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June 18, 2012

Via Electronic Mail

Michael Rithmire
Office of National Security and Technology Transfer Controls
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Ave. Room H4514
Washington, D.C. 20230

RE: Proposed Revisions to the Export Administration Regulations: Control of Energetic Materials and Related Articles that the President Determines No Longer Warrant Control Under the United States Munitions List

Dear Mr. Rithmire:

Sigma-Aldrich Corporation ("SIAL") appreciates the opportunity to comment upon the proposed revisions to the Export Administration Regulations ("EAR"): Control of Energetic Materials and Related Articles that the President Determines No Longer Warrant Control under the United States Munitions List, published in the Federal Register (77 Fed. Reg. 25932) on May 2, 2012 (the "Proposed Rule"). This Proposed Rule has been published in conjunction with a proposed rule from the Department of State, Directorate of Defense Trade Controls, which would amend the list of articles controlled by U.S. Munitions List ("USML") Category V.

SIAL is a leading life science and high technology company. Our chemical and biochemical products and kits are used in scientific research, including genomic and proteomic research, biotechnology, pharmaceutical development, the diagnosis of disease and as key components in pharmaceutical, diagnostic and other high technology manufacturing.

SIAL commends the U.S. Government's efforts to amend the U.S. Munitions List ("USML"), Category V, and its related controls within the Commerce Control List ("CCL"). We agree with the view expressed in the preamble to the Proposed Rule that such changes would enhance national security by, among others, "permitting the U.S. government to focus its resources on controlling, monitoring, investigating, analyzing, and if need be, prohibiting exports and reesxports of more significant items to destinations, end users and end uses of greater concern than NATO allies and other multi-regime partners."

With this in mind, SIAL requests that the Department of Commerce consider revising its Proposed Rule to capture certain additional items that we have suggested to the Department of State ought to be removed from USML Category V. Specifically, SIAL recommends that Certified Reference Standards, Certified Reference Materials and Standard Reference Materials (referred to collectively as "CRS") that contain trace amounts of certain chemicals controlled by USML Category V be removed from USML Category V and controlled under the CCL. We recommend creating a new ECCN 1C994 as the best option for controlling these CRS; alternatively, we suggest capturing them explicitly under the newly proposed ECCN 1C608.

SIAL offers the following comments with respect to these recommended changes that we consider to be most critical:

CRS with Trace Amounts of USML Category V Chemicals Should be Controlled by the CCL

CRS that contain less than 0.5 grams total quantity of one or more USML Category V chemicals, when such amount comprises less than or equal to 1% of the total quantity of the CRS, should be specifically excepted from control under the ITAR and instead should be controlled for export under the CCL.

CRS are most often used as reference materials in analytical laboratories. By definition, a CRS covered under this proposed change lacks explosive properties and is not designed or intended to be used as an explosive. In essence, the function of a CRS is to test a piece of equipment to ensure that the equipment can detect the known material (here explosives) contained in the CRS, so that when an unknown sample (such as soil or water) is tested on the equipment, the equipment can compare the contents of the unknown sample against known CRS previously used to calibrate the equipment. For this calibration to work, each CRS contains a trace amount of the material that the equipment will be used to detect so as to calibrate the equipment to ensure it is working properly for detection of such materials.

Recommended Creation of New ECCN 1C994 to Control CRS Removed from USML

> ***Proposed text of new ECCN created for CRS containing certain trace chemicals under USML Cat V: ECCN 1C994***
>
> 1C994: *Certified Reference Standards, Certified Reference Materials and Standard Reference Materials which item is a mixture or compound that contains less than 0.5 grams total quantity of one or more USML Category V chemicals and such amount comprises less than or equal to1% of the total quantity of the Certified Reference Standard, Certified Research Material or Standard Reference Material, and where such items lack explosive characteristics.*

SIAL suggests that these CRS containing trace amounts of USML Category V materials, once removed from the USML, be controlled by a new ECCN Category: 1C994. We recommend that this new ECCN 1C994 have controls parallel to those in ECCN 1C995; hence, it would be controlled for Anti-Terrorism purposes and for Regional Stability reasons for export or reexport to Iraq, or transfer within Iraq. We believe controls parallel to those in ECCN 1C995 are appropriate given the nature of CRS, the amount of Category V materials contained in each and the non-explosive nature of the CRS. Removal of these from the USML and subsequent control of them pursuant to AT1 and RS for Iraq would not create national security risks. To the contrary, removing CRS from the USML would promote the underlying goal of export control reform of building higher walls around fewer items that truly warrant substantial controls.

