8th Indo Global summit and Expo on
Vaccines, Therapeutics & Healthcare (VTH-2015)
November 02-04, 2015 HICC, Hyderabad, India

**Chandrashekhar G Raut**
Sci-E & OIC
National Institute of Virology, Bangalore Unit,
RGICD Premises, 1st Main Someshwarnagar,
Near NIMHANS, DRC Post, Bangalore- 560029, India
Email: cgrniv@yahoo.co.in

# Need of strengthening the well defined *in- vivo* Systems for pre-clinical evaluation of vaccines in India

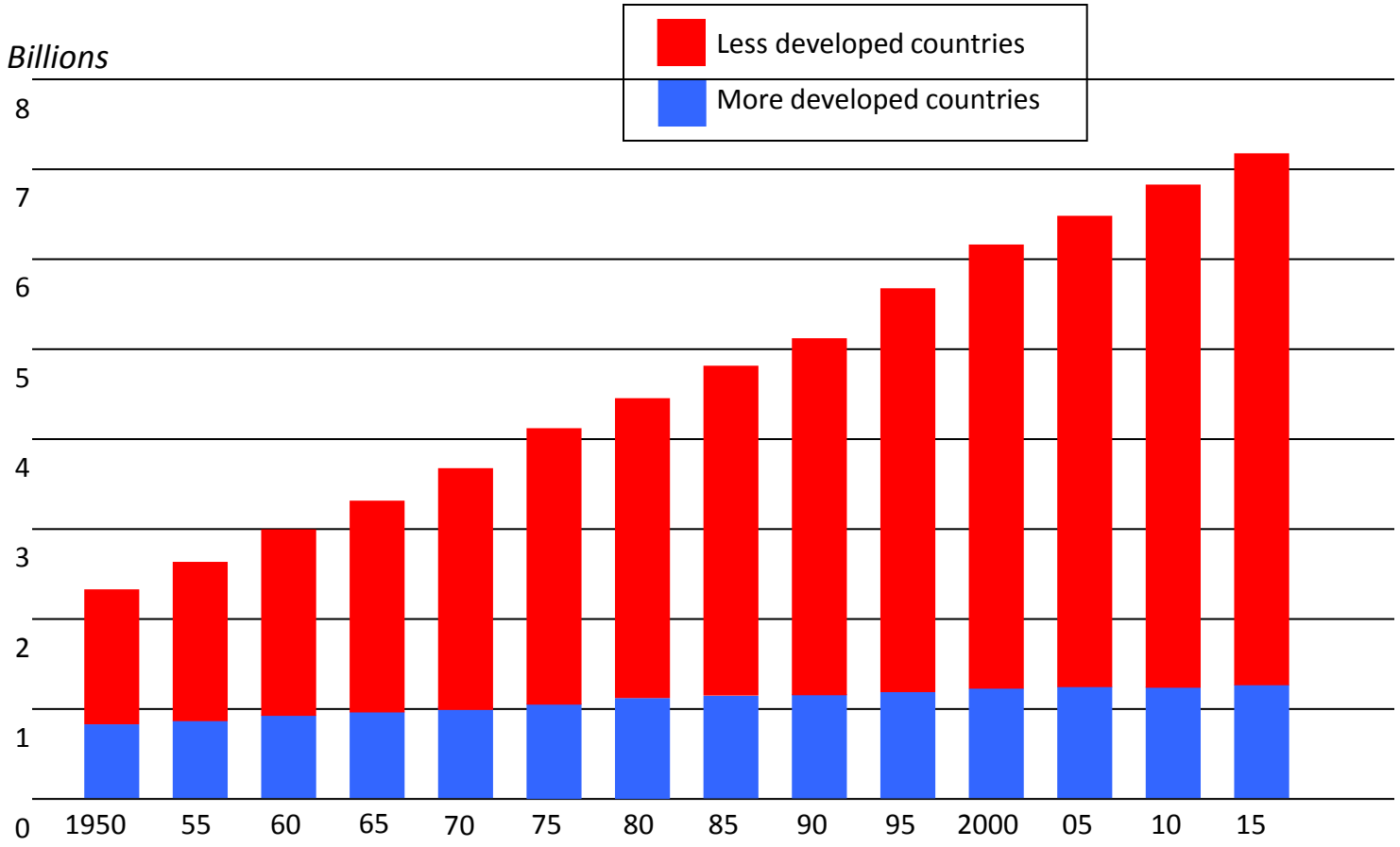
## Present situation : key words

**Population increasing, New area of land available occupied for housing , Agriculture land area decreasing , Ecological changes , Basic needs- Air, Water, Food ; Luxury – increasing , Recycling- Waste management; Density; Microorganisms ; Herd Immunity ; Susceptible population; Vaccines, Therapeutics, Healthcare; Lifestyle ; NCDs increasing ; For production of desired product- known defined raw materials; Safety and efficacy of products; Use of lab animals / *in vivo* systems; Defined lab animals – genetically & microbiologically……**

