

FIFTEENTH CONGRESS OF THE
REPUBLIC OF THE PHILIPPINES
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SENATE

Senate Bill No. 1168

1168 VILLAR

INTRODUCED BY HON. MANNY VILLAR

EXPLANATORY NOTE

The Constitution, Article 11, Section 15 provides that "The State shall protect and promote the right to health of the people and instill health consciousness among them."

There is no law that regulates the use of pesticide chemicals on food despite the hazardous effects pesticide chemicals may have on the food we consume. In accordance with the above-quoted constitutional mandate, this bill provides for a method whereby the State regulates the use of pesticide chemicals on food.


MANNY VILLAR

JUL 12 09:25

SENATE

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AN ACT TO REGULATE PESTICIDE CHEMICAL RESIDUES IN FOOD

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

ARTICLE I
PRELIMINARY PROVISIONS

Section 1. Short Title. This Act may be cited as the "Pesticide Food Safety Act."

Section 2. Declaration of Policy. It is the policy of the state to protect and promote the right to health of the people and instill health consciousness among them. To this end the state shall regulate the usage of pesticide chemicals in the processing of food.

Section 3. Definition of Terms. As used in this Act, the following terms shall mean:

(a) "Pesticide Chemical" means-

(1) (A) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and

(B) any substance or mixture of substances intended for used as a plant regulator, defoliant or dessicant:

(2) (A) in the case of a pesticide other than a plant regulator, defoliant, or dessicant, an ingredient which will prevent, destroy, repel, or mitigate any pest;

(B) in the case of a plant regulator, an ingredient which through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof:

(C) in the case of a desiccant an ingredient which will artificially accelerate the dying of plant tissue.

(b) "Defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant with or without causing abscission.

(c) "Desiccant" means any substance or mixture of substances intended for artificially accelerating the drying of plant tissues.

(d) "Pesticide Chemical Residue" means a residue in or on food of--

(1) any pesticide chemical or

(2) any other substance that is present in the commodity or food as a result of the metabolism or other degradation of pesticide chemical regardless of whether the residue may be detected.

(e) "Processed Food" means any food that has been subject to processing from a raw agricultural commodity.

(f) "Administrator" means the Administrator of the National Food Authority.

(g) "Secretary" means the Secretary of Agriculture

ARTICLE II TOLERANCE AND EXEMPTION FOR PESTICIDE CHEMICAL RESIDUES

Section 4. Requirements for Tolerance or Exemption

(a) General Rule - Any pesticide chemical residue shall be deemed unsafe unless--

(1) a tolerance for such residue is in effect under this Act and the quantity of such residue is within the limits of such tolerance: or

(2) an exemption for such residue is in effect under this Act and such residue complies with such exemption.

(b) Effect of a Tolerance or Exemption - While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, such food shall not by reason of bearing or containing any amount of such residue be considered to be adulterated if such food complies with such tolerance or exemption.

Section 5. Tolerances:

(a) Authority - In General - The Administrator may promulgate regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue--

(1) in response to a petition filed under Article III, Section 22; or

(2) on the initiative of Administrator under Article III, Section 29.

(b) Expiration Date - A regulation under this paragraph may provide for an expiration date for the tolerance.

(c) Separate Tolerances - The Administrator may establish a separate tolerance under subparagraph (a) for a pesticide chemical residue with respect to food at each of the following times:

(1) At the time the food is harvested;

(2) At the time the food is purchased at retail; and

(3) After the food is processed.

Section 6. Standard for Tolerance - (a) General Rule -

(1) a tolerance may be established for a pesticide chemical residue only if the risk to human health from dietary exposure to the pesticide chemical residue is negligible; and

(2) the tolerance for a pesticide chemical residue shall be revoked or modified unless the risk to human health from dietary exposure to the pesticide chemical residue is negligible.

(b) Negligible Risk -- For purposes of this paragraph, a risk to human health from dietary exposure to a pesticide chemical residue is negligible only if dietary exposure to the residue is reasonably certain to cause no harm to human health and the tolerance for such residue meets the requirements of safety.

Section 7. Tolerances Level - If the administrator is able to identify a level at which a pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health, the administrator may establish or leave in effect a level for a tolerance for such residue only if the Administrator finds that such tolerance will provide an ample margin of safety for each population group set out in Section 13.

Section 8. Tolerances, Threshold Pesticides. Considerations. The level described in Section 7 shall be based on consideration of--

(a) the nature of the toxic effects caused by such residue and data regarding the prevalence of the same effects caused by other chemicals:

(b) the validity, completeness, and the reliability of the data about the pesticide chemical residue;

(c) the variability of individual sensitivities and sensitivities of population subgroups to the adverse effects from such residue; and

(d) the possibility that human susceptibility to such adverse effects is significantly greater than that of test animals.

Section 9. Tolerances. Threshold Pesticides Margin of Safety. A margin of safety for a level of a pesticide chemical residue is not ample unless human exposure per unit of body measurement to the pesticide chemical residue and other chemicals that cause the same effect is at least 100 times less than the no observable effect level in animals on which the pesticide chemical residue was tested, and if human data are available, at least 10 times less than the no observable effect level is the level of exposure to a pesticide chemical that reliable data derived from exposure of humans or animals to the pesticide chemical, demonstrate will cause no adverse effect.

Section 10. Tolerances Non-threshold Pesticides. If the Administrator is not able to identify a level at which a pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health or if the Administrator finds that a pesticide chemical residue causes cancer in animals or humans, the Administrator may establish a level in effect for such residue only if the Administrator finds that such level--

(a) will not cause or contribute to in individuals exposed to such pesticide chemical residue a lifetime risk of an adverse human health effect that occurs at a rate of one in a million or a risk of an adverse human health effect that occurs at a rate of one conservative risk assessment models;

(b) is the lowest level reasonably required to allow the accomplishment of the physical or other technical effect for which the use of the pesticide chemical residue is removed to the extent possible in accordance with good manufacturing practice.

Section 11. Tolerances Exposure Except as provided in Section 12, in determining dietary exposure to a pesticide chemical residue the administrator