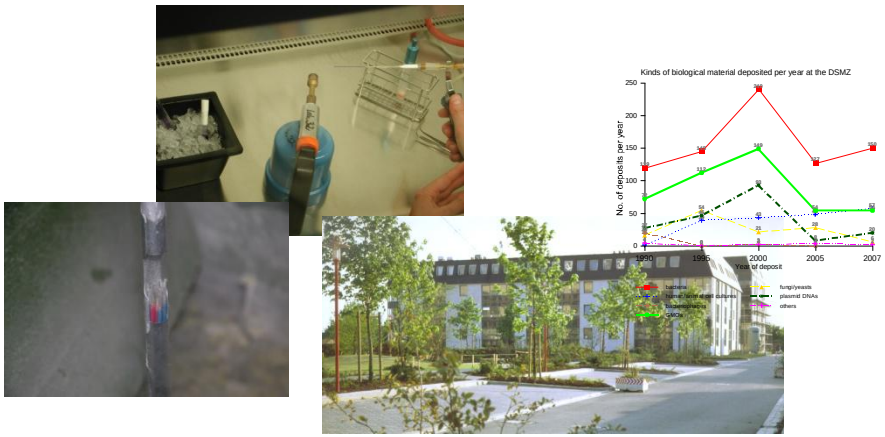
IDAs - 30 YEARS OF EXPERIENCES WORLD-WIDE



Dr. Vera Weihs
Leibniz-Institut DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH
Inhoffenstr. 7 B
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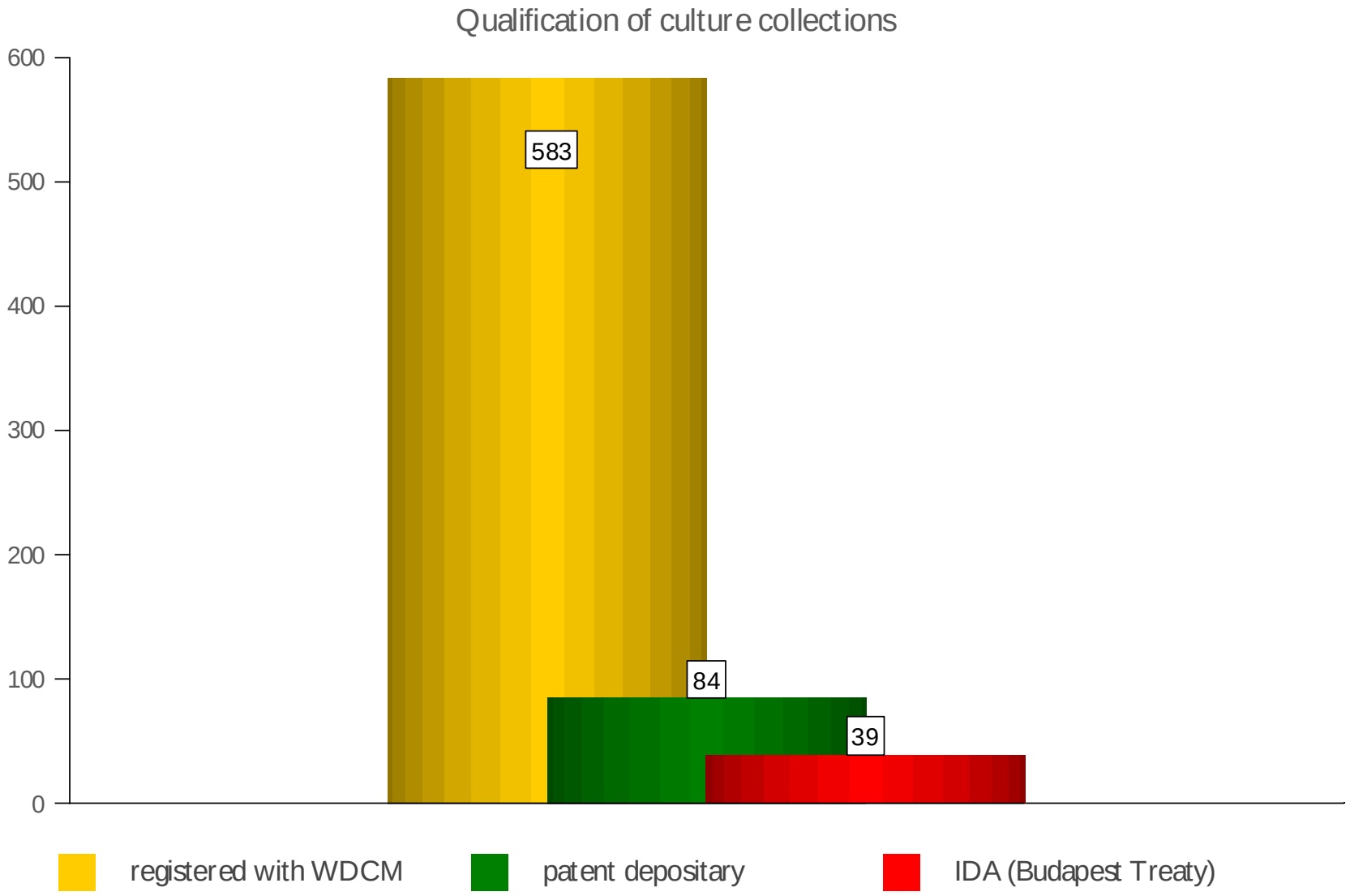
Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

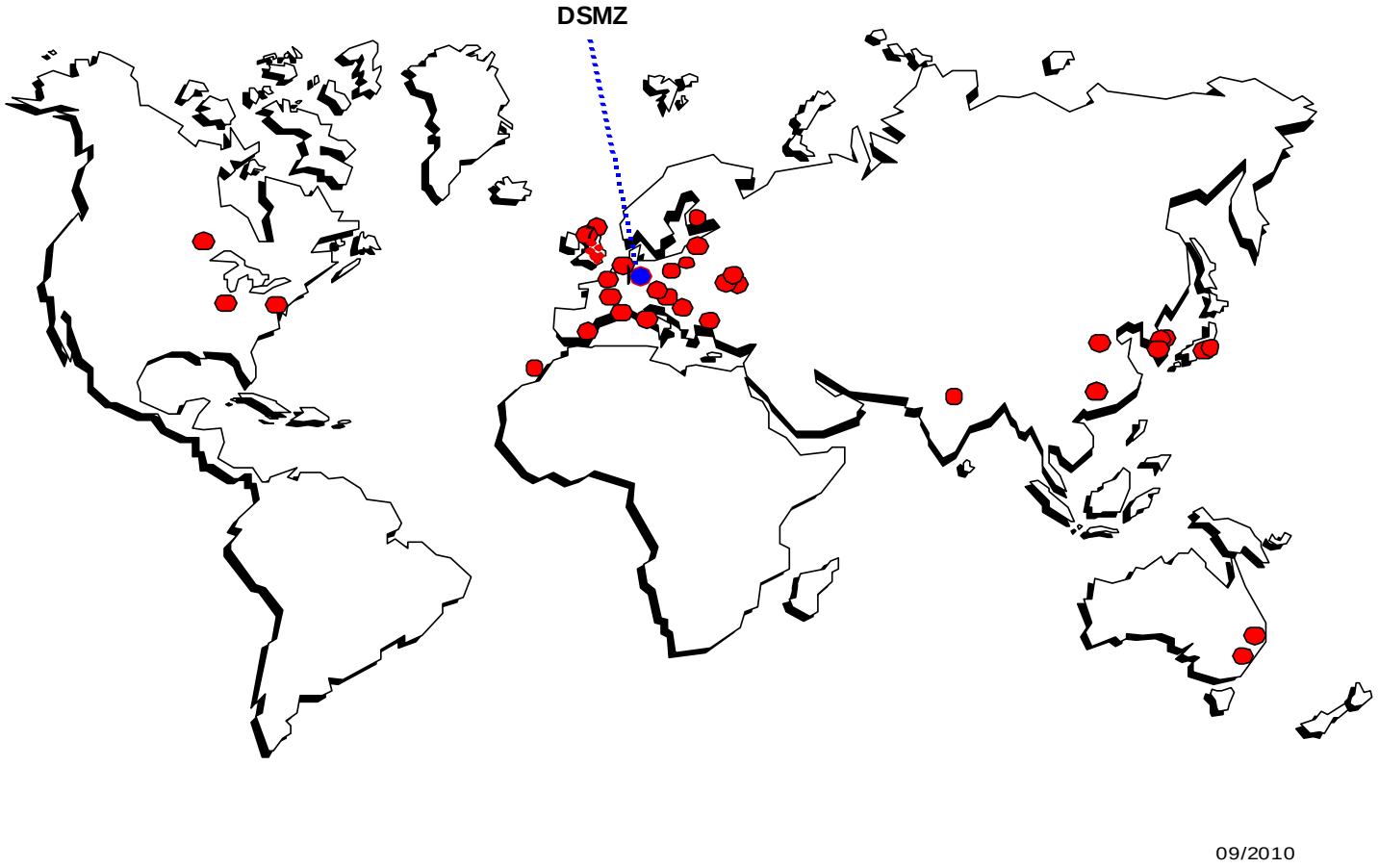
done in 1977, in force since 1980

→ Certain culture collections are recognized as „**I**nternational **D**epositary **A**uthorities“