# Trends in Global Population

Global Population: 1950-2015

Total




Source: US Bureau of the Census

# Rapidly Increasing Urbanization



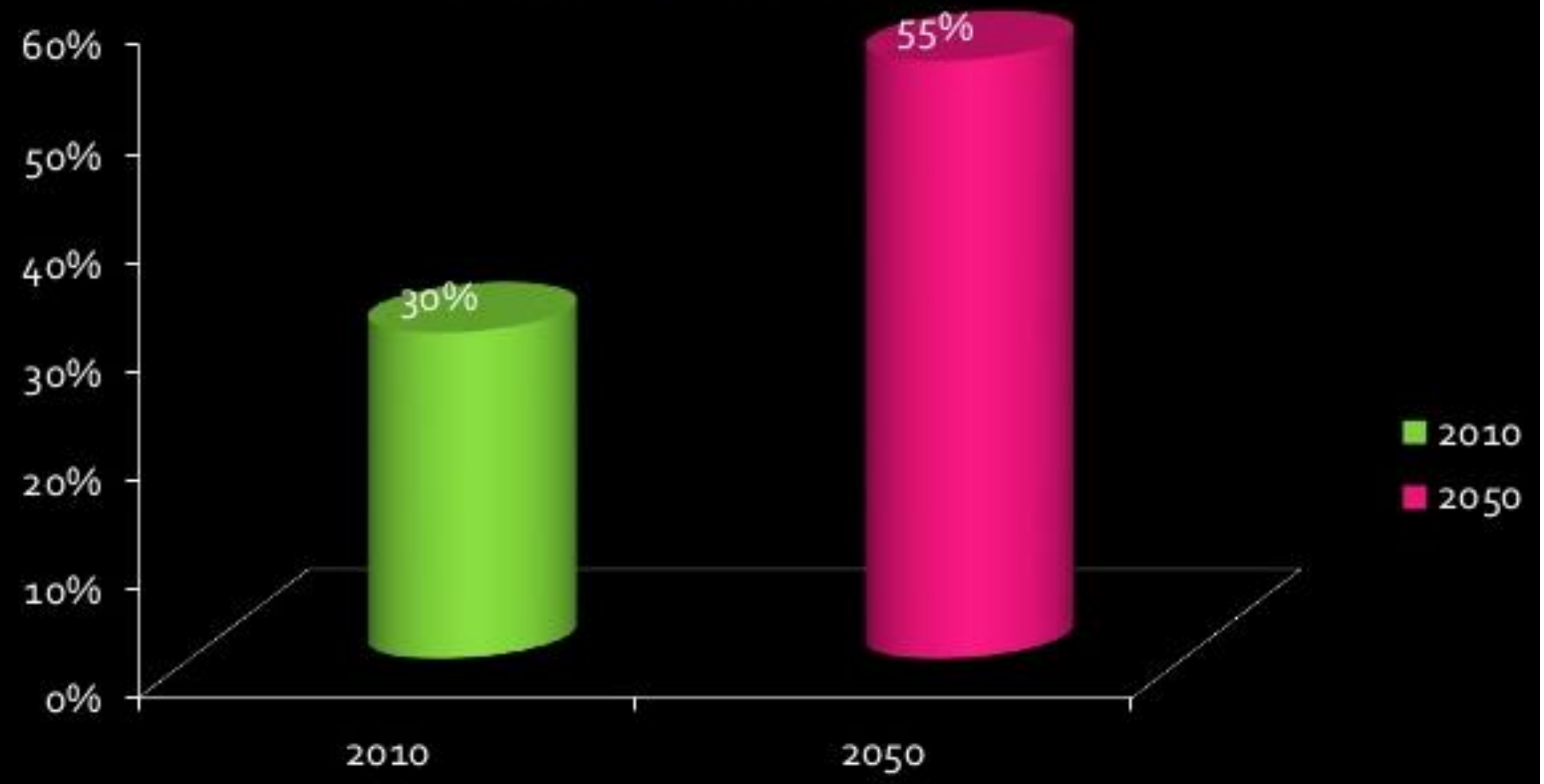
**2000**

- **47% world population living in urban areas**

**2030**

- **60% world population living in urban areas**

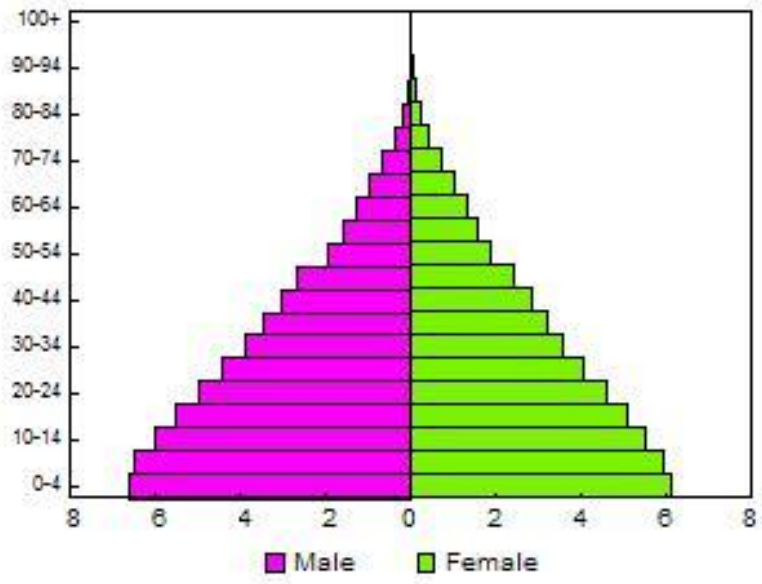
# Projected mid-year population, residing in urban areas, India, 2010-2050



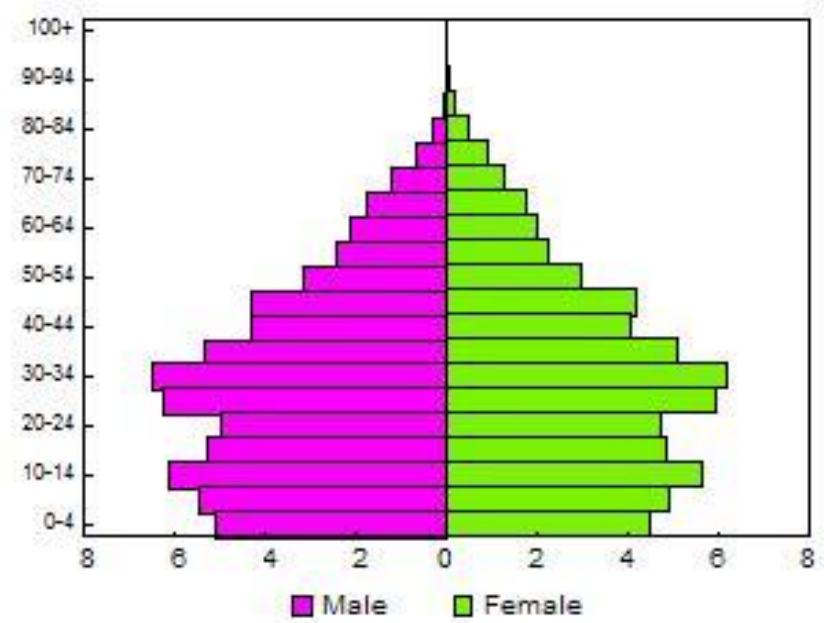

Source: World Urbanization Prospects. The 2007 Revision. Highlights. Department of Economic and Social Affairs Population Division.United Nations New York, 2008.

