

# Strengthening Oversight over Dual-use Research in Asia

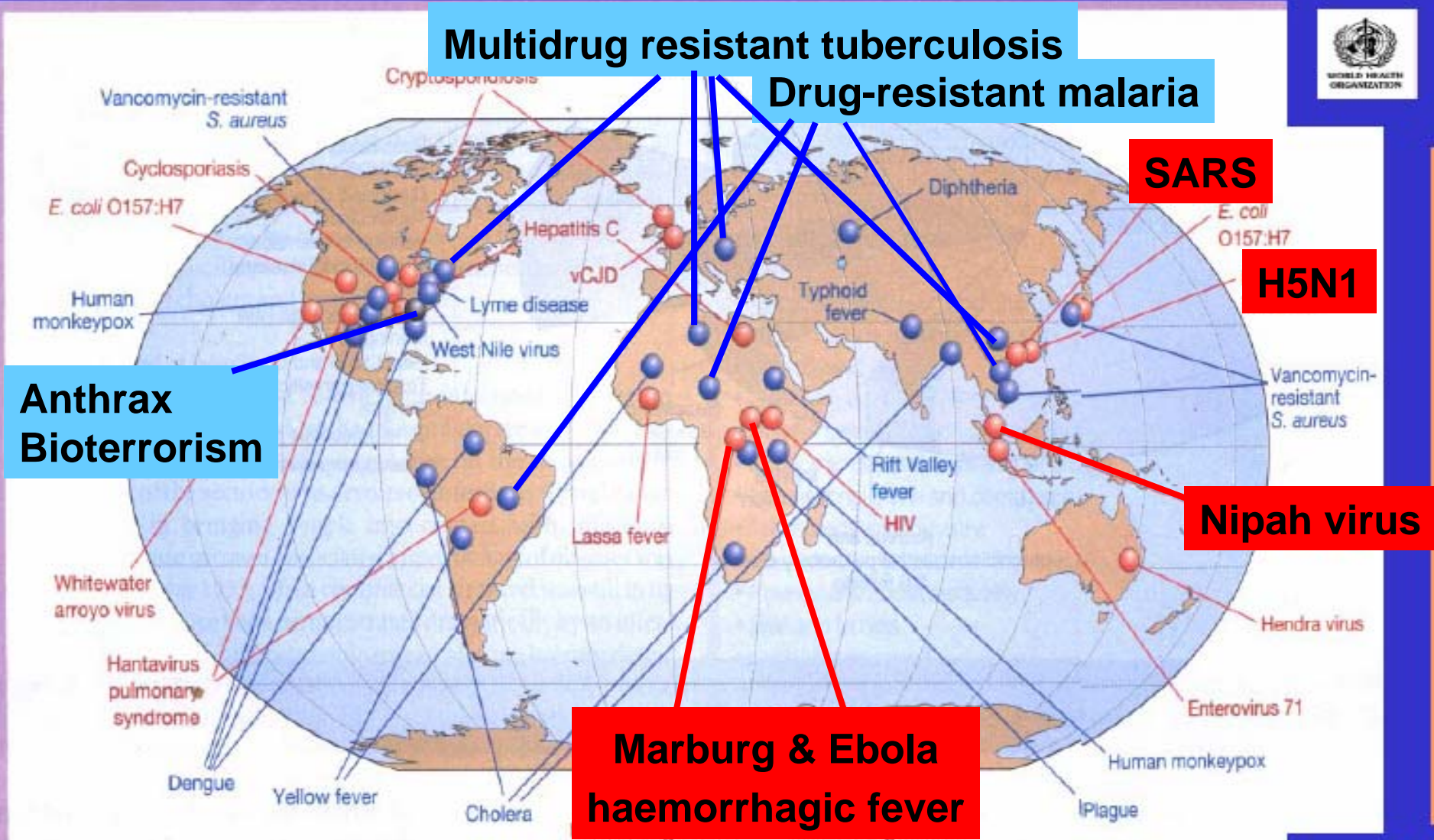


**Dr. Ruud Valyasevi**  
Deputy director

**National Center for Genetic Engineering and Biotechnology**

# Global Biological Threats:

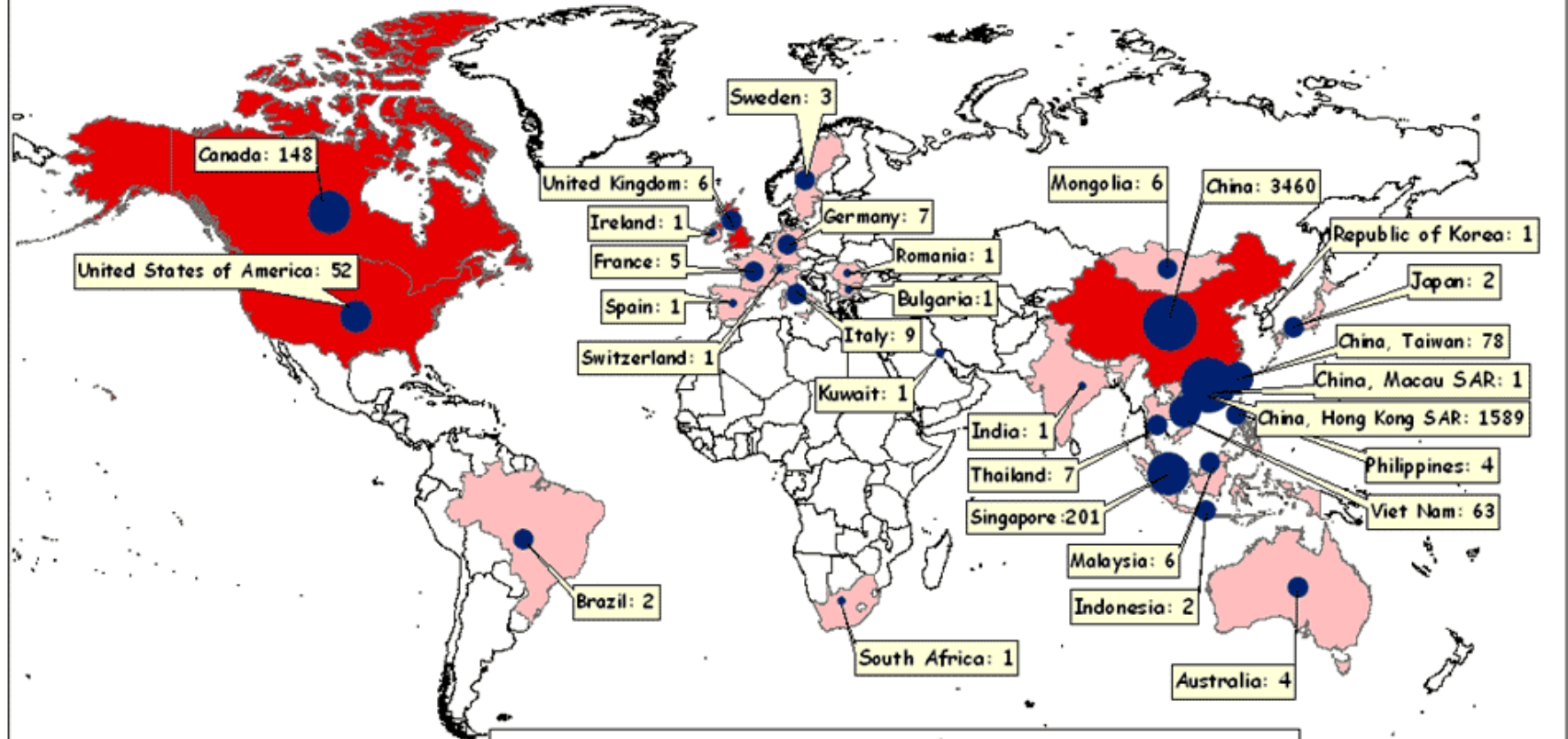
*Different regions are encountering different*



