

**Component** Army

**Data Call for reply to Representative Blumenauer OSD-11374-10  
Granted Indemnification in accordance with Public Law 85-804 since 2005**

Contracting Activity	Contract Number	Contractor	Memorandum of Decision Date	DUNS	Services/Supply	Lawsuit Filed	Amount of Reimbursement
U.S. Army Contracting Command, Research, Development and Engineering Command, Natick Contracting Division	DAMD17-98-C-8052	Emergent BioDefense Operations Lansing, Inc.	15-Nov-00	26489018	Anthrax Vaccine Adsorbed (AVA)	Yes	\$646,351.50
U.S. Army Contracting Command, Research, Development and Engineering Command, Natick Contracting Division	W9113M-07-P-0025	Cangene Corporation, Winnipeg Canada	13-Jun-08	244844056	Vaccinia Immune Globulin	No	None
U.S. Army Contracting Command, Research, Development and Engineering Command, Natick Contracting Division	W9113M-09-C-0159	Canadian Commercial Corp, Ottawa Canada	20-Aug-10	207884594	Vaccinia Immune Globulin	No	None
U.S. Army Contracting Command, Research, Development and Engineering Command, Natick Contracting Division	W911SR-05-D-0008	Mason & Hanger Corporation	17-Apr-07	148033574	Chemical Demilitarization	No	None
Center for Disease Control and Prevention of the U.S. Department of Health and Human Services & JPEOCBD	200-2002-00004	Acambis Inc	22-Jan-08	DUNS Not on file	ACAM2000 Smallpox Vaccine	No	None
U.S. Army Contracting Command, Research, Development and Engineering Command, Natick Contracting Division	W9113M-04-D-0002	BioPort Corporation	28-Sep-04, amended 10-Nov-05	26489018	Anthrax Vaccine Adsorbed (AVA)	No	None
U.S. Army Joint Munitions Command Attn: Contracting and PARC Center	DAAA09-03-D-0023	Bechtel Parsons Blue Grass, A Joint Venture	3-Apr-06	132084539	Chemical Demilitarization	No	None
U.S. Army Operations Support Command Attn: Contracting and PARC Center	DAAA09-02-D-0025	Bechtel National, Inc	3-Apr-06	89176176	Chemical Demilitarization	No	None
U.S. Army Sustainment Command	DACA87-89-C-0076	EG&G Defense Materials, Inc	5-Jan-09	798311874	Chemical Demilitarization	No	None



DEPARTMENT OF THE ARMY  
OFFICE OF THE ASSISTANT SECRETARY OF THE ARMY  
ACQUISITION LOGISTICS AND TECHNOLOGY  
103 ARMY PENTAGON  
WASHINGTON, DC 20310-0103

OCT 5 2010

DETERMINATION AND FINDINGS  
UNDER FEDERAL ACQUISITION REGULATION CLAUSE 52.250-1

FINDINGS

1. Emergent BioDefense Operations Lansing Incorporated (Emergent), formerly known as BioPort Corporation, has requested payment of certain litigation expenses on the basis of the indemnification clause in its contract with the Army for the manufacture of Anthrax Vaccine. The Army contracting activity responsible for the contract has evaluated Emergent's request and calculated a proposed payment amount. The purpose of this Determination and Findings, executed pursuant to Federal Acquisition Regulation (FAR) Clause 52.250-1, is to obtain the agency head's determination that the amount proposed for payment is just and reasonable.
2. On 15 September 1998, the U.S. Army Medical Research Acquisition Activity awarded Contract DAMD17-98-C-8052 to BioPort Corporation (now Emergent). The contract required the manufacture and delivery of Food and Drug Administration (FDA)-licensed Anthrax Vaccine.
3. In a Memorandum of Decision (MoD) dated 15 November 2000, the Secretary of the Army authorized the inclusion of FAR Clause 52.250-1, Indemnification Under Public Law 85-804, in this contract. The MoD included a specific definition of the unusually hazardous risks to which the indemnification clause applies.
4. By letter dated 5 December 2008, Emergent submitted a final invoice in the amount of \$1,578,382.07, for reimbursement under Public Law 85-804 of litigation expenses it states were incurred as a result of Department of Defense (DoD) use of its product. Emergent's request identified \$2,200,287.89 in litigation and settlement costs related to fourteen lawsuits, reduced by \$621,905.82 for its insurance recovery net of legal fees incurred to obtain reimbursement from its insurer, for a total invoice amount of \$1,578,382.07.
5. The Contracting Officer and supporting legal counsel undertook a comprehensive review of Emergent's request to ensure that all costs were: (1) properly attributable to Contract DAMD17-98-C-8052, (2) within the limitations of the contract's indemnification clause as approved in the Secretary of the Army's MoD, and (3) just and reasonable. The Contracting Officer's evaluation of the Emergent's request is recorded in memorandum, subject: Contractor Claim for Reimbursement Under Indemnification Clause FAR 52.250-1, Contract Number DAMD17-98-C-8052, dated 13 April 2009.
6. Based upon her review, the Contracting Officer has proposed a litigation expense payment in the amount of \$646,351.50 in connection with 2 of the 14 lawsuits. She

concluded that there was no entitlement to payment in connection with the remaining 12 lawsuits. A spreadsheet summarizing the Contracting Officer's adjustments to Emergent's request is provided at enclosure 1.

a. As an initial step, the Contracting Officer prorated the amounts paid by Emergent's insurance carrier over all fourteen lawsuits due to a lack of traceability between insurance payments received by Emergent and the corresponding lawsuit. A spreadsheet summarizing the prorated share calculations is provided at enclosure 2. For each lawsuit, the Contracting Officer deducted the prorated insurance reimbursement from the amount of claimed litigation and/or settlement costs.

b. The Contracting Officer then evaluated the litigation costs invoiced for each lawsuit to ensure that they were properly allocable to Contract DAMD17-98-C-8052 and were consistent with the contract's indemnification clause. The Contracting Officer concluded that there was no entitlement to payment in connection with twelve of the fourteen lawsuits based upon one or more of the following considerations:

(1) The contractor's failure to establish that costs invoiced for a particular lawsuit were attributable to vaccine lots delivered under Contract DAMD17-98-C-8052.

(2) The costs invoiced for a particular lawsuit fell below Emergent's insurance deductible amount (\$25,000 per occurrence) and, thus, were ineligible for indemnification payment pursuant to FAR Clause 52.250-1(c).

(3) The costs invoiced for a particular lawsuit were not incurred in defense of cases predicated upon "death, personal injury or loss of, damage to or loss of use of property and, thus, were ineligible for indemnification payment pursuant to FAR Clause 52.250-1(b). This category involved costs incurred in connection with: (1) litigation related to the validity of DoD's vaccination program, (2) Qui Tam litigation associated with an Food and Drug Administration filing by Emergent, or (3) contract dispute litigation between Emergent and its insurance carrier.

(4) The contractor's failure to provide requisite notice to the Contracting Officer contrary to FAR Clause 52.250-1(g) – cited by the Contracting Officer only as a secondary factor in her conclusion.

(5) The invoiced costs did not arise out of or result from a risk identified in the contract as unusually hazardous contrary to FAR Clause 52.250-1(c)(1) – also cited only as a secondary factor.

c. The Contracting Officer concluded that Emergent is entitled to payment in connection with the remaining two lawsuits (Adamus v BioPort Corp, et al and Ammend et al, v. BioPort Inc. (sic)). The Contracting Officer, supported by her legal counsel, concluded that the invoiced costs represented reasonable and customary charges for litigation expenses based upon the nature of the work and the level of legal expertise. As noted above, the Contracting Officer deducted the prorated insurance

reimbursements allocated to these two cases from the invoice amounts. Also, pursuant to FAR Clause 52.250-1(c), she adjusted the invoiced amounts based upon Emergent's insurance deductible.

7. The U.S. Army Research, Development and Engineering Command Contracting Activity currently oversees the contracting office responsible for Contract DAMD17-98-C-8052. The Principal Assistant Responsible for Contracting for that organization has reviewed Emergent's request and the Contracting Officer's analysis. He concurs with the Contracting Officer's methodology and conclusions, and he recommends that the agency head determine the amount proposed for payment, \$646,351.50, to be just and reasonable.

8. FAR Clause 52.250-1 provides that the Government shall make no payment under this clause unless the agency head determines that the amount is just and reasonable. Under Headquarters, Department of the Army General Orders No. 3 (2002), the Assistant Secretary of the Army (Acquisition, Logistics and Technology) exercises the authorities of the agency head for contracting, procurement, and acquisition matters.

DETERMINATION

Based upon the foregoing findings, I hereby determine that the amount proposed for payment, \$646,351.50, is just and reasonable.



Malcolm R. O'Neill

2 Encls

Assistant Secretary of the Army  
(Acquisition, Logistics and Technology)

Case	Amount Claimed	Amounts Disallowed	Insurance payment Reduction <sup>3</sup>	Insurance Deductible Reduction	Amount Approved	Basis for Action Codes
1 Suk v. BioPort	\$22,760.12	\$22,760.12	0	0	0	#1, #2
2 Reid v BioPort	\$18,520.52	\$18,520.52	0	0	0	#1, #2, #6
3 Fleming v. BioPort	\$23,009.62	\$23,009.62	0	0	0	#1, #2
4 Golbitz v. BioPort	\$358.40	\$358.40	0	0	0	#1, #2, #6
5 Emery v. BioPort	\$155,991.66	\$155,991.66	0	0	0	#1, #2 (in part)
6 Savage v. BioPort	\$57,131.00	\$57,131.00	0	0	0	#1, #2 (in part)
	10,000	10,000	0	0	0	n/a
7 Stevens v. Battelle	\$42,395.74	\$42,395.74	0	0	0	#1, #2 (in part)
8 Maersk Litigation	\$8,073.00	\$8,073.00	0	0	0	#2
9 Doe v. Rumsfeld	\$21,872.45	\$21,872.45	0	0	0	#1, #2, #3 & #7
10 Bates, v. Rumsfeld	\$19,106.75	\$19,106.75	0	0	0	#1, #2, #3 & #7
11 US v BioPort <sup>1</sup>	\$526,508.06	\$526,508.06	0	0	0	#1, #4, #7, #2 (in part)
12 Evanston v Emergent	\$393,611.04	\$393,611.04	0	0	0	#1, #5, #7 & # 2 (in part)
13 Adamus v. BioPort	\$142,704.99	n/a	\$64,891.27	\$25,000	\$52,813.72	#2 (in part)
	\$17,500.00	n/a	\$17,500.00	n/a	0	n/a
14 Ammehd v. BioPort <sup>2</sup>	\$1,134,355.58	n/a	\$515,817.80	\$25,000	\$593,537.78	#2 (in part)
Totals	\$2,593,898.93	\$1,299,338.36	\$598,209.07	\$50,000	\$646,351.50	

**Code #1** = Litigation costs did not deal with any vaccinations or dealt with vaccine lots not substantiated as being associated with the contract cited as basis for the request for reimbursement. (NOTE: On March 24, 2008 Emergent was notified that a separate invoice must be provided if claims are against more than one Contract. Emergent BioDefense responded on Apr 15, 2008 with the following: "All claims are submitted under the 8052 contract." Additionally, on 1-23-09--Emergent verified that it had provided all information that tied particular plaintiffs to particular lots of vaccine.)

