Vaccine Stockpiling

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Safeguarding Animal Health
Vaccine Stockpile vs Bank

- National Veterinary Stockpile (NVS)
- North American Foot-and-Mouth Disease Vaccine Bank (NAFMDVB)
North American Foot-and-Mouth Disease Vaccine Bank (NAFMDVB)

- The NAFMDVB (not the NVS) procures FMDV vaccine Trilateral organization (U.S., Mexico, Canada) established in 1982

- Source of money to buy vaccine - 2 NAFMDVB accounts:
  1. Trust Fund that contains Canadian and Mexican no-year money
  2. U.S. Appropriated Funds (spent during current fiscal year.)

- Annual contributions approved by Commissioners (e.g., Dr. Shere for the U.S.) at following percentages: Canada 10%; Mexico 20%; U.S. 70%
NAFMDVDB under review

Summary of Foot-and-Mouth Disease Preparedness and Vaccine
Secretary’s Advisory Committee on Animal Health:
%26mouth_disease_2015.pdf

• “given the current size of the North American bank holdings, we have
capability to conduct only a small vaccination campaign”
• “amount needed has been the subject of discussion”
• “Dr. Jim Roth of Iowa State University described a bank of 250 million
doses across multiple strains”
• “The North American FMD Vaccine Bank would need to be
modernized”
• “APHIS would have to address the funding gap by working with various
stakeholder groups, looking at different budget authorities as well as
the possibility of a public private partnership”

Safeguarding Animal Health
Excerpt from Dr. Roth’s testimony before Congressional Ag Subcommittee Feb 11, 2016

Six Types of FMD Outbreak

Size of FMD Outbreak (in terms of animals, premises, and jurisdictions affected)

Response Shifts from Emphasis on Stamping-Out to Emphasis on Alternate Strategies (duration of FMD response)

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NAFMDVB under review

Summary of Foot-and-Mouth Disease Preparedness and Vaccine Secretary’s Advisory Committee on Animal Health – published findings:

• A bank of 250 million doses across multiple strains, which would require an investment of $150 million per year for 5 years.

• For context, the entirety of VS’ budget is $280 million to $300 million per year.
Homeland Security Presidential Directive / HSPD-9 led to the creation of the NVS

Section 18. a) A National Veterinary Stockpile (NVS) containing sufficient amounts of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy and that will be capable of deployment within 24 hours of an outbreak.
January 30, 2004

Subject: Defense of United States Agriculture and Food

Purpose: (1) This directive establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies.

Background: (2) The United States agriculture and food systems are vulnerable to disease, pest, or poisonous agents that occur naturally, are unintentionally introduced, or are intentionally delivered by acts of terrorism. America’s agriculture and food system is an extensive, open, interconnected, diverse, and complex structure providing potential targets for terrorist attacks. We should provide the best protection possible against a successful attack on the United States agriculture and food system, which could have catastrophic health and economic effects.
Office of Science and Technology Policy

- Congress established the Office of Science and Technology Policy in 1976
- Broad mandate to advise the President and others within the Executive Office on the effects of science and technology on domestic and international affairs
- Authorized to lead interagency efforts to develop and implement sound science and technology policies and budgets, and to work with the private sector, state and local governments, science and higher education communities, and other nations toward this end
National Science and Technology Council

- NSTC established by Executive Order on November 23, 1993
- Cabinet-level Council is the principal means within the executive branch to coordinate science and technology policy across the diverse entities that make up the Federal research and development enterprise
- Primary objective - the establishment of clear national goals for Federal science and technology investments in a broad array of areas spanning virtually all the mission areas of the executive branch
OSTP/NSTC FADT WG

Foreign Animal Disease Threats Working Groups

- Basic research WG
- Modeling WG
- Depopulation, Decontamination & Disposal
- Veterinary Countermeasures WG (e.g. vaccines)
FADT - 4 Working Groups (WG)

1. Basic Research WG: Explores opportunities to enhance basic research to better understand disease spread and infection;

2. FAD Modeling WG: Coordinates interagency efforts to enhance the utility of modeling, simulation, and analysis tools for strategic planning and exploration of control strategies and response options for FAD outbreaks at multiple scales;
3. Depopulation, Decontamination, and Disposal Working Group: Coordinates efforts to develop disease eradication methods, tools, and strategies to facilitate rapid response and recovery;
4. Veterinary Countermeasures Working Group: Manages efforts to develop vaccines and diagnostics to protect against FADs.
   - Identify, list and rank (tiers) highest threats, then
   - Focused on one disease at a time
High Consequence FADs – APHIS Fact Sheet - 2013

The list divides diseases into tiers according to risk level

Tier 1 diseases are those of national concern
• most significant threat to animal agriculture
• highest risks and consequences
Tier 1 diseases- marked with an * are those APHIS identified as threats that need to be considered in program priorities and countermeasure stockpile requirements; × = stockpiled or banked