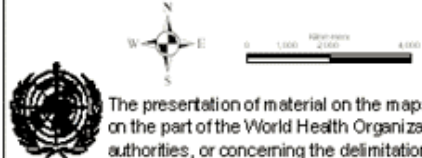
# SARS

## SARS : Cumulative Number of Reported Probable Cases

Total number of cases: 5663 as of 30 April 2003, 17:00 GMT+2



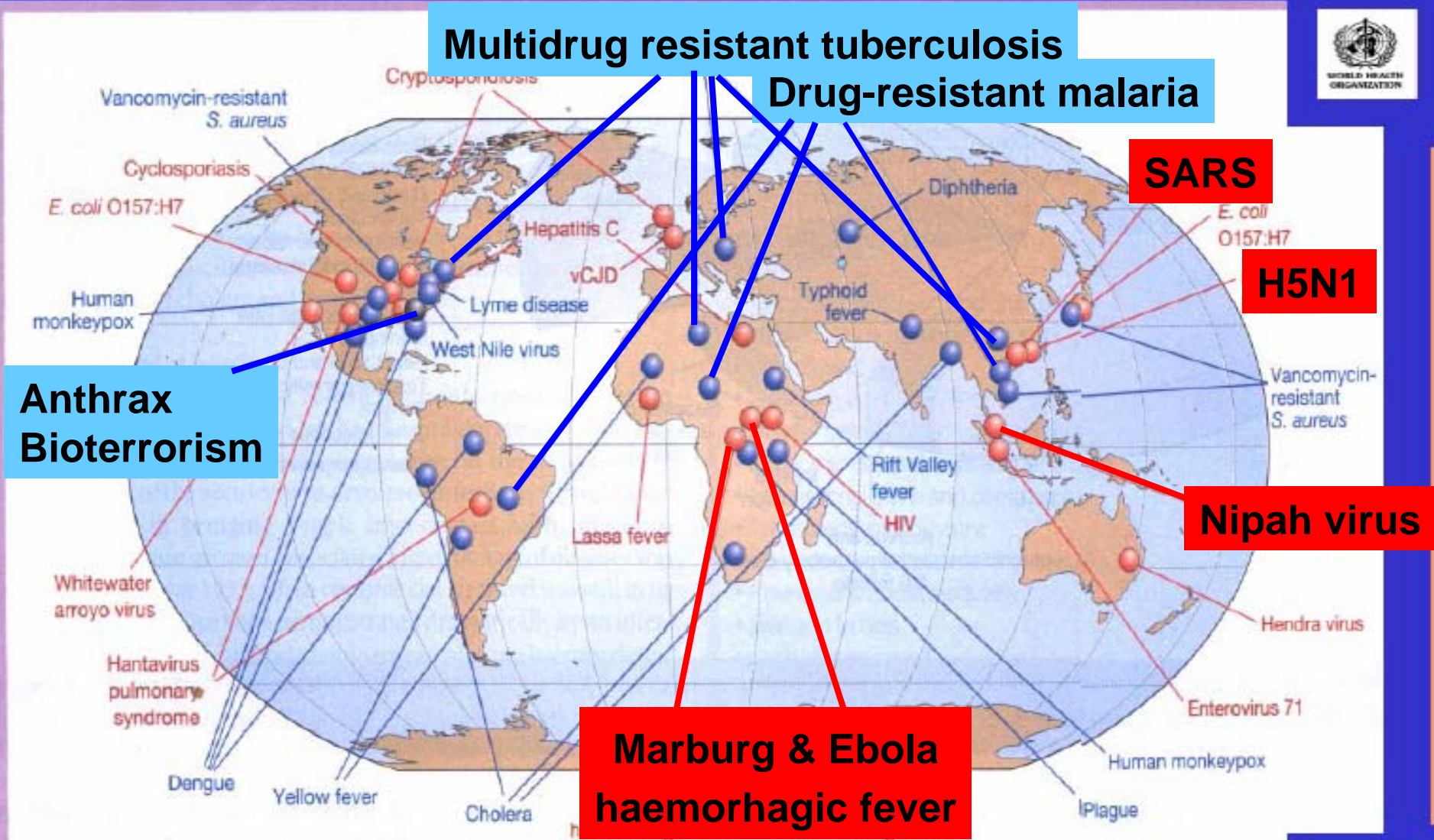
Cumulative number of Reported Cases (From 1 November 02 to 30 April 03)		Type of transmission	
•	1	●	101 - 1000
●	2 - 10	●	> 1000
●	11 - 100	■	no local transmission
		■	local transmission



Data Source: World Health Organization  
 Map Production: Public Health Mapping Team  
 Communicable Diseases (CDS)  
 ©World Health Organization, April 2003