**Code #2** = The entire amount sought (or portion) fell below the "per occurrence" indemnification clause insurance deductible exclusion (i.e., \$25,000 under the Evanston Insurance policy).

**Code #3** = Litigation costs were not incurred in defense of cases predicated upon "claims by third parties... for death, personal injury; or loss of, damage to, or loss of use of property" as required by the indemnification clause; but rather were incurred in support of litigation related to the validity of the DoD vaccination program.

**Code #4** = Litigation costs were not incurred in defense of cases predicated upon "claims by third parties... for death, personal injury; or loss of, damage to, or loss of use of property" as required by the indemnification clause; but rather were incurred in support of litigation related to a Qui Tam action associated with purported fraud in a FDA filing.

**Code #5** = Litigation costs were not incurred in defense of cases predicated upon "claims by third parties... for death, personal injury; or loss of, damage to, or loss of use of property" as required by the indemnification clause; but rather were incurred in support of litigation related to private internal company litigation related to a contract dispute between Emergent and its insurance carrier.

**Code #6** = Failure to provide required notice to the Contracting Officer.

**Code #7** = Did not arise out of or result from a risk identified in the contract as unusual hazardous or nuclear.

<sup>1</sup> Qui Tam action = RUSSELL E. DINGLE, THOMAS L. REMPFER, UNITED STATES OF AMERICA, EX REL.,

<sup>2</sup> Includes Allaire, Ruigo, Bonasse, and Lahiff

<sup>3</sup> These amounts reflect prorated shares of the Evanston Insurance Co reimbursements that could not be identified as payments for specific cases. Calculation based on a percentage of the total costs claimed. (See attached chart entitled "Prorated Share Calculation"). Also, Evanston Settlement Agreement included \$137,500 reimbursement for "Thimerosal" litigation, unrelated to AVA, and not included herein.

Prorated Share Calculation Enclosure 2

Case	Litigation Costs Claimed	Percent of total claimed	Distribution Amount of Insur Reimbursement	Subtotal	Minus per occurrence Insurance Deductible	Recommended amount of claimed costs to be reimbursed
Bates, et al., v. Rumsfeld, et al.	\$ 19,106.75	0.8794%	\$8,688.28		-\$25,000.00	\$0.00
Doe v. Rumsfeld	\$ 21,872.00	1.0066%	\$9,945.71		-\$25,000.00	\$0.00
Emery v. BioPort Corp.	\$ 155,991.66	7.1793%	\$70,933.03		-\$25,000.00	\$0.00
Golbitz v. BioPort Corp., et al	\$ 358.40	0.0165%	\$162.97		-\$25,000.00	\$0.00
Louisiana Anthrax Litigation/ Fleming v. BioPort Corp., et al.	\$ 23,009.62	1.0590%	\$10,463.01		-\$25,000.00	\$0.00
Maersk Litigation	\$ 8,073.00	0.3716%	\$3,670.98		-\$25,000.00	\$0.00
United States ex rel. Dingle and Rempfer v. BioPort Corp., et al. (Qui Tam)	\$ 526,508.06	24.2319%	\$239,415.43		-\$25,000.00	\$0.00
Reid	\$ 18,520.52	0.8524%	\$8,421.71		-\$25,000.00	\$0.00
Savage v. BioPort, Inc. (sic)	\$ 57,131.00	2.6294%	\$25,978.79		-\$25,000.00	\$0.00
Settlement Costs (Savage v. BioPort, Inc. (sic))	\$ -					
(Reimbursed by Evanston Ins Co. \$10,000 shown below)						
Suk v. BioPort Corp., et al.	\$ 22,760.12	1.0475%	\$10,349.55	\$77,813.72	-\$25,000.00	\$0.00
Adamus v. BioPort Corp., et al.	\$ 142,704.99	6.5678%	\$64,891.27		-\$25,000.00	\$52,813.72
Settlement Costs (Adamus v. BioPort Corp., et al.)	\$ -					
(Reimbursed by Evanston Ins Co. \$17,500 shown below)						
Stevens v. Battelle Memorial Inst, et al.	\$ 42,395.74	1.9512%	\$19,278.33		-\$25,000.00	\$0.00
Ammend, et al. v. BioPort Inc. (sic) (includes Allaire, Rugo, Bonasse, and Lahiff)	\$ 1,134,355.58	52.2074%	\$515,817.80	\$618,537.78	-\$25,000.00	\$593,537.78
Evanston Insurance Co. v. BioPort Corp.-Litigation costs not included for purposes of this calculation	\$ -					
<b>Subtotal</b>	\$ 2,172,787.44	100.0000%	\$988,016.86			\$646,351.50
Defense Costs Previously Reimbursed by Evanston Ins Co. Prior to Oct 2008	\$710,000.00					
Defense Costs Reimbursed by Evanston Ins Co. in October 2008	\$278,016.86					
Indemnification for 2 Settlements Paid by Evanston Ins Co. in Oct. 2008	\$27,500.00					
Total Reimbursed by Insurance Co.	\$1,015,516.86					

Note: Settlement with Evanston Ins Co. included \$137,500 for unrelated litigation (not related to AVA) and is not represented in any of the amounts shown above.



SECRETARY OF THE ARMY  
WASHINGTON

NOV 15 2000

MEMORANDUM OF DECISION

SUBJECT: Authority under Public Law (PL) 85-804 to include an Indemnification Clause in Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052 with BioPort Corporation (BioPort)

BioPort has requested that the Department of the Army include indemnification clauses in Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052 consistent with PL 85-804 (codified at 50 U.S.C. 1431-1435) and Federal Acquisition Regulation (FAR) 50.403-1.

Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052 all cover activities related to the production and testing of Anthrax Vaccine Adsorbed (AVA). Production and testing of AVA require interaction with one of the most lethal biological agents known to man. In light of the production, storage, handling, testing, packaging, and transporting of vaccine and/or biological agent contemplated by Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052, I find that performance of these contracts subjects BioPort to unusually hazardous risks.

In addition to risks surrounding actual production of the vaccine, the delivery of AVA for use by the government to protect its soldiers, sailors, airmen, and marines presents both the possibility for adverse reactions in some recipients of the vaccine, and the possibility that the desired immunological effect will not be obtained by all recipients. Although AVA has been extensively tested under the auspices of the Food and Drug Administration, the size of the DoD vaccination program may reveal unforewarned idiosyncratic adverse reactions. Moreover, there is no way to be certain that the pathogen used in tests measuring vaccine efficacy will be sufficiently similar to the pathogen that the U.S. forces might encounter to confer immunity. In light of these concerns, and in light of the uncertain and evolving state of product liability law with regard to vaccines, I find that performance of Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052 subjects BioPort to unusually hazardous risks that extend beyond production and delivery of AVA under the contract.

Attachment No. 2 to  
Modification No. P00022 to  
Contract DAMD17-98-C-8052  
Page 1 of 4

Consistent with the above, the definition of unusually hazardous risks to which the indemnification clauses in Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052 will apply as follows:

Release (or alleged release) of an infectious agent or toxic material into the environment in connection with activities undertaken pursuant to the contract that results (or allegedly results), either directly or indirectly, in human exposure to or environmental damage by an infectious material or toxic material involved with the production or testing of vaccines pursuant to the contract. Such activities may include, but are not limited to (1) storage, use, testing, or handling of live vaccine products, their intermediate precursors or infectious agents or toxins that are used as challenge materials for test of the products or intermediates; (2) transportation of such substances; and (3) disposal of such substances.

Adverse reaction (or alleged adverse reaction) in a human from administration of a vaccine or other material used in the production or testing of the vaccine, in conjunction with or as a result of the performance of the contract, or administration of a vaccine produced, tested, or delivered under the contract.

The term adverse reaction includes anaphylaxis and other foreseeable and unforeseeable adverse reactions. Such reactions include, but are not limited to: (1) reactions directly attributable to and resulting from the administration of the vaccine or other material involved with the vaccine, production or testing (to include challenge materials); (2) reactions that manifest long after exposure, but which are directly attributable to and resulting from the administration of the vaccine or other material involved with the production or testing of the vaccine; (3) the failure of the vaccine to perform as intended or otherwise confer immunity; or (4) performance by the vaccine in a manner not intended.

Notwithstanding any other provision in the indemnification clause or this Memorandum of Decision, BioPort and its subcontractor(s) shall not be indemnified against grossly negligent or criminal behavior on the part of the contractor's or subcontractor's directors, officer, or managers who have supervision over, or

direction of, all or substantially all of the operations at any one plant or separate locations where the contract or a subcontract is being performed.

I have reviewed the availability, cost, and terms of private insurance to cover these risks, as well as the viability of self-insurance, and conclude that adequate insurance to cover the unusually hazardous risks described above is not reasonably available to BioPort. I have also reviewed BioPort's program of workers' compensation insurance. On the basis of these reviews, I find that use of indemnification clauses in Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052 will facilitate the national defense.

In view of the foregoing and pursuant to the authority vested in me by PL 85-804 and Executive Order 10789, as amended, I hereby authorize the Contracting Officer to include the indemnification clause set forth at FAR 52.250-1 (including its Alternate I, if applicable) in Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052 for the unusually hazardous risks identified above.

