

# BIOSAFETY & ENVIRONMENTAL UPDATE



Monthly Update on Biosafety, Environmental Regulatory  
Affairs Relating to Biopharmaceutical Industry

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## Highlights:

- *Strategic National Stockpile*
- *Capacity Building in Biosafety*
- *Smallpox Vaccination—Adverse Events Update*
- *FDA Strategic Plan to Protect Public Health*
- *New EMEA Guidance on Use of Bovine Serum*
- *GeneVault—Rapid Detection of Biowarfare Agents*
- *New ASM Guidelines for Agents of Bioterrorism*
- *NIH Success in Technology Transfer Program*
- *Ready or Not?*

## STRATEGIC NATIONAL STOCKPILE

CDC is in-charge of the Strategic National Stockpile (SNS), which was formerly National Pharmaceutical Stockpile (NPS). NPS was created in 1999 by the DHHS under a Congressional Mandate with a mission to provide a re-supply of large quantities of medical materiel (including vaccines) to state and local communities during an emergency within twelve hours of the federal decision to deploy.

The Homeland Security Act of 2002 tasked the Department of Homeland Security (DHS) with defining the goals and performance requirements of the NPS Program as well as managing the actual deployment of assets. Effective on 1 March 2003, the NPS became the Strategic National Stockpile (SNS) managed jointly by DHS and HHS.

The SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, airway maintenance supplies, and medical/surgical items. The SNS is designed to supplement and re-supply state and local public health agencies in the event of a national emergency anywhere and at anytime within the U.S. or its territories

The decision to deploy SNS assets may be based on evidence showing the overt release of an agent that might adversely affect public health. It is more likely, however, that subtle indicators, such as unusual morbidity and/or mortality identified through the nation's disease outbreak surveillance and epidemiology network, will alert health officials to the possibility (and confirmation) of a biological or chemical incident or a national emergency.

According to CDC, one of the most important considerations in determining the composition of SNS Program assets is the medical vulnerability of the US civilian populations. Others include (but not limited to), current biological and/or chemical threats, the availability of medical materiel, and the ease of dissemination of pharmaceuticals.

For More Information: <http://www.bt.cdc.gov/stockpile/index.asp>

## **REVISION TO LABELING AND STORAGE REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA**

The Food and Drug Administration (FDA) is proposing to revise the labeling and storage requirements for certain human blood and blood components, including Source Plasma, by combining, simplifying, and updating specific regulations applicable to container labeling and instruction circulars, and the shipping and storage temperatures for frozen noncellular blood components.

This proposed rule would facilitate the use of a labeling system using machine-readable information that would be acceptable as a replacement for the "ABC Coda bar" system for labeling blood and blood components.

FDA is taking this action as part of its "Blood Initiative" to comprehensively review and, as necessary, revise its regulations, policies, guidance, and procedures related to the licensing and regulation of blood products. This proposed rule is intended to help ensure the continued safety of the blood supply, and to help ensure consistency in container labeling and storage temperatures.

For More Information:

<http://www.fda.gov/cber/rules/labelstorbld.htm>

## **CAPACITY BUILDING IN BIOSAFETY**

According to a report by the UNEP, public concerns about potential risks to the environment and human health posed by living modified organisms (LMO) produced by modern biotechnology are rising. To address this issue, UNEP is actively promoting building capacity in biosafety at the national, regional and international levels.

The UNEP International Technical Guidelines for Safety in Biotechnology constitute our main tool to facilitate the development of biosafety expertise and regulatory frameworks all over the world.

Key stakeholders in this effort—government agencies, NGOs and industries—are encouraged to provide relevant information on biosafety mechanisms to the newly established UNEP International Register on Biosafety. A complement to the guidelines, the Register is a response to the growing need of countries for information concerning LMOs and invasive species.

According to UNEP, these guidelines will assist the countries in interpreting and implementing the obligations of the multilateral protocol with biosafety implications. Furthermore, they will facilitate the development of national capacities to assess and manage risks, establish adequate information systems and develop expert human resources in biotechnology.

For More Information:

[www.unep.ch/biosafety/newsletterbsf3.pdf](http://www.unep.ch/biosafety/newsletterbsf3.pdf)

## SMALLPOX VACCINATION—ADVERSE EVENTS

According to CDC, a total of 38,257 civilian healthcare and public health workers in 55 jurisdictions were administered smallpox vaccine between January 24 and August 8, 2003.

DVC June-July Biosafety Updates summarized the adverse events reports as of June 2003. The following is the update for the period June to August 2003.

Adverse events are reported according to a weight-of-evidence scheme, where cases verified by virologic testing are classified as "confirmed". Cases were classified as "probable" where possible alternative etiologies were examined and excluded and supportive information for the diagnosis is found. Cases were classified as "suspect" when clinical features compatible with the diagnosis, but further confirmatory investigation is required.

Using this scheme, CDC reported between June 21-August 8, 2003, one probable case of myo/pericarditis and one confirmed case of inadvertent inoculation. During the vaccination program, no cases of eczema vaccinatum, erythema multiforme major, fetal vaccinia, or progressive vaccinia have been reported.

