), Hungary (1), Latvia (1), Poland (3), Slovakia (1).

⁵ In Australia (2), Belgium (1), Canada (1), Finland (1), France (1), Germany (1), Italy (3), Japan (2), Netherlands (Kingdom of the) (1), Portugal (1), Spain (2), Switzerland (1), the United Kingdom (7) and the United States of America (3).

⁶ In Chile (1) and Mexico (1).

Changes in the Regulations under the Budapest Treaty

6. In 2022, the Assembly of the Budapest Union decided to amend Rule 11.4(a)(i) and (b) of the Budapest Treaty, extending the languages of certain communications addressed to IDAs to the six official WIPO languages. These changes entered into force on January 1, 2023.

7. In addition, in line with the decision of the Assembly, the International Bureau (IB) published [the new Forms under the Budapest Treaty](#) in the six official WIPO languages. These forms now include designated spaces for email addresses and telephone numbers of relevant parties.

Notifications and communications

8. The Budapest Treaty regulates various kinds of communications from the Contracting States and intergovernmental industrial property organizations to the IB. They may concern, for example, the acquisition of the status of an IDA or the requirements of an IDA for accepting deposits, including changes in the schedule of fees charged by an IDA. In addition to the notifications of new accessions/ratifications to the Budapest Treaty and new declarations under Article 9(1)(a), the IB notifies and publishes these [communications](#) on the Budapest Treaty website.

9. Since July 2022, the IB notified and published the communications received from the United Kingdom, the European Patent Office, Poland, Japan, Spain, the United States of America, Finland and Portugal (in the order of publication).

Update of the Guide to the Deposit of Microorganisms under the Budapest Treaty

10. [The Guide to the Deposit of Microorganisms under the Budapest Treaty](#) contains information about the requirements to be met and the procedure to be followed by users of the Budapest system in depositing microorganisms and obtaining samples of the deposited microorganisms under the Budapest Treaty.

11. In addition to a general introduction to the Budapest Treaty and general requirements for deposit and furnishing of samples, the Guide provides in Section D the technical and administrative requirements of each IDA in receiving a deposit of a microorganism and furnishing of samples of deposited microorganisms (for example, the kinds of microorganisms accepted, the form and quantity in which microorganisms shall be received, the schedule of the fees, etc.).

12. Section D is regularly updated, based on the information received from the Contracting States or the IDAs (as the case may be). In 2024, information from 16 IDAs was updated.

13. Section E of the Guide contains information on the requirements of the intellectual property (IP) offices and regional patent organizations concerning the deposit of microorganisms and furnishing of their samples under the Budapest Treaty (for example, when the deposit shall be made, the conditions under which a sample of a deposited microorganism used in a patent application is available). The IB requests regularly the Contracting States to provide or update information regarding their requirements concerned.

14. In 2024, the IB updated Section E with the information received from Belarus, Bulgaria, Chile, the Czech Republic, Hungary, Iceland, Latvia, Peru, Poland, the Republic of Moldova, Serbia, Singapore, Slovenia, Spain, Türkiye, the United Kingdom, EPO and OAPI.

Statistics

15. The IB collects and publishes annual statistics regarding [the number of microorganisms deposited and the number of samples of deposited microorganisms furnished](#) under the Budapest Treaty, based on data received from IDAs. Figure 1 below shows that in 2022, a total of 9,808 microorganisms were deposited with IDAs. This made an increase of 12 per cent from the number of deposits made in 2021. The number of microorganisms deposited has been steadily increasing since 2002 (with a notable exception in 2020) and doubled over the last 10 years. Figure 2 provides the breakdown of microorganisms deposited in 2022, sorted by country of the IDA's location.