- African swine fever*
- classical swine fever* ×
- foot-and-mouth disease* ×
- avian influenza (any strain that is highly pathogenic or has zoonotic significance)* ×
- virulent Newcastle disease*
Tier 2 diseases

• transmitted primarily by pests
• how quickly these diseases spread and APHIS’ ability to control or eradicate an outbreak depends largely on whether these pests are present in the environment
• and, whether they can transmit the disease between animals
Tier 2 diseases *= stockpiled

- Heartwater (ticks – seen on imported tortoises)
- New World screwworm (blowfly – Cochliomyia)
- Rift Valley fever*× (mosquito-borne, many species)
- Venezuelan equine encephalitis* (mosquitos)
Tier 3 diseases

- pose less risk and fewer consequences than Tier 1 or 2
- inclusion because of their potential negative impact on animal or human health
Tier 3 diseases (+ = zoonotic)

- African horse sickness
- contagious bovine pleuropneumonia
- glanders+ and melioidosis+ (Burkholderia sp.)
- henipaviruses (Hendra and Nipah)*+
- rinderpest* and peste des petits ruminants*
- tropical bont tick (can spread heartwater disease in animals and African tick-bite fever in people)
What high consequence FAD list means

• important to emergency preparedness planners
• guides program priorities (e.g., what to stockpile)
• influence funding for research and response activities
How was list developed?

- any FAD with potential negative impact
- anything identified as an agriculture select agent
- zoonotic potential
- potential for introduction into the U.S.
- endemic diseases not included; excludes:
  - Brucellosis
  - Bovine tuberculosis
  - Scrapie
8 criteria to differentiate high and low consequence FADs

1. epizootic potential; can it rapidly spread and infect a large number of animals
2. economic impact
3. impact on trade (domestic and international)
4. zoonotic potential
5. animal morbidity and mortality
6. cross-species potential
7. how rapidly can it be detected
8. ability to vaccinate for the disease
How the NVS buys **vaccine**

First – a request for Information (RFI)

1. Solicits information
2. Find out who makes what we want to buy
3. Explains NVS requirements
4. Next Slide – example RFI in FedBiz Ops
FedBizOps Request for Information

Classical Swine Fever Virus Vaccine (Chinese Strain)
Solicitation Number: CSFvaccine
Agency: Department of Agriculture
Office: Animal and Plant Health Inspection Service
Location: Administrative Services Division/Contracting

Original Synopsis
Jan 13, 2015
11:33 am

Safeguarding Animal Health
FedBizOps Request for Information

BACKGROUND:
The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Veterinary Stockpile (NVS) is issuing this sources sought synopsis as a means of conducting market research to identify parties having an interest in and the resources to support this requirement for obtaining Classical Swine Fever Virus Vaccine (Chinese strain). The result of this market research will contribute to determining the method of procurement. The applicable North American Industry Classification System (NAICS) code assigned to this procurement is 325414 with a size standard of 500 employees.

REQUIREMENT:
The vaccine(s) must be (1) in on-going production, distribution, and use in one or more jurisdictions or countries in the world; (2) suitable for use in swine; (3) and while not required to be eligible for award, a contractor will eventually have to obtain either a US license or permit for the vaccine.
FedBizOps CSFV Vaccine Solicitation

Classical Swine Fever (CSF) Virus Vaccine

Solicitation Number: AG-6395-S-14-0137
Agency: Department of Agriculture
Office: Animal and Plant Health Inspection Service
Location: Administrative Services Division/Contracting

Safeguarding Animal Health
So what’s in the NVS stockpile

Avian Influenza Virus Vaccine, H5N3 Subtype, KV
• North American strain
• Zoetis
• Code 1057.R3 – licensed
• Label claim for chickens

Avian Influenza Virus Vaccine, H5N1 Subtype, KV
• Eurasian strain
• Reverse genetics technology at SEPRL to make Master Seed
• Zoetis
• Code 1057.R1 – conditional license
• Label claim for chickens
So what’s in the NVS stockpile

Avian Influenza Virus Vaccine, RNA
- Eurasian strain
- Harrisvaccines
- Code 1905.D0 – conditional license
- Label claim for chickens

Avian Influenza-Marek’s Disease, H5 Subtype, Serotype 3, Live Marek’s Disease Vector
- One day of age administration - label claim for chickens
- Biomune Company
- Code 1062.R0 – licensed
- Label claim for chickens
Avian influenza vaccines – licensed product restrictions

Preparation shall be in accordance with the provisions of the Act, the regulations made thereunder, and additional restrictions or requirements when listed below.

1. Distribution in each State shall be limited to authorized recipients designated by proper State officials—under such additional conditions as these authorities may require.
2. Export distribution shall be limited to authorized recipients designated by proper animal health regulatory officials—under such additional conditions as these authorities may require.
3. Domestic distribution and use shall be under the supervision or control of USDA, APHIS, Veterinary Services, as part of an official USDA animal disease control program.
Has U.S. used AI H5 or H7 vaccines?

