

Topic 5.- Practices of the IDAs under the Budapest Treaty

National Collection of Cultures of Microorganisms (CNCM)

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Executive and Administrative Head of CNCM

National Collection of Cultures of Microorganisms CNCM

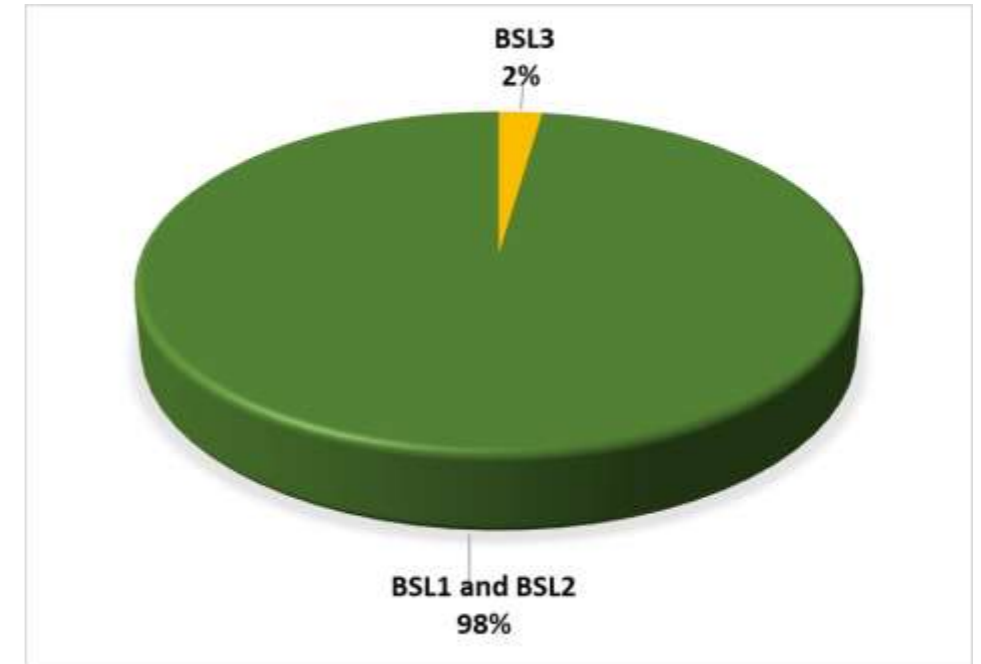
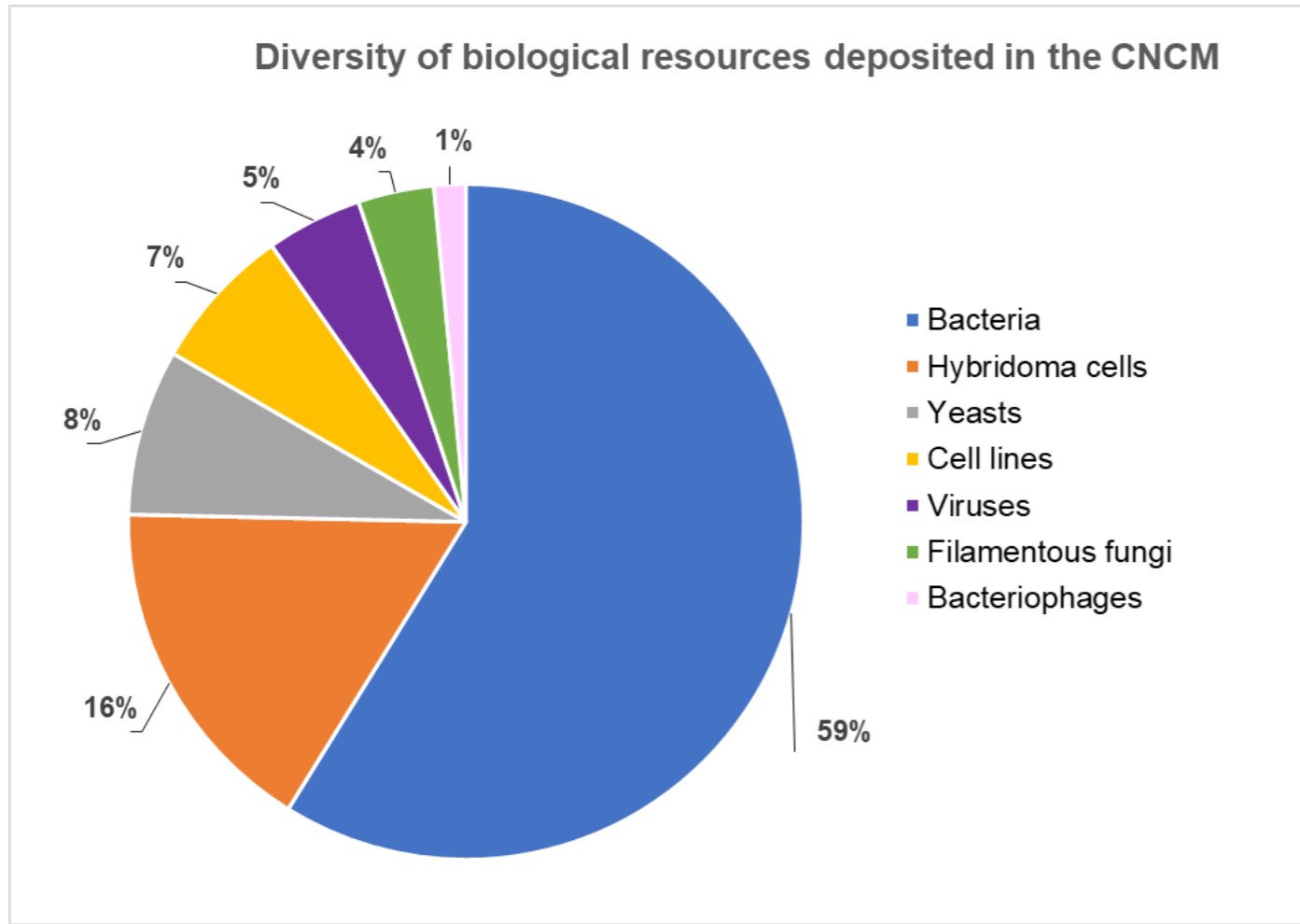
General Information