→ Any contracting state must recognize a deposit made in any IDA

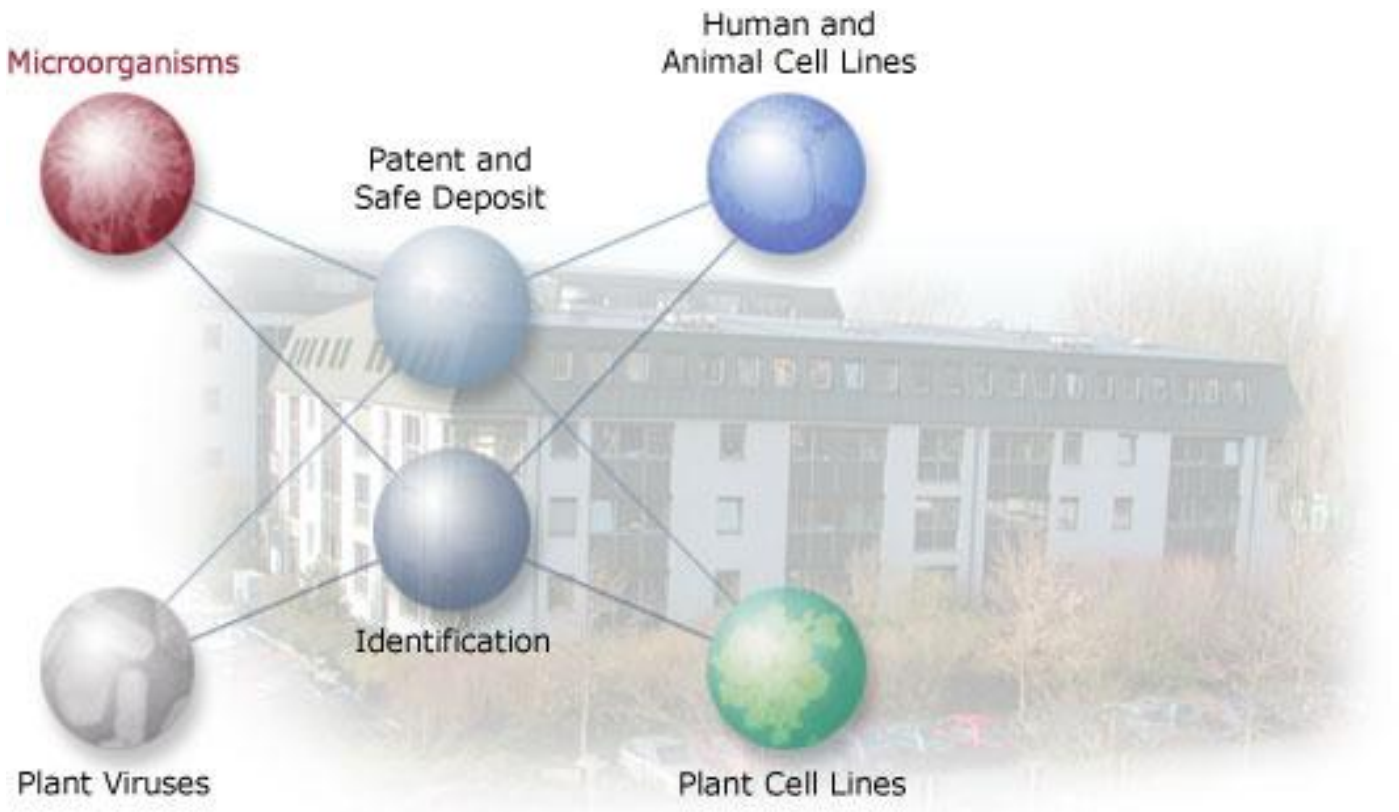

Qualification of culture collections
600
500
400
300
200
100
0
583
84
39
registered with WDCM
patent depositary
IDA (Budapest Treaty)