Figure 1

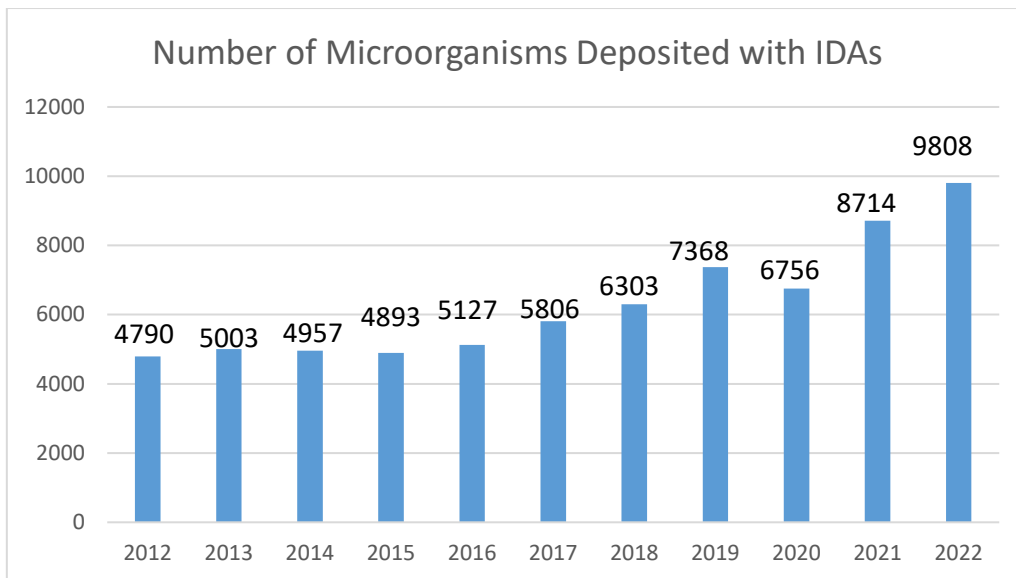
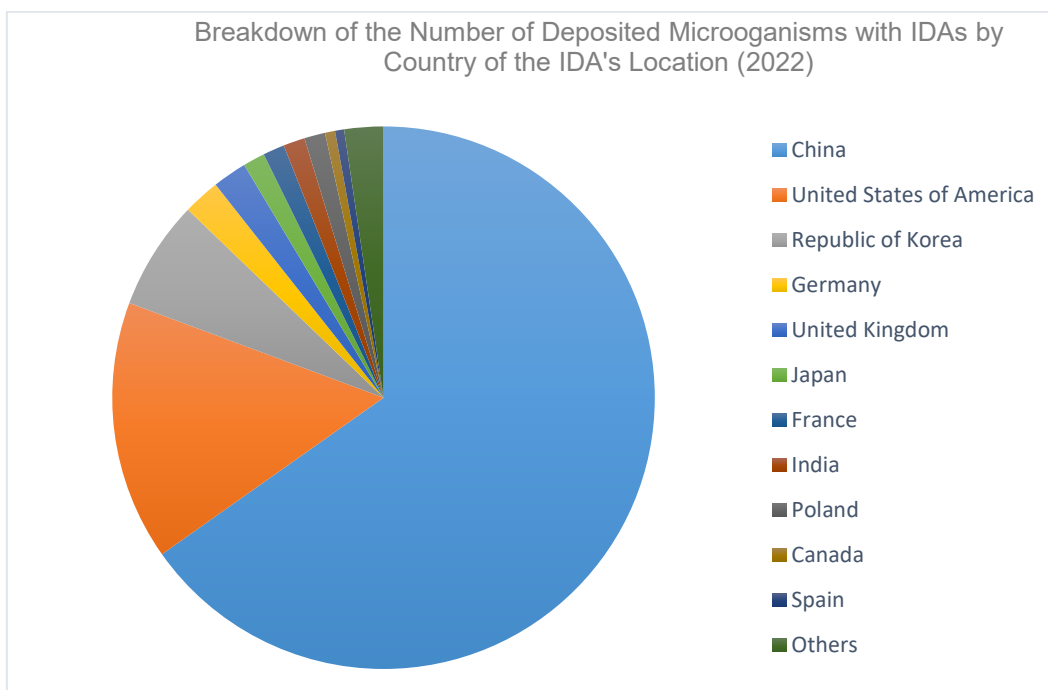
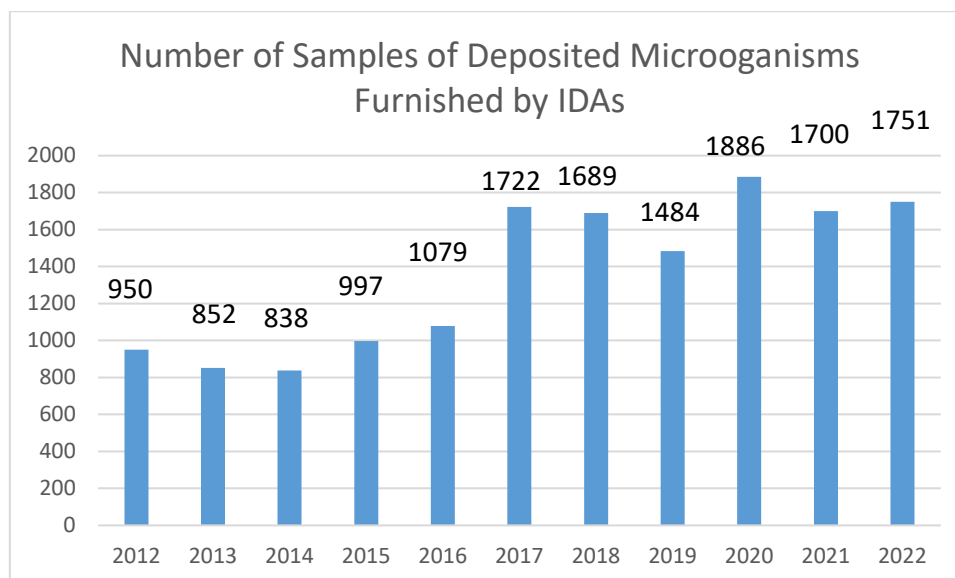