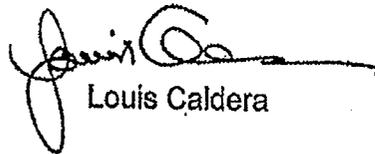
As permitted by FAR 50.403-2(d)(2); FAR clause 52.250-1, and justified by the circumstances, I also delegate to the Contracting Officer authority to approve pass-through indemnification to BioPort's subcontractors. I authorize inclusion of the indemnification clause in first-tier subcontracts under Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052, provided the pass-through indemnification is limited to the unusually hazardous risks defined in this Memorandum of Decision and contingent on the Contracting Officer approving the pass-through indemnification in writing. I also authorize inclusion of the indemnification clause in certain second-tier subcontracts under Contract No. DAMD17-91-C-1139, Contract No. DAMD17-97-D-0003, and Contract No. DAMD17-98-C-8052, provided the pass-through indemnification is limited to the unusually hazardous risks defined above, provided the Contracting Officer determines in writing that critical supplies or services are not reasonably available from a second-tier subcontractor without indemnification, and contingent on the Contracting Officer approving the pass-through indemnification in writing.

Should it prove necessary in implementing this Memorandum of Decision to incorporate language into the contracts to clarify, directly or by reference, terms found in the indemnification clause, the contracting officer shall not

include any such language without the prior review and approval of the Deputy Assistant Secretary of the Army (Procurement).

It is not possible to determine the actual or estimated cost to the Government as the result of the use of these indemnification clauses, inasmuch as the liability of the Government, if any, will depend upon the occurrence of an incident described in the statement of unusually hazardous risks.

The contractual documents executed pursuant to this authorization shall comply with the requirements of FAR 50.4. This Memorandum of Decision shall be incorporated in its entirety into the contracts to which the approved indemnification authority is to apply. Further, the Memorandum of Decision incorporated into the contracts shall be specifically cross-referenced to the indemnification clause at FAR 52.250-1 (or its Alternate I, if a cost-type contract) which shall be set forth in the contract(s) in full.



Louis Caldera



SECRETARY OF THE ARMY  
WASHINGTON

13 JUN 2008

MEMORANDUM OF DECISION

SUBJECT: Authority under Public Law (P.L.) 85-804 and Executive Order 10789, as amended, to include an Indemnification Clause in Purchase Order W9113M-07-P-0025

1. The Cangene Corporation (Cangene) requests the U.S. Army include an indemnification clause under Title 50 United States Code (U.S.C.) Sections 1431-1435, P.L. 85-804 in Purchase Order W9113M-07-P-0025, awarded on February 15, 2007 for the purchase of 48 vials of Vaccinia Immune Globulin (VIG).

2. Department of Defense (DoD) Directive 6205.3 designates the U.S. Army as the DoD Executive Agent for the biological warfare defense immunization program. The U.S. Army's responsibilities under this designation include vaccine acquisition. The smallpox vaccine system is one of the vaccines acquired under this program. VIG is a component of the smallpox vaccine system and is used to treat the relatively rare instances of severe adverse reactions to the smallpox vaccine. VIG is the only product available for this purpose.

3. The U.S. Food and Drug Administration (FDA) has approved the use of VIG to treat adverse reactions to the smallpox vaccine. Notwithstanding VIG's FDA licensure status, I find that performance under Purchase Order W9113M-07-P-0025 subjects Cangene, as the VIG manufacturer, to the following unusually hazardous risks:

a. The risk of adverse reaction whether foreseeable or unforeseeable, from the administration to humans of the VIG product manufactured or delivered under this contract.

b. The risk of the VIG product's failure to effectively treat or mitigate adverse reactions in humans to a vaccinia vaccine, whether foreseeable or unforeseeable, including but not limited to eczema vaccinatum, progressive vaccinia, generalized vaccinia, vaccinia infections, and inadvertent autoinoculation.

4. This finding is based upon the uncertain and evolving state of product liability law with respect to vaccines, as well as the following additional considerations:

a. The unavoidable absence of scientific data concerning VIG's effectiveness in treating adverse reactions to additional varieties of smallpox vaccine that were developed subsequent to FDA's approval of VIG;

b. The possibility that exigent circumstances may necessitate that DoD personnel use the VIG in a manner not fully indicated in the FDA approval or in conjunction with other treatments thereby making it difficult to assess which product was the cause of any resulting harm;

SUBJECT: Authority under P.L. 85-804 and Executive Order 10789, as amended, to Include an Indemnification Clause in Purchase Order W9113M-07-P-0025

c. The possibility that DoD personnel may use the product in overseas locations, where there may be limited data available on the administration and storage conditions of the product.

5. Cangene is the only supplier of VIG, and it has stated that it is unwilling to provide DoD with the VIG unless the purchase order provides for indemnification. In view of this position, as well as the DoD's requirement for the smallpox vaccine system, to include VIG, for force protection purposes, I determine that the use of an indemnification clause in this purchase order will facilitate the national defense.

6. On June 29, 2006, the Department of Homeland Security designated VIG as a Qualified Anti-terrorism Technology under the Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (SAFETY Act, Title 6 U.S.C. Section 442(b)). The SAFETY Act designation affords Cangene, as the VIG manufacturer, certain protections from third party liability claims. These protections, however, apply only when the VIG is administered in conjunction with an "act of terrorism" within the meaning of the act, and thus, may not afford Cangene liability protection from all potential claims associated with DoD usage of VIG. Based upon this consideration, as well as the DoD's requirement for this product for force protection purposes, I determine that the use of an indemnification clause is necessary for the timely and effective conduct of the United States Military or intelligence activities, notwithstanding the authority provided under the SAFETY Act.

7. In evaluating Cangene's request, I have considered the availability, cost, and terms of private insurance to cover these risks, as well as the viability of self-insurance, and have concluded that adequate insurance to cover these unusually hazardous risks are not reasonably available to Cangene. I have also considered Cangene's program of worker's compensation insurance.

8. In view of the foregoing and pursuant to the authority vested in me by Title 50 U.S.C. Sections 1431-1435 (P.L. 85-804) and Executive Order 10789, as amended, I hereby authorize the contracting officer to include the indemnification clause as set forth at Federal Acquisition Regulation (FAR) Subpart 52.250-1 in purchase order W9113M-07-P-0025, provided that the clause defines the unusually hazardous risks precisely as described in this memorandum.

9. This clause shall not be applicable to risks that result from an "act of terrorism," as defined by Title 6, U.S.C. Section 444(2), or that are otherwise within the scope of the SAFETY Act's liability protections. It also shall not apply to risks that are covered under any insurance policy payable to Cangene, regardless of whether such insurance was in effect either before the delivery of VIG to the U.S. Army or purchased specifically for the execution of the purchase order. Notwithstanding any other provision in the indemnification clause or this Memorandum of Decision (MOD), Cangene Corporation shall not be indemnified against grossly negligent or criminal behavior on the part of Cangene Corporation's directors, officers, or managers who have supervision over, or

SUBJECT: Authority under P.L. 85-804 and Executive Order 10789, as amended, to Include an Indemnification Clause in Purchase Order W9113M-07-P-0025

direction of, all or substantially all of the operations at any facility where the purchase order or a subcontract is being performed.

10. Should it prove necessary in implementing this MOD, to incorporate language into the contract to clarify, directly or by reference, terms found in the indemnification clause or this MOD, the contracting officer shall not include any such clarifying language without the prior review and approval of the Deputy Assistant Secretary of the Army (Policy and Procurement).

11. It is not possible to determine the actual or estimated costs to the Government as a result of the use of this indemnification clause since the liability of the Government, if any, will depend upon the occurrences of incidents described in the statement of unusually hazardous risks.

12. The contractual documents executed pursuant to this authorization shall comply with the requirements of the FAR Subparts 28.3 and 50.4 as implemented by the DoD and the Department of the U.S. Army. This MOD shall be incorporated in its entirety into purchase order W9113M-07-P-0025. Further, the MOD incorporated into the purchase order shall specifically cross-reference to the indemnification clause at FAR 52.250-1, which shall be set forth in the purchase order in full text.



Pete Geren



SECRETARY OF THE ARMY  
WASHINGTON

AUG 20 2010

MEMORANDUM OF DECISION

SUBJECT: Authority under Public Law (PL) 85-804 to include an Indemnification Clause in Contract Number W9113M-09-C-0159 with the Canadian Commercial Corporation (CCC), 11<sup>th</sup> Floor, 50 O'Connor Street, Ottawa, Ontario, Canada, Awarded for the Production and Delivery of Vaccinia Immune Globulin (VIG)

1. Pursuant to Title 50, United States Code (U.S.C.), Sections 1431-1435 (PL 85-804), as implemented in Federal Acquisition Regulation (FAR) Part 50, the CCC has requested addition of indemnification clause to Contract Number W9113M-09-C-0159 for the production and delivery of VIG. In accordance with FAR 52.250-1(e), the CCC also has requested authorization to extend the indemnification to its subcontractor Cangene Corporation.
2. Department of Defense (DoD) Directive 6205.3 designates the Department of the Army (DA) as the DoD Executive Agent for the biological warfare defense immunization program. The DA's responsibilities under this designation include vaccine acquisition. The smallpox vaccine system is one of the vaccines acquired under this program. VIG is a component of the smallpox vaccine system and is used to treat the relatively rare instances of severe adverse reactions to the smallpox vaccine. VIG is the only product available for this purpose.
3. The U.S. Food and Drug Administration (FDA) has approved the use of VIG to treat adverse reactions to the smallpox vaccine. Notwithstanding VIG's FDA licensure status, I find performance under Contract W9113M-09-C-0159 subjects the CCC to the following unusually hazardous risks:
  - a. The risk of adverse reaction whether foreseeable or unforeseeable, from the administration to humans of the VIG product manufactured or delivered under this contract.
  - b. The risk of the VIG product's failure to effectively treat or mitigate adverse reactions in humans to a vaccinia vaccine, whether foreseeable or unforeseeable, including but not limited to eczema vaccinatum, progressive vaccinia, generalized vaccinia, vaccinia infections, and inadvertent autoinoculation.
4. While the likelihood of either risk occurring is considered small, my finding is based upon the uncertainties and enormous potential financial liabilities associated with vaccine product liability litigation, as well as the following additional considerations:
  - a. The unavoidable absence of scientific data concerning VIG's effectiveness in treating adverse reactions to additional varieties of smallpox vaccine that were developed subsequent to FDA's approval of VIG;

**SUBJECT: Authority under Public Law (PL) 85-804 to include an Indemnification Clause in Contract Number W9113M-09-C-0159 with the Canadian Commercial Corporation (CCC), 11<sup>th</sup> Floor, 50 O'Connor Street, Ottawa, Ontario, Canada, Awarded for the Production and Delivery of Vaccinia Immune Globulin (VIG)**

b. The possibility that exigent circumstances may necessitate that DoD personnel use the VIG in a manner not fully indicated in the FDA approval or in conjunction with other treatments, thereby making it difficult to assess which product was the cause of any resulting harm;

c. The possibility that DoD personnel may use the product in overseas locations, where there is the possibility of limited data available on the administration and storage conditions of the product.