IDAs World-Wide



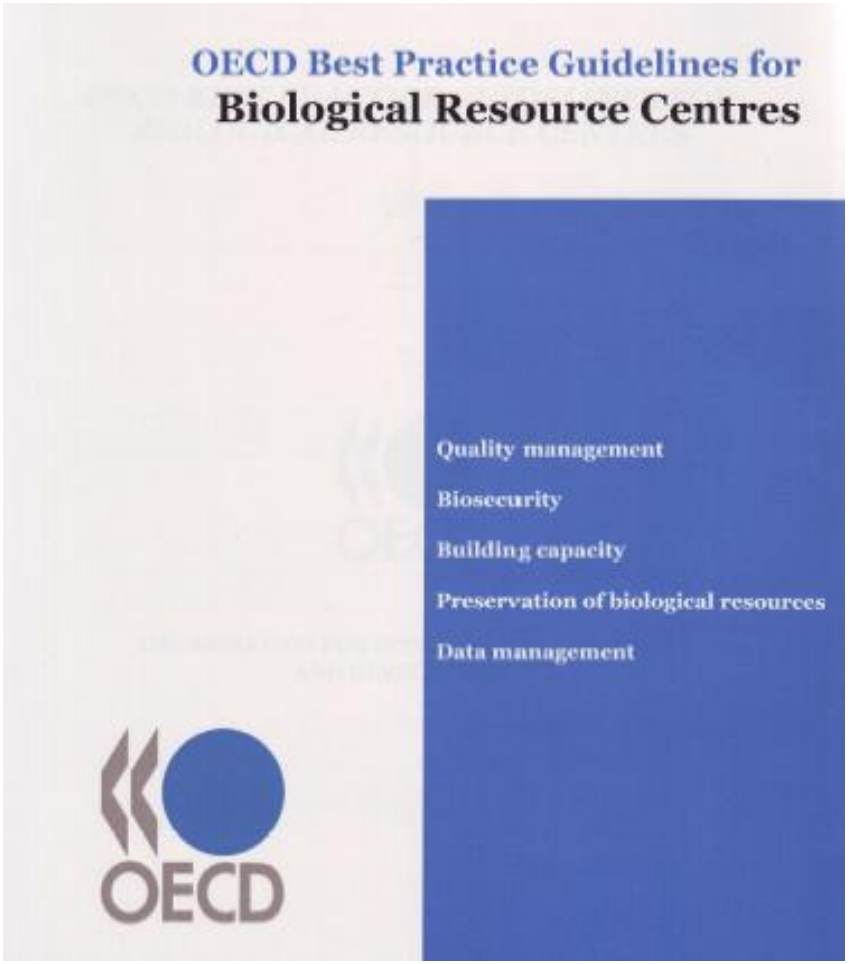
39 as of 09/2010

The DSMZ – a Biological Resource Center

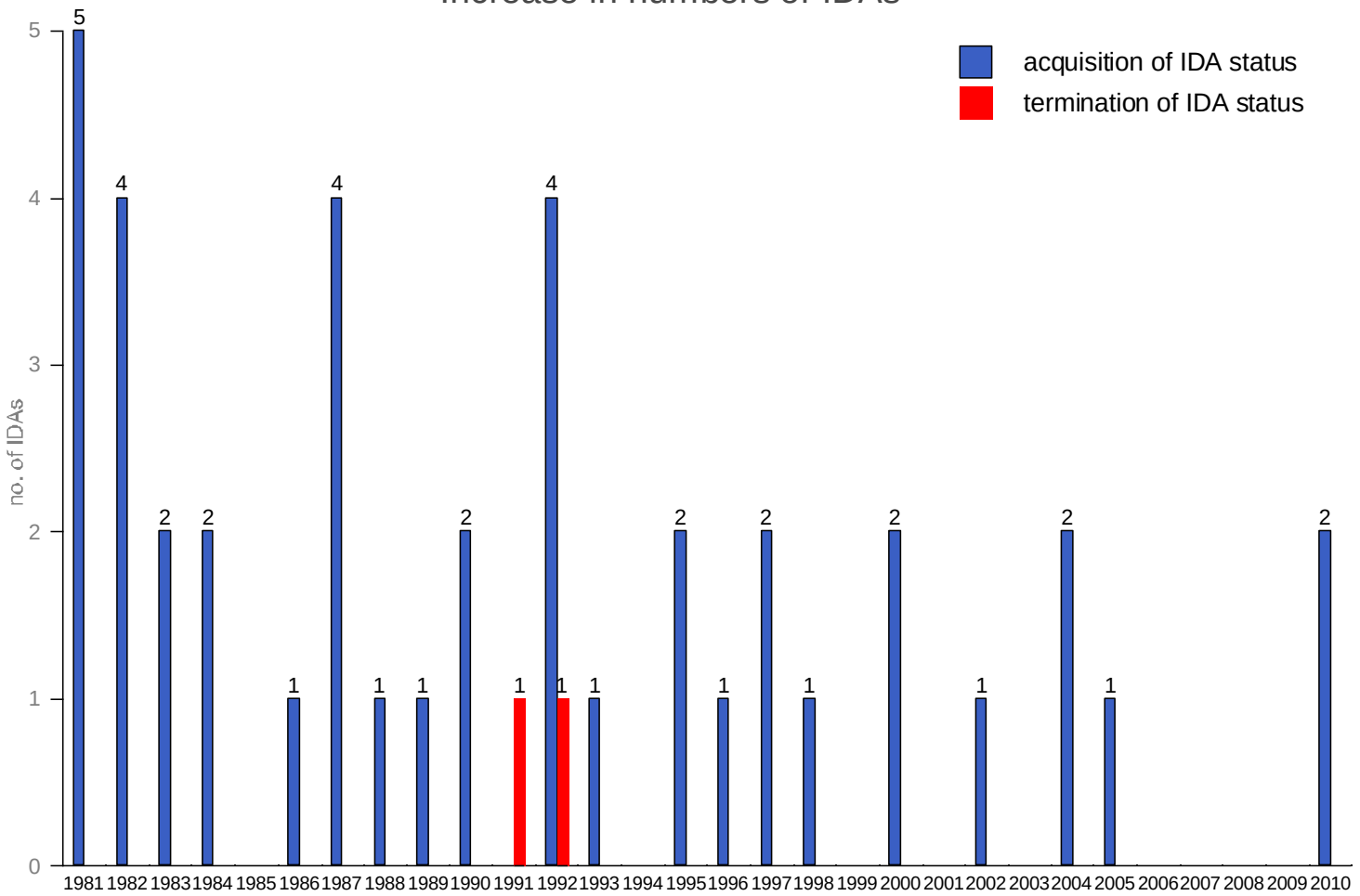


BRC‘s According to OECD

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

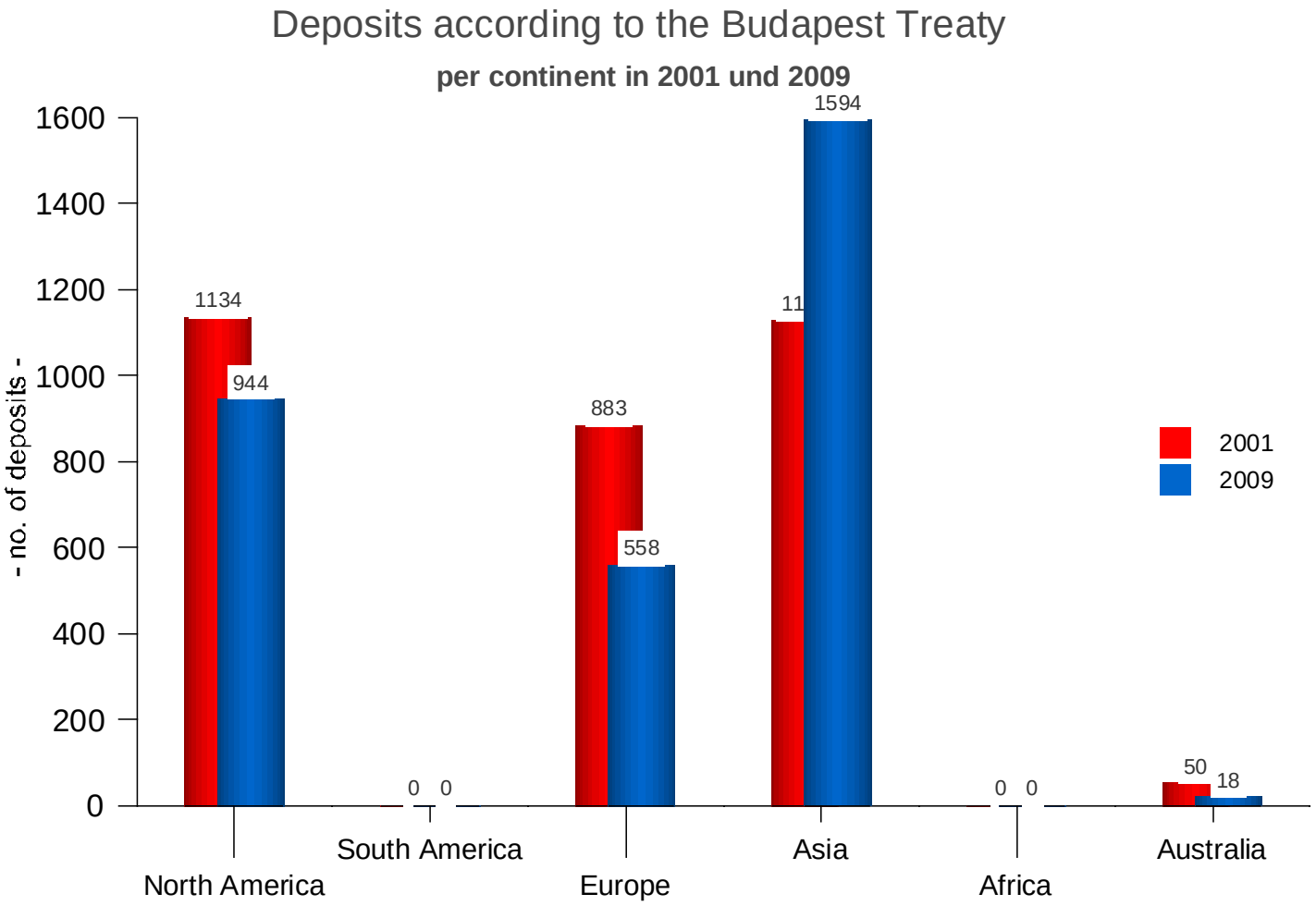


Increase in numbers of IDAs



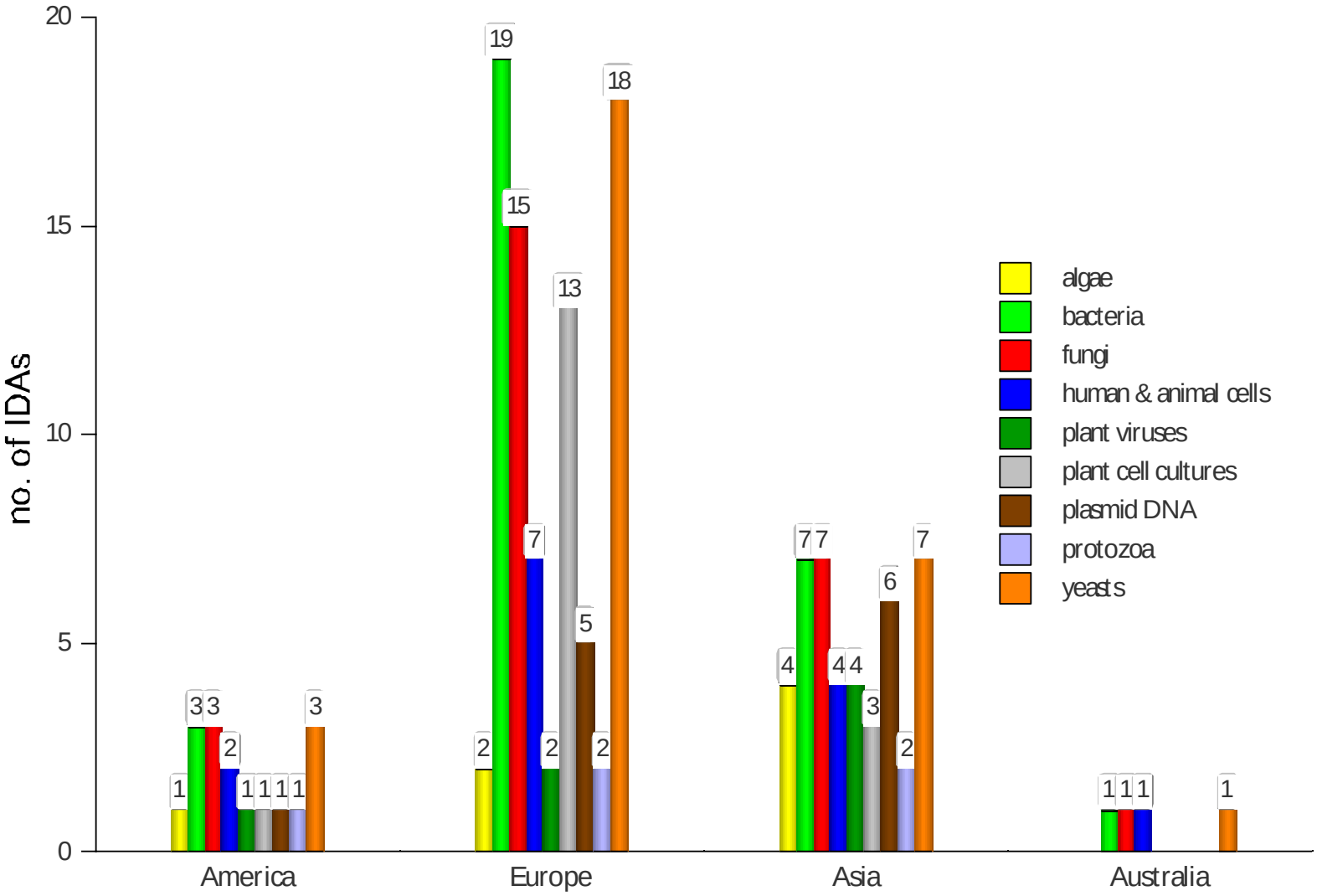
1981: ATCC, NRRL, FRI, CBS, DSM

2010: CBA, VTTCC


Deposits according to the Budapest Treaty
per continent in 2001 und 2009
- no. of deposits -
1600
1400
1200
1000
800
600
400
200
0
1134
944
0
0
883
558
11
1594
0
0
50
18
2001
2009
North America
South America
Europe
Asia
Africa
Australia

Total: 70.000

Kinds of Microorganisms Accepted for Deposit/Continent



***IDA** (12 out of 39)*	***Kinds of Biological Material Material Accepted***	*Containment level*
ABC	Animal and human cell lines	2
ATCC	Algae, bacteria, fungi, yeasts, embryos, human, animal and plant cell cultures, bacteriophages, animal and plant viruses, seeds, DNA, RNA, protozoa	4 3 for GEMs
BCCM	Bacteria, fungi, yeasts, plasmid DNA, RNA, animal and human cell lines*	2 * 3
BNA	Microalgae, cyanobacteria and macroalgae	1
CBS	Bacteria, fungi, yeasts, bacteriophages, plasmid DNA	3; 2 for GEMs
CCAP	Algae, free-living protozoa, microorganisms	1
DSMZ	Bacteria, fungi, yeasts, bacteriophages, plasmid DNA, plant viruses, plant cell cultures, animal and human cell cultures, murine embryos	2
IMI	Fungi, bacteria, nematodes	2
IPOD	Fungi, yeasts, bacteria, plasmid DNA, animal cell cultures, embryos, protozoa, plant cell cultures, seeds, algae	1-2
KCLRF	Animal, human and plant cell cultures	1
NCAIM	Bacteria, fungi, yeasts	1-2
VKM	Bacteria, fungi, yeasts	1

Definition of Risk Groups - WHO

Group 1

Unlikely to cause human disease

Risk Group 2

Can cause human disease; low risk for the employees; unlikely to spread to the community; effective prophylaxis and treatment

Risk Group 3

Can cause severe human disease; serious hazard for the employee; risk to spread to the community; effective prophylaxis and treatment

Risk Group 4

Causes severe human disease; serious hazard to the employee; high risk to spread to the community; no effective prophylaxis or treatment

Classification of Microorganisms – Legal Background

International WHO Laboratory Biosafety Manual (2004)

Europe Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work (European Parliament) (2000)

national

Canada Laboratory Biosafety Guidelines, Health Canada (Laboratory Center for Disease Control) (2004)

Germany Classification of fungi/bacteria, TRBA 460/466, Federal Ministry for Labour and Social Order

USA Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services Public Health Service, CDC and NIH (2007)

China General Biosafety Standards for Microbiological and Biomedical Laboratories Ministry of Health (2003)

Tasks of an IDA

The IDA has to

- test the viability of the biological material promptly after its receipt
- **store the biological material in a genetically unchanged way**
- release samples for trials and examinations to authorized parties
- comply with the demand of secrecy about deposited strains
- be impartial and objective

Why is it Advisable to Preserve Microorganisms?

Microorganisms are genetically instable and can change their properties by subsequent cultivation

Microorganisms have to be available on a long-term basis with known, specific and stable properties

Industry needs genetically stable production strains

Important isolates/mutants resulting from scientific efforts need to be maintained to prevent renewed enrichment/isolation

It must be guaranteed within a project that all the research has been performed with the same organisms from the very beginning until its end

Reasons für the Preservation of Biological Material

Maintenance of the material

- Without contaminations
- Without genetical changes

Principles of Preservation

- Reduction of the microbial metabolism, ideally to nil
- Yet preserving the viability of the cells

- Lowering the temperature
- Depriving the cells of water

Survey: Different Preservation Methods

METHOD	SUCCESSFULLY PRESERVED ORGANISMS	SHELF-LIFE	GENETIC STABILITY
storage under parrafin oil	yeasts, fungi, some bacteria	fungi: 5-20 y bacteria: 2-5 y	low
storage in distilled water	yeasts, filamentous fungi, acti-nomycetes; not: enterobacteria	1-5 y	low
drying in gelatin discs	enterobacteria, staphylococci, pseudomonads; spore-forming fungi	1/2-7 y	medium
storage in sterile soil, sand etc.	spore-forming bacteria and fungi non-sporeformers	10-15 y 1-5 y	good
L-drying	bacteria, fungi, yeasts, animal viruses, protozoa	2-5 y	good
drying on glass beads or porcelain rings	fungi, bacteria, mycoplasms	5-10 y sporeformers: 10-15 y	good
freeze-drying	**bacteria, some yeasts**	**> 40 y**	**good**
storage at domestic refrigerator temperature	bacteria	several weeks/months	low
storage at -20☜C in glycerol	bacteria	several months - 2 y	medium
storage at -60 - -80☜C in glycerol	bacteria	5 y	good
storage in liquid nitrogen at -196☜C	**bacteria, fungi, yeasts, plant cell cultures, animal cell cultures**	**> 30 y**	**good**
maintenance on glass-beads	bacteria	> 10 y	good

Storage in Liquid Nitrogen I

Storage in Liquid Nitrogen II

Storage in Liquid Nitrogen III

Storage in Liquid Nitrogen IV

Drying of Microorganisms

Storage of Dried Cultures

Tasks of an IDA

The IDA has to

- test the viability of the biological material promptly after its receipt
- store the biological material in a genetically unchanged way
- release samples for trials and examinations to authorized parties
- comply with the demand of secrecy about deposited strains
- be impartial and objective