# Population : India & China 2000 & 2050

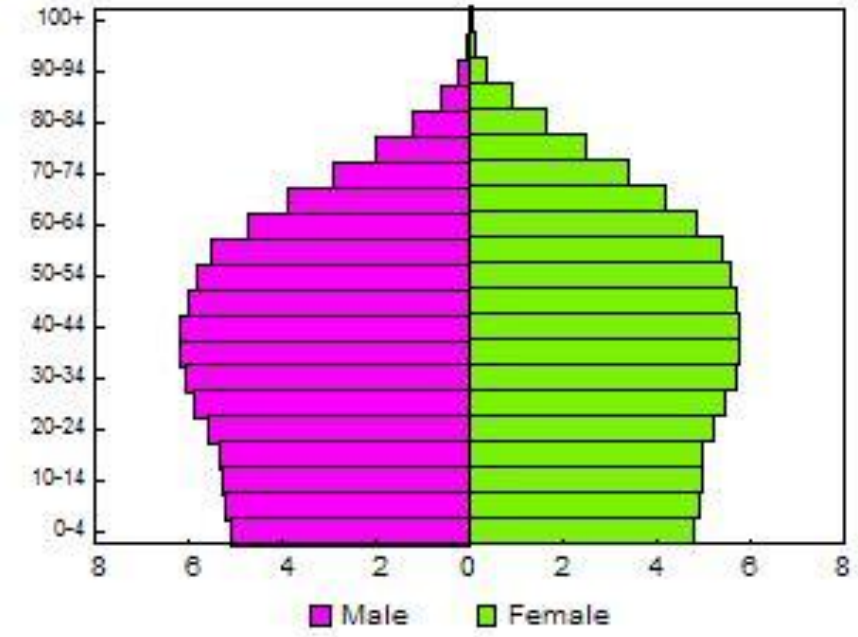
## India



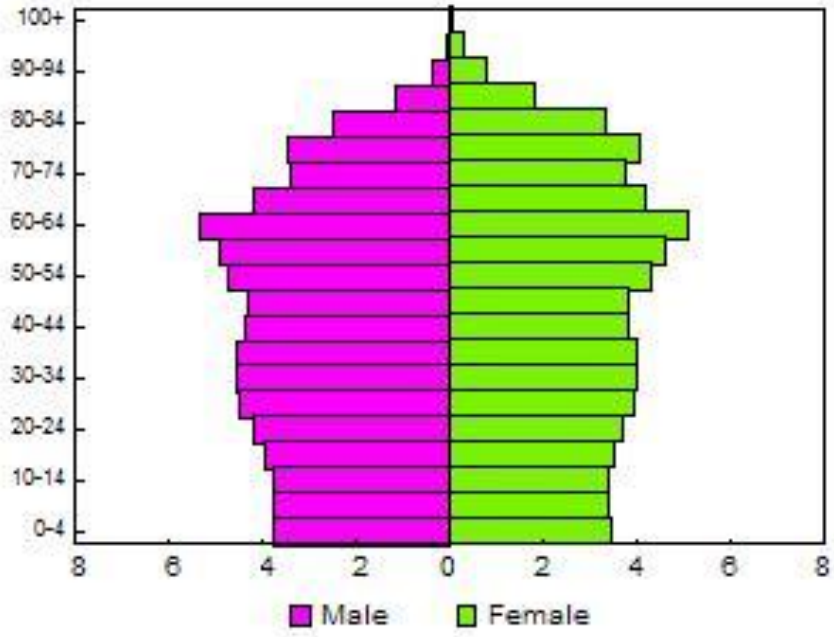

## China

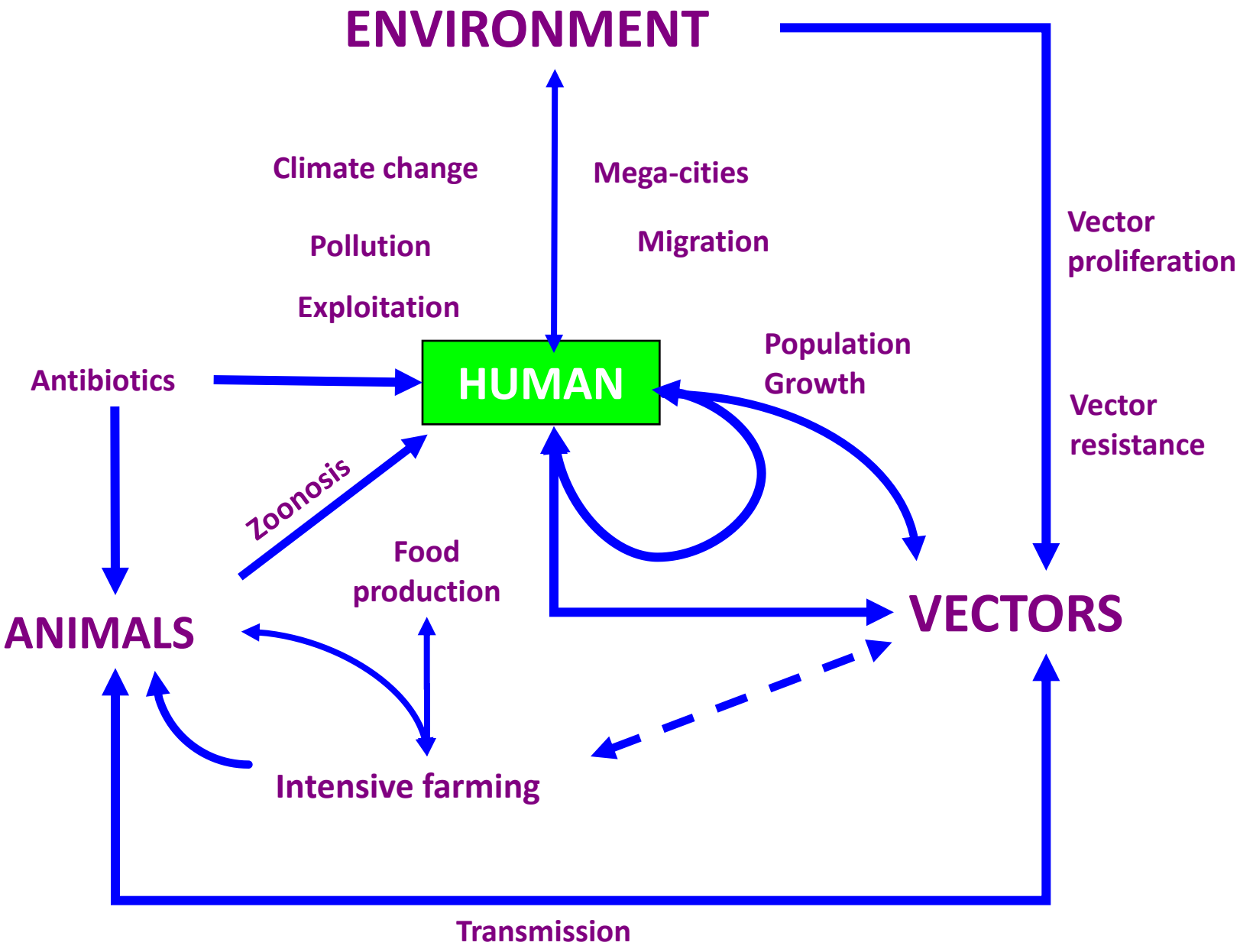



**2000**



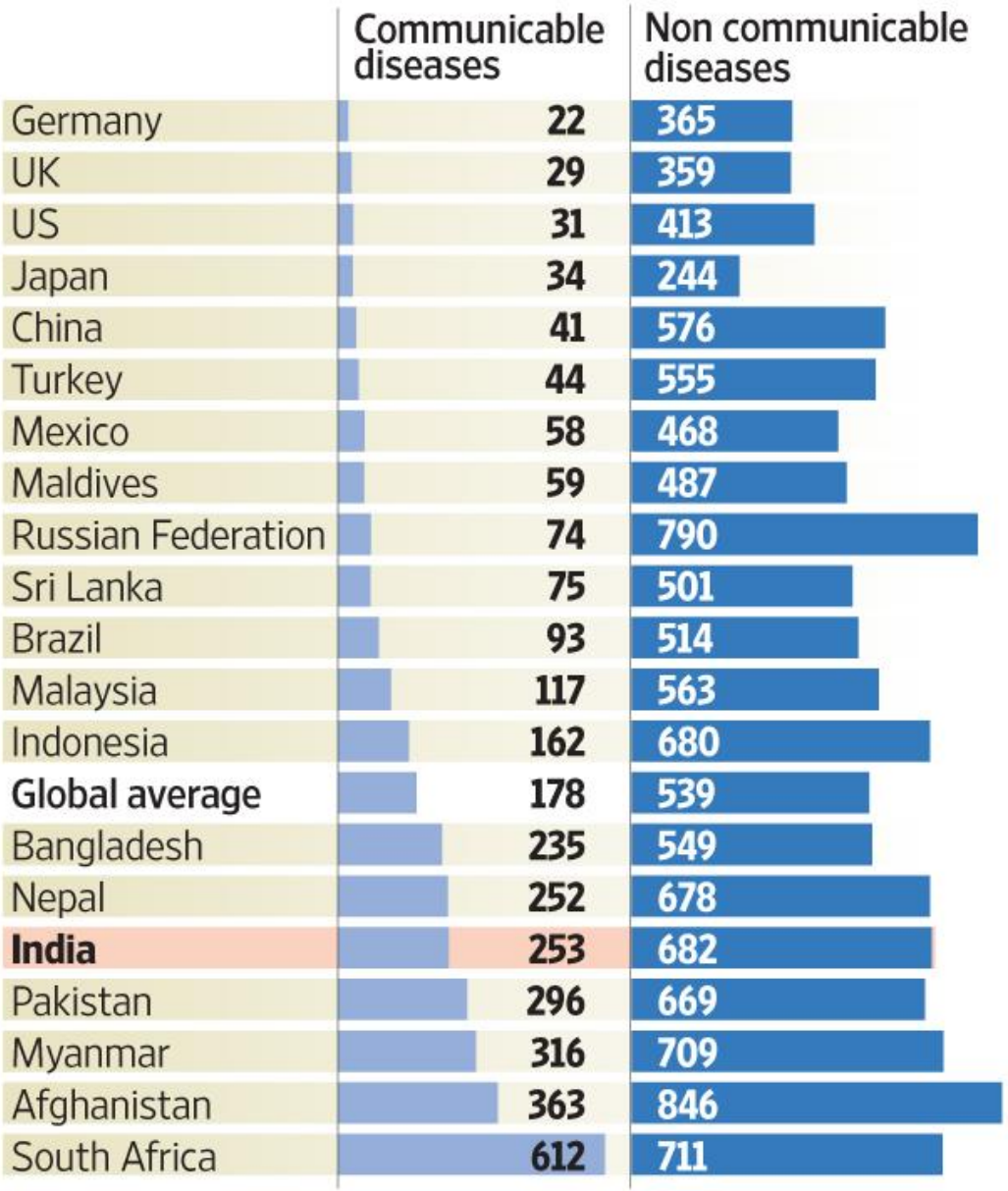

**2050**



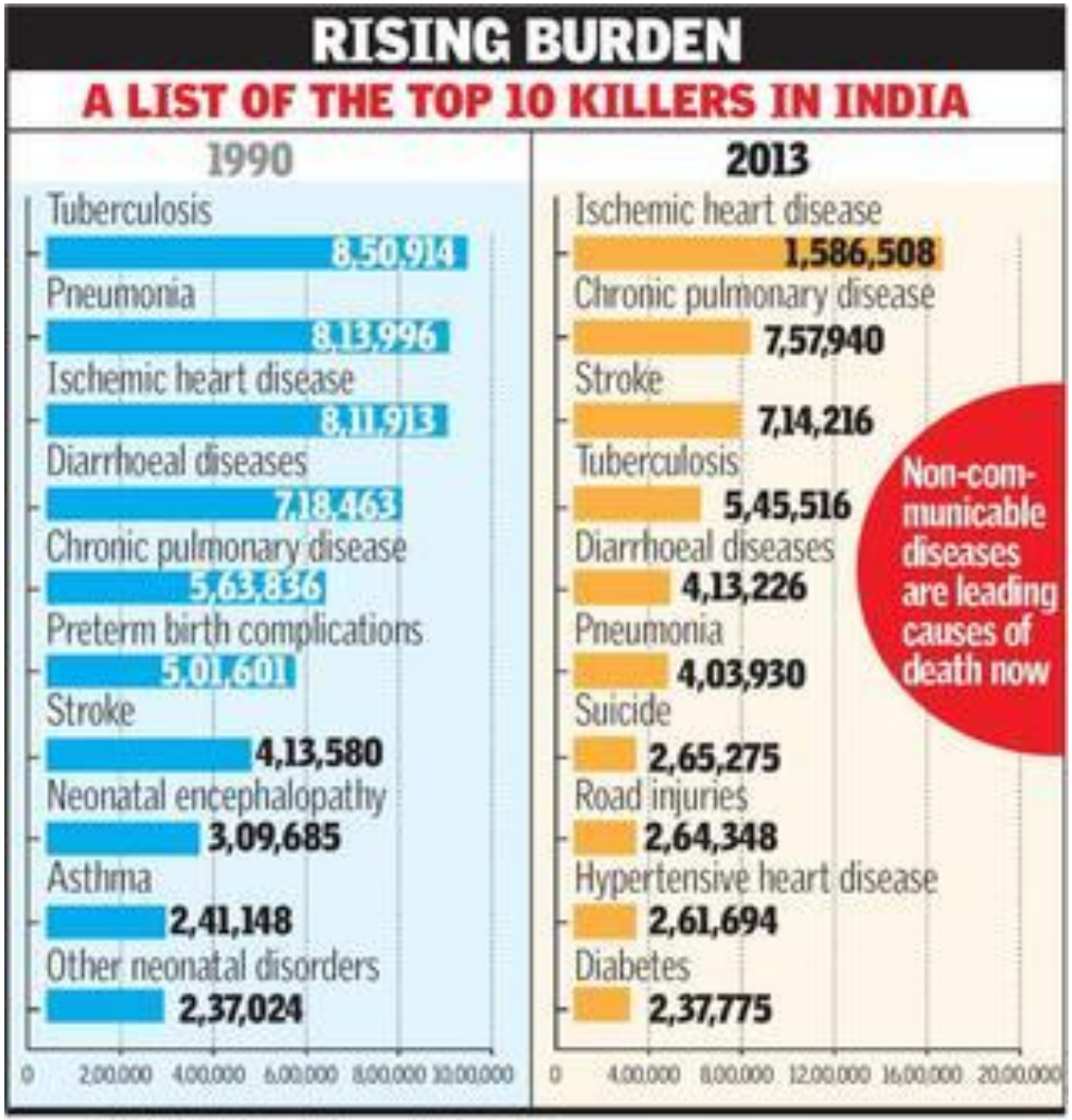

ENVIRONMENT
Climate change
Pollution
Exploitation
Mega-cities
Migration
Vector proliferation
Antibiotics
HUMAN
Population Growth
Vector resistance
Zoonosis
Food production
ANIMALS
VECTORS
Intensive farming
Transmission

# DEATHS FROM DISEASES ACROSS COUNTRIES

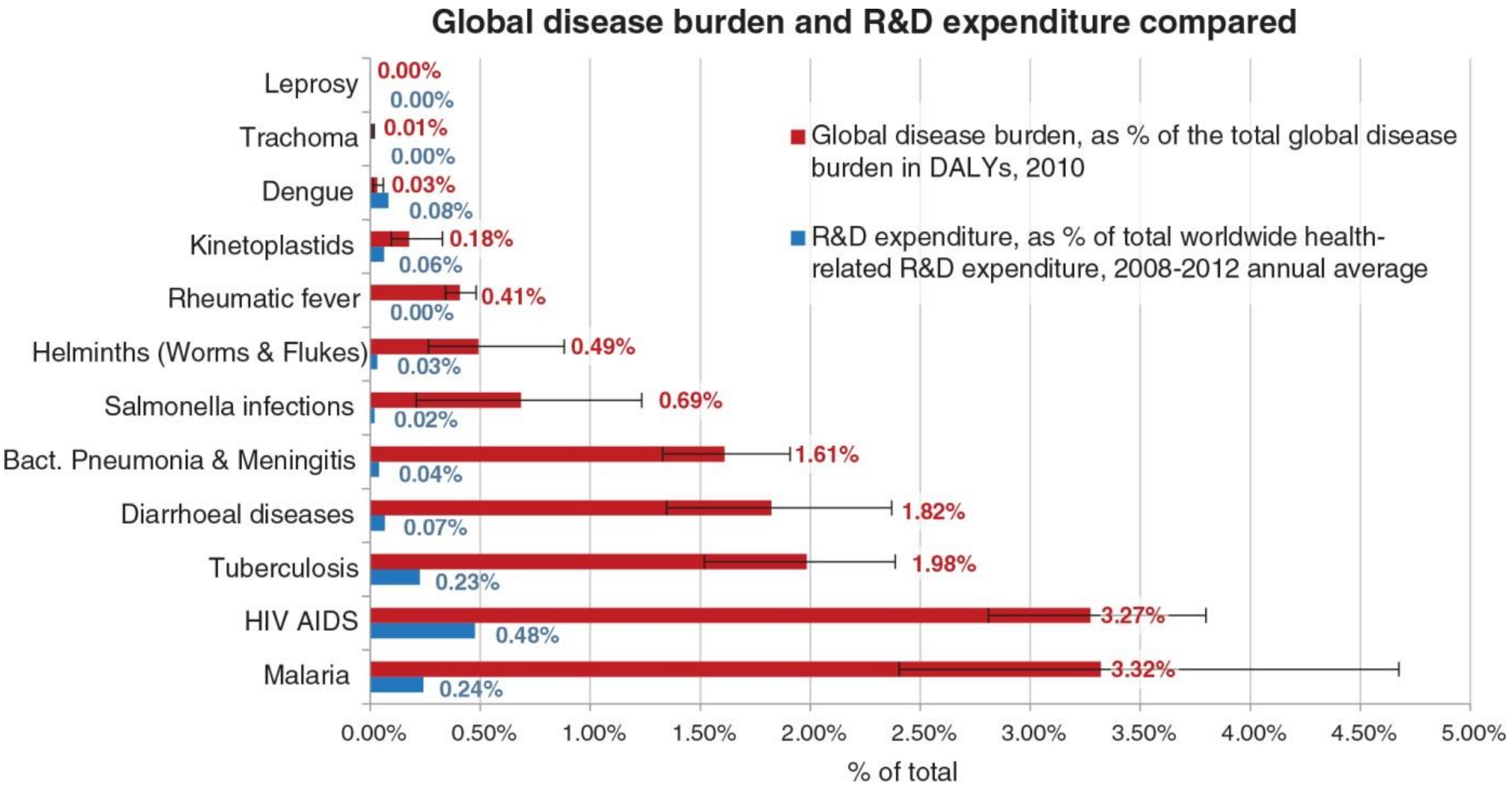
Age-standardized mortality rates by causes
(per 100 000 population)




Source: NSSO, WHO




*Source: Global Burden of Disease Study, 2013*


Global disease burden and R&D expenditure compared
Leprosy
Trachoma
Dengue
Kinetoplastids
Rheumatic fever
Helminths (Worms & Flukes)
Salmonella infections
Bact. Pneumonia & Meningitis
Diarrhoeal diseases
Tuberculosis
HIV AIDS
Malaria
0.00%
0.00%
0.01%
0.00%
0.03%
0.08%
0.18%
0.06%
0.41%
0.00%
0.49%
0.03%
0.69%
0.02%
1.61%
0.04%
1.82%
0.07%
1.98%
0.23%
3.27%
0.48%
3.32%
0.24%
Global disease burden, as % of the total global disease burden in DALYs, 2010
R&D expenditure, as % of total worldwide health-related R&D expenditure, 2008-2012 annual average
0.00%
0.50%
1.00%
1.50%
2.00%
2.50%
3.00%
3.50%
4.00%
4.50%
5.00%
% of total