- **Since 1984**, the CNCM (*Collection Nationale de Cultures de Microorganismes*) has the status of International Depository Authority (IDA) under the Budapest Treaty (BT) on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.
- It is an autonomous entity with the **sole mission** of preserving biological materials deposited under the BT.
- Is the **only collection in France** with the IDA status.
- **Hosted at the Institut Pasteur**, Paris, France, thanks to an agreement between the INPI (National Institute of Industrial Property) and the Institut Pasteur.



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Biological Resources at the CNCM



TOTAL IDA Collection: 5,651 deposits

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Ministère de l'Enseignement supérieur,
de la Recherche et de l'Innovation



Declaration for the use
of GMOs in a confined
environment (MESRI)



Restricted Regime Zone (ZRR),
on the system for protecting the
national scientific and technical
potential (PPST)



Obligations of IDAs

Comply with national, European and
international regulations

Scientific information is facultative = not
enough information about the deposited
microorganisms (mainly in older deposits)
because the depositor is not obliged to
provide such information (secrecy).



Declaration of holding and
utilization of Highly Pathogenic
Microorganisms and Toxins
(MOT) followed by the ANSM



Nagoya Protocol on Access
and Benefit-Sharing



The General Data Protection
Regulation (GDPR)



Institut Pasteur

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Handling of the deposited materials after the mandatory storage period (30+5 years)

Rule 9

Storage of Microorganisms

9.1 Duration of the Storage

Any microorganism deposited with an international depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.

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Contract

- To date, all biological materials are preserved, despite what is indicated in the contract.
- Electronic signatures are not used on the recommendation of legal professionals.

17.- Each time the CNCM considers advisable to send a sample of a subculture from the above-identified microorganism to the depositor (**), with a view to an authenticity check, the depositor (**) shall verify the expression of the relevant properties by the microorganism in the said subculture; the form included in the sending shall be duly completed, signed and returned to the CNCM within a three-months time limit after the sample has been received.

The depositor (**) recognizes, where the above-referred form is not returned to the CNCM in the time allotted to, the properties of the said subculture are to be considered identical to the properties of the subculture transmitted to the CNCM at the date of deposit.

18.- The depositor can not withdraw, cancel or modify the deposit during the storage period provided for in Rule 9.1 of the Budapest Treaty or in Point 11 of the bilateral Agreement.

The above-identified microorganism shall in any case be stored by the CNCM for a period of 35 years.

19.- When the storage period expires, the whole biological material shall be destroyed, except in the case of a particular agreement made at the request of the depositor during the thirty fifth year of storage.

20.- If for any reason the CNCM cannot furnish samples of the above-identified microorganism once accepted and its viability stated, the depositor shall proceed to a new deposit of the microorganism which was originally deposited, in compliance with the applicable regulations, within a three-months time limit after he has received the relevant notification by the CNCM.