5. Cangene Corporation, the subcontractor under the CCC, is the only supplier of VIG and it has stated that it is unwilling to provide DoD with the VIG unless the contract provides for indemnification. In view of the CCC's inability to perform its contract due to its subcontractor's unwillingness to provide VIG without indemnification, as well as the DoD's requirement for the smallpox vaccine system, to include VIG, for force protection purposes, I determine that the use of an indemnification clause in this contract will facilitate the national defense.

6. On 29 June 2006, the Department of Homeland Security designated VIG as a Qualified Anti-terrorism Technology under the Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (SAFETY Act), Title 6 U.S.C. Section 442(b)). The SAFETY Act designation affords Cangene Corporation, the manufacturer of VIG, certain protections from third party liability claims. These protections, however, apply only when the VIG is administered in conjunction with an "act of terrorism" within the meaning of the act and thus, may not afford Cangene liability protection from all potential claims associated with DoD usage of VIG. Based upon this consideration, as well as the DoD's requirement for this product for force protection purposes, I determine that the use of an indemnification clause is necessary for the timely and effective conduct of the United States military or intelligence activities, notwithstanding the authority provided under the SAFETY Act.

7. The CCC does not have any general liability insurance for protection from business risks, and without indemnification, the CCC would expose its own capital base to the extent of the loss. If the loss exceeded the capital base, then the Government of Canada, being self insured, provides financial protection to the CCC and is ultimately responsible for any debts or liability claims in excess of the CCC's capital base. In evaluating the CCC's request, I have considered the CCC's role as prime contractor acting as an agent of the Government of Canada and their inability to use private

SUBJECT: Authority under Public Law (PL) 85-804 to include an Indemnification Clause in Contract Number W9113M-09-C-0159 with the Canadian Commercial Corporation (CCC), 11<sup>th</sup> Floor, 50 O'Connor Street, Ottawa, Ontario, Canada, Awarded for the Production and Delivery of Vaccinia Immune Globulin (VIG)

insurance to cover these risks, the attempts by the subcontractor Cangene Corporation to obtain reasonable insurance, as well as the viability of self-insurance by the CCC, and I have concluded that adequate insurance to cover these unusually hazardous risks is not reasonably available to the CCC or Cangene Corp. I have also considered both the CCC and Cangene's programs of worker's compensation insurance.

8. In view of the foregoing and pursuant to the authority vested in me by Title 50 U.S.C. Sections 1431-1435 (PL 85-804) and Executive Order 10789, as amended, I hereby authorize the contracting officer to include the indemnification clause as set forth at FAR Subpart 52.250-1 in contract W9113M-09-C-0159, provided that the clause defines the unusually hazardous risks precisely as described in this memorandum. As permitted by FAR 50.104-3(b)(4)(ii) and subsection (e) of the clause at FAR 52.250-1, I also authorize the contracting officer to approve the CCC's written request to indemnify its subcontractor Cangene Corporation in its subcontract with Cangene Corporation to an extent that is no greater than the DA indemnification to CCC.

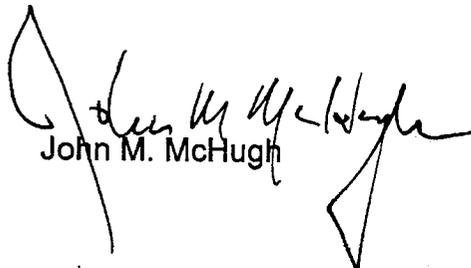
9. This clause shall not apply to risks that result from an "act of terrorism," as defined by Title 6 U.S.C. Sections 444(2), or that are otherwise within the scope of the SAFETY Act's liability protections. It also shall not apply to risks that are covered under any insurance policy or other financial protections payable to the CCC, whether in effect before the delivery of VIG to the DA, or put into effect specifically for the execution of the contract. Notwithstanding any other provision in the indemnification clause or this Memorandum of Decision (MoD), the CCC shall not be indemnified against grossly negligent or criminal behavior on the part of directors, officers, or managers who have supervision over, or direction of, all or substantially all of the operations at any facility where the purchase order or a subcontract is being performed.

10. Should it prove necessary in implementing this MoD to incorporate language into the contract to clarify, directly or by reference, terms found in the indemnification clause or this MoD, the contracting officer shall not include any such clarifying language without the prior review and approval of the Deputy Assistant Secretary of the Army (Procurement).

11. It is not possible to determine the actual or estimated costs to the Government as a result of the use of this indemnification clause. The liability of the Government, if any, will depend upon the occurrences of incidents described in the definition of unusually hazardous risks.

SUBJECT: Authority under Public Law (PL) 85-804 to include an Indemnification Clause in Contract Number W9113M-09-C-0159 with the Canadian Commercial Corporation (CCC), 11<sup>th</sup> Floor, 50 O'Connor Street, Ottawa, Ontario, Canada, Awarded for the Production and Delivery of Vaccinia Immune Globulin (VIG)

12. The contractual documents executed pursuant to this authorization shall comply with all FAR, Defense FAR Supplement, and Army FAR Supplement requirements. This MoD shall be incorporated in its entirety into contract W9113M-09-C-0159. In addition, the MoD incorporated into the contract shall specifically cross-reference to the indemnification clause at FAR 52.250-1, which shall be set forth in the contract in full text.



John M. McHugh



DEPARTMENT OF THE ARMY  
WASHINGTON DC 20310

APR 17 2007

MEMORANDUM OF DECISION

SUBJECT: Authority Under Public Law 85-804 to Include an Indemnification Clause in Contract No. W911SR-05-D-0008

1. ~~Mason and Hanger Corporation, a subsidiary of Day and Zimmermann, Incorporated, has requested that the U.S. Army include an indemnification clause under Title 50 United States Code (U.S.C.) Section 1431-1435 (Public Law 85-804) in contract W911SR-05-D-0008 for the care, maintenance, surveillance, and safety of Newport Chemical Depot, in accordance with Federal Acquisition Regulation Subpart 50.403-1. The Newport Chemical Depot is a former production facility for chemical agent O-Ethyl S-Diisopropylaminomethyl Methylphosphonothiolate (VX) and explosives Trinitrotoluene and Hexahydro-1,3,5-trinitro-1,3,5-triazine.~~
2. Under contract W911SR-05-D-0008, Mason and Hanger Corporation is responsible for storing, transporting, safeguarding, and monitoring the condition of the tonne containers which house the VX agent and other explosives, propellants or incendiary materials in addition to other base level support functions that may cause the discovery of unknown hazardous substances or materials. Given Mason and Hanger Corporation's role as the operating contractor for this facility and the destructive damaging capabilities of chemical agents, explosives or other incendiary material, a catastrophic incident occurring during the performance of this contract may subject ~~Mason and Hanger Corporation to an enormous financial liability.~~ Mason and Hanger Corporation could also be required, as a result of the lawful performance of its duties as facilities operator, to incur enormous environmental assessment, investigation, response and remediation costs, and legal defense costs associated therewith, under applicable environmental laws and regulations, because of sudden or nonsudden release of contaminants or the threat thereof. Therefore, I find that performance of this contract will subject Mason and Hanger Corporation to certain unusually hazardous risks that are set forth in Enclosure A, Definition of Unusually Hazardous Risks and Limitations on Coverage.
3. I have considered the availability, cost and terms of private insurance to cover these risks, as well as the viability of self-insurance, and have concluded that adequate insurance to cover these unusually hazardous risks is not reasonably available to Mason and Hanger Corporation. On the basis of this review, I find that the use of an indemnification clause in this contract will facilitate the national defense.
4. In view of the foregoing and pursuant to the authority vested in me by Title 50 U.S.C. Section 1431-1435 (Public Law 85-804), and Executive Order 10789, as amended, I hereby authorize the contracting officer to include the indemnification clause as set forth

**SUBJECT: Authority under Public Law 85-804 to include an Indemnification Clause in Contract No. W911SR-05-D-0008**

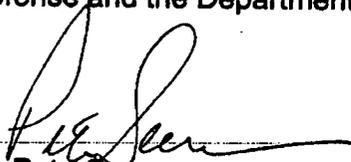
at Federal Acquisition Regulation Subpart 52.250-1, with Alternate I, in contract Number W911SR-05-D-0008 provided that the clause defines the unusually hazardous risks precisely as it is described in Enclosure A, Definition of Unusually Hazardous Risks and Limitations on Coverage.

5. Should it prove necessary, in implementing this Memorandum of Decision, to incorporate language into the contract to clarify, directly or by reference, terms found in the indemnification clause or this Memorandum of Decision with its Enclosures, the contracting officer shall not include any such clarifying language without the prior review and approval of the Deputy Assistant Secretary of the Army (Policy and Procurement).

6. It is not possible to determine the actual or estimated cost to the government as a result of the use of this indemnification clause since the liability of the government, if any, will depend upon the occurrences of incidents described in the statement of unusually hazardous risks.

7. The contractual documents executed pursuant to this authorization shall comply with the requirements of Federal Acquisition Regulation Subparts 28.3 and 50.4 as implemented by the Department of Defense and the Department of the Army.

Encls



Pete Geren

Acting Secretary of the Army

**DEFINITION OF UNUSUALLY HAZARDOUS RISKS AND LIMITATIONS ON  
COVERAGE**

**(a) Definition of Unusually Hazardous Risks**

(1) The risk of exposure to Toxic Chemical Substances during the course of shipment, storage, treatment, use, disposal, transportation, remediation, or other handling (collectively, "Handling") or from the explosion or detonation or discharge or leakage of munitions or other items or components thereof.

(2) The risk of release, including threatened release, whether on-site, or off-site, sudden or nonsudden, of any nerve agents, including VX, during the course of their Handling, provided that such agents were,

(a) Present at or released from the facility prior to the Contractor's operation of, or Handling at the facility, whether known or unknown by the Government or Contractor at such time or,

(b) Introduced into the facility as a result of action by a party other than the Contractor or the Contractor's agents.