Japanese encephalitis

Influenza –Swine flu

Hepatitis E



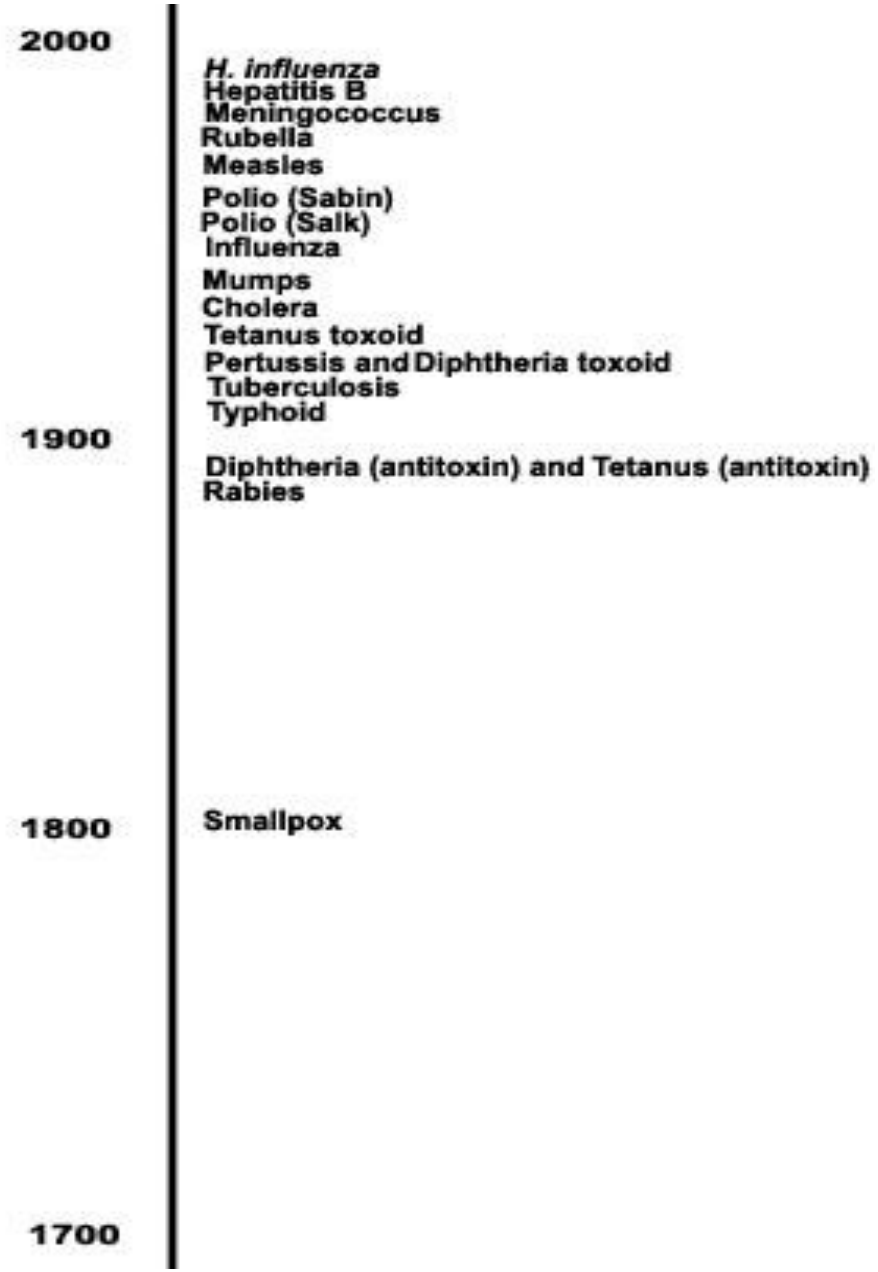

Nipah virus

Enteric viruses

# Vaccines-Historical Perspective

- ***7th century***- Indian Buddhists' drank snake venom to protect against snake bite.
- ***10th century***- Variolation to prevent smallpox in China and Turkey.
- ***Early 1700s***- Variolation introduced into England.
- ***1760-70***- The Jennerian era.
- ***1875-1910***- Dawn of Immunological Science.
- ***1910-30***- Early bacterial vaccines, toxins and toxoids.
- ***1930-50***- Early viral vaccines: yellow fever and Influenza.
- ***1950-1970***- The tissue culture revolution: poliomyelitis, measles, mumps and rubella.
- ***1970-1990***- Dawn of the molecular era: hepatitis B, *Streptococcus pneumonia*, *Hemophilus influenza* B.
- ***Today***- Glycoconjugate vaccines, rotavirus vaccine, human papilloma virus vaccine and herpes zoster vaccine.