For LPAI the answer is yes

1995 - a targeted vaccination program in Utah turkeys against H5N3

2003 - a targeted vaccination program in caged layers in Connecticut against H7N2

For HPAI the answer is no (so far)
Other vaccines in the NVS stockpile

Classical Swine Fever Vaccine
- Classical Swine Fever Virus Vaccine, Live Pestivirus
- CSFV E2 gene in BVDV backbone
- DIVA capable (if ELISA not based on E2 antibody detection)
- Zoetis
- Code 18F1.RO – Permit in progress

Classical Swine Fever Vaccine
- Classical Swine Fever Virus Vaccine, Modified Live Virus
- Chinese (aka C) strain
- Not DIVA capable, but
- One dose, early onset of immunity, oral administration
- IDT Biologika/Reimser
- Code 1885.20 – Permit issued June 1, 2016
Other vaccines in the NVS stockpile

Rift Valley Fever Virus Vaccine
- Rift Valley Fever Vaccine, Modified Live Virus
- Not DIVA capable
- Cattle label claim, not pregnant animals
- Zoetis
- Code 1820.20 – conditional license
How does NVS learn about products of interest?

1. IICAB Vaccine directory is a good source
2. Vaccine directory URL: http://www.cfsph.iastate.edu/Vaccines/index/php
3. I use “Sort by Disease”
4. If Contracting Officer asks who makes vaccines I direct them to IICAB vaccine directory
5. If you know of a product that’s not listed let IICAB know so it can be added to the directory
Example - sorted by disease for CSF

Vaccines: Classical Swine Fever

**Agrovet**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Type</th>
<th>Strain/Subtype</th>
<th>Adjuvant</th>
<th>Licensed Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classical Swine Fever vaccine</td>
<td>Live</td>
<td>LK-VN11W1IM</td>
<td>None</td>
<td>Russia</td>
</tr>
<tr>
<td>Classical Swine Fever VGNKI vaccine</td>
<td>Live</td>
<td>K</td>
<td>None</td>
<td>Russia</td>
</tr>
<tr>
<td>Subivac</td>
<td>Not Available</td>
<td>Not Available</td>
<td>None</td>
<td>Russia</td>
</tr>
</tbody>
</table>

**Bistar Laboratories Ltd.**

<table>
<thead>
<tr>
<th>Product Name</th>
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</tr>
</thead>
<tbody>
<tr>
<td>BSL-HC</td>
<td>Live</td>
<td>GPE</td>
<td>Not Available</td>
<td>Singapore</td>
</tr>
</tbody>
</table>
How do I bid on an NVS contract?

https://uscontractorregistration.com/additional-services/
Additional Services

The federal government, in the Small Business Act of 2008, create a number of federal set-aside programs to help smaller, economically and/or socially disadvantaged businesses compete in the federal marketplace. The Federal Government has “set-aside” 23% of all government contracting dollars for small businesses.
Complete new user registration information

New User Registration

First Name *

Last Name *

Business Name

Industry

Address

Street Address
Call the US Federal Contractor Registration Helpline from 8 am to 7 pm EST at 877-252-2700 Ext 2 for immediate help finding contracts.

US Federal Contractor Registration helps businesses find federal opportunities by searching FPDS.gov, FBO.gov, USAspending.gov, and GSA.gov and sending them a resulting list of relevant solicitations on which they should bid. This service is superior to similar services offered through a federal Procurement Technical Assistance Center (PTAC). US Federal Contractor Registration also helps its clients complete and renew their System for Award Management (SAM) Registration(s).
Fed Biz Ops example

Avian Influenza Vaccines, Eurasian HPAI H5

Department of Agriculture

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) intends to award multiple commercial, indefinite-delivery indefinite-quantity (IDIQ) contracts for vaccines and vaccine combinations effective against Eurasian highly pathogenic avian influenza.

Opportunity #
ag-6395-s-16-0005

Source
fbo.gov

SHOW MORE

Safeguarding Animal Health
Avian Influenza Vaccines, Eurasian HPAI H5

Department of Agriculture

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) intends to award multiple commercial, indefinite-delivery indefinite-quantity (IDIQ) contracts for vaccines and vaccine combinations effective against Eurasian highly pathogenic avian influenza virus H5 clade 2.3.4.4 (EA H5) in order to establish an emergency vaccine stockpile.

The APHIS National Veterinary Stockpile (NVS) is the nation's repository of critical veterinary supplies, equipment, and service resources. It exists because of the nation's concern over animal diseases of catastrophic proportions that would

- deplete State and local response inventories,
- generate surge requirements that would overwhelm commercial sources, and
- prevent unaffected States from providing significant help for fear of the threat crossing their borders

NVS's ability to deploy within 24 hours large amounts of critical veterinary resources ensures states have what they...
Questions?

Safeguarding Animal Health