(3) The risks of release, including threatened release, whether on-site, or off-site, sudden or nonsudden, of any substance or material (including but not limited to Toxic Chemical Substances and munitions or components of munitions that contain them) but excluding nerve agents, the Handling of which is or becomes regulated under law, during the course of their Handling, provided that such agents, substance or material was either,

(a) Present at or released from the facility prior to the Contractor's operation of, or Handling at the facility, whether known or unknown by the Government or Contractor at such time;

(b) Obtained by or provided to the Contractor for incorporation into Toxic Chemical Substances;

(c) Required by or designated in Government specifications or other relevant technical documentation to support the Handling of Toxic Chemical Substances or products;

(d) Generated by the Contractor's Handling of Toxic Chemical Substances or provided to the Contractor by the Government or its agents for Handling; or

(e) Introduced into the facility as a result of action by a party other than the Contractor or the Contractor's agents.

**(b) Limitations on Coverage**

(1) Notwithstanding any other provision in the indemnification clause and this Enclosure A to the Memorandum of Decision, the Contractor shall not be indemnified against local, state, or federal civil or criminal fines or penalties levied by local, state or federal tribunals, nor shall this clause indemnify the Contractor against the costs of defending, settling, or otherwise participating in any such civil or criminal actions brought in local, state, or federal tribunals.

(2) In the event of a sudden or nonsudden release described in Paragraph a. (3) above, the Contractor shall not be indemnified if the Government can demonstrate that said release was the result of noncompliance (with the actual knowledge of such noncompliance, lack of good faith, or willful misconduct on the part of the Contractor's principal officials) with applicable environmental laws or regulations, unless:

(a) Such noncompliance was specifically directed or authorized by the Contracting Officer;

(b) Such noncompliance followed specific warnings of potential noncompliance or specific instances of potential noncompliance that were reported by the Contractor to the Contracting Officer and necessary authorization or appropriations to correct the conditions were not received from the Government, or although necessary authorizations or appropriations had been received, the Contractor had insufficient time in which to correct the conditions.

**(c) Definitions**

(1) For the purposes of the indemnification clause and this Enclosure A to the Memorandum of Decision, the term "nonsudden release" shall mean a release occurring over a relatively long period of time which involves continuous or repeated environmental exposure arising from the same or similar causes. The term "sudden release" for purposes of the indemnification clause shall mean a release occurring abruptly or instantaneously and continuing for a relatively short period of time, except that any intentional release of substances or materials shall in all events be considered a nonsudden release, even though the period in which the substances or materials are introduced into the environment may be brief.

(2) For the purposes of the indemnification clause and this Enclosure A to the Memorandum of Decision, the term "Toxic Chemical Substances" means the chemicals listed in the List of Lethal Chemical Agents (Newport Site) located at Enclosure B, and their naturally occurring breakdown products, but does not include residues and wastes

produced from the demilitarization process except to the extent that these residues and wastes contain, or are deemed by a court or agency of competent jurisdiction to contain, chemicals from the List of Lethal Chemical Agents (Newport Site).

(d) Nothing in this Enclosure A to the Memorandum of Decision shall be deemed to preclude or prejudice the allowability of costs (subject to the availability of funds) under other applicable contract provisions.

List of Lethal Chemical Agents (Newport Site)

Specific Chemical Agents/Precursors

No.	A. Chemical Agents	CAS Registry Number
(1)	O-Alkyl (C10, incl. Cycloalkyl) alkyl (Me, Et, N-Pr or I-Pr)-phosphonofluoridates e.g. Sarin; O-Isopropyl methylphosphonofluoridate Soman; O-Pinalcolyl methylphosphonofluoridate	107-44-8 96-64-0
(2)	O-Alkyl (C10, incl. Cycloalkyl) N, N-dialkyl (Me, Et, N-Pr or I-Pr) phosphoramidocyanidates e.g. Tabun; O-Ethyl N, N-dimethyl phosphoramidocyanidate	77-81-6
(3)	O-Alkyl (H or C10, incl. Cycloalkyl) S-2-dialkyl (Me, Et, N-Pr)-aminoethyl alkyl (Me, Et, N-Pr or I-Pr) phosphonothiolates and corresponding alkylated or protonated salts e.g. VX; O-Ethyl S-2-diisopropylaminoethyl methyl phosphonothiolate	50782-69-9
(4)	Sulfur mustards 2-Chloroethylchloromethylsulfide Mustard gas; Bis(2-chloroethyl)sulfide Bis(2-chloroethylthio)methane Sesquimustard; 1,2 Bis(2-chloroethylthio)ethane 1,3-Bis(2-chloroethylthio)-n-propane 1,4-Bis(2-chloroethylthio)-n-butane 1,5-Bis(2-chloroethylthio)-n-pentane Bis(2-chloroethylthiomethyl)ether Q-Mustard: Bis(2-chloroethylthioethyl)ether	2625-76-5 505-60-2 63869-13-6 3563-36-8 63905-10-2 not assigned not assigned 63918-90-1 63918-89-8
(5)	Lewisites Lewisite 1: 2-Chlorovinylchloroarsine Lewisite 2: Bis(2-chlorovinyl)chloroarsine Lewisite 3: Tris(2-chlorovinyl)arsine	541-25-3 40334-69-8 40334-70-1
(6)	Nitrogen mustards HN1: Bis(2-chloroethyl)ethylamine HN2: Bis(2-chloroethyl)methylamine HN3: Tris(2-chloroethyl)amine	538-07-8 51-75-2 555-77-1
<b>B. Precursors</b>		
(7)	Alkyl (Me, Et, n-Pr or I-Pr) phosphonyldifluorides e.g. DF; Methylphosphonyldifluoride	676-99-3
(8)	O-Alkyl (H or C10, incl. Cycloalkyl) O-2-dialkyl (Me, Et, n-Pr or I-Pr)-aminoethyl alkyl (Me, Et, n-Pr or I-Pr) phosphonites and corresponding alkylated or protonated salts e.g. QL: O-Ethyl O-2-diisopropylaminoethyl methylphosphonite	57856-11-8
(9)	Chlorosarin: O-Isopropyl methylphosphonochloridate	11445-76-7
(10)	Chlorosoman: O-Pinacolyl methylphosphonochloridate	7040-57-5



SECRETARY OF THE ARMY  
WASHINGTON

22 JAN 2008

MEMORANDUM OF DECISION

SUBJECT: Authorization to Agree to Pay Potential Indemnification Costs Under an Interagency Agreement with the Department of Health and Human Services (DHHS) for the Procurement of ACAM2000™ Smallpox Vaccine

1. Department of Defense Directive (DoDD) 6205.3 designates the Secretary of the Army as the DoD Executive Agent for the biological warfare defense immunization program. The Army's responsibilities under this designation include vaccine acquisition. The vaccine acquisition program is administered by the Joint Program Executive Officer for Chemical and Biological Defense (JPEOCBD).

2. The DoD has a current requirement for approximately 1.0 million doses of smallpox vaccine for force protection purposes, that can be met only through stocks owned by the Centers for Disease Control and Prevention (CDC) of the United States Department of Health and Human Services (DHHS). JPEOCBD intends to procure the required doses through an interagency agreement with the CDC, executed under the authority of the Economy Act, 31 U.S.C 1535. The interagency agreement will encompass the current requirement, and it will provide a procurement framework for up to 12 million doses over a 10 year period.

3. The DHHS possesses legal authority to include indemnification provisions in its contracts in connection with national defense functions (see Executive Order No. 13232, dated October 20, 2001, 66 Federal Register 53941). Based upon this authority, the Secretary of Health and Human Services (HHS) approved, by Memorandum of Decision (MOD) dated September 25, 2003, the inclusion of an indemnification clause in previously-awarded Contract No. 200-2002-00004 with Acambis Inc. for smallpox vaccine. A copy of the DHHS MOD is at Enclosure 1, and it is incorporated by reference into this MOD. Smallpox vaccine that the CDC will provide to the JPEOCBD was procured from Acambis Inc. under the now-indemnified contract.

4. The DHHS indemnification is broad in scope. It encompasses "all risks arising out of or related to the development, manufacture, testing, labeling, packaging, storage, transportation, sale, use, administration, or, if directed by the Government under the Contract, disposal, of all Vaccine associated with the Contract," and it includes risks "relating to, or arising from alleged: (1) adverse events associated with the Vaccine; (2) failure of the Vaccine to provide immunological effect; (3) transmission of the vaccinia virus; and (4) release of the Vaccine into the environment." "Vaccine" is defined to include the vaccine itself, as well as its labeling, packaging, diluent, needles, and any of their respective components and any material derived from the vaccine. The indemnification applies to Acambis Inc., its subsidiaries, divisions, and organizational

**SUBJECT: Authorization to Agree to Pay Potential Indemnification Costs Under an Interagency Agreement with the Department of Health and Human Services (DHHS) for the Procurement of ACAM2000™ Smallpox Vaccine**

units, and any of Acambis' predecessor entities, together with their officers, directors, employees, agents, successors and assigns. The indemnification provision does not specify a monetary cap and, therefore, subjects the DHHS to a potentially large but undetermined contingent liability. It also does not specify a time limit on claims.

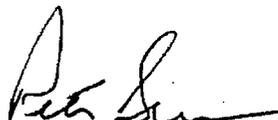
5. The possibility exists that the DHHS could receive indemnification claims in connection with vaccine provided to the Army under the pending interagency acquisition. For this reason, the DHHS requests, as a condition of providing the vaccine, that the DoD agree to reimburse it for any indemnification costs that arise in connection with vaccine transferred under the interagency agreement. The proposed clause to address the DHHS request is as follows:

Pursuant to title 50, United States Code, section 1431, Executive Order 10789, as amended, and title 31 United States Code, section 1535, the Department of Defense (DoD) agrees to assume all liability for its use of smallpox vaccine acquired under this Economy Act order to the same extent that the Department of Health and Human Services (DHHS) previously agreed to indemnify Acambis Inc. in connection with the production of, or any other action concerning, vaccine procured under DHHS Contract No. 200-2002-00004. In the event that Acambis Inc. requests indemnification in connection with vaccine provided to the DoD under this Economy Act order, the DHHS and the DoD shall conduct a joint evaluation to determine whether any payment is appropriate, and the DoD shall reimburse the DHHS in the amount of any payments made to Acambis Inc.