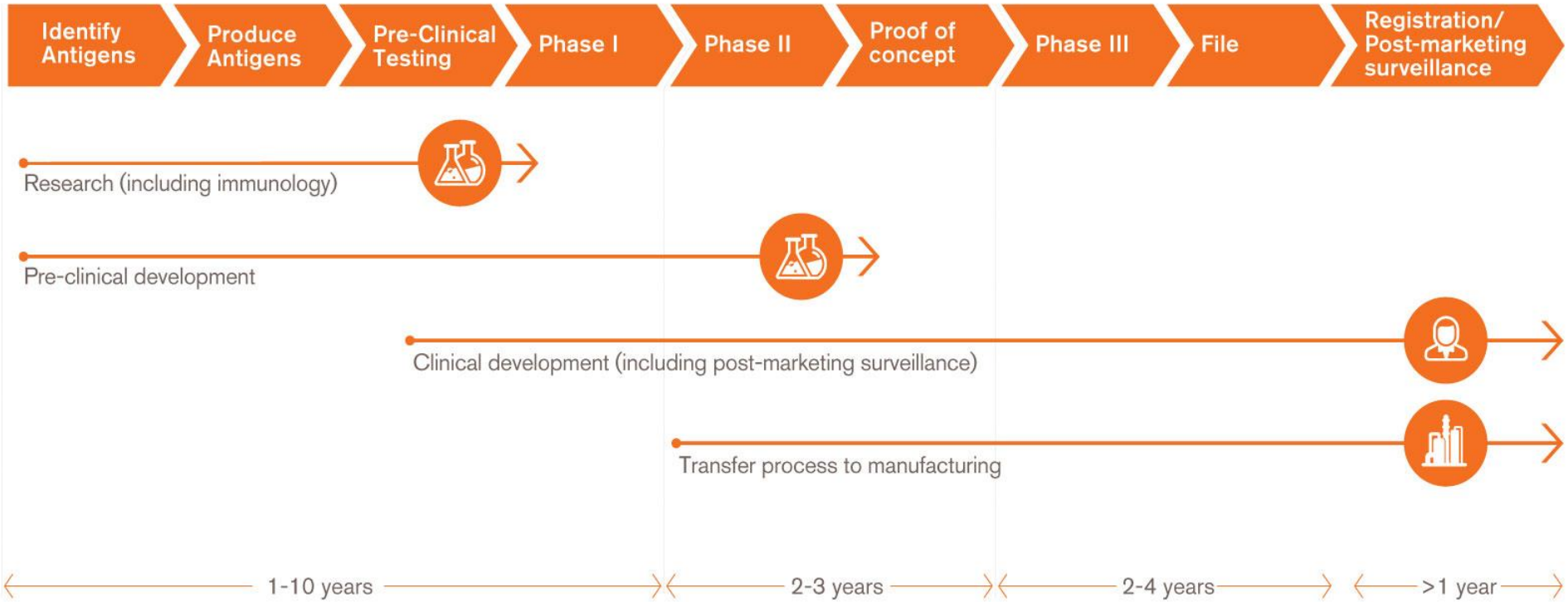
# Years of Vaccine development



# The Ideal Vaccine

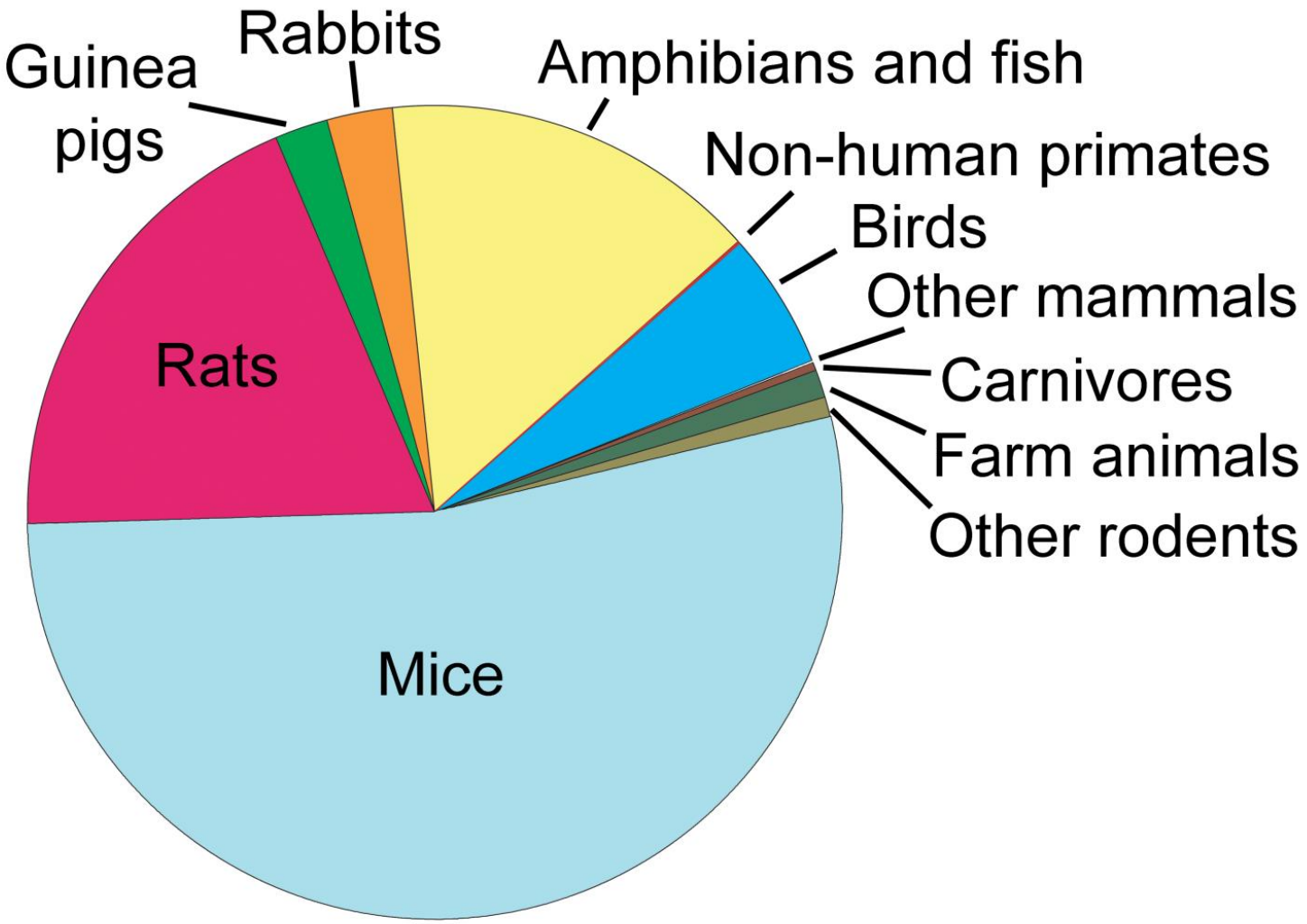
- Immunogenic
- Long lasting immunity
- Safe
- Stable in field conditions
- Combined
- Single dose
- Affordable (and accessible) to all

# Vaccine development

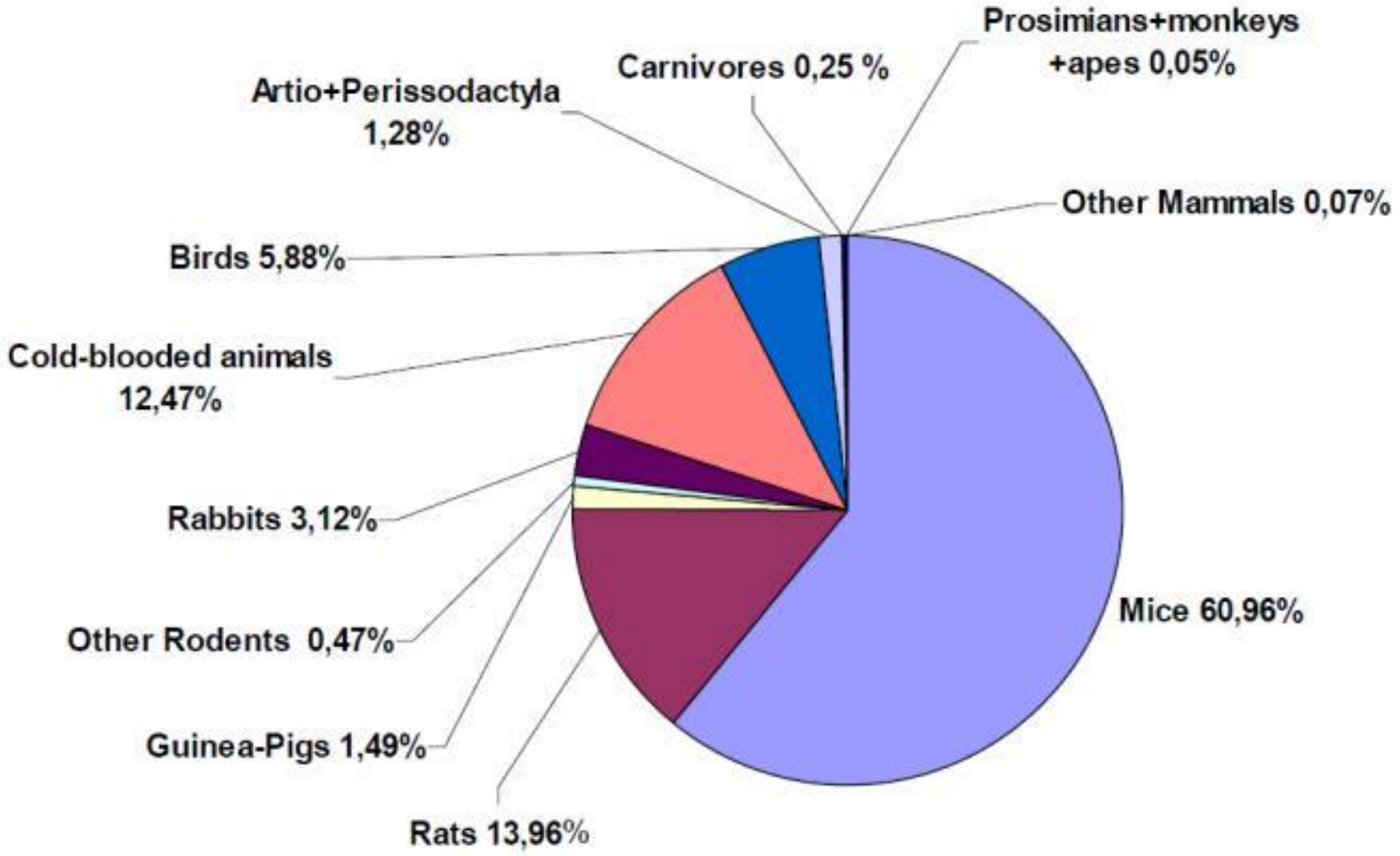


Historically, there has been a close and longstanding association between microbiology and vaccine development and the use of laboratory animals.

