

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

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

ACTION: Action under the *NIH Guidelines*.

SUMMARY: The *NIH Guidelines* currently require that recombinant DNA experiments designed to create new transgenic rodents 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).

On July 20, 2010 the NIH Office of Biotechnology Activities (OBA) published a proposed action (75 FR 42114) to amend Section III-E-3 and to add a new Section to Appendix C (Appendix C-VII) of the *NIH Guidelines* so as to exempt breeding of almost all transgenic rodents that can be housed at BL1, with the exception of rodents that contain a transgene 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. After receiving public comment on the proposed changes, OBA is implementing these changes.

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

Background: Section III-E of the *NIH Guidelines* addresses experiments for which IBC registration 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 although IBC review and approval is still required, such approval need not be obtained prior to initiating the research. This is in contrast to all other experiments described in the *NIH Guidelines* for which IBC review and approval is required prior to initiation of the experiment.

Under the *NIH Guidelines* (Section III-F-6), certain experiments can be exempted from the *NIH Guidelines* if they do not present a significant risk to public health or the environment and the NIH Director approves this action. These exemptions are delineated in Appendix C of the *NIH Guidelines*.

Currently, the purchase or transfer of transgenic rodents that require BL1 containment are exempt from the *NIH Guidelines* under Appendix C. This action would extend that exemption to most experiments that involve the generation of transgenic rodents by breeding, as long as the transgenic rodents can be appropriately maintained under BL1 conditions. The rationale for this change is that three decades of working with and breeding transgenic rodents have demonstrated that the overwhelming majority of experiments involving breeding of transgenic rodents that can be housed under BL1 conditions results in progeny that can also be housed under BL1 conditions. Thus these breeding experiments do not pose an appreciable risk to human health or to the environment. In addition, while registration with the IBC is not a significant burden, the total number of registrations required can constitute 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 two categories of breeding experiments for which IBC registration will be required in order to ensure that a risk assessment is conducted and that the resulting rodent is disposed of appropriately:

(a) Breeding experiments involving transgenic rodents that contain more than 50 percent of the genome of an exogenous eukaryotic virus from a single family, in order to prevent inadvertent reconstitution of an exogenous virus in the resultant transgenic rodent; and

(b) breeding experiments in which the transgenic rodent's transgene is under the control of a gammaretroviral long terminal repeat (LTR), in order to address 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.*, murine leukemia virus, feline leukemia virus, xenotropic murine leukemia-related virus), the requirement for registration is limited to rodents containing a transgene under control of these LTRs.

OBA received nine comments in response to the July 20, 2010 **Federal Register** notice of proposed changes. All were supportive of the change and emphasized that the current registration requirements impose a significant administrative burden on IBCs that is not necessary to protect public health, laboratory workers or the environment. One comment noted that making these experiments exempt would free up valuable resources (time and money) for their IBC, Institutional Animal Care and Use Committee, and researchers. One comment asked for clarification regarding how to assess whether breeding a transgenic rodent containing a partial gammaretroviral LTR sequence must be registered with the IBC. The key issue is not the percentage of the LTR sequence, but rather whether it is functional or not, *i.e.* whether there is sufficient LTR sequence to direct the expression of a transgene.

The following changes will be made 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 and 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:

- (1) Both parental rodents can be housed under BL1 containment; *and*
- (2) Neither parental transgenic rodent contains the following genetic modifications:
 - (a) Incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or
 - (b) Incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and
- (3) The transgenic rodent that results from this breeding is not expected to contain 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 will be renumbered to Appendix C-VIII and Appendices C-VIII-A through C-VIII-E, respectively.

For clarity the following is 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: January 10, 2011.

Jacqueline Corrigan-Curay,

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

[FR Doc. 2011–1037 Filed 1–18–11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Record of Vessel Foreign Repair or Equipment Purchase

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

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information: 1651–0027.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Record of Vessel Foreign Repair or Equipment Purchase (CBP Form 226). This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Written comments should be received on or before March 21, 2011, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 5th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 5th 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). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). 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: Record of Vessel Foreign Repair or Equipment Purchase.

OMB Number: 1651–0027.

Form Number: CBP Form 226.

Abstract: 19 U.S.C. 1466(a) provides for a 50 percent *ad valorem* duty assessed on a vessel master or owner for any repairs, purchases, or expenses incurred in a foreign country by a commercial vessel registered in the United States. CBP Form 226, Record of Vessel Foreign Repair or Equipment Purchase, is used by the master or owner of a vessel to declare and file entry on equipment, repairs, parts, or materials purchased for the vessel in a foreign country. This information enables CBP to assess duties on these foreign repairs, parts or materials. CBP Form 226 is provided for by 19 CFR 4.7 and 4.14 and is accessible at http://forms.cbp.gov/pdf/CBP_Form_226.pdf.

Current Actions: CBP proposes to extend the expiration date of this information collection with a change to the burden hours. There is no change to the information being collected.

Type of Review: Extension (with change).

Affected Public: Businesses.

Estimated Number of Respondents: 100.

Estimated Number of Responses per Respondent: 11.

Estimated Number of Total Annual Responses: 1,100.

Estimated Time per Response: 45 minutes.

Estimated Total Annual Burden Hours: 825.

Dated: January 12, 2011.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2011–947 Filed 1–18–11; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5496–N–01]

Notice of Federal Advisory Committee Meeting—the Manufactured Housing Consensus Committee

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Announcement of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of an upcoming meeting of the Manufactured Housing Consensus Committee (the Committee) to be held via telephone conference. This meeting is open to the general public, which may participate by following the instructions below.

DATES: The conference call meeting will be held on Thursday, January 27, 2011, by conference call from 11 a.m. to 1 p.m. EST.

Conference Call: Members of the public who wish to join the call may call the toll free number 877–320–2367 and enter pass code 4191690. Additional information concerning the conference call can be obtained from the Department's Consensus Committee Administering Organization, the National Fire Protection Association (NFPA). Interested parties can access the NFPA Web site to obtain additional information about the Manufactured Housing Consensus Committee and the Administering Organization. The link can be found at: <http://www.nfpa.org/categoryList.asp?categoryID=858>. Locate *Quick Links* on the webpage and select *Meeting Notices*.

Alternately, interested parties may contact Jill McGovern of NFPA at (617) 984–7404 (this is not a toll-free number) for conference call information.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Cocke, Deputy Administrator, Office of Manufactured Housing Programs, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–6409 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Notice of this meeting is provided in accordance with Sections 10(a) and (b) of the Federal Advisory Committee Act (5 U.S.C. App. 2) and 41 CFR 102–3.150. The Manufactured Housing Consensus Committee was established under Section 604(a)(3) of the National Manufactured Housing Construction