# Global Biological Threats:

*Different regions are encountering different*



Multidrug resistant tuberculosis

Drug-resistant malaria

SARS

H5N1

Anthrax  
Bioterrorism

Nipah virus

Marburg & Ebola  
haemorrhagic fever

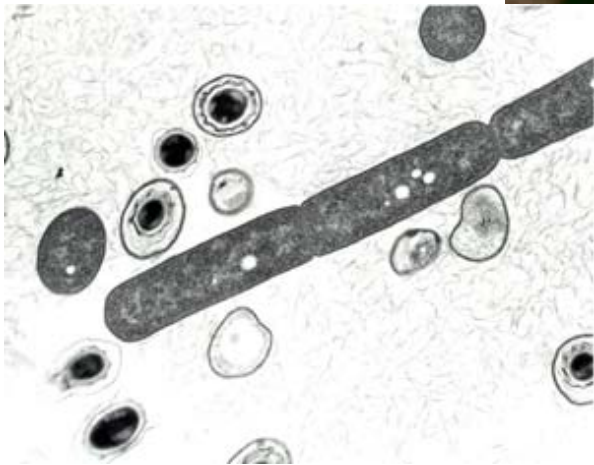
> > **Perceptions** < <

*there any different perception  
 biological threat in Asia & the*

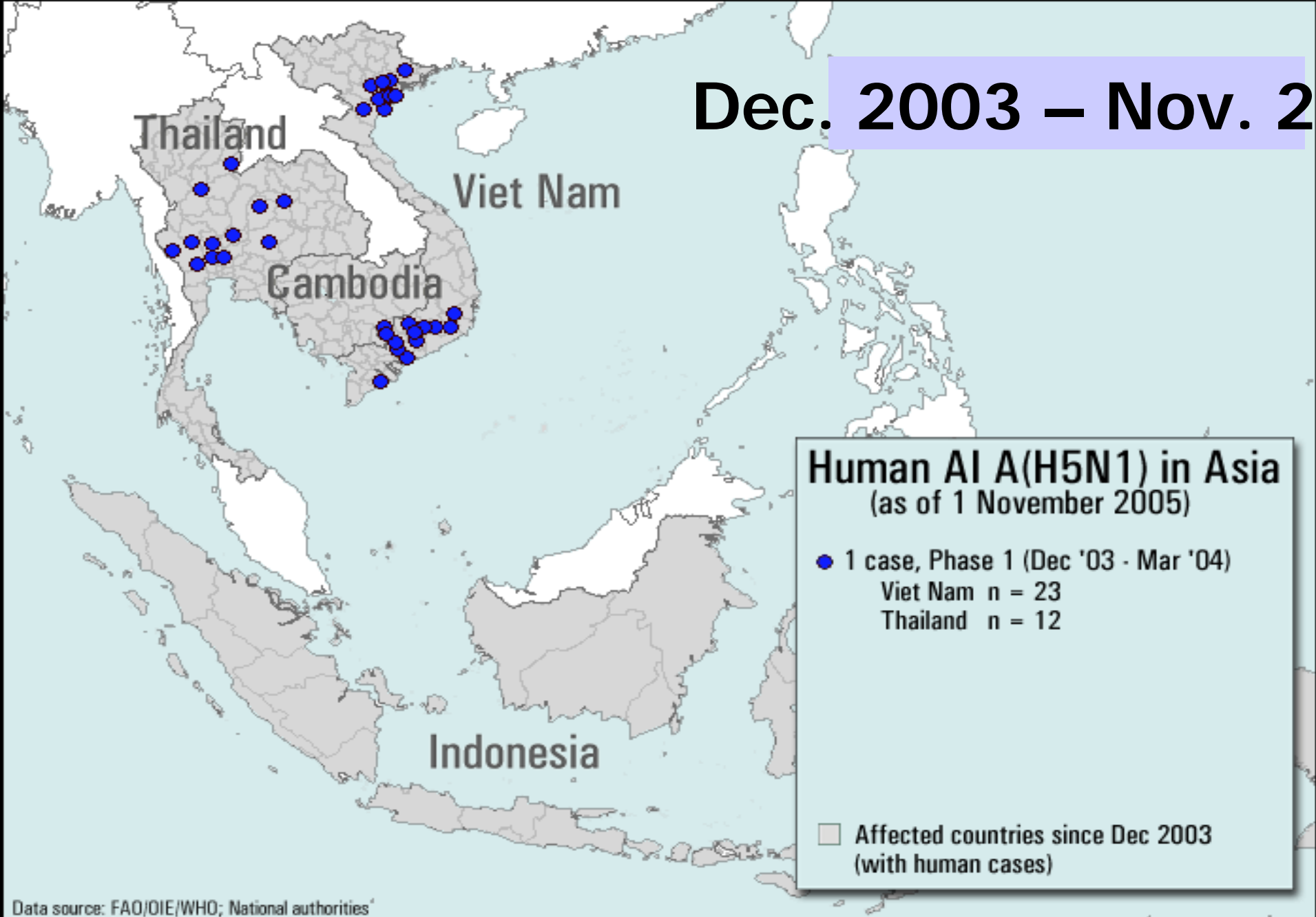
1995: **Aum Shinrikyo** sect releases an i in the Tokyo Subway caused the injured 12 death. The sect also was reported to **anthrax spores** from high building in To



2001: **Anthrax letters** injured 23 people  
The events also spawned innumerable  
including several cases in Thailand.



Dec. 2003 – Nov. 2005



Data source: FAO/OIE/WHO; National authorities



Disclaimer: The presentation of material on the maps contained herein does not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or areas or its authorities of its frontiers or boundaries.



# Nature 21 July 2005

## VIETNAM

On 14 July the official Vietnam news agency reported no new human cases of avian flu since 4 June, and said that the government felt infection had been "well-contained". But the same day the *Tien Phong* newspaper reported a further human death, as well as three known and a dozen suspect cases. If confirmed, the death would bring the country's total to 40, with 20 fatalities since the start of the year.

## INDIA

In response to the outbreak of H5N1 among migratory birds in China, India announced last week that it will monitor 50 of their arrival points. Bar-headed geese in particular will migrate across the Himalayas in coming months. Blood samples will be taken from birds and tested in a high-security laboratory in Bhopal.

## THAILAND

Five new outbreaks in poultry published by the World Organization for Animal Health (OIE) on 15 July signal the failure of a huge government campaign to eradicate the disease, and show that bird flu is now endemic in the country. The outbreaks started on 5 and 6 July, in three districts of Suphanburi province. The country has reported no human cases since last October.

## INDONESIA

The president of Indonesia, Susilo Bambang Yudhoyono, asked his government on 17 July to be open about the suspected deaths from avian flu of three members of the same family. "The cause of their deaths must be made clear," he said. "It should not be covered up." A one-year-old girl died on 9 July. Her father, a civil servant, died on 12 July and her nine-year-old sister two days later. If the initial diagnosis of avian flu is confirmed, this family cluster would

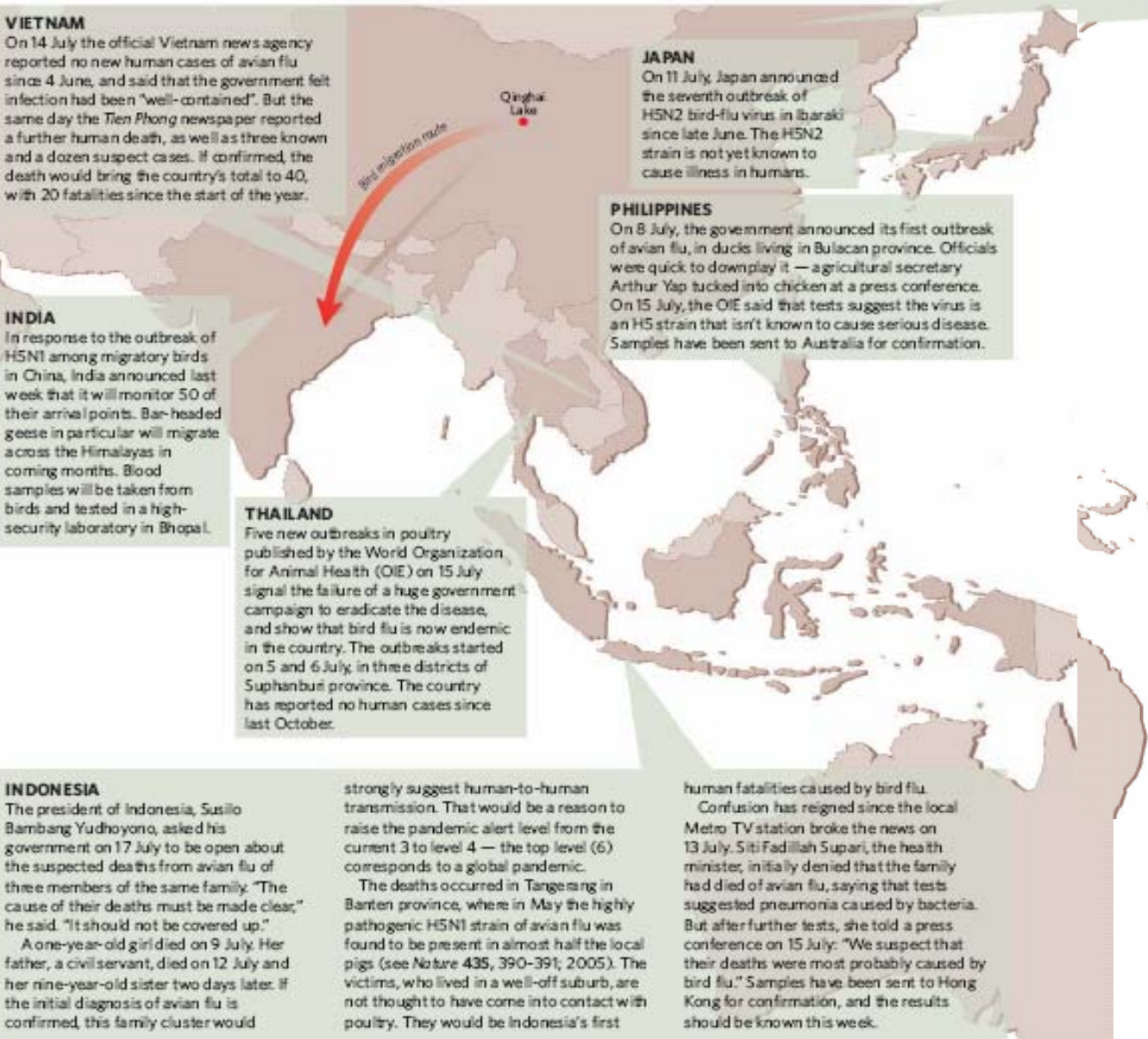
strongly suggest human-to-human transmission. That would be a reason to raise the pandemic alert level from the current 3 to level 4 — the top level (6) corresponds to a global pandemic. The deaths occurred in Tangerang in Banten province, where in May the highly pathogenic H5N1 strain of avian flu was found to be present in almost half the local pigs (see *Nature* 435, 390-391; 2005). The victims, who lived in a well-off suburb, are not thought to have come into contact with poultry. They would be Indonesia's first

## JAPAN

On 11 July, Japan announced the seventh outbreak of H5N2 bird-flu virus in Ibaraki since late June. The H5N2 strain is not yet known to cause illness in humans.