Furnishing of Samples acc. to the Budapest Treaty

11.1 To Interested **Industrial Property Offices**

When? --> At any Time on Request to the IDA

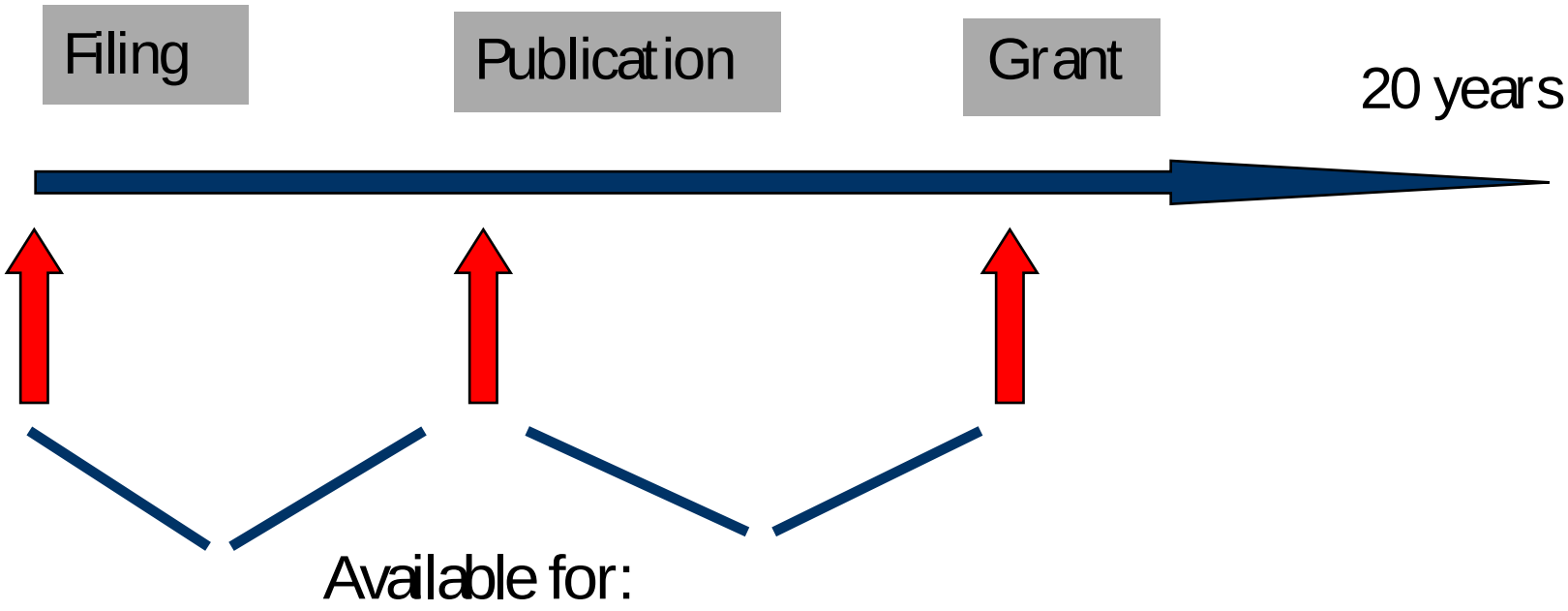
11.2 To the **Depositor or with the Authorization of the Depositor** to Third Parties

When? --> At any Time on Request to the IDA

11.3 To **Parties Legally Entitled**

When? --> By Confirmation of the Request by the Responsible Patent Office

Furnishing of Samples - When ? To Whom ?



Patent Office

Depositor

Authorized Third Party

Patent Office

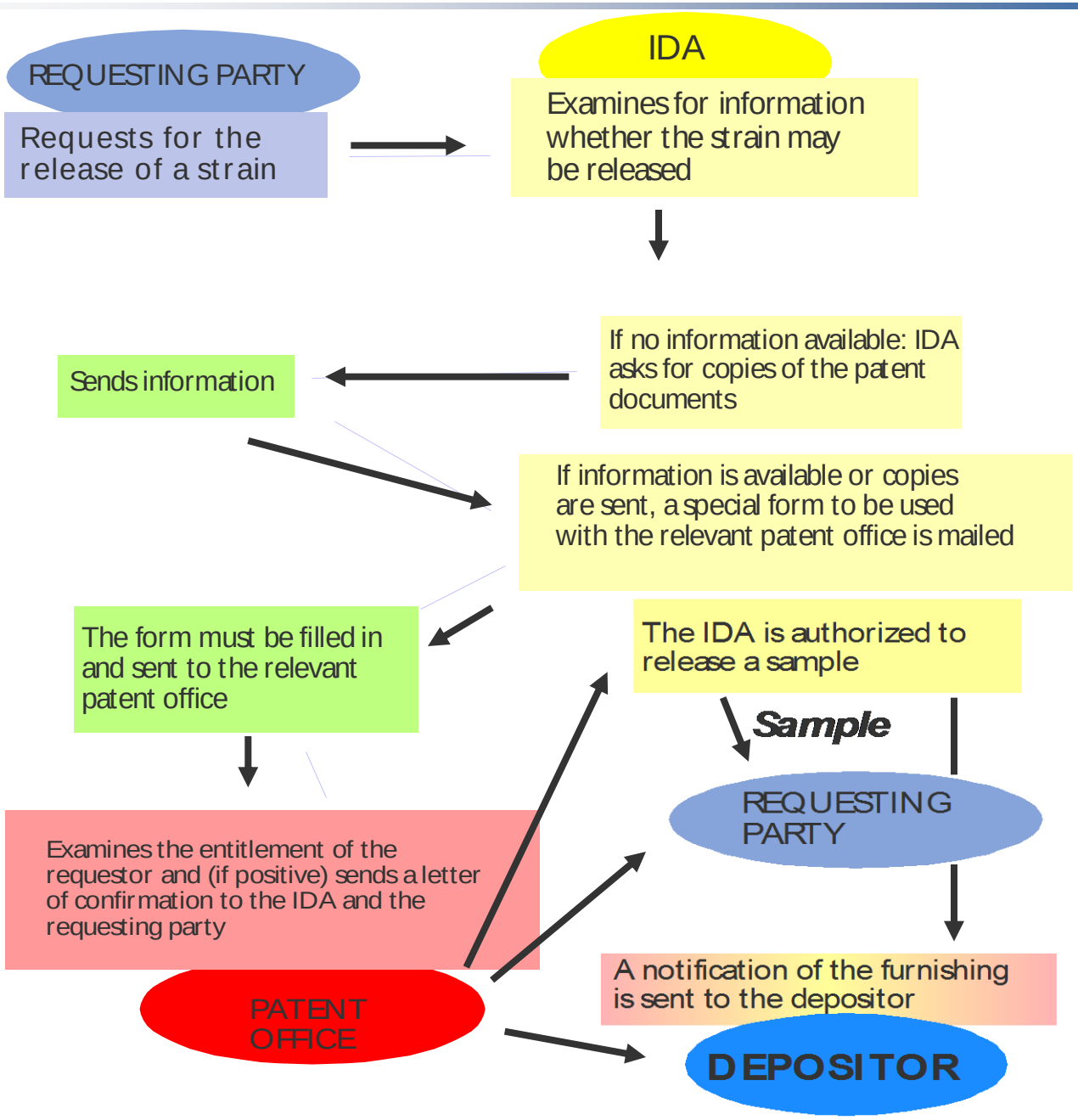
Depositor

Authorized Third Party

+

Certified Third Parties

Release of a Patent Strain to Parties Legally Entitled



Registrations/Allowances which Might be Necessary

Registration of the working area for the handling of

- ►human pathogens
- ►animal pathogens
- ►plant pathogens
- ►genetically engineered organisms

Personal allowances according to

Act dealing with the prevention and control of infectious diseases in man

Infectious diseases of animals enactment

Plant inspection act

Law regulating genetic engineering

Restrictions for the Shipment – Import/Export

Import or quarantine restrictions

EEC Directive restricting ex-/import of plant pathogens

EEC Directive restricting ex-/import of epidemics of animals

EEC Regulations for the control of exports of dual-use goods

Act on the control of war weapons

Criteria for the Dispatch of Biological Material

Risk Group	Destination	Take notice of ...	action/proof	dispatch by
1	Home Country	Genetic engineering act Plant protection act Infectious diseases of animals act	Registered Laboratory Permission Permission	mail
	Foreign country	EU: Plant Protection Act Air mail might not be admitted! Act on the Control of War Weapons **Total embargo ?**	Permission Only for civil use! **No dispatch!**	mail/air mail or air freight
2 3	Home Country	Infectious Diseases Act Infectious Diseases of Animals Act Plant Protection Act Genetic Engineering Act Act on the Control of War Weapons	Permission Permission Permission Registered laboratory Only for civil use!	Courier service
4	Foreign country	EEC Regulation for the Control of Exports of Dual-Use Goods Act on the Control of War Weapons Import/quarantine restrictions EU: Plant Protection Act **Embargo ?**	Authorization Only for civil use! Import permit Permission **No dispatch!**	

Transport of Biological Material

Pathogenic material - a menace or danger during transportation for:

Postal employees,
airport personnel,
secretaries and others
who could be exposed hazardously

national and international laws and regulations to reduce the possibility of an inadvertent release of microorganisms