The reasons based on good practice as for Depository Authorities that lead to refuse the release of samples are entirely left to the assessment of the CNCM.

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THE SCIENTIST(S)
in charge of the microorganism

Date et signature(s)

(continued)

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DE LA PROPRIÉTÉ
INDUSTRIELLE



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Procedures for furnishing of samples

- **Access to biological materials with more than 30 (+5) years follows the Rule 11 of the regulations under the BT.** No changes. There is no legal framework that clarifies that we can do something different.

Requests from depositors

- Requests from depositors to continue maintaining the conditions for furnishing samples (confidentiality, secret). *Examples: depositors that have a **commercial product on the market** or want to exploit their biological materials through **an MTA or scientific and commercial agreements**, even though the patent has fallen into the public domain.*
- Requests from depositors that want to recover their biological materials to prevent them from being available to the public.

Requests from the public

- Requests for accessing biological material from **expired patents**. *They insist that materials should be available since the patent has fallen into the public domain. They cannot have access to these materials other than from the IDA or the depositor.*

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The impact of continuing to preserve biological materials

Infrastructure, Energy Consumption, Sustainability

- TOTAL IDA Collection: 5,651 deposits (~141,275 samples)
- 30 years (1993)
 - Deposits from 1984 to 1993: 1,078 deposits (~ 24,794 samples)
- 35 years (1998)
 - Deposits from 1984 to 1988: 653 deposits (15,019 samples)



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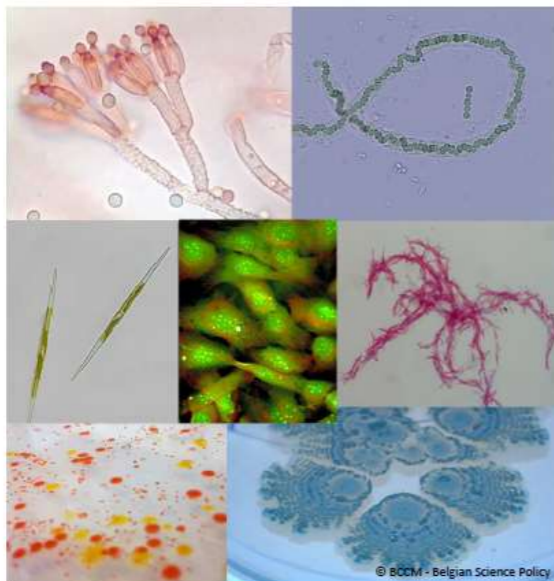
The interest of continuing to preserve biological materials not associated to patents (expired patents, when there was never a patent).

- For deposits of more than 30 years, if the patent has already expired,
 - future of these deposits?
 - possible utilisation/valorisation?
 - deposits in which depositors don't exist anymore (e.g. the company closed and did not transfer the rights to another), depositors are not reachable, etc.
 - if there was never a patent.
- For current deposits,
 - how many deposits are really associated with patent procedures?
 - for deposits not-associated with patents, which is the interest on R&D, Innovation, etc. for IPOs?

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THE BUDAPEST TREATY

CODE OF PRACTICE FOR IDAs



End of the period of storage

The IDA must store the deposited material for a period of at least 30 years after the date of deposit (or for a period of at least 5 years after the most recent request for the furnishing of a sample of the deposited organism was received by the IDA). At the end of the storage period of 30 years the IDA checks whether a sample was released in the course of the five preceding years. If so, the storage period is extended by 5 years from the reception date of said request. The latter will apply also if any further sample request is received in the period of extension.

The said request may be made by any of the parties mentioned in Rule 11 of the Regulations under the BT.

It is advisable that IDAs make suitable arrangements about what to do with the deposited material

- make the material publically available,
- extension of the deposit against a fee.

In the case of absence of such arrangements, civil law is applicable.

For current deposits:

- In the 29th year of the storage period set out in Rule 9.1 of the Regulations under the BT, request information from the depositor whether he wishes to extend the storage period against a fee. In the absence of agreement to such extension, make the deposit publically available,
- Agreements concluded with the depositor must be respected.

Post Budapest deposit release features:

- Availability as under 11.3(b) to "requesting parties",
- Fees identical to those of Budapest samples.

In case a depositor requests the prolongation of its patent deposit after the required period of preservation, the IDA can charge the depositor for this additional storage time. However, no IDA is obliged to accept any request for prolongation beyond the period stipulated in Rule 9.1 of the Regulations under the BT.

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Which is the future of the
microorganisms stored for more than
30 (+5) years?



Regulations*



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



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