DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Proposed Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of proposed action under the *NIH Guidelines.*

SUMMARY: Under the *NIH Guidelines,* experiments involving the generation of transgenic rodents by recombinant DNA technology must be registered with the Institutional Biosafety Committee (IBC). Specifically, Section III–E–3 of the *NIH Guidelines* addresses the generation of transgenic rodents that may be housed under biosafety level (BL) 1 conditions and allows the work to proceed simultaneously with registration of the experiment with the IBC. The IBC must then review and approve the experiment. The *NIH Guidelines* address two pathways for "generation of a transgenic rodent": altering the animal's genome using recombinant DNA technology or breeding one or more transgenic rodents to create a new transgenic rodent (*i.e.,* breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent).

The NIH Office of Biotechnology Activities (OBA) received a request that the breeding of well-characterized transgenic rodents that can be maintained under BL1 conditions be exempt from the *NIH Guidelines.* The rationale is that these experiments pose little if any biosafety risk and therefore the requirement for registration with the IBC may impose an administrative burden without enhancing the safe conduct of this research. In response to this request, OBA brought a proposal to amend the *NIH Guidelines* to the Recombinant DNA Advisory Committee (RAC) for consideration. The initial proposal was discussed at the March 11, 2010 RAC meeting and a revised proposal was discussed at the June 16, 2010 RAC meeting (Webcasts of these discussions are available at *http://oba.od.nih.gov/rdna_rac/rac_meetings.html*). The RAC endorsed a proposal that would exempt from the *NIH Guidelines* the breeding of almost all transgenic rodents that can be housed at BL1, with the exception of rodents that contain a gene encoding more than fifty percent of an exogenous eukaryotic virus and transgenic rodents in which the transgene is under the control of a gammaretroviral promoter. This notice seeks public comment on this proposal.

DATES: The public is encouraged to submit written comments on these proposed changes. Comments may be submitted to the OBA in paper or electronic form at the OBA mailing, fax, and e-mail addresses shown below under the heading **FOR FURTHER INFORMATION CONTACT**. All comments received by September 1, 2010 will be considered. All written comments received in response to this notice will be available for public inspection in the NIH OBA office, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892–7985, (Phone: 301–496–9838) weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional information about these proposed changes, please contact OBA by e-mail at *oba@od.nih.gov,* or telephone at 301–496–9838. Comments can be submitted to the same email address or by fax to 301–496–9839 or mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892–7985.

Background: Section III–E of the *NIH Guidelines* addresses experiments for which IBC notification is required at the time the research is initiated. Experiments covered in this section of the *NIH Guidelines* are considered to be of low biosafety risk and therefore although IBC review and approval is still required, such approval need not be obtained prior to initiating research. This is in contrast to all other covered experiments described in the *NIH Guidelines* for which IBC review and approval is required prior to initiation of the experiment.

Under the *NIH Guidelines,* certain experiments can be exempted from the *NIH Guidelines* if they do not present a significant risk to public health or the environment (Section III–F–6). These exemptions are delineated in Appendix C of the *NIH Guidelines.* OBA was recently approached regarding the Section III–E–3 requirement to register the breeding of transgenic rodents and whether such experiments met the criteria for exemption under Section III–F–6. OBA sought the advice of the RAC on this issue.

Currently, the purchase or transfer of transgenic rodents that require BL1 containment are exempt from the *NIH Guidelines.* This proposal would extend that exemption to almost all experiments that involve the generation of transgenic rodents by breeding, as long as the transgenic rodents are appropriate to be maintained under BL1 conditions. The rationale is that three decades of experience working with and breeding transgenic rodents has demonstrated that the overwhelming majority of experiments involving breeding of transgenic rodents that can be housed under BL1 conditions result in a rodent that can be appropriately housed under BL1 conditions. These breeding experiments do not pose an appreciable risk to human health or to the environment. In addition, while the registration with the IBC is not a significant burden, the total number of registrations required constitutes a significant collective administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk.