Transport by Mail I

Regulated by: UN Letter Post Compendium

Dangerous Goods are **not** to be transported

Only possible exception: Infectious substances

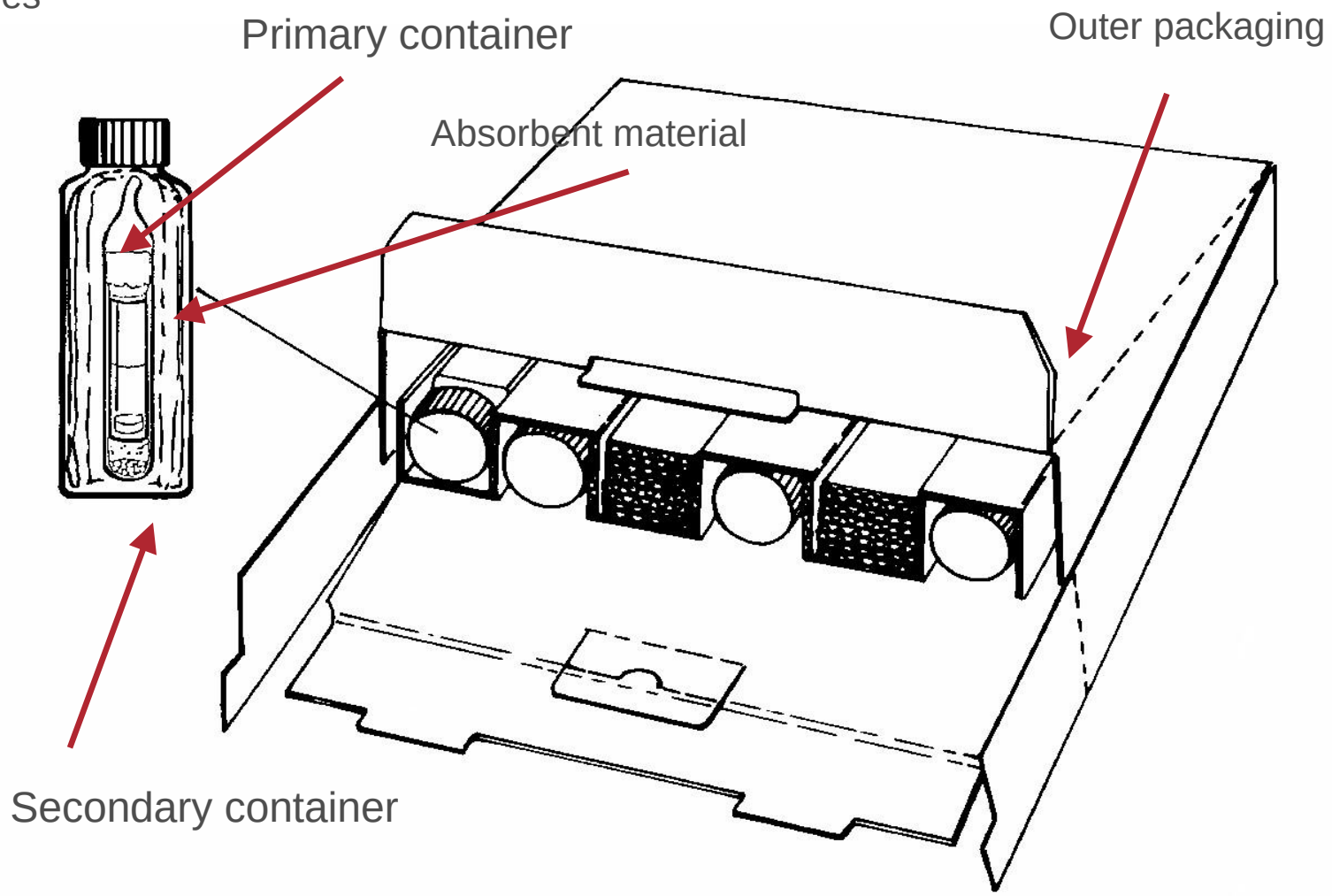
Triple packaging acc. to UPU Letter Post Manual Articles 16 and RL 129

Applicable for risk group 1 organisms

And following PI 650 DGR

Applicable for biological substances, category B

Triple Packaging for Non-Infectious Substances



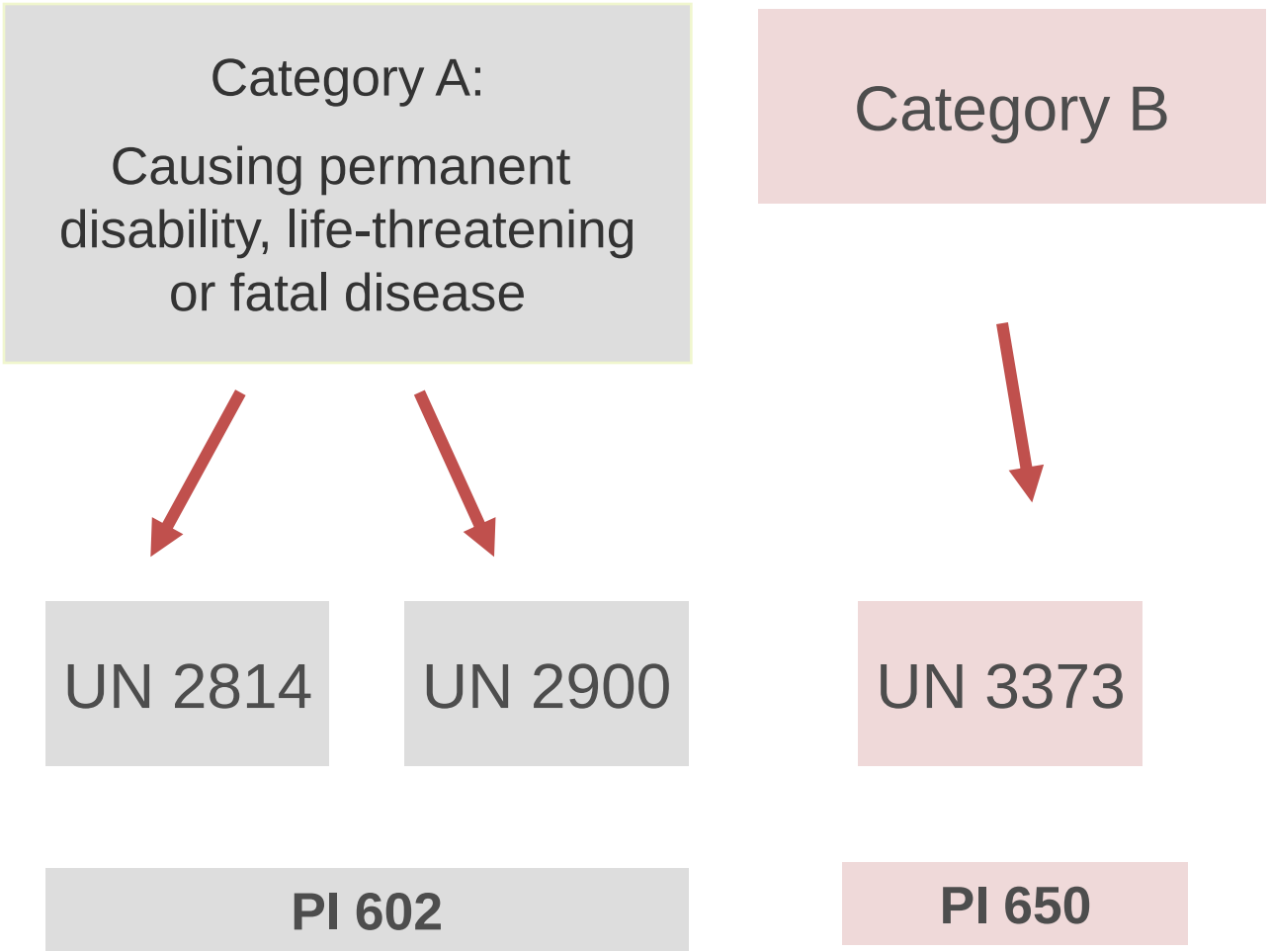
Transport of Dangerous Goods as Freight

Regulated by:

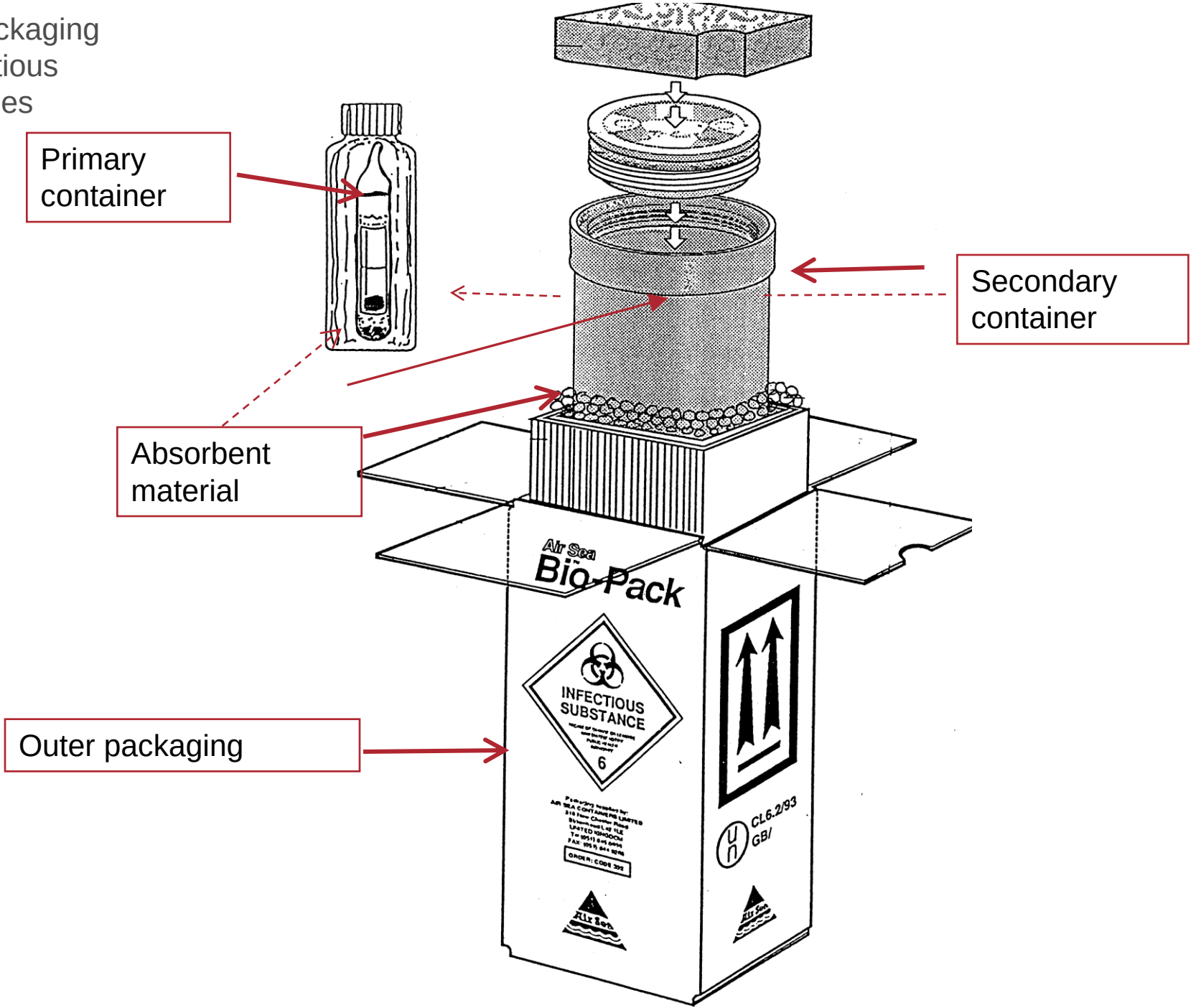
on the road	ADR – **A**ccord Européen Relatif au Transport International des Marchandises **D**angereuses par **R**outes
by rail	COTIF/RID – **R**egulations concerning the **i**nternational carriage of **d**angerous goods by rail
by sea	IMDG – **I**nternational **M**aritime **D**angerous **G**oods Code
by air	IATA – **I**nternational **A**ir **T**ransport **A**ssociation **D**angerous **G**oods **R**egulations

Transport in specified containers !!