6. In view of the DoD's requirement for smallpox vaccine for force protection purposes, I determine that the inclusion of the above clause in the interagency agreement with DHHS will facilitate the national defense. I also have considered the authority provided under the Subtitle G of Title VIII of the Homeland Security Act of 2002, Public Law 107-296, and I determine that the inclusion of the above clause in the interagency agreement with DHHS is necessary for the timely and effective conduct of United States military activities. Based upon these considerations and the circumstances described in the DHHS MOD, I hereby approve the inclusion of the above-stated clause, or substantially similar text, in the interagency agreement with the DHHS. Any indemnification costs, attributable to vaccine provided under this Economy Act order, and determined to be just and reasonable in accordance with the indemnification clause in the DHHS's contract with Acambis Inc. (Federal Acquisition Regulation 52.250-1), shall be treated as part of the actual cost of providing the DoD with vaccine and paid to the DHHS pursuant to the Economy Act, 31 U.S.C 1535.

**SUBJECT: Authorization to Agree to Pay Potential Indemnification Costs Under an Interagency Agreement with the Department of Health and Human Services (DHHS) for the Procurement of ACAM2000™ Smallpox Vaccine**

7. This MOD presently applies only to vaccine procured under DHHS Contract No. 200-2002-00004. This MOD may be amended should the Secretary of Health and Human Services authorize the inclusion of an indemnification clause in a follow-on contract for additional smallpox vaccine that may be provided to the DoD pursuant to the pending interagency agreement.



Pete Geren



SECRETARY OF THE ARMY  
WASHINGTON

10 NOV 2005

AMENDED MEMORANDUM OF DECISION

SUBJECT: Amendment One to Memorandum of Decision—Authority Under Public Law 85-804 and Executive Order 10789, as Amended, to Include an Indemnification Clause in Contract No. W9113M-04-D-0002

1. Memorandum of Decision (MoD), subject: Authority Under Public Law 85-804 and Executive Order 10789, as Amended, to Include an Indemnification Clause in Contract No. W9113M-04-D-0002, dated September 28, 2004 ("September 28, 2004 MoD"), applied only to anthrax vaccine adsorbed (AVA) procured under Contract No. W9113M-04-D-0002 for distribution to Department of Defense (DoD) personnel or for support of DoD operations worldwide (Enclosure 1). On September 13, 2005, Director, Office of Management and Budget (OMB) approved the U.S. Army's request to extend indemnification coverage under this contract to AVA provided to other Federal agencies (Enclosure 2).

2. I hereby determine that the facts and circumstances supporting the September 28, 2004 MoD remain valid, and that the use of an indemnification clause in Contract No. W9113M-04-D-0002 continues to facilitate the national defense and is necessary for the timely and effective conduct of United States military or intelligence activities. Based upon OMB's September 13, 2005 approval, the September 28, 2004 MoD is hereby amended to apply to all AVA procured under Contract No. W9113M-04-D-0002. As stated in OMB's September 13, 2005 approval, Contract No. W9113M-04-D-0002 will require BioPort to seek coverage under the Support Anti-Terrorism by Fostering Effective Technologies Act, Title 6, United States Code, sections 441-444. With the exception of its last paragraph, all terms and conditions of the September 28, 2004 MoD, to include the "Definition of Unusually Hazardous Risks and Limitations On Coverage" (Enclosure 3), remain unchanged and are incorporated by reference into this amended MoD.

3. The contractual documents executed pursuant to this authorization will comply with Federal Acquisition Regulation (FAR) Subpart 50.4. Contract No. W9113M-04-D-0002 will incorporate this amended MoD in its entirety, and the amended MoD will be annotated in the contract to refer to the indemnification clause at FAR 52.250-1, that will be included in full text.

  
Francis J. Harvey

Enclosures



DEPARTMENT OF THE ARMY  
WASHINGTON, DC

SEP 28 2004



MEMORANDUM OF DECISION

SUBJECT: Authority Under Public Law 85-804 and Executive Order 10789, as Amended, to Include an Indemnification Clause in Contract No. W9113M-04-D-0002

BioPort Corporation (BioPort) has requested that the Department of the Army include an indemnification clause under Title 50 United States Code (U.S.C.), Section 1431-1435 (Public Law 85-804) in Contract No. W9113M-04-D-0002 for Anthrax Vaccine Adsorbed (AVA).

Under Contract No. W9113M-04-D-0002, awarded on January 2, 2004, BioPort is responsible for the manufacturing, testing, bottling, and storing of AVA. These activities require interaction with one of the most lethal biological agents known to man. In addition to risks surrounding actual manufacture of the vaccine, the delivery of AVA for use by the Department of Defense presents opportunity for allegations of adverse reactions and litigation by anti-vaccine groups. Despite the Food and Drug Administration's January 5, 2004 final order that "the licensed anthrax vaccine, Anthrax Vaccine Adsorbed, is safe and effective for the prevention of anthrax disease - regardless of the route of exposure," there continues to be significant litigation alleging adverse reactions to the vaccine. In light of these concerns, I find that performance of Contract No. W9113M-04-D-0002 subjects BioPort to certain unusually hazardous risks, as set forth in Tab A, Definition of Unusually Hazardous Risks and Limitations on Coverage.

In evaluating BioPort's indemnification request, I have considered the availability, cost and terms of private insurance to cover these risks, as well as the viability of self-insurance, and have concluded that adequate insurance to cover these unusually hazardous risks is not reasonably available to BioPort Corporation. I have also considered BioPort Corporation's program of worker's compensation insurance.

BioPort is the nation's sole producer of Food and Drug Administration-licensed AVA, a product that is required by the Department of Defense (DoD) to ensure personnel readiness, and affording BioPort protection from significant litigation-related financial exposure logically helps it remain in business. For this reason, I determine that the use of an indemnification clause in this contract will facilitate the national defense. Consistent with section 25(a) of Executive Order 10789, I also have considered the authority provided under subtitle G of title VIII of the Homeland Security Act of 2002, Public Law 107-296, and I determine that use of an indemnification clause is necessary for the timely and effective conduct of United States military or intelligence activities.

In view of the foregoing, I hereby authorize the contracting officer to amend Contract No. W9113M-04-D-0002, without additional consideration, to include the indemnification clause set forth at Federal Acquisition Regulation (FAR) 52.250-1, provided that the clause defines the unusually hazardous risks precisely as they are

described at Tab A of this Memorandum of Decision (MOD), entitled Definition of Unusually Hazardous Risks and Limitations on Coverage.

As permitted by FAR 50.403-2(d)(2) and FAR Clause 52.250-1, and where justified by the circumstances, I authorize the contracting officer to permit BioPort to provide for indemnification of its first and second-tier subcontractors, provided that the indemnification is limited to the unusually hazardous risks defined in this MOD, and provided that the contracting officer approves BioPort's request for subcontractor indemnification in writing. In addition to these requirements, the contracting officer may approve the indemnification of second-tier subcontractors only if she determines in writing that critical supplies or services are not reasonably available without such indemnification.

Should it prove necessary in implementing this MOD to insert language into the contract to clarify, directly or by reference, terms found in the indemnification clause or this MOD with its Tab A, the contracting officer shall not utilize any such clarifying language without the prior review and approval of the Deputy Assistant Secretary of the Army (Policy and Procurement).

It is not possible to determine the actual or estimated cost to the Government as a result of the use of this indemnification clause since the liability of the Government, if any, will depend upon the occurrences of incidents described in the Definition of Unusually Hazardous Risks and Limitations on Coverage.

The contractual documents executed pursuant to this authorization shall comply with FAR Subpart 50.4. Contract No. W9113M-04-D-0002 shall incorporate this MOD in its entirety, and the MOD shall be annotated in the contract to refer to the indemnification clause at FAR 52.250-1, that shall be included in full text.

This MOD, including TAB A, applies to the maximum quantity of AVA that may be procured under Contract No. W9113M-04-D-0002 for distribution to DoD personnel or for support of DoD operations worldwide. I recognize that, subject to the DoD's requirements and the contract's maximum quantity limitations, other Federal agencies may wish to obtain AVA, pursuant to the Economy Act, Title 31 U.S.C. Section 1535. At the present time, this MOD does not apply to AVA procured by the Army on behalf of the DoD for these other governmental agencies. Consistent with Section 25(b) of Executive Order 10789, as amended, the Army will seek approval of the Director of the Office of Management and Budget (OMB) prior to exercising indemnification authority with respect to such AVA. Should OMB grant such approval, this MOD shall be modified accordingly.



R. L. Brownlee  
Acting Secretary of the Army

SEP 28 2004

## TAB A

### DEFINITION OF UNUSUALLY HAZARDOUS RISKS AND LIMITATIONS ON COVERAGE

#### a. Definition of Unusually Hazardous Risks.

Release (or alleged release) of an infectious agent or toxic material into the environment in connection with activities undertaken pursuant to the contract that results (or allegedly results), either directly or indirectly, in human exposure to or environmental damage by an infectious material or toxic material involved with the production or testing of vaccines pursuant to the contract. Such activities may include, but are not limited to: (1) storage, use, testing, or handling of the live vaccine products, their intermediate precursors or infectious agents or toxins that are used as challenge materials for test of the products or intermediates; (2) transportation of such substances; and (3) disposal of such substances.

Adverse reaction (or alleged adverse reaction) in a human from administration of a vaccine or other material used in the production or testing of the vaccine, in conjunction with or as a result of the performance of the contract, or administration of a vaccine produced, tested, or delivered under the contract.

The term adverse reaction includes anaphylaxis and other foreseeable and unforeseeable adverse reactions. Such reactions include, but are not limited to: (1) reactions directly attributable to and resulting from the administration of the vaccine or other material involved with the vaccine production or testing (to include challenge materials); (2) reactions that manifest long after exposure, but which are directly attributable to and resulting from the administration of the vaccine or other material involved with the production, or testing of the vaccine; (3) the failure of the vaccine to perform as intended or otherwise confer immunity; or (4) performance by the vaccine in a manner not intended.

#### b. Limitations on Coverage.

Notwithstanding any other provision in the indemnification clause or Memorandum of Decision, BioPort Corporation and its subcontractors shall not be indemnified against grossly negligent or criminal behavior on the part of BioPort Corporation's or its subcontractors' directors, officers, or managers who have supervision over, or direction of, all or substantially all of the operations at any one plant or separate locations where the contract or a subcontract is being performed.