## PHILIPPINES

On 8 July, the government announced its first outbreak of avian flu, in ducks living in Bulacan province. Officials were quick to downplay it — agricultural secretary Arthur Yap tucked into chicken at a press conference. On 15 July, the OIE said that tests suggest the virus is an H5 strain that isn't known to cause serious disease. Samples have been sent to Australia for confirmation.



## CHINA

Recent headlines from Xinhuanet, China's semi-official news agency, include "Bird flu outbreak in Qinghai 'under control'" and "International organizations 'impressed' by China's commitment in fighting bird flu". They give the impression that China is well in control of the H5N1 outbreaks among thousands of migratory birds at Qinghai Lake in western China, and in Xinjiang province near the border with Kazakhstan (see *Nature* 435, 542-543; 2005).

But this is difficult to verify because China does not allow free movement of international experts or journalists to the outbreak zones. China's grip on information now looks set to be tightened further through new rules that require all research on avian flu to be vetted by its agriculture ministry.

Concerns came to a head on 8 July, when Xinhuanet quoted Jia Youling, director-general of the agriculture ministry's veterinary bureau, as asserting that a paper on the Qinghai outbreak published online by *Nature* on 6 July "made the wrong conclusion". Jia also accused the authors of never having visited Qinghai, and of carrying out their research illegally because their labs did not meet safety standards and they did not have government approval for the work.

The article's authors included Guan Yi from the Joint Influenza Research Center, run by Shantou University in mainland China and the University of Hong Kong, and Robert Webster, a flu expert at St Jude Children's Research Hospital in Memphis, Tennessee. It concluded that the Qinghai virus is a new, highly virulent form of H5N1, and that the birds risk spreading the virus across Asia as they migrate over the coming months (H. Chen *et al.* *Nature* 436, 191; 2005). A paper published simultaneously in *Science* reached similar conclusions (J. Liu *et al.* *Science* doi:10.1126/science.1115273; 2005).

Jia objected in particular to an additional conclusion in the *Nature* paper that the isolates were similar to ones "isolated from poultry markets in Fujian, Guangdong, Hunan and Yunnan provinces during 2005". China has not declared any avian flu outbreaks in poultry to international authorities this year. "The article's conclusion lacks credibility," Jia is reported as saying. "No bird flu has broken out in southern China since the beginning of this year."

Guan refutes Jia's allegations, saying that his lab meets the World Health Organization's standards for biosafety and collaborates with flu experts around the world. He reiterates that his team found H5N1 in samples taken from poultry in the region this year.

Guan interprets Jia's stance as one more example of government 'pressure' on scientists trying to investigate the country's flu outbreaks. On 16 June, the Chinese agriculture ministry warned that it would "regulate and investigate research and testing without permission, to stop unauthorized work". This warning follows a series of rules it published on 31 May, requiring scientists to apply for permission to collect and study H5N1 samples, and to have their results double-checked by the ministry.

human fatalities caused by bird flu. Confusion has reigned since the local Metro TV station broke the news on 13 July. Siti Fadillah Supari, the health minister, initially denied that the family had died of avian flu, saying that tests suggested pneumonia caused by bacteria. But after further tests, she told a press conference on 15 July: "We suspect that their deaths were most probably caused by bird flu." Samples have been sent to Hong Kong for confirmation, and the results should be known this week.

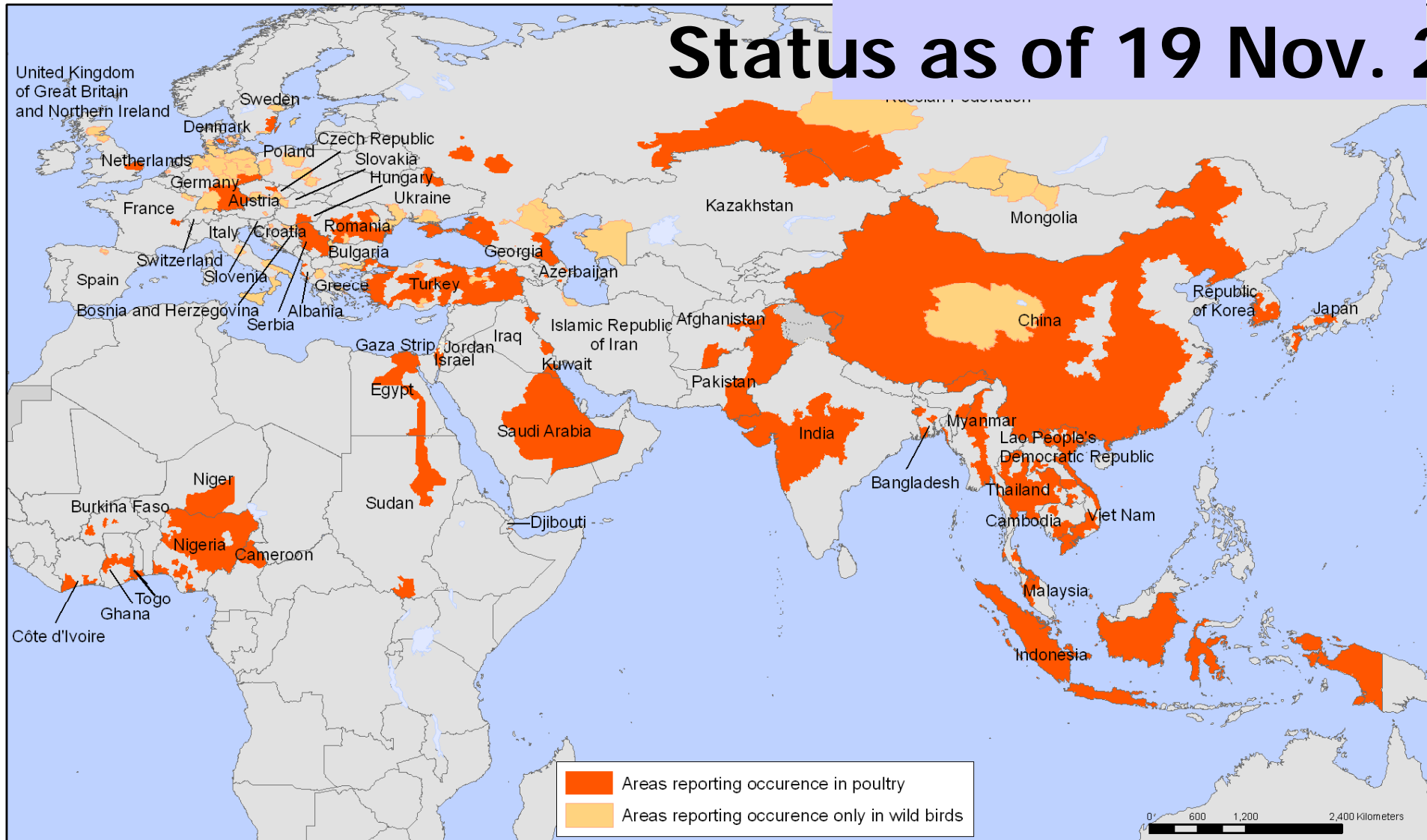
# The latest confirmed H5N1 in animals,



Areas reporting confirmed occurrence of H5N1 avian influenza in poultry and wild birds since 2003