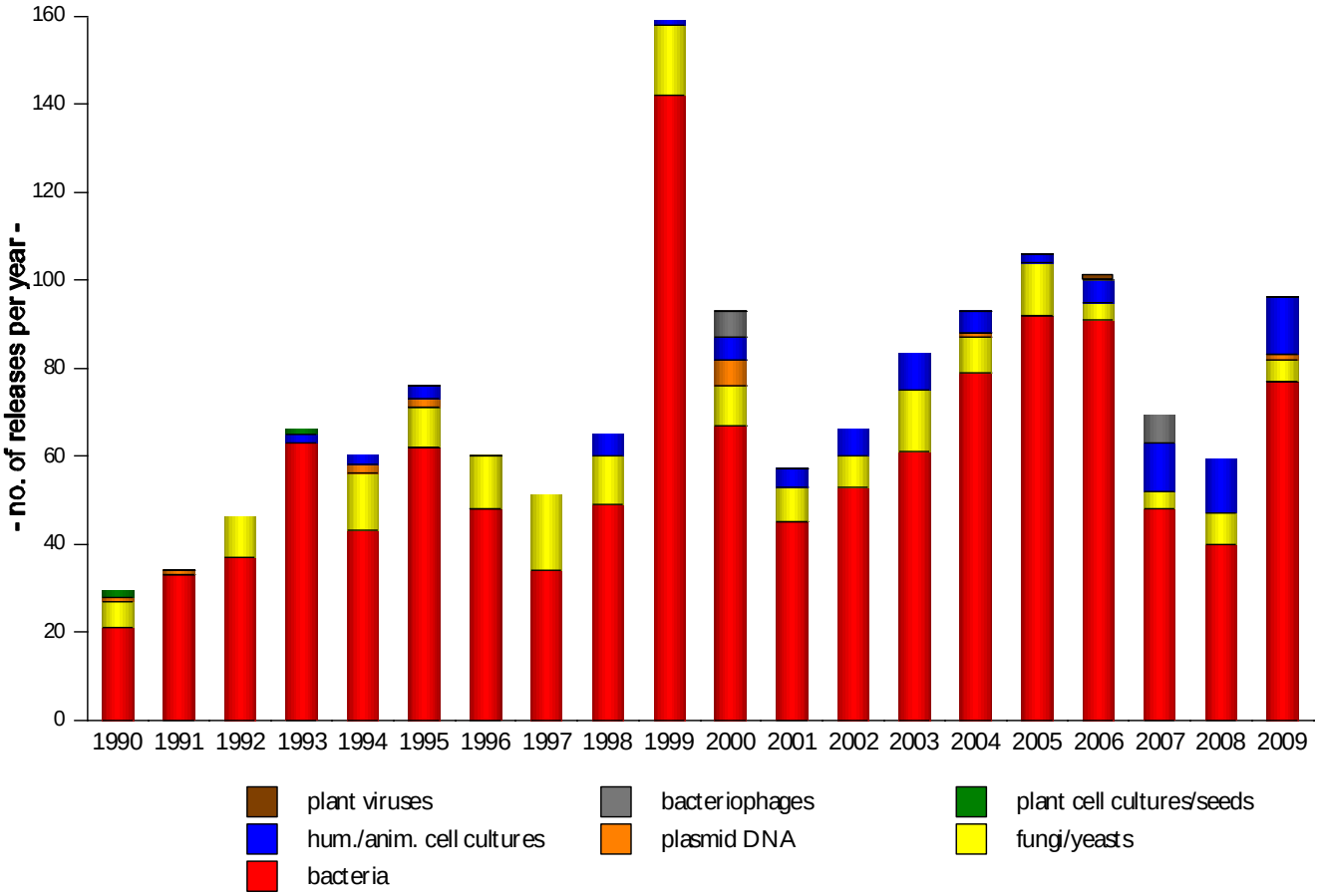
Classification of Infectious Substances



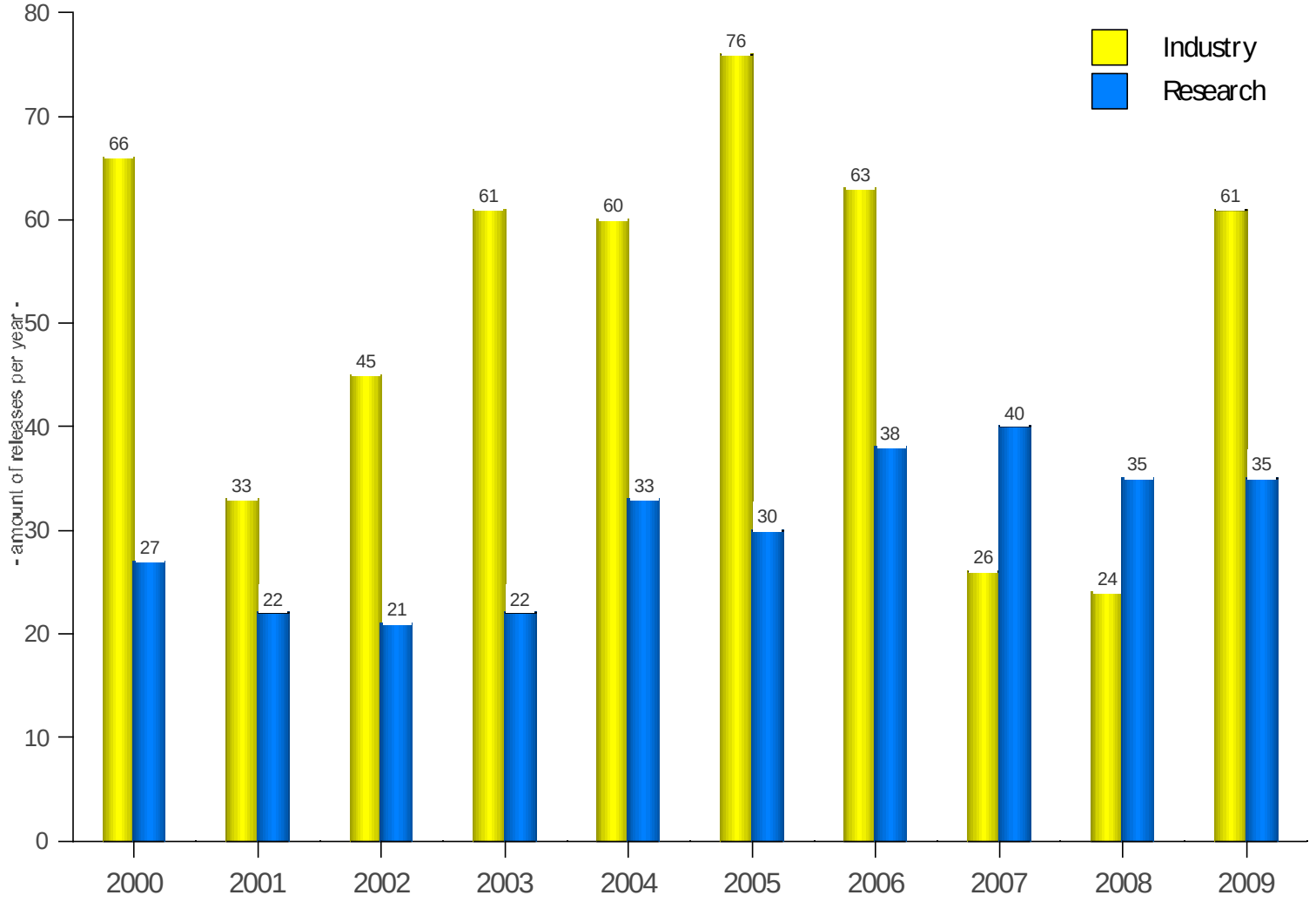
Triple Packaging For Infectious Substances

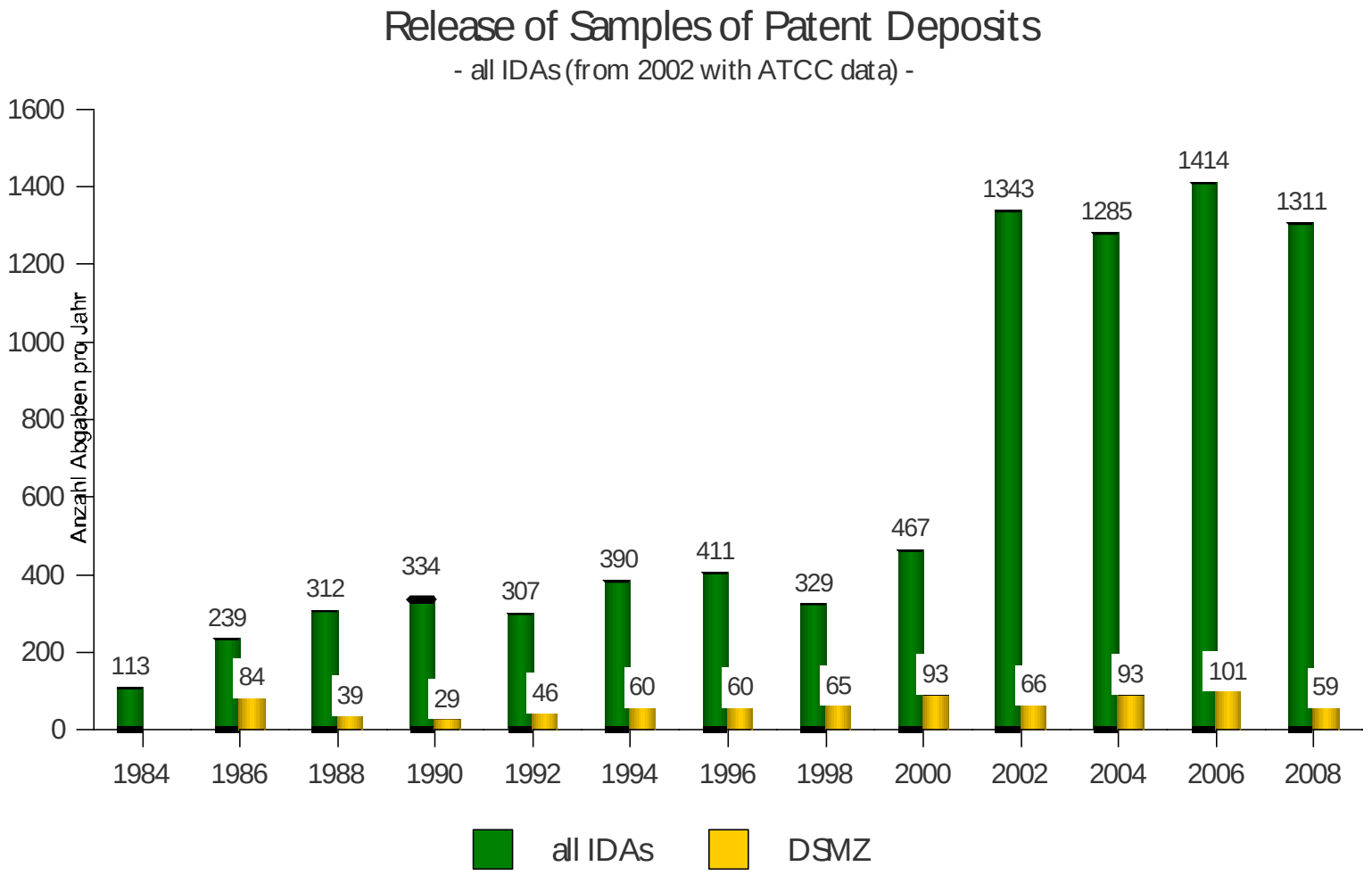


No. of Releases of Patent Strains at the DSMZ



Releases of Patent Strains – to Whom? (at the DSMZ)