A summary of the adverse events reported according to the CDC weight-of-evidence scheme between January-August 2003 is as follows:

	Total Cases (January 24 to August 8, 2003)		
	Suspect	Probable	Confirmed
Inadvertent inoculation	11	-	10
General vaccinia	2	-	1
Ocular vaccinia	1	-	2
Myo/pericarditis	17	5	-
Post-vaccinial encephalitis	1	-	-

Compilation based on CDC/MMWR. August 29, 2003. Volume 52(34):819-820.

**SARS—HOW IT CHANGED THE WORLD IN LESS THAN SIX MONTHS**

According to the report in the latest Bulletin of the World Health Organization (2003, 81[8]), the global outbreak of severe acute respiratory syndrome (SARS) can be traced to one man and one night he spent in a Hong Kong hotel on February 21, 2003.

But scientists are yet unclear how Dr. Liu Jianlun, a 65-year-old medical doctor from China's Guangdong province, where the mysterious virus originated, could have transferred the SARS virus to at least 16 other guests on the same floor during his brief stay.

But there is no doubt those travelers fanned out across the world, triggering outbreaks in Singapore, Toronto in Canada, and Hanoi in Viet Nam as well as in Hong Kong itself. In less than four months, some 4000 cases and 550 deaths of SARS outside China and Taiwan can be traced to Dr Jianlun's visit to Hong Kong; the Metropole Hotel is considering turning the ninth floor (he stayed in room 911) into a SARS museum; and SARS has proved that the worst-case scenario long mooted by infectious disease experts can come true; but also that such an outbreak, for all its speed and force, can be contained.

According to the WHO report, SARS has traveled more widely, swiftly and lethally than any other recent new disease so far. By the end of June 2003, the total of cases was 8456 in 30 countries and areas, 809 of which had resulted in death.

As a comparison, HIV/AIDS took two decades to cover the globe, owing partly to its incubation period of up to 10 years. Ebola, which has caused periodic out-breaks in Africa since 1976, and two new Asian diseases, caused by the Nipah and Hendra viruses, have not traveled extensively. In the case of Ebola, this is because the patient quickly becomes much too ill to travel; and for Nipah and Hendra it is because neither virus established efficient human-to-human transmission.

According to WHO, there is no parallel to SARS as first new disease to cause a global havoc in such a short period of time—about 6 months.

For More Information:  
<http://www.who.int/bulletin/en/>



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## *New EMEA Guidance*

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### **GUIDANCE ON THE USE OF BOVINE SERUM**

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### **TWO-PHASE COLLABORATION TO IMPROVE DIAGNOSTIC TESTING:**

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The European Agency for the Evaluation of Medicinal Products (EMA) has recently issued a "Note for Guidance on the Use of Bovine Serum in the Manufacture of Human Biological Medicinal Products (CPMP/BWP/1793/02)". It was adopted by the Committee for Proprietary Medicinal Products (CPMP), in July 2003. The new guidance becomes effective October 1, 2003.

This Note for Guidance outlines the general principles, which should be applied to the control of the quality and safety of bovine serum used during the manufacture of human biological medicinal products, including vaccines and biotech products.

The document provides guidance on points such as types and source of serum, batch preparation, appropriate Certificates of Analysis, testing for adventitious agents and viral inactivation.

DVC Biosafety and Environmental Affairs hold a copy of the new guidance, so please let us know if you require a copy.

For More Information:  
<http://www.emea.eu.int/>

EraGen Biosciences (Madison, WI) will perform a two-phase research collaboration with the Blood Center of Southeastern Wisconsin (Milwaukee, WI) to improve diagnostic testing and research to explore methods to reduce lengthy DNA testing from weeks to as little as one day.

The collaboration focuses on applications such as blood clotting and bleeding disorders. Phase I of the agreement has successfully demonstrated that EraGen's MULTI-CODE(R) and GENE-CODE(R) Assays offer rapid, precise and versatile molecular level diagnostics. Phase II will focus on collaborative product development of new diagnostic tests.

Based in Madison, Wisconsin, EraGen Biosciences is a growing life science company that designs, develops and commercializes products and technologies that accelerate the drug discovery process, advance molecular diagnostics and functional proteomics.

For More Information on EraGen,  
<http://www.eragen.com/>

The Blood Center of Southeastern Wisconsin is a transfusion medicine center and a leader in the diagnostic testing of blood, blood research and blood banking.

For More Information,  
<http://www.bloodctrwise.org/>







## READY OR NOT?

### APHL Chemical Terrorism Project

According to a recent study funded by the Association of Public Health Laboratories (APHL), public health laboratories are not yet ready to meet the analytical testing requirements in the event of chemical terrorism. Although the federal government funded development of the Laboratory Response Network for Bioterrorism (LRN), a multi-tiered system of laboratories with the resources to detect and identify bioterrorism agents, no such capability was development to include chemical agents.

APHL published last month the results of a study started in the Summer of 2002 to assess national laboratory readiness for a chemical terrorism attack. Salient findings of the study are:

1. **Testing Capability:** The nation lacks needed laboratory capability because environmental testing methods for chemical weapons have not been developed, or are not available to the states.
2. **Worker Safety:** The safety of laboratories and others is not assured under current circumstances.
3. **Federal Support for States** is inadequate to support analytical capability development in all states
4. **Chronic shortage** of laboratory Workforce to meet surge.

For More Details: <http://www.aphl.org/>

### YOUR COMMENTS AND SUGGESTIONS ARE WELCOME

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