SECRETARY OF THE ARMY  
WASHINGTON DC 20310

03 APR 2006

## MEMORANDUM OF DECISION

SUBJECT: Authority under Public Law 85-804 to Include an Indemnification Clause in Contract No. DAAA09-03-D-0023

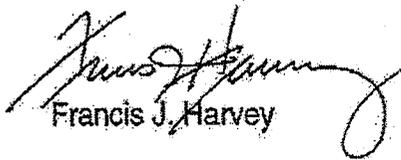
1. In accordance with Federal Acquisition Regulation (FAR) 50.403-1, Bechtel Parsons Blue Grass (BPBG) has requested that, pursuant to authority provided in Public Law 85-804, the Army include an indemnification clause in its Contract No. DAAA09-03-D-0023 and all subsequent Delivery and Task Orders issued thereunder for the design, construction, equipment acquisition and installation, systemization, pilot testing, operations, maintenance and closure of the Blue Grass Chemical Agent Destruction Pilot Plant (BGCAPP), Richmond, Kentucky.
2. Under this contract, BPBG is responsible for all facets of the process to dispose of chemical agent stored at the Blue Grass Chemical Depot, Richmond, Kentucky. The potential for hazardous events exists during every phase of this contract. Upon review of the functions and responsibilities that BPBG will have, I find that execution of such will subject the contractor to certain unusually hazardous risks which are defined in the Definition of Unusually Hazardous Risks (Enclosure).
3. I have considered the availability, costs, and terms of private insurance to cover these risks, as well as the viability of self-insurance, and have concluded that adequate insurance to cover the unusually hazardous risks is not reasonably available.
4. It is not possible to determine the actual or estimated cost to the Government as a result of the use of an indemnification clause since the liability of the Government, if any, will depend upon the occurrence of an incident related to the performance of the contract.
5. I find that the use of an indemnification clause in the contract will facilitate the national defense.
6. In view of the foregoing and pursuant to the authority vested in me by Public Law 85-804 (Title 50 United States Code 1431-1436) and Executive Order 10789, as amended, I hereby authorize the inclusion of the indemnification clause prescribed in FAR 52.250-1, with its Alternate 1, in Contract No. DAAA09-03-D-0023 for the BGCAPP, provided the clause defines the unusually hazardous risks and includes the limitations on coverage precisely as described in the enclosed definition. I further authorize its inclusion in subcontracts at any tier under this contract, provided the pass-through

AH. 054

SUBJECT: Authority Under Public Law 85-804 to Include an Indemnification Clause in Contract No. DAAA09-03-D-0023 .

indemnification is limited to the defined unusually hazardous risks and provided that the Contracting Officer approves each pass-through indemnification in writing.

7. The contractual document executed pursuant to this authorization shall comply with the requirements of FAR Subpart 50.4 and 28.3, as implemented by the Department of Defense and the Department of the Army.



Francis J. Harvey

Enclosure

## Definition of Unusually Hazardous Risks

### 1. The risks of:

a. Sudden or slow release of, and exposure to, lethal chemical agents during the disposal of stockpiles of chemical munitions, mines or other forms of weapons-related containerization and during facility decommissioning and closure.

b. Explosion, detonation or combustion of explosives, propellants or incendiary materials during the course of disposal of stockpiles or chemical munitions, mines or other forms of weapons-related containerization.

c. Contamination present at or released from the installation prior to the contractor's construction or operation of the chemical demilitarization facility, whether known or unknown by the government or contractor at such time.

d. Contamination resulting from the activities of third parties when the contractor has no control over such activities or parties.

e. Contamination resulting from the placement of components and materials from decommissioning and placement of wastes and residues from demilitarization, destruction, or closure in accordance with the contract and all applicable laws and regulations.

2. Provided that the indemnification clause shall in no way indemnify the contractor against local, state or federal civil or criminal fines or penalties levied by local, state or federal tribunals, nor shall this clause indemnify the contractor against the costs of defending, settling or otherwise participating in such civil or criminal actions brought in local, state or federal tribunals.

3. The term "lethal chemical agents" for purpose of this clause shall mean the chemicals in the attached list and their naturally occurring breakdown products but does not include residues and wastes produced from the demilitarization process except to the extent that these residues and wastes contain, or are deemed by a court or agency of competent jurisdiction to contain chemicals from the attached list and their naturally occurring breakdown products.

4. The term "disposal", for purpose of this clause, includes the reconfiguration, destruction or demilitarization and interim storage and movement of chemical munitions, mines or other forms of weapons-related containerization, decontamination of equipment and facilities, and the transportation and placement of wastes and residues from reconfiguration, destruction or demilitarization.

5. The term "damage to property" in this clause shall include costs of monitoring, investigation, removal, response and remediation for property (to include groundwater) due to the risks above once certification of closure in accordance with the closure plan has

been accepted by the State or the Environmental Protection Agency, and contract performance has been completed and accepted by the Army.

## List of Lethal Chemical Agents

No	A. Chemical Agents	CAS Registry
1	O-Alkyl (C10, incl. Cycloalkyl) alkyl (Me, Et, N-Pr or I-Pr) – phosphonofluoridates e.g., Sarin; O-Isopropyl methylphosphonofluoridate Soman; O-Pinacolyl methylphosphonofluoridate	107-44-8 96-64-0
2	O-Alkyl (C 10, incl. Cycloalkyl) N, N-dialkyl (Me, Et, N-Pr or I-Pr) phosphoramidocyanidates e.g., Tabun; O-Ethyl N, N-dimethyl phosphoramidocyanidate	77-81-6
3	O-Alkyl (H or C 10, incl. Cycloalkyl) S-2-dialkyl (Me, Et, N-Pr)-aminoethyl alkyl (Me, Et, N-Pr or I-Pr) phosphonothiolates and corresponding alkylated or protonated salts e.g., VX; O-Ethyl S-2- diisopropylaminoethyl methyl phosphonothiolate	50782-69-9
4	Sulfur mustards 2-Chloroethylchloromethylsulfide Mustard gas; Bis(2-chloroethyl)sulfide Bis(2-chloroethylthio)methane Sesquimustard; 1,2 Bis(2-chloroethylthio)ethane 1,3-Bis(2-chloroethylthio)-n-propane 1,4-Bis(2-chloroethylthio)-n-butane 1,5-Bis(2-chloroethylthio)-n-pentane Bis(2-chloroethylthiomethyl)ether Q-Mustard: Bis(2-chloroethylthioethyl)ether	2625-76-5 505-60-2 63869-13-6 3563-36-8 63905-10-2 not assigned not assigned 63918-90-1 63918-89-8
5	Lewisites Lewisite 1: 2-Chlorovinyl dichloroarsine Lewisite 2: Bis(2-chlorovinyl)chloroarsine Lewisite 3: Tris(2-chlorovinyl)arsine	541-25-3 40334-69-8 40334-70-1
6	Nitrogen Mustards HN1: Bis(2-chloroethyl)ethylamine HN2: Bis(2-chloroethyl)methylamine HN3: Tris(2-chloroethyl)amine	538-07-8 51-75-2 555-77-1
<b>B. Precursors</b>		
7	Alkyl (Me, Et, n-PR or I-Pr) phosphonyl difluorides e.g., DF; Methylphosphonyl difluoride	676-99-3
8	O-Alkyl (H or C 10, incl. Cycloalkyl) O-2-dialkyl (Me, Et, n-PR or I-Pr)-aminoethyl alkyl (Me, Et, n-PR or I-Pr) phosphonites and corresponding alkylated or protonated salts e.g., QL; O-Ethyl O-2- diisopropylaminoethyl methylphosphonite	57856-11-8
9	Chlorosarin: O-Isopropyl methylphosphonochloridate	11445-76-7
10	Chlorosoman: O-Pinacolyl methylphosphonochloridate	7040-57-5



03 APR 2006

## MEMORANDUM OF DECISION

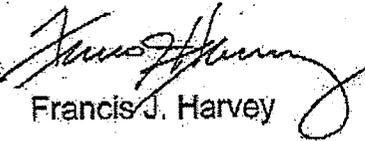
SUBJECT: Authority Under Public Law 85-804 to Include an Indemnification Clause in Contract No. DAAA09-02-D-0025

1. In accordance with Federal Acquisition Regulation (FAR) 50.403-1, Bechtel National, Incorporated (BNI) has requested that, pursuant to authority provided in Public Law 85-804, the U.S. Army include an indemnification clause in its Contract No. DAAA09-02-D-0025 and all Delivery and Task Orders thereunder for the design, construction, equipment acquisition and installation, systemization, pilot testing, operations, maintenance, and closure of the Pueblo Chemical Agent Destruction Pilot Plant (PCAPP), Pueblo, Colorado.
2. Under this contract, BNI is responsible for all facets of the process to dispose of chemical agent stored at the Pueblo Chemical Depot, Pueblo, Colorado. The potential for hazardous events exists during every phase of this contract. Upon review of the functions and responsibilities that BNI will have, I find that execution of such will subject the contractor to certain unusually hazardous risks which are defined in the Definition of Unusually Hazardous Risks (Enclosure).
3. I have considered the availability, costs, and terms of private insurance to cover these risks, as well as the viability of self-insurance, and have concluded that adequate insurance to cover the unusually hazardous risks is not reasonably available.
4. It is not possible to determine the actual or estimated cost to the Government as a result of the use of an indemnification clause since the liability of the Government, if any, will depend upon the occurrence of an incident related to the performance of the contract.
5. I find that the use of an indemnification clause in the contract will facilitate the national defense.
6. In view of the foregoing and pursuant to the authority vested in me by Public Law 85-804 (Title 50 United States Code 1431-1436) and Executive Order 10789, as amended, I hereby authorize the inclusion of the indemnification clause prescribed in FAR 52.250-1, with its Alternate 1, in Contract No. DAAA09-02-D-0025 for the Pueblo Chemical Agent Destruction Pilot Plant (PCAPP), provided the clause defines the unusually hazardous risks and includes the limitations on coverage precisely as described in the enclosed definition. I further authorize its inclusion in subcontracts (at any tier) under this contract, provided the pass-through indemnification is limited to the

SUBJECT: Authority Under Public Law 85-804 to Include an Indemnification Clause in Contract No. DAAA09-02-D-0025

defined unusually hazardous risks and provided that the Contracting Officer approves each pass-through indemnification in writing.

7. The contractual document executed pursuant to this authorization will comply with the requirements of FAR Subpart 50.4 and 28.3, as implemented by the Department of Defense and the Department of the Army.