> 13.000 samples

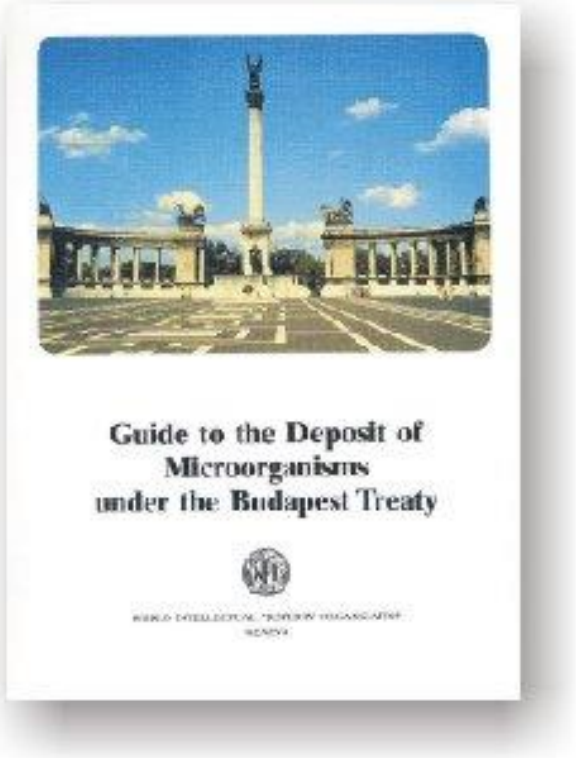
Guide to the Deposit of Microorganisms under the Budapest Treaty

Outline of *general* requirements for a deposit and the furnishing of samples

Detailed description of *specific* requirements of individual IDAs and Industrial Property Offices

Checklists

Model forms



Complications
Which
Might Arise

- Refusal to accept the biological material
- New deposit
- Transfer of a deposited organism
- Conversion of deposits made outside the Budapest Treaty
- Type strains as patent deposits

Complications Which Might Arise

Refusal to accept the biological material

The organism is not of the kind of organisms the IDA furnished assurances

The cultivation are so exceptional that the IDA is technically not in a position to handle the organism

The organism is received in a condition that indicates that it is impossible to handle it

The organism proves to be non-viable at the first viability check

Note: No valid deposit, no deposition number !

Complications
Which
Might Arise

Refusal to accept the biological material

New deposit

The organism proves to be non-viable at a later viability check

Ex- or import restrictions give the depositor the right to newly deposit with another IDA

Note: The original deposition date remains valid !

Complications
Which
Might Arise

Refusal to accept the biological material

New deposit

Transfer of a deposited organism

The IDA temporarily, partly or permanently ceases to carry out its functions

Note: The original deposition date remains valid !

Complications Which Might Arise

Refusal to accept the biological material

New deposit

Transfer of a deposited organism

Conversion of deposits made outside the Budapest Treaty

- from a non-Budapest patent deposit to a deposit acc. to the BT
- from a non-Budapest, non-patent deposit to a deposit acc. to the BT
- from a safe deposit to a deposit acc. to the BT

Note:The original deposition date **does not** necessarily remain valid !

Complications
Which
Might Arise

Refusal to accept the biological material

New deposit

Transfer of a deposited organism

Conversion of deposits made outside the Budapest Treaty

Type strains as patent deposits

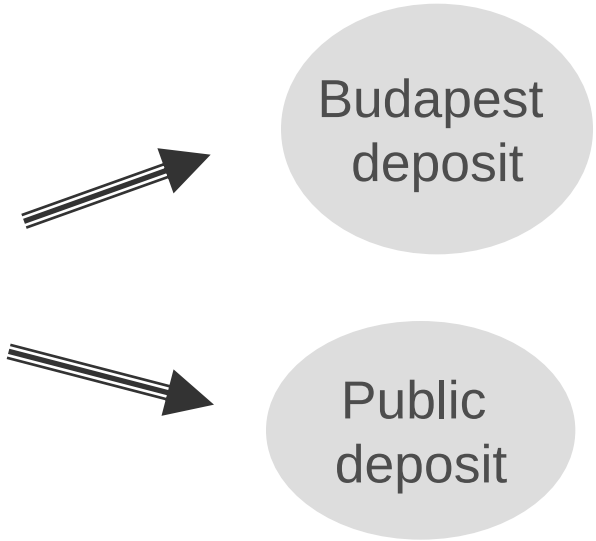
Type strains as patent deposits

readily available for the scientific community

covered by patent protection

Patent protection or scientific merits?

Two parallel deposits with two different deposition numbers



Code of Practise for IDA‘s

Aim:
- Harmonization of the procedure of patent deposits acc. to the Treaty
- Help for existing and future depositaries to comply with the Treaty, dealing with problems during a deposition procedure

Obligations of the depositor

- information to be given by the depositor
- Deposit of mixed cultures
- unofficial notifications
- payment for a deposit
- withdrawal of a deposit
- conversion of a deposit
- co-deposit by more than one depositor
- selling the rights on a deposit
- depositor versus applicant of a patent

Obligations of the IDA

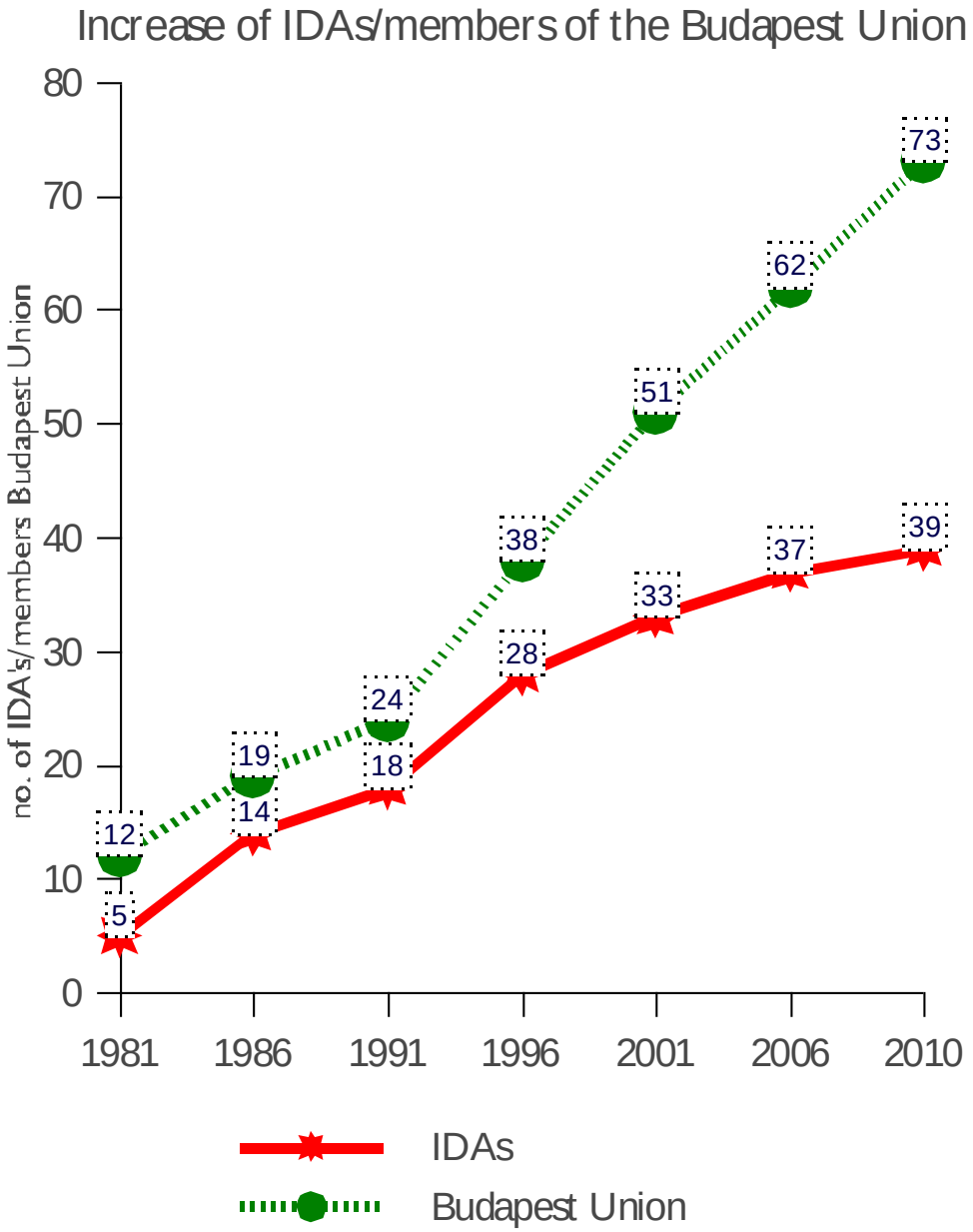
- acceptance of a deposit, deposition procedure
- test methods and criteria for viability testing
- contamination of deposited cultures
- responsibility for authenticity and purity of deposited cultures
- request for information about a deposited culture or related deposit documents
- end of the period of storage

