EPA ICR No. 2195.03 **OMB Control No. 2070-0169**

ATTACHMENT A

Sections 3(c)(5), 3(g), 4(g)(2), and 25 of the Federal Insecticide, Fungicide, and Rodenticide Act

ATTACHMENT A: FIFRA SECTIONS 3(c)(5), 3(g), 4(g)(2), and 25

FIFRA Section 3(c)(5)

(5) APPROVAL OF REGISTRATION.—The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d) of this section—
(A) its composition is such as to warrant the proposed claims for it;
(B) its labeling and other material required to be submitted comply with the requirements of this Act;
(C) it will perform its intended function without unreasonable adverse effects on the environment; and
(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.
The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 24(c) of this Act, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

FIFRA Section 3(g)

(g) REGISTRATION REVIEW.—
(1)(A) GENERAL RULE.—The registrations of pesticides are to be periodically reviewed. The Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations. The goal of these regulations shall be a review of a pesticide's registration every 15 years. No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 6.
(B) LIMITATION.—Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this Act.
(2)(A) DATA.—The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.
(B) DATA SUBMISSION, COMPENSATION, AND EXEMPTION.—
For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

FIFRA Section 4(g)(2)

(g) PHASE FIVE.—
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(2) REREGISTRATION AND OTHER ACTIONS.—
(A) IN GENERAL.—The Administrator shall make a determination as to eligibility for reregistration—
(i) for all active ingredients subject to reregistration under this section for which tolerances or exemptions from tolerances are required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), not later than the last date for tolerance reassessment established under section 408(q)(1)(C) of that Act (21 U.S.C. 346a(q)(1)(C)); and
(ii) for all other active ingredients subject to reregistration under this section, not later than October 3, 2008.
(B) PRODUCT-SPECIFIC DATA.—
(i) IN GENERAL.—Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B) and shall review such data within 90 days after its submission.
(ii) TIMING.—
(I) IN GENERAL.—Subject to subclause (II), the Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.
(II) EXTRAORDINARY CIRCUMSTANCES.—In the case of extraordinary circumstances, the Administrator may provide such a longer period, of not more than 2 additional years, for submission of data to the Administrator under this subparagraph.
(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 3(c)(5). If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).
(D) DETERMINATION TO NOT REREGISTER.—
(i) IN GENERAL.—If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.
(ii) TIMING FOR REGULATORY ACTION.—Regulatory action under clause (i) shall be completed as expeditiously as possible.
(E) As soon as the Administrator has sufficient information with respect to the dietary risk of a particular active ingredient, but in any event no later than the time the Administrator makes a determination under subparagraph (C) or (D) with respect to pesticides containing a particular active ingredient, the Administrator shall—
(i) reassess each associated tolerance and exemption from the requirement for a

tolerance issued under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a);
(ii) determine whether such tolerance or exemption meets the requirements of that Act;
(iii) determine whether additional tolerances or exemptions should be issued;
(iv) publish in the Federal Register a notice setting forth the determinations made under this subparagraph; and
(v) commence promptly such proceedings under this Act and section 408 of the Federal Food, Drug, and Cosmetic Act as are warranted by such determinations.

FIFRA Section 25

AUTHORITY OF ADMINISTRATOR.
(a) IN GENERAL.—
(1) REGULATIONS.—The Administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides, including public health pesticides, and differences in environmental risk and the appropriate data for evaluating such risk between agricultural, nonagricultural, and public health pesticides.
(2) PROCEDURE.—
(A) PROPOSED REGULATIONS.—At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.
(B) FINAL REGULATIONS.—At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail

food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect.

(C) TIME REQUIREMENTS.—The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator and the Secretary.

(D) PUBLICATION IN THE FEDERAL REGISTER.—The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or final regulation, publish such notification in the Federal Register.

(3) CONGRESSIONAL COMMITTEES.—At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(4) CONGRESSIONAL REVIEW OF REGULATIONS.—Simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

(b) EXEMPTION OF PESTICIDES.—The Administrator may exempt from the requirements of this Act by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act.

(c) OTHER AUTHORITY.—The Administrator, after notice and opportunity for hearing, is authorized—

(1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other microorganisms on or in living man or other living animals) which is injurious to health or the environment;

(2) to determine any pesticide which contains any substance or substances in quantities highly toxic to man;

(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91–601)) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act as well as to accomplish the other purposes of this Act;

(4) to specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) or section 7 of this Act upon the Administrator's determination that application of such provision is necessary to effectuate the purposes of this Act;

(5) to prescribe regulations requiring any pesticide to be colored or discolored if the Administrator determines that such requirement is feasible and is necessary for the protection of health and the environment; and

(6) to determine and establish suitable names to be used in the ingredient statement.

(d) SCIENTIFIC ADVISORY PANEL.—

(1) IN GENERAL.—The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 6(b) and of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 6(b) or 25(a), as applicable, the advisory panel
has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver.
The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the advisory panel submitted under this
subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel.
The panel referred to in this subsection shall consist of 7 members appointed by the Administrator from a list of 12 nominees, 6
nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences. If a vacancy occurs on the panel due to expiration of a term, resignation, or any other reason, each replacement shall be selected by the Administrator from a group of 4 nominees, 2 submitted by each of the nominating entities named in this subsection. The Administrator may extend the term of a panel member until the new member is appointed to fill the vacancy. If a vacancy occurs due to resignation, or reason other than expiration of a term, the Administrator shall appoint a member to serve during the unexpired term utilizing the nomination process set forth in this subsection. Should the list of nominees provided under this subsection be unsatisfactory, the Administrator may request an additional set of nominees from the nominating entities. The Administrator may require such information from the nominees to the advisory panel as the Administrator deems necessary, and the Administrator shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the panel shall receive per

diem compensation at a rate not in excess of that fixed for GS–18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. The advisory panel established under this section shall be permanent. In performing the functions assigned by this Act, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Whenever the Administrator exercises authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

(2) SCIENCE REVIEW BOARD.—There is established a Science Review Board to consist of 60 scientists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the Panel. Members of the Board shall be selected in the same manner as members of temporary subpanels created under paragraph (1). Members of the Board shall be compensated in the same manner as members of the Panel.

(e) PEER REVIEW.—The Administrator shall, by written procedures, provide for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this Act by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide. Whenever the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term "peer review" shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriate disciplines.