Status as of 19 November 2007  
Latest available update

## Status as of 19 Nov. 2007



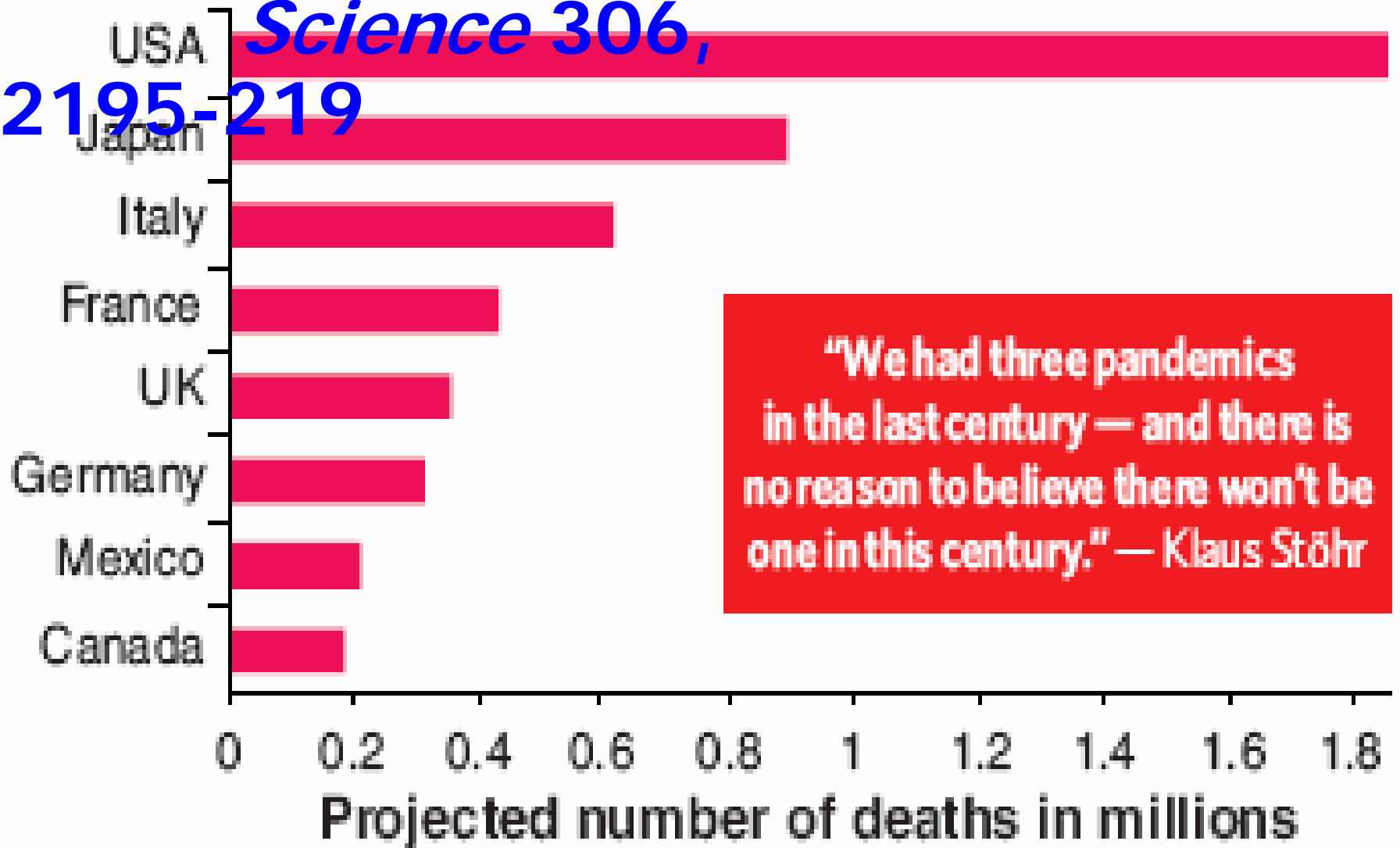
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Data Source: World Organisation for Animal Health (OIE) and national governments  
Map Production: Public Health Mapping and GIS  
Communicable Diseases (CDS) World Health Organization

Source: StÖhr K. and  
Esceid M. (2004)

*Science* 306,  
2195-2199

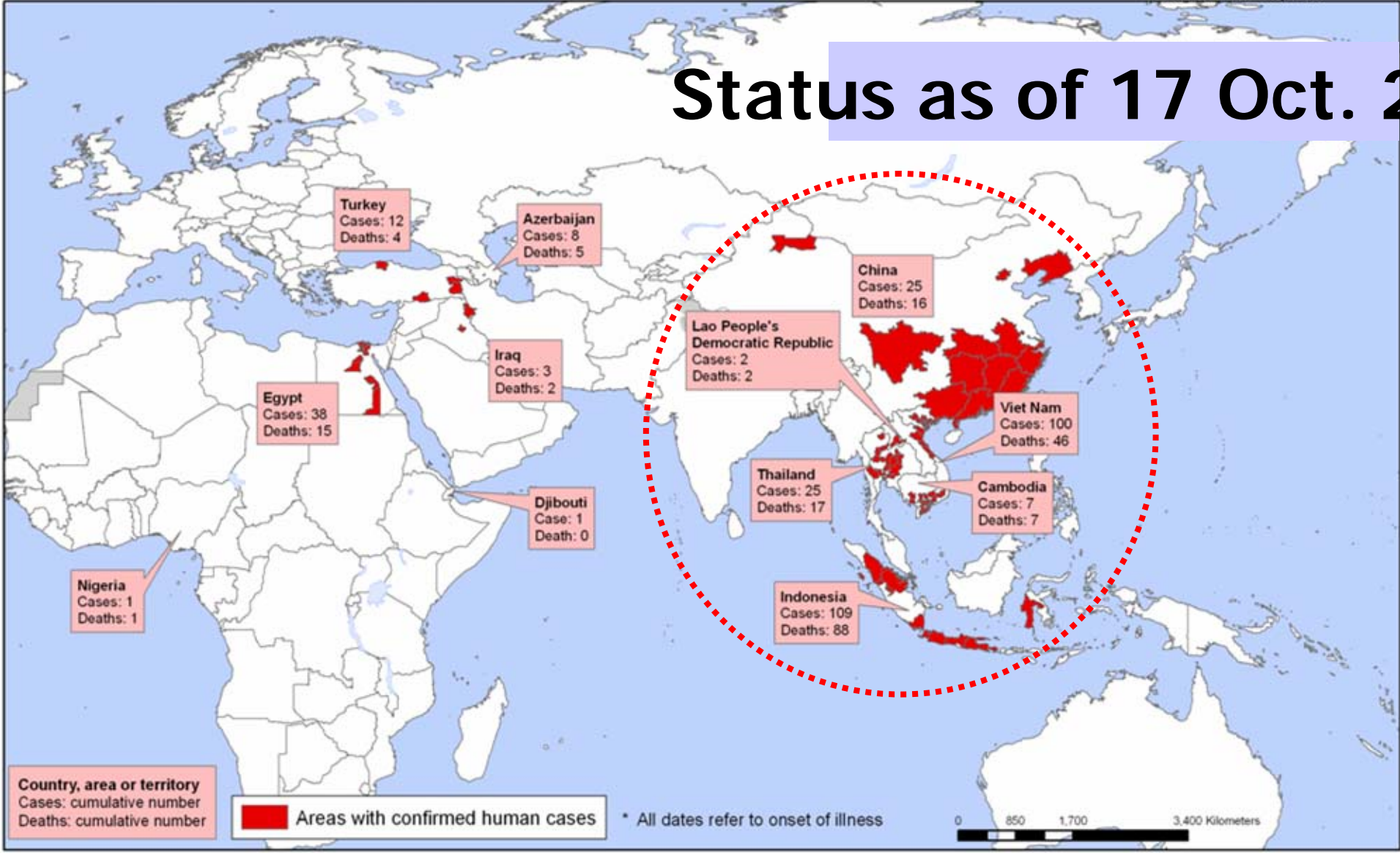


“We had three pandemics  
in the last century — and there is  
no reason to believe there won't be  
one in this century.” — Klaus Stöhr