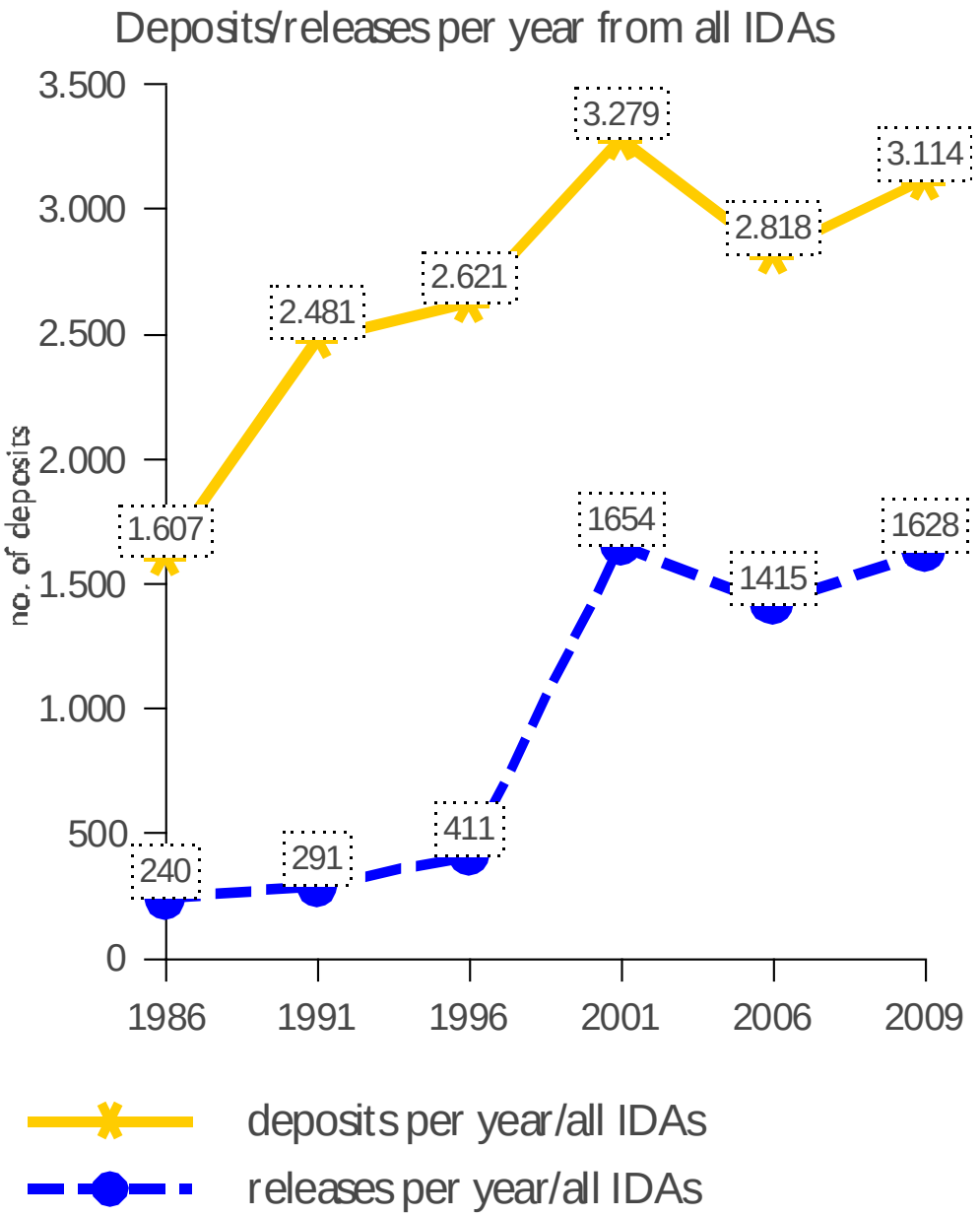
Future

Increasing or decreasing deposit numbers?

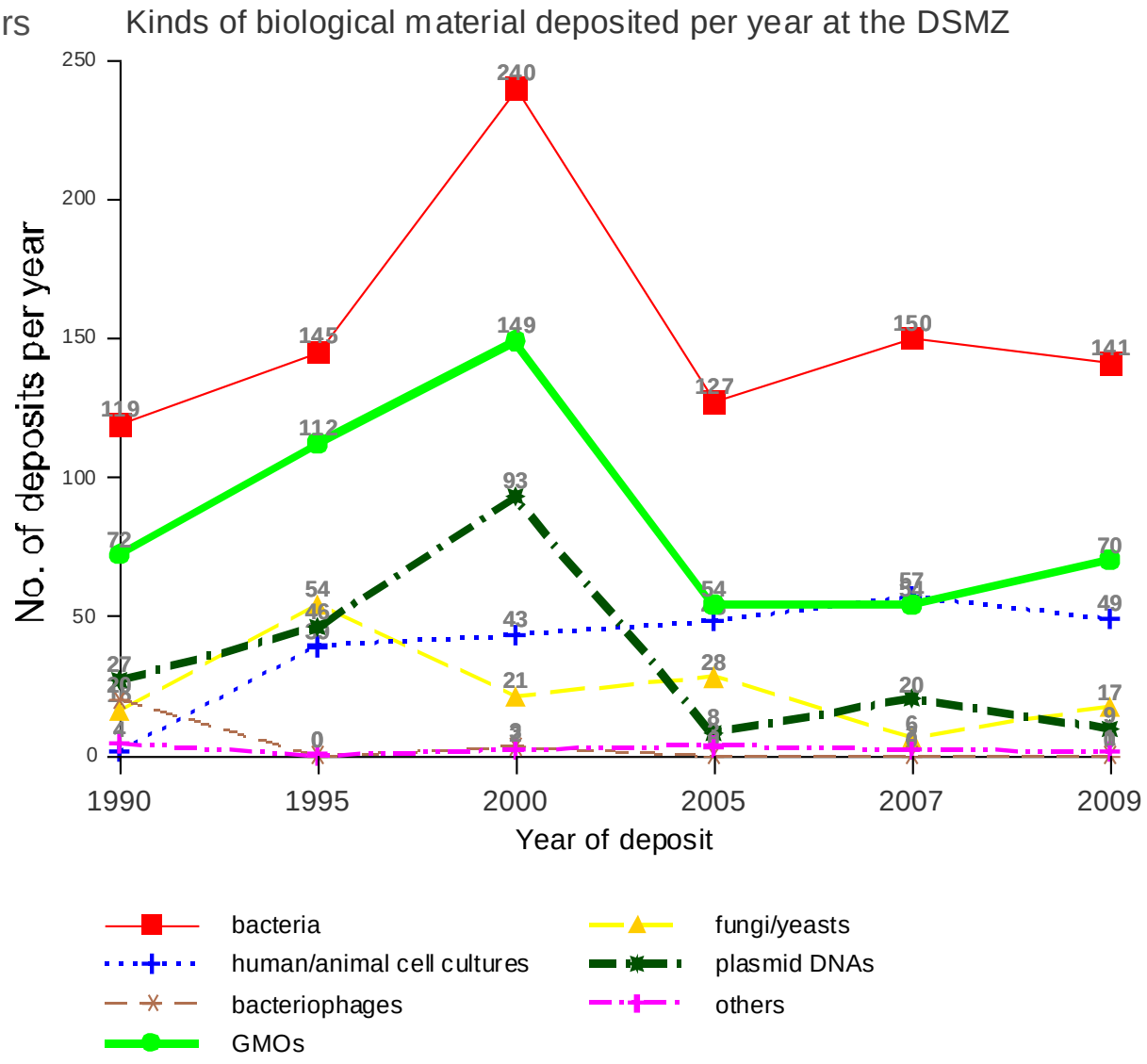
Influenced by the deposit of DNA sequences instead of patent deposits of the replicable biological material

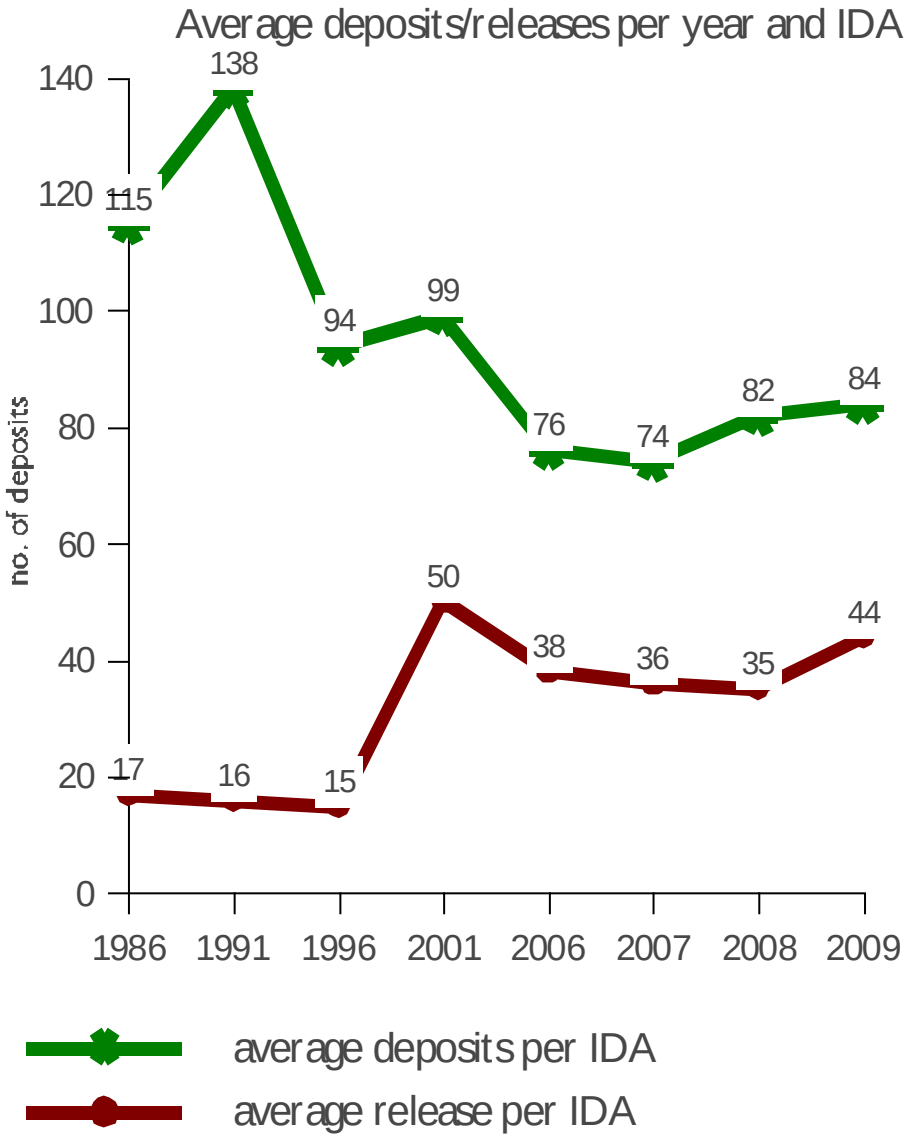
Influenced by increasing number of IDAs


Increase of IDAs/members of the Budapest Union
no. of IDA's/members Budapest Union
0
10
20
30
40
50
60
70
80
1981
1986
1991
1996
2001
2006
2010
5
14
18
28
33
37
39
12
19
24
38
51
62
73
IDAs
Budapest Union


Deposits/releases per year from all IDAs
no. of deposits
3.500
3.000
2.500
2.000
1.500
1.000
500
0
1986
1991
1996
2001
2006
2009
1.607
2.481
2.621
3.279
2.818
3.114
240
291
411
1654
1415
1628
deposits per year/all IDAs
releases per year/all IDAs

Development of Patent Deposit Numbers




Average deposits/releases per year and IDA
no. of deposits
140
120
100
80
60
40
20
0
1986
1991
1996
2001
2006
2007
2008
2009
115
138
94
99
76
74
82
84
17
16
15
50
38
36
35
44
average deposits per IDA
average release per IDA

Thank you for your Attention!

Questions?

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