  
Francis J. Harvey

Enclosure

## Definition of Unusually Hazardous Risks

### 1. The risks of:

a. Sudden or slow release of, and exposure to, lethal chemical agents during the disposal of stockpiles of chemical munitions, mines or other forms of weapons-related containerization and during facility decommissioning and closure.

b. Explosion, detonation or combustion of explosives, propellants or incendiary materials during the course of disposal of stockpiles or chemical munitions, mines or other forms of weapons-related containerization.

c. Contamination present at or released from the installation prior to the contractor's construction or operation of the chemical demilitarization facility, whether known or unknown by the government or contractor at such time.

d. Contamination resulting from the activities of third parties when the contractor has no control over such activities or parties.

e. Contamination resulting from the placement of components and materials from decommissioning and placement of wastes and residues from demilitarization, destruction, or closure in accordance with the contract and all applicable laws and regulations.

2. Provided that the indemnification clause will in no way indemnify the contractor against local, state or federal civil or criminal fines or penalties levied by local, state or federal tribunals, nor will this clause indemnify the contractor against the costs of defending, settling or otherwise participating in such civil or criminal actions brought in local, state or federal tribunals.

3. The term "lethal chemical agents" for purpose of this clause will mean the chemicals in the enclosed list and their naturally occurring breakdown products but does not include residues and wastes produced from the demilitarization process except to the extent that these residues and wastes contain, or are deemed by a court or agency of competent jurisdiction to contain chemicals from the enclosed list and their naturally occurring breakdown products.

4. The term "disposal", for purpose of this clause, includes the reconfiguration, destruction or demilitarization and interim storage and movement of chemical munitions, mines or other forms of weapons-related containerization, decontamination of equipment and facilities, and the transportation and placement of wastes and residues from reconfiguration, destruction or demilitarization.

5. The term "damage to property" in this clause will include costs of monitoring, investigation, removal, response and remediation for property (to include groundwater) due to the risks above once certification of closure in accordance with the closure plan has been accepted by the State or the Environmental Protection Agency, and contract performance has been completed and accepted by the U.S. Army.

List of Lethal Chemical Agents

No	A. Chemical Agents	CAS Registry
1	O-Alkyl (C10, incl. Cycloalkyl) alkyl (Me, Et, N-Pr or I-Pr) – phosphonoflouridates e.g., Sarin; O-Isopropyl methylphosphonoflouridate Soman; O-Pinalcolyl methylphosphonoflouridate	107-44-8 96-64-0
2	O-Alkyl (C 10, incl. Cycloalkyl) N, N-dialkyl (Me, Et, N-Pr or I-Pr) phosphoramidocyanidates e.g., Tabun; O-Ethyl N, N-dimethyl phosphoramidocyanidate	77-81-6
3	O-Alkyl (H or C 10, incl. Cycloalkyl) S-2-dialkyl (Me, Et, N-Pr)-aminoethyl alkyl (Me, Et, N-Pr or I-Pr) phosphonothiolates and corresponding alkylated or protonated salts e.g., VX; O-Ethyl S-2- diisopropylaminoethyl methyl phosphonothiolate	50782-69-9
4	Sulfur mustards 2-Chloroethylchloromethylsulfide Mustard gas; Bis(2-chloroethyl)sulfide Bis(2-chloroethylthio)methane Sesquimustard: 1,2 Bis(2-chloroethylthio)ethane 1,3-Bis(2-chloroethylthio)-n-propane 1,4-Bis(2-chloroethylthio)-n-butane 1,5-Bis(2-chloroethylthio)-n-pentane Bis(2-chloroethylthiomethyl)ether Q-Mustard: Bis(2-chloroethylthioethyl)ether	2625-76-5 505-60-2 63869-13-6 3563-36-8 63905-10-2 not assigned not assigned 63918-90-1 63918-89-8
5	Lewisites Lewisite 1: 2-Chlorovinyl dichloroarsine Lewisite 2: Bis(2-chlorovinyl)chloroarsine Lewisite 3: Tris(2-chlorovinyl)arsine	541-25-3 40334-69-8 40334-70-1
6	Nitrogen Mustards HN1: Bis(2-chloroethyl)ethylamine HN2: Bis(2-chloroethyl)methylamine HN3: Tris(2-chloroethyl)amine	538-07-8 51-75-2 555-77-1
<u>B. Precursors</u>		
7	Alkyl (Me, Et, n-PR or I-Pr) phosphonyl diflourides e.g., DF; Methylphosphonyl chlflouride	676-99-3
8	O-Alkyl (H or C 10, incl. Cycloalkyl) O-2-dialkyl (Me, Et, n-PR or I-Pr)-aminoethyl alkyl (Me, Et, n-PR or I-Pr) phosphonites and corresponding adkylated or protonated salts e.g., QL: O-Ethyl O-2-diisopropylaminoethyl methylphosphonite	57856-11-8
9	Chlorosarin: O-Isopropyl methylphosphonochloddate	11445-76-7
10	Chlorosoman: O-Pinacolyl methylphosphonochloridate	7040-57-5



**SECRETARY OF THE ARMY  
WASHINGTON**

**JAN 05 2009**

**MEMORANDUM OF DECISION**

**SUBJECT: Authority Under Public Law (P.L.) 85-804 and Executive Order 10789, as amended, to Approve Indemnification for Additional Work in Contract DACA87-89-C-0076 with EG&G Defense Materials, Incorporated (Inc.)**

- 1. In accordance with the Federal Acquisition Regulation (FAR) 50.104-3(a), EG&G Defense Materials, Inc. EG&G has requested that, pursuant to authority provided in P.L. 85-804, the U.S. Army approve indemnification for additional work that has been added to contract DACA87-89-C-0076 for the Tooele Chemical Agent Disposal Facility (TOCDF), Tooele, Utah in September 2008. This additional work includes the closure of the Chemical Agent Munitions Disposal System (CAMDS) and disposal of CAMDS and Deseret Chemical Depot (DCD) wastes.**
- 2. On September 6, 1989, the U.S. Army awarded contract DACA87-89-C-0076 to EG&G for the site preparation, construction, systemization, operation, maintenance, and decommission of the TOCDF Facility, at Tooele Army Depot (TAD), Tooele, Utah. The purpose of the facility is to demilitarize the chemical weapons stockpile stored at TAD. In a Memorandum of Decision (MOD) signed by the Secretary of the Army (SA) on March 27, 1992, the SA concluded that, given the tremendous lethal potential of chemical weapons, a catastrophic incident involving the facility may subject EG&G to enormous financial liability and thus performance of the contract would subject EG&G to unusually hazardous risks, as defined in the enclosure to the memorandum. In the MOD, the SA authorized the contracting officer to include the indemnification clause Federal Acquisition Regulation (FAR) 52.250-1, Alternate I, Indemnification Under P.L. 85-804, in contract DACA87-89-C-0076. The contract was modified to include the indemnification clause in Modification P00048, dated May 21, 1992.**
- 3. In Modification P00356, dated September 23, 2008, closure of the CAMDS and disposal of CAMDS and DCD wastes were added to the requirements of the TOCDF contract. The CAMDS facility is also located at TAD, now known as the DCD. The CAMDS facility was designed and built as the primary test and development facility for the Nation's chemical stockpile disposal program and was used to destroy more than 39,000 chemical agent filled munitions. Since the CAMDS has completed its mission, it must now be decommissioned and closed to fulfill U.S. treaty obligations, as well as environmental laws and regulations. The DCD wastes were generated as a result of storage and maintenance of the chemical agent stockpile located at DCD and must also be disposed. The closure of CAMDS and disposal of CAMDS and DCD wastes will present EG&G with unusually hazardous risks that are very similar to those associated with the current TOCDF effort. EG&G is requesting indemnification utilizing the same definition of unusually hazardous risks for CAMDS closure and disposal of CAMDS and DCD waste which is currently included in contract DACA87-89-C-0076. The proposed definition reflects the administrative name change from TAD to DCD. Upon review of**

**SUBJECT: Authority Under Public Law (P.L.) 85-804 and Executive Order 10789, as amended, to Approve Indemnification for Additional Work in Contract DACA87-89-C-0076 with EG&G Defense Materials, Incorporated (Inc.)**

functions and responsibilities that EG&G will have for CAMDS closure and disposal of CAMDS and DCD wastes, I find that execution of such will subject the contractor to certain unusually hazardous risks.

4. I have considered the availability, cost and terms of private insurance to cover these risks, as well as the viability of self-insurance, and have concluded that adequate insurance to cover the unusually hazardous risks is not reasonably available.
5. It is not possible to determine the actual or estimated cost to the Government as a result of the use of an indemnification clause since the liability of the Government, if any, will depend upon the occurrence of an incident related to the performance of the contract.
6. I find that modification of the existing contract to include indemnification for the closure of CAMDS and disposal of CAMDS and DCD wastes will facilitate the national defense.
7. In view of the foregoing and pursuant to the authority vested in me by P.L. 85-804 (Title 50 United States Code Sections 1431-1436) and Executive Order 10789, as amended, I hereby authorize the contracting officer to execute a contract modification to extend the indemnification clause (FAR 52.250-1 with its Alternate I) coverage in contract DACA87-89-C-0076 to include closure of the CAMDS and disposal of CAMDS and DCD wastes, provided the clause defines the unusually hazardous risks and includes the limitations on coverage precisely as described in the enclosed definition. I further authorize its modification and/or inclusion in existing and/or new subcontracts (at any tier) under this contract, provided the pass-through indemnification is limited to the defined unusually hazardous risks and provided that the Contracting Officer approves each pass-through indemnification in writing.
8. The indemnification clause shall in no way indemnify the contractor against local, state, or federal civil or criminal fines or penalties levied by local, state, or federal tribunals, nor shall this clause indemnify the contractor against the costs of defending, settling or otherwise participating in such civil or criminal actions brought in local, state, or federal tribunals.

**SUBJECT: Authority Under Public Law (P.L.) 85-804 and Executive Order 10789, as amended, to Approve Indemnification for Additional Work in Contract DACA87-89-C-0076 with EG&G Defense Materials, Incorporated (Inc.)**

**9. The contractual document executed pursuant to this authorization shall comply with the requirements of FAR Subpart 50.1 and 28.3, as implemented by the Department of Defense and the Department of the Army.**



**Pete Geren**

**Encl**