Figure 2



16. Regarding the samples of deposited microorganisms furnished by IDAs, a total number of 1,751 samples were furnished in 2022 (Figure 3).

Figure 3



17. Table 3 indicates the breakdown of the number of furnished samples by the types of parties who requested samples of the deposited materials under the Budapest Treaty. The vast majority of the samples of deposited microorganisms are furnished by IDAs to the depositor or to a party authorized by the depositor under Rule 11.2 of the Regulations. The total number of samples furnished to IP offices under Rule 11.1 had been very low: either in a single digit number per year or zero in some years. However, the number has risen sharply in 2021 – in total, 100 samples were furnished to IP offices. This trend continued in 2022, counting 87 samples furnished to IP offices in 2022.

18. With respect to the total number of samples furnished to legally entitled parties under Rule 11.3, it had been falling steadily from 467 samples in 2017 to 246 samples in 2021. This is an almost 50 per cent decrease during the last five-year period. In 2022, the number increased slightly to 287 furnished samples.

Table 3: Total Number of Samples Furnished by the IDAs

	2017 ⁷	2018	2019	2020	2021	2022
Samples furnished to Industrial Property Offices (Rule 11.1)	5	1	3	8	100	87
Samples furnished to depositor or authorized parties (Rule 11.2)	1,243	1,275	1,174	1,619	1,354	1,377
Samples furnished to parties legally entitled (Rule 11.3)	467	413	307	259	246	287

⁷ In 2017, one IDA notified the total number of furnished samples (7 samples), without specifying the breakdown by the types of parties to which the samples were furnished. Therefore, the total number of furnished samples in 2017 (Figure 3) counts 1,722 samples while the total number calculated from the data in Table 3 amounts to 1,715 samples.