# The confirmed H5N1 human cases, since 2003

Areas with confirmed human cases of H5N1 avian influenza since 2003 \*

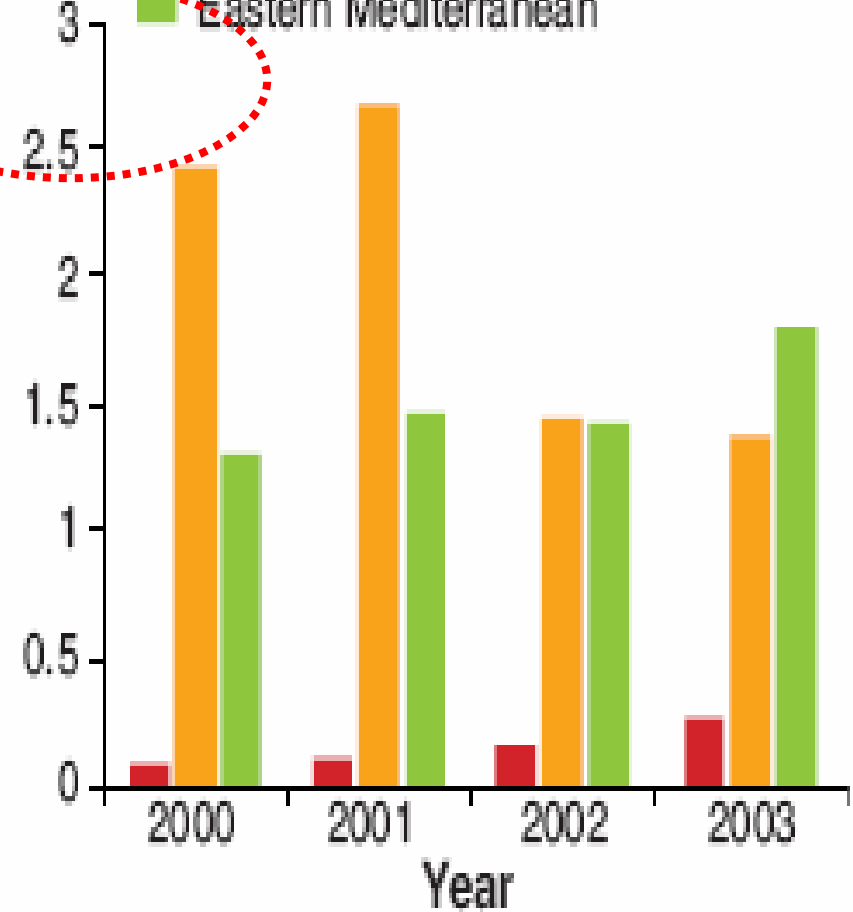
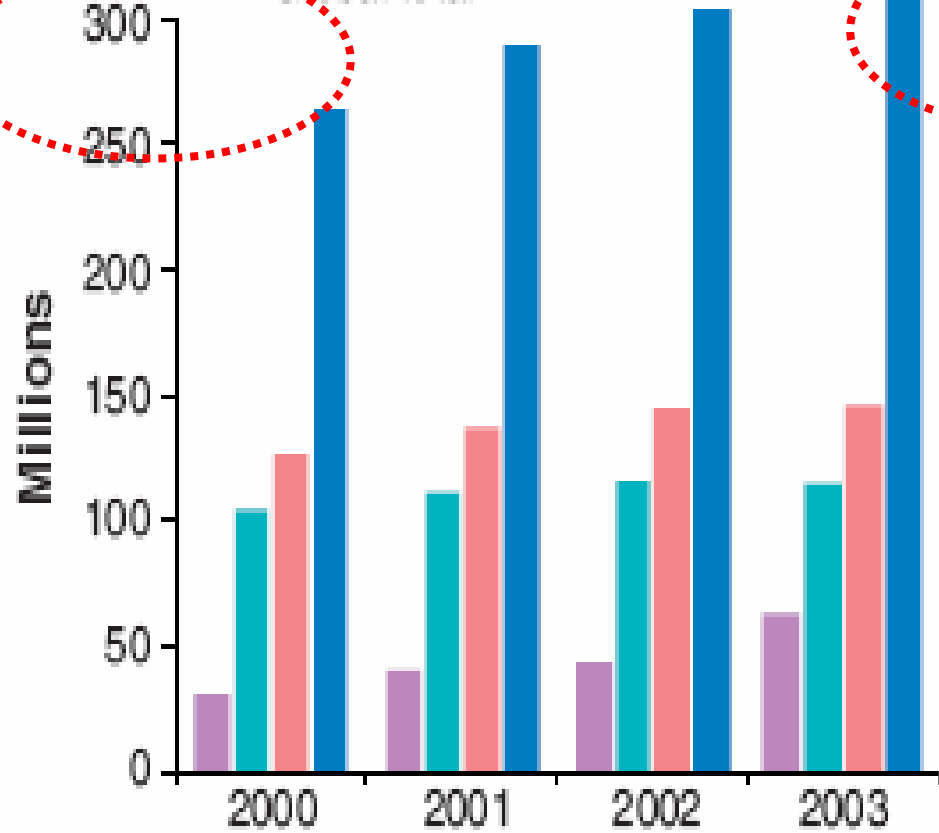
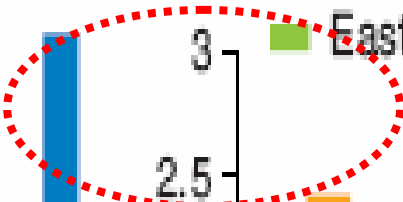
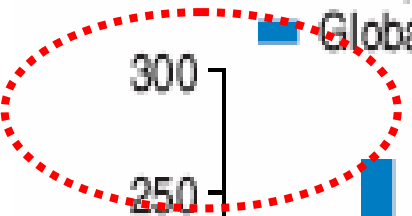
Status as of 17 Oct. 2007



# Distribution of Influenza Vaccine

*Source: The International Federation of Pharmaceutical Manufacturers Associations*

- Western Pacific
- Americas
- Europe
- Global total
- Southeast Asia
- Africa
- Eastern Mediterranean



# New Vaccine Sharing System Needed!

## AVIAN INFLUENZA

### Indonesia Earns Flu Accord At World Health Assembly

NEWS >>>  
THIS WEEK



No ballot considers  
Serafini  
1112



A final gains  
credibility  
1113

#### AVIAN INFLUENZA

### Indonesia Earns Flu Accord At World Health Assembly

Indonesia's battle to ensure access to flu vaccines that could save the lives of millions of its citizens during a pandemic reached a fevered climax earlier this week at the World Health Assembly (WHA), the annual meeting of member states of the World Health Organization (WHO) in Geneva, Switzerland. Supported by other developing countries, Indonesia demanded action and once again employed its valuable bargaining chip: cooperation in a 55-year-old global network of virus sample sharing that acts as the cornerstone of the world's defenses against flu.

As science went to press, a WHA committee had approved a draft resolution, hammered out in 5 days of long and often tense meetings, that called on WHO to do more to help developing nations obtain access to vaccines and establish an international working group to change the rules of the virus-sharing system. (The draft was widely expected to be approved by the entire WHA on Wednesday.) "It was very, very, very difficult to reach an agreement," Indonesian Health Minister Siti Fadilah Supari, who participated in the negotiations, told Science.