For the aforementioned reasons, SIAL suggested in its comments to DDTC to revise the proposed text of USML Category V to include the following additional interpretation in a new subsection V(k)(6):

> *Certified Reference Standards, Certified Reference Materials and Standard Reference Materials are not controlled under this Category V where such item is a mixture or compound of non-controlled and controlled items if it contains less than 0.5 grams total quantity of one or more USML Category V chemicals, when such amount comprises less than or equal to 1% of the total quantity of the Certified Reference Standard, Certified Research Material or Standard Reference Material, and where such items lack explosive characteristics.*

SIAL believes that while DDTC would be designating a different threshold for the control of trace amounts of these chemicals within a CRS, the CCL provides a robust regulatory framework to effectively control these trace amounts of chemicals.

Examples of CRS that would be affected if this suggested change is adopted:

Material name within Solvent Mixture	Regulated component	Quantity of regulated component	% of regulated component	Current USML Category	Proposed revised USML Category
HMX in Acetonitrile	HMX	0.0012 g	0.1%	V(a)(12)(i)	V(a)(15)
RDX in Acetonitrile	RDX	0.0012 g	0.1%	V(a)(20)(i)	V(a)(23)(i)
Tetryl in Acetonitrile	Tetryl	0.0012 g	0.1%	V(a)(25)	V(a)(29)
Butanetriol Trinitrate in Pyridine	Butanetriol	0.00008 g	0.008%	V(b)(e)(3)	V(b)(e)(3)

SIAL sells a variety of each of the listed CRS as both standard catalog offerings and custom-made products.

While it may be possible to isolate the regulated USML Category V chemical from the solvent in these CRS, the process involved would be labor-intensive and not cost-effective, particularly given the amount of USML controlled material that would be yielded from each vial. These types of CRS are typically sold in ampules of approximately 1 to 5 milliliters. For instance, to yield one kilogram of HMX, RMX or Tetryl from any of the first three items listed above, one would have to accumulate 833,000 product ampules. At current prices, this would cost approximately $16,600,000. The materials contained in all of the ampules would need to be combined and then the Acetonitrile would need to be evaporated off. Evaporation at an ambient temperature would take days; evaporation by heating would take only hours; however, this evaporation method requires costly laboratory equipment (prices for rotary evaporators start at approximately $32,000) and great care, as the heat could char the regulated material. Regardless how the Acetonitrile is evaporated, degradation of the regulated material cannot be ruled out. After all of this effort and cost, the process would yield only 1 kilogram of regulated material. Sales to our customers are typically in quantities of a few to a few dozen; selling hundreds of thousands of ampules to our customers would stand out under any circumstances and we would not make such a sale assuming we have sufficient supply without further inquiry.

For all of these reasons, we believe movement of these CRS to control under the CCL in a newly created ECCN 1C994, subject to controls that parallel ECCN 1C995 would be appropriate and consistent with the goals of the Export Control Reform Initiative.

If Additional Controls Are Deemed Warranted Under CCL: Include in ECCN 1C608

In the alternative, if DDTC and BIS believe more stringent controls under the EAR are warranted than would be appropriate for a new ECCN 1C994 as suggested above, SIAL respectfully suggests that the items removed from USML Category V pursuant to proposed new subsection V(k)(6) described above be controlled under a new ECCN 1C608.o as follows:

> ***Proposed text of new ECCN created for CRS containing certain trace chemicals under USML Cat V: ECCN 1C608.o***
>
> 1C608.o: *Certified Reference Standards, Certified Reference Materials and Standard Reference Materials which item is a mixture or compound that contains less than 0.5 grams total quantity of one or more USML Category V chemicals and such amount comprises less than or equal to 1% of the total quantity of the Certified Reference Standard, Certified Research Material or Standard Reference Material, and where such items lack explosive characteristics.*

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We appreciate the U.S. Government's effort to give industry the opportunity to comment on the revisions to USML Category V and revisions to the CCL before it becomes law. Should you have any questions about our proposed comments or if you would like additional information, please do not hesitate to contact Leigh Davidson at (314) 910-2387 or leigh.davidson@sial.com.

Respectfully submitted,

George L. Miller
Senior Vice President, General Counsel and Secretary
Sigma–Aldrich Corporation