# Use of lab animals

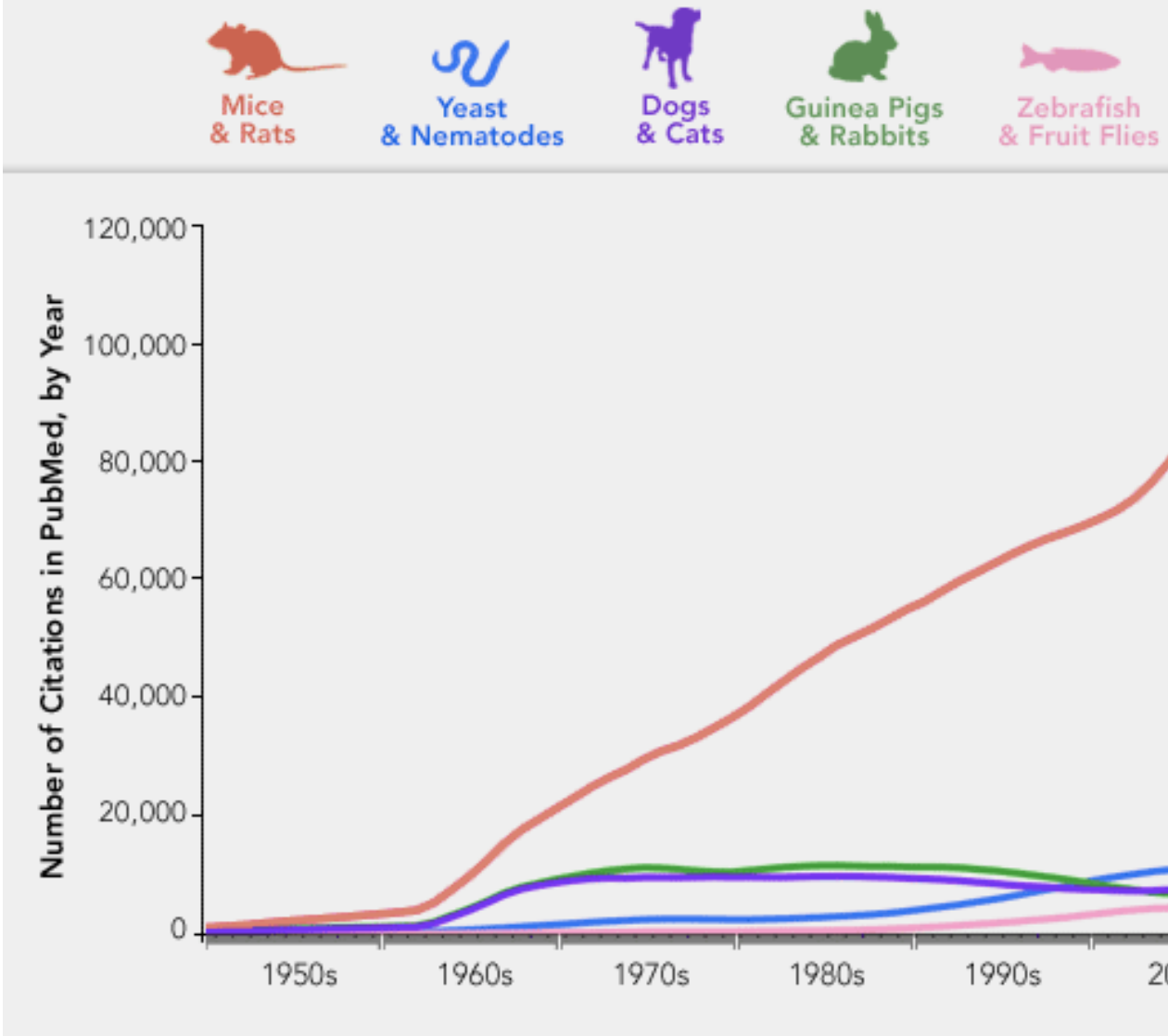


# Percentages of animals used by classes in the Member States



# ANIMALS CITED IN BIOMEDICAL RESEARCH PAPERS

1950-2010



# Defined status of lab animals

**Genetic level**
Species
Breed
Strain
Transgenic

**Microbiological level**
Known microflora of the species
Bacteria
Viruses
Parasites

**Authentic sources:**
Animals
Feed
Materials

Infrastructure specieswise
Housing Equipments

**Monitoring**
Frequency
Data maintenance
Normal parameters specieswise
Accreditation
Improvements

# Monitoring authority

**CPCSEA: "Committee for the Purpose of Control and Supervision of Experiments on Animals" under MoEF&CC, GOI**

**Guidelines available**

**IAEC: Institutional Animal Ethics Committee**

**Nominees – nationwide**

**About 2000 lab animal facilities registered with CPCSEA**

**Recent developments: Online submission of projects, reports, new registration, renewal , etc….**

**IAEC can approve : projects on mice, rats, guinea pig, rabbits, birds**

**Large animals: Equines, Dogs, Farm animals needs approval from IAEC & CPCSEA**

**Rehabilitation issues – progress is going on**

# Different strains of mice (Inbred )



C3H/Hej



C57BL/6



DBA/2





Athymic nude mice

# Other species of lab animals



Rat



Guinea pig



Rabbit – New Zealand White



Rabbit- Sandy Half Lop

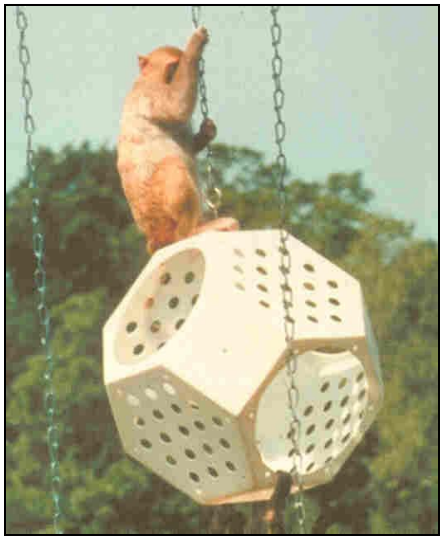
**NHP- Rehabilitation ,**
**ecofriendly ,**
**with enrichment**







# Rehabilitation: Enrichment of the monkeys









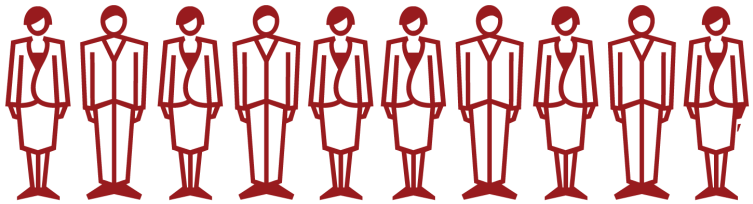




**Stainless steel Mirrors;**
**Ladders;**
**Other Play things**



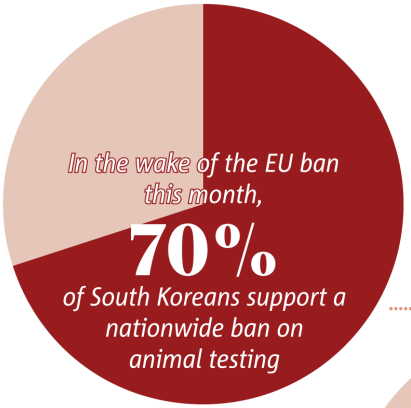
# Ban on use of lab animals in Cosmetic Industry

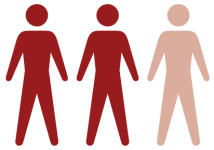


The British cosmetics industry is worth more than

**£15bn**

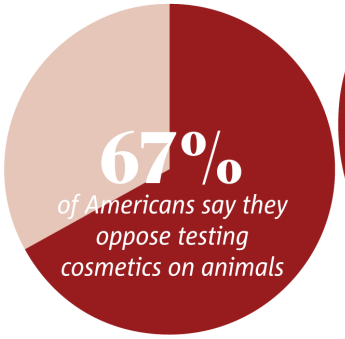
a year and employs almost 1m people

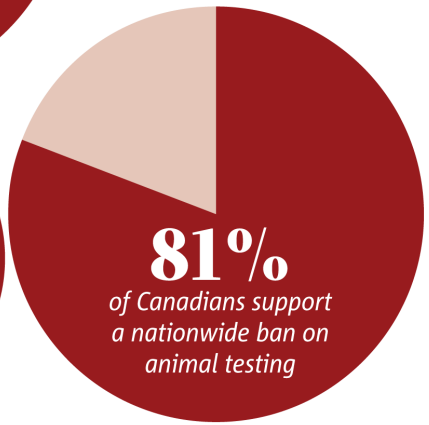


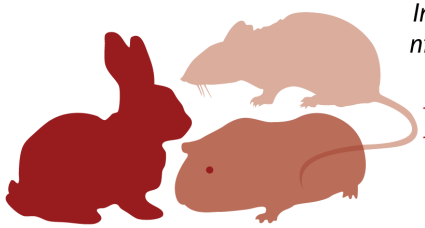



**2** out of **3**

people in Brazil want a ban on animal testing in their country



In the US, many cosmetic companies userabbits, guinea pigs, mice and rats to test

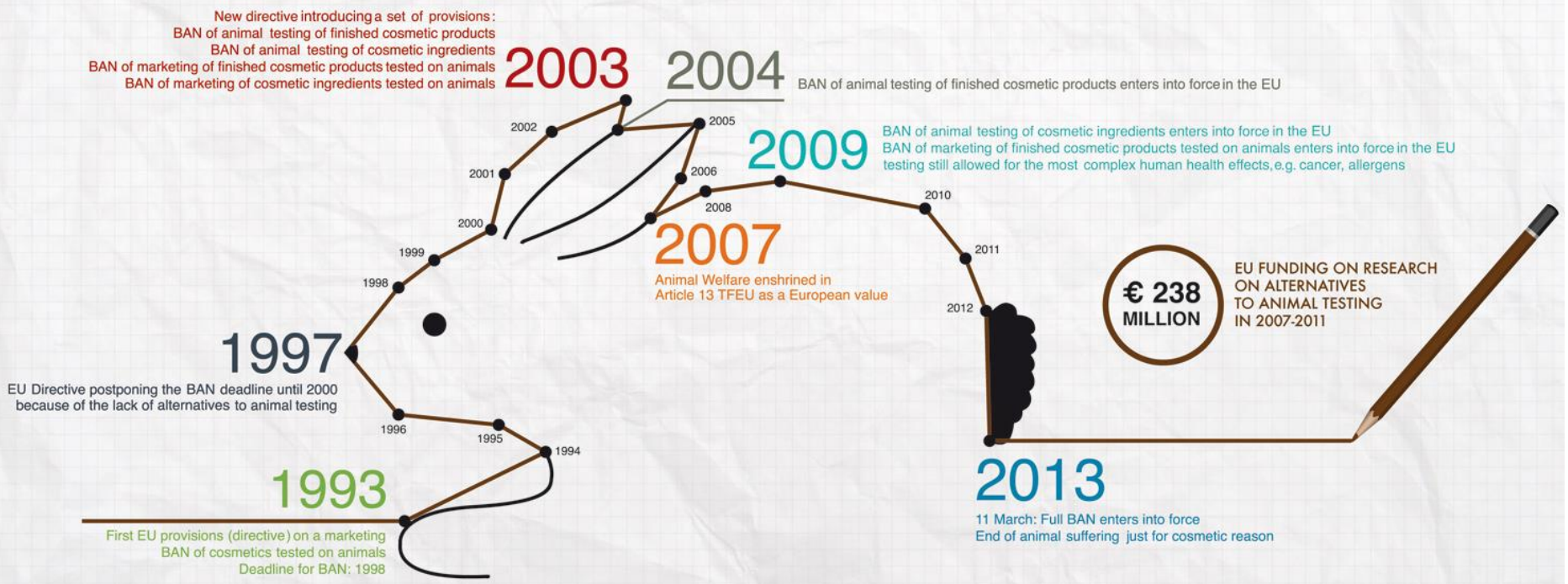
**ingredients**

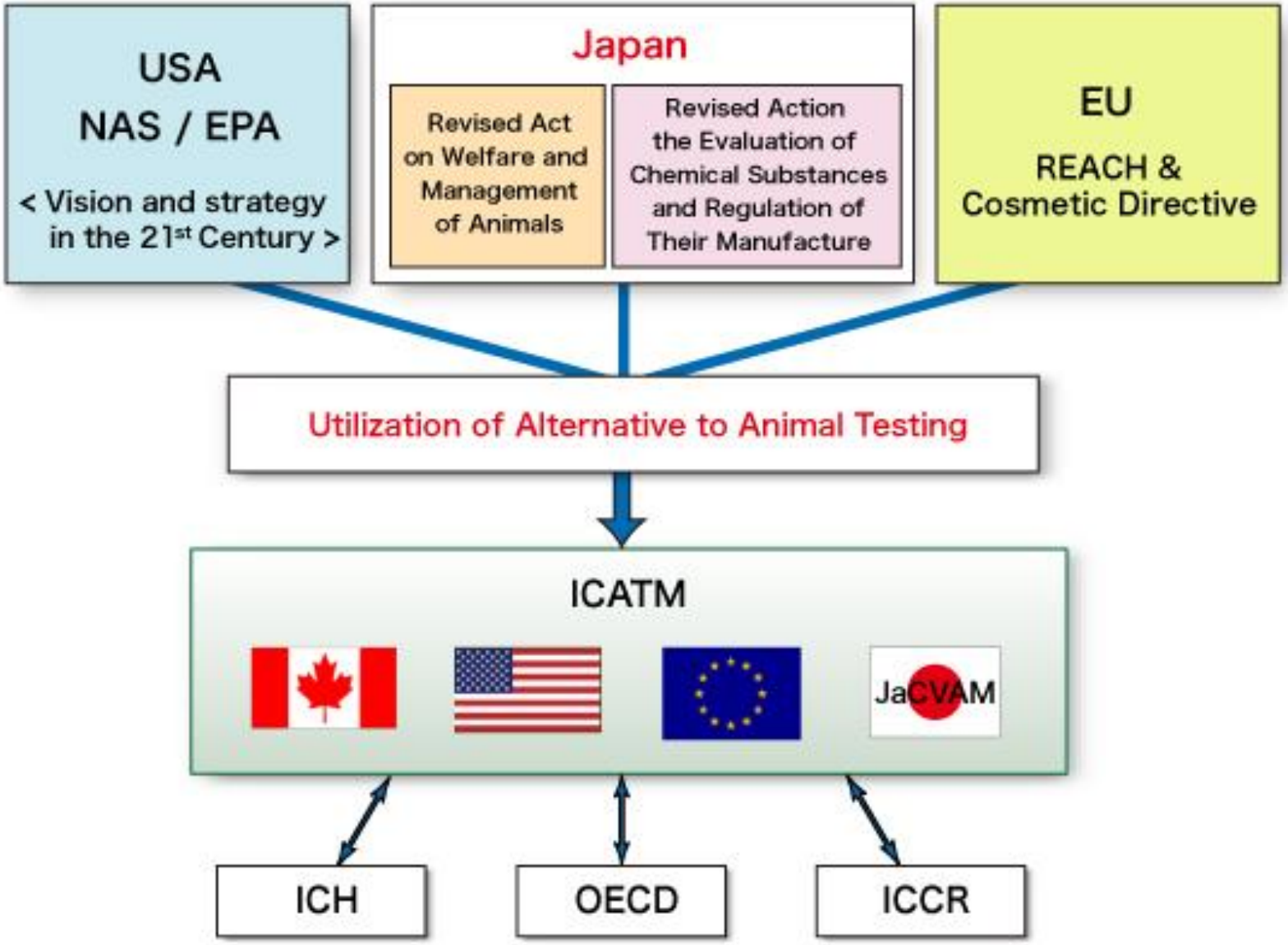
and products or hire outside organisations to conduct research on their behalf

Sources: ***European Union, Cosmetic Executive Women UK, Humane Society of the United States, Humane Society International***

# CONNECTING THE DOTS FOR ANIMALS:

## HISTORY OF THE EU BAN ON ANIMAL TESTING FOR COSMETICS




USA
NAS / EPA
< Vision and strategy in the 21st Century >
Japan
Revised Act on Welfare and Management of Animals
Revised Action the Evaluation of Chemical Substances and Regulation of Their Manufacture
EU
REACH & Cosmetic Directive
Utilization of Alternative to Animal Testing
ICATM
JaCVAM
ICH
OECD
ICCR

# Alternatives to animal testing

**Cell culture can be an alternative to animal use in some cases. For example, cultured cells have been developed to create monoclonal antibodies; prior to this, production required animals to undergo a procedure likely to cause pain and distress.**

**However, even though cell or tissue culture methods may reduce the number of experiments performed on intact animals, the maintenance of cells in culture normally requires the use of animal-derived serum.**

**Although exact figures are difficult to obtain, some have estimated that one million fetal cows are sacrificed each year to obtain the world's supply of fetal bovine serum, used to grow cultured cells.**

# Alternatives to Lab Animals use

**Medical imaging is able to demonstrate to researchers both how drugs are metabolized by use of microdosing, and the detailed condition of organ tissue.**

**Bioengineered monkeys with human genetic diseases**

**The Three Rs (3Rs) are guiding principles for more ethical use of animals in testing. These were first described by W.M.S. Russell and R.L. Burch in 1959.**

**The 3Rs are:**

**Replacement which refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aims. These methods include computer modeling.**

**Reduction which refers to methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.**

**Refinement which refers to methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used. These methods include non-invasive techniques.**

**Rehabilitation : Large animals**

## Public –Private Partnership

**With proper understanding aiming national importance.**

**Very good facilities at Govt Institutions- to be utilized according to the national programmes.**

# THANKS