Meeting of Member States and IDAs under the Budapest Treaty

19. One of the main features of the Budapest system is that the Contracting States shall recognize the effect of a deposit of a microorganism with any IDAs for the purposes of their patent procedure. Therefore, while IDAs are located in only some of the Contracting States, services delivered by any IDAs may potentially concern IP offices of any of the Member States. This means that cooperation between IP offices and IDAs takes place both at the national and international level.
20. As shown in Tables 1 and 2, since the entry into force of the Budapest Treaty in 1980, the number of Contracting States and IDAs has grown steadily. To provide an opportunity for the Member States and IDAs to share information and experiences at the international level on the implementation of the Treaty, the IB organized and hosted a Meeting of the Member States and IDAs under the Budapest Treaty, on November 13 and 14, 2023, in Geneva.
21. The Meeting was attended by 92 participants from 36 Member States, two intergovernmental industrial property organizations and 29 IDAs.
22. The objective of the Meeting was to hold discussions between Member States and IDAs, in an in-person format, on various topics regarding the deposit of microorganisms in relation to the patent procedure. It was an *ad hoc* meeting, which was not designed to make any decisions or recommendations. The Meeting allowed the participants to have a fruitful exchange of views in an informal atmosphere.
23. The program of the Meeting addressed the following topics:
- Topic 1: Presentation of recent developments in the Budapest system;
 - Topic 2: Deposit of biological material;
 - Topic 3: Furnishing of samples of the deposited biological materials;
 - Topic 4: Cooperation between IDAs and IP offices;
 - Topic 5: Practices of the IDAs under the Budapest Treaty. Under this topic, the IDAs presented their practices on: (a) the handling of the deposited biological material after the mandatory storage period prescribed in the Budapest Treaty; (b) the Nagoya Protocol; (c) other issues;
 - Topic 6: Deposit of biological materials: technology trends and emerging practices in IDAs;
 - Topic 7: Technological advancement in biotechnology: impacts on the enabling disclosure requirement and the deposit of biological materials;
 - Topic 8: Future development in the Budapest System.
24. To facilitate comprehensive discussions on each topic, presentations were delivered by speakers representing IP offices, IDAs, and external experts, as outlined in the program.. Three background documents regarding the Handling of Microorganisms Deposited under the Budapest Treaty after the Period of Storage, the Furnishing of samples of deposited biological material, and the Nagoya Protocol and the Budapest Treaty were prepared by the IB to support the discussion on Topics 3 and 5. [All documents](#) prepared by the IB, including the Summary Report of the Meeting, as well as the presentations, are available on the Meeting website.

25. Under Topic 8, participants also discussed whether there were any areas in the Budapest system that might be improved and how they might be addressed. Paragraph 38 of the Summary Report outlines the main messages that emerged under that Topic, as follows:

- communication among IP offices, IDAs and the IB, at the national and international level, and with depositors and patent applicants, should be improved;
- IP offices, IDAs and the IB may consider creating more opportunities for exchange of best practices and experiences;
- IDAs and IP offices may explore new means of sharing information and data in order to support the operation of the organizations;
- the Contracting States of the Budapest Treaty may provide guidance on how samples of deposited biological material should be handled by the IDAs after the storage period prescribed in the Budapest Treaty;
- technological advancements that may assist IDAs to better preserve and transmit the deposited biological material, including new kinds of material, should be followed;
- potential of genome sequencing information to complement the deposit of physical biological materials may be explored.

26. With a view to facilitating communication and cooperation between IP offices and IDAs, and taking the opportunity of the request for updates in Section E of the Guide (see paragraph 13), the IB invited the IP offices to provide an email address that may be used by the IDAs to contact them. Based on the information received, Section E of the Guide was updated accordingly. The IB is also exploring the feasibility of improving the searchability of published patent documents that are related to deposited biological material in PATENTSCOPE.

27. The Assembly of the Budapest Union is invited to take note of the "Activity Report on the Operation of the Budapest System" (document BP/A/41/1).

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