There are still some breeding experiments for which IBC registration would be required in order to ensure that a risk assessment is conducted and that the resulting rodent is disposed of appropriately. The proposed exemption would retain the requirement to register with the IBC when the genome of one of the parental transgenic rodents contains more than 50 percent of the genome of an exogenous, eukaryotic virus from a single family or if the transgenic rodent's transgene is under the control of a gammaretroviral long terminal repeat (LTR). The restriction regarding exogenous eukaryotic viruses is designed to prevent inadvertent reconstitution of an exogenous virus in the resultant transgenic mouse. The restriction regarding transgenes under control of a gammaretroviral long terminal repeat addresses the small risk of recombination with endogenous retroviruses which could potentially result in mobilization of the transgene via a replication-competent mouse retrovirus. As the risk of recombination and possible transmission to humans is more likely with gammaretroviral LTRs (e.g., MLV, XMRV, FeLV), the requirement for registration is limited to rodents containing a transgene under control of these LTRs.

Specifically, the following changes are proposed to Appendix C of the *NIH Guidelines:*

Appendix C–VII. Generation of BL1 Transgenic Rodents via Breeding

The breeding of two different transgenic rodents or the breeding of a transgenic rodent with a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at BL1 containment will be exempt from the *NIH Guidelines* if:

Both parental rodents can be housed under BL1 containment, and neither parental transgenic rodent contains the following genetic modifications:

(a) More than one-half of the genome of an exogenous virus from a single Family of viruses; or

(b) A transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and

It is anticipated that the transgenic rodent that results from this breeding:

(a) Will contain no more than one-half of an exogenous viral genome from a single Family of viruses.

The current Appendix C–VII and Appendices C–VII–A through C–VII–E would be renumbered to Appendix C–VIII and Appendices C–VIII–A though C–VIII–E, respectively.

For clarity the following will be added to Section III–E–3.

Section III–E–3–a. Experiments involving the breeding of certain BL1 transgenic rodents are exempt under Section III–F, *Exempt Experiments* (*See* Appendix C–VII, *Generation of BL1 Transgenic Rodents via Breeding*).

Dated: July 9, 2010.

Jacqueline Corrigan-Curay,

Acting Director, Office of Biotechnology Activities, National Institutes of Health.

[FR Doc. 2010–17668 Filed 7–19–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Camin Cargo Control, Inc., 230 Marion Ave., Linden, NJ 07036, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.*

DATES: The accreditation and approval of Camin Cargo Control, Inc., as commercial gauger and laboratory became effective on April 29, 2010. The next triennial inspection date will be scheduled for April 2013.

FOR FURTHER INFORMATION CONTACT: Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: July 9, 2010.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

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BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Passenger and Crew Manifest

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information: 1651–0088.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, U.S. Customs and Border (CBP) invites the general public and other Federal agencies to comment on an information collection requirement concerning the Passenger and Crew Manifest (Advance Passenger Information System-APIS). This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before September 20, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn.: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to U.S. Customs and Border Protection, Attn.: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Passenger and Crew Manifest (Advance Passenger Information System-APIS).

OMB Number: 1651–0088.

Form Number: None.

Abstract: The Advance Passenger Information System (APIS) is an automated method in which U.S. Customs and Border Protection (CBP) receives information on passengers and crew onboard inbound and outbound international flights before their arrival in or departure from the United States. APIS data includes biographical information for international air passengers arriving in or departing from the United States, allowing the data to be checked against CBP databases.

The information is submitted for both commercial and private aircraft flights. Specific data elements required for each passenger and crew member include: full name; date of birth; gender; citizenship; document type; passport number, country of issuance and expiration date; and alien registration number where applicable.

APIS is authorized under the Aviation and Transportation Security Act, Public Law 107–71. Under this statute, the transmission of passenger and crew manifest information is required even for flights where the passengers and