Under the Global Influenza Surveillance Network, countries send virus samples from the field to one of four WHO centers in London, Australia, Tokyo, and Melbourne. At these sites, a tally as of the viruses helps track viral evolution and resistance to drugs, judge the risk of a pandemic, and most critically, grade the development of vaccines.

Indonesia, a continuing H5N1 hot spot, has rebelled against the system, which Supari describes as "very unfair" because Indonesia receives no guarantee about access to pandemic vaccines

in return for participating in the surveillance network. Nine Western countries currently have influenza vaccine factories, but experts say they won't be able to produce nearly enough vaccine for the entire world. Indonesia is also angered that researchers in other countries were taking out patents based in part on Indonesian viruses.

In January, Indonesia pulled out of the flu-sharing system, denying WHO new influenza strains. That led to intense talks between the country and WHO officials—and filed proposals from Indonesia to resume sharing. WHO, which shares Indonesia's concerns but says the country's actions are a "threat to global health security," has put forth several proposals to improve access to vaccines. For instance, it has developed a technology-transfer plan that could eventually give some developing nations their own flu vaccine manufacturing capacity; in April, it awarded six contracts—Brazil, India, Indonesia, Mexico, Thailand, and Vietnam—a total of \$18 million in seed money to develop the necessary

plants. WHO has also proposed to form a stockpile of H5N1 vaccine that could be used in developing countries as needed but its size is uncertain.

At the start of the WHA, Supari announced that Indonesia had resumed sharing influenza viruses, and WHO confirms that the network has recently received these samples. But Indonesia also jumped on the opportunity of the WHA to press its case. It pointed to the 1992 Convention on Biological Diversity, which stipulates that a country has to share in the benefits if others make use of its genetic resources. Carlos Correa, an intellectual-property expert at the University of Illinois at Urbana-Champaign, agrees that the convention applies to all genetic resources, including viruses. "Indonesia has a fair claim," he concludes. WHO is still consulting legal experts about the issue, says Assistant Director-General David Heymann.

The arguments about exactly what developing nations also get in return for their participation in the surveillance network took place behind closed doors in a "drafting group" composed of several dozen countries. Supari says the United States, in particular, opposed Indonesia's demands. (David Holman, the health attaché at the U.S. mission in Geneva, was not available for comment.)

The draft resolution that finally emerged late Tuesday afternoon calls on WHO members to keep sharing their viruses—and it asks WHO to take a range of measures to ensure that developing countries can produce their own vaccine and to guarantee "fair and equitable distribution" if a pandemic occurs. The resolution also calls for representatives from 24 countries around the world to propose changes to the rules of the global surveillance system that would benefit the developing world. To add them another 30 points, the group would have to ensure increased participation of scientists from developing countries in the research and wider recognition of their role.

Supari says Indonesia got most of what it wanted. But David Pedoni, a retired pharma executive and a longtime advocate for pandemic preparedness, says the resolution doesn't go far enough to address the fundamental problem: the scarcity of vaccine production capacity. "If I were the minister of health of Indonesia, I would not be satisfied," Pedoni says.

—DAVID PEDONI  
With reporting by Derek Huxford



Standing her ground. Indonesian Health Minister Siti Fadilah Supari says the current virus-sharing system is "very unfair."

Downloaded from www.sciencemag.org on June 27, 2007



Standing her ground. Indonesian Health Minister Siti Fadilah Supari says the current virus-sharing system is "very unfair."

# New Win-Win Procedures Required for

# the Success of the World's Vaccines & Drugs Development!



## Indonesia fights for rights to bird flu samples

11:41 26 November 2007

New Scientist staff and Reuters

Indonesia will not share bird flu virus samples unless richer countries agree to give developing nations control over their use and access to cheap vaccines, a spokeswoman from the nation's health ministry said on Monday.

Health officials from around the world failed to reach an agreement on a new virus sharing system at talks hosted by the World Health Organisation (WHO) in Geneva last week.

Indonesia, the nation worst hit by bird flu with 91 human deaths, has held back its virus samples since August 2007 and wants guarantees from richer nations and drug makers that poor countries get access to affordable vaccines derived from the samples.

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### PRINT EDITION

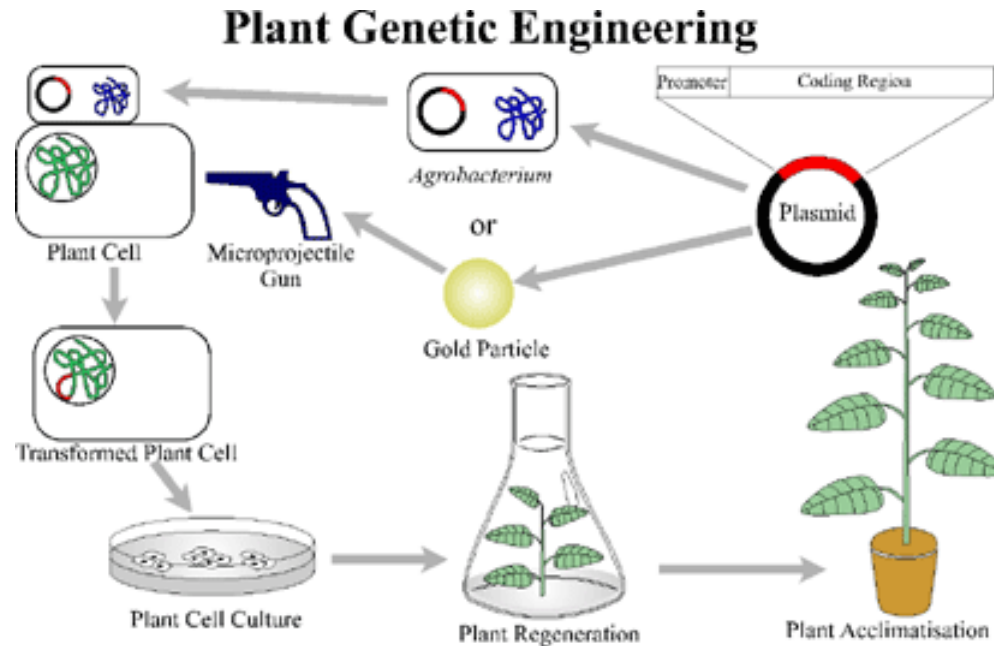
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# Measures to Regulate Research in Laboratories



# Institutional Biosafety Committee (IBC)

Government and independent institutions with r-DNA work aiming to procure, produce or release created organisms into the environment must form a body called the Institutional Biosafety Committee (IBC)



แนวทางปฏิบัติเพื่อความปลอดภัยทางชีวภาพ  
สำหรับการดำเนินงานด้านเทคโนโลยีชีวภาพสมัยใหม่  
หรือพันธุวิศวกรรม

**BIOSAFETY GUIDELINES**  
FOR WORK RELATED TO MODERN BIOTECHNOLOGY  
OR GENETIC ENGINEERING

คณะกรรมการกลางด้านความปลอดภัยทางชีวภาพ  
NATIONAL BIOSAFETY COMMITTEE (NBC)

ศูนย์พันธุวิศวกรรมและเทคโนโลยีชีวภาพแห่งชาติ  
NATIONAL CENTER FOR GENETIC ENGINEERING AND BIOTECHNOLOGY (BIOTEC)

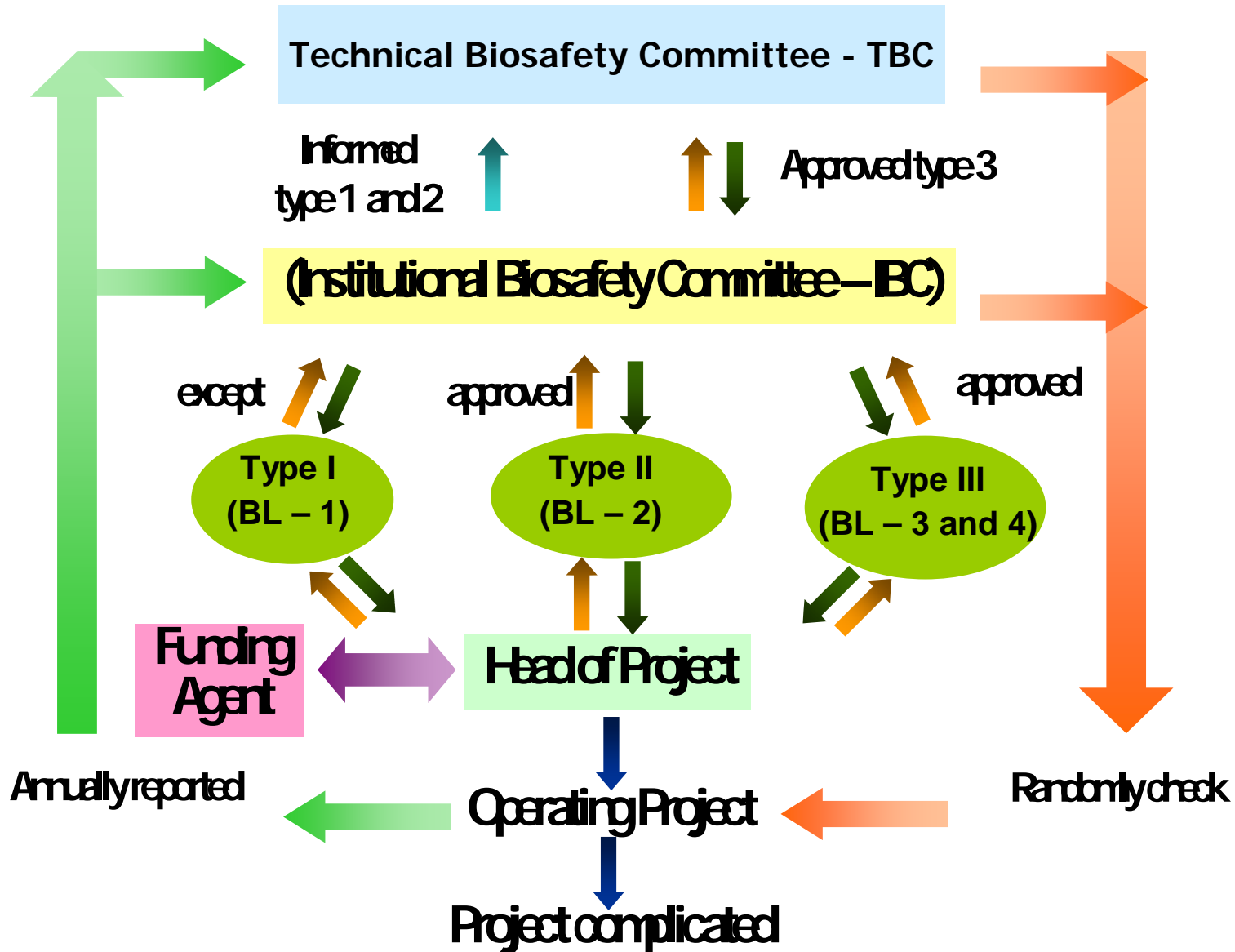
สำนักงานพัฒนาวิทยาศาสตร์และเทคโนโลยีแห่งชาติ  
NATIONAL SCIENCE AND TECHNOLOGY DEVELOPMENT AGENCY (NSTDA)

กระทรวงวิทยาศาสตร์และเทคโนโลยี  
MINISTRY OF SCIENCE AND TECHNOLOGY (MOST)

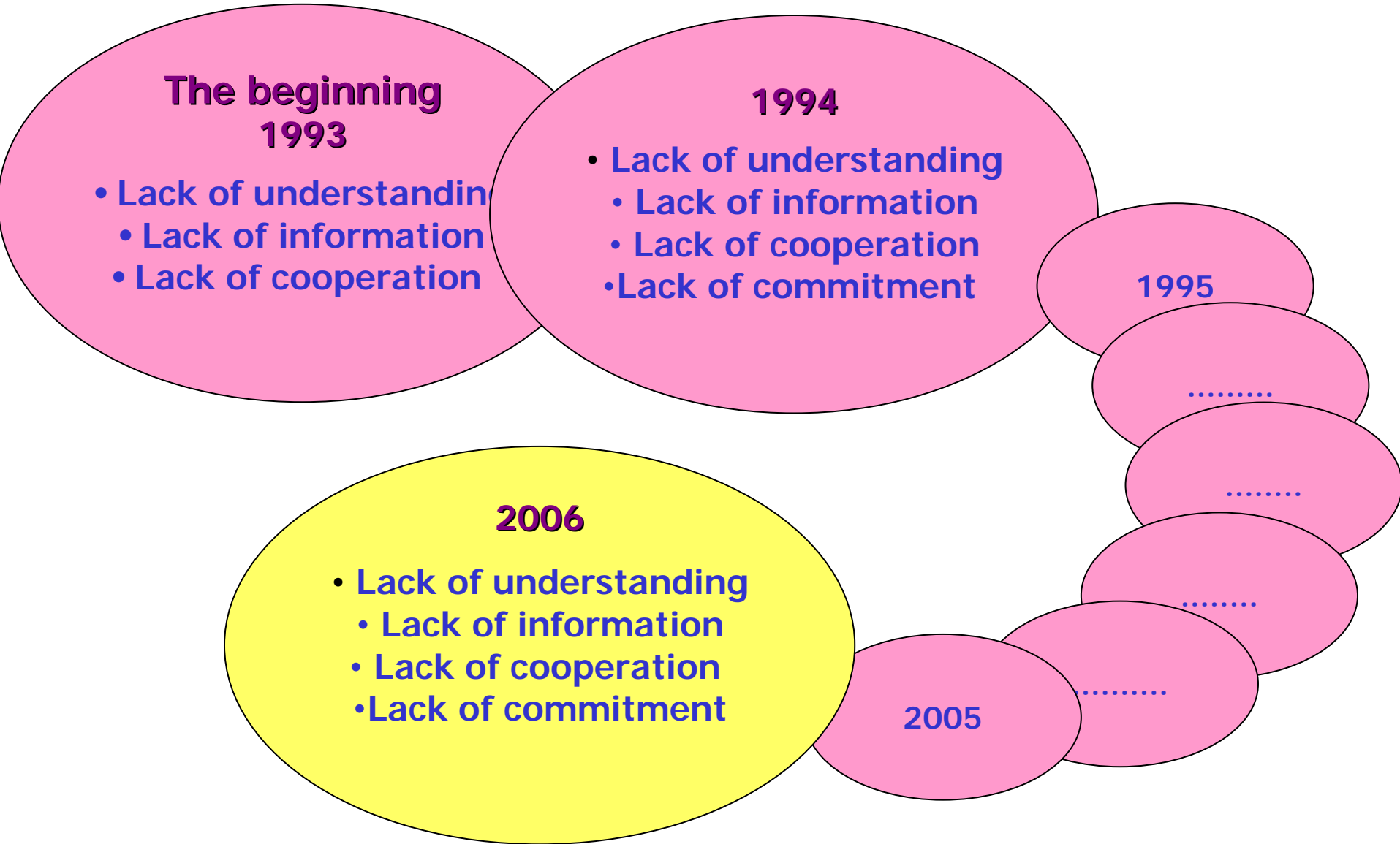
พฤศจิกายน 2547  
NOVEMBER 2004

# Biosafety Guidelines for Work Related to Modern Biotechnology or Genetic Engineering

# Process of Biosafety Guidelines



# Challenges of IBCs





# 2006 IBC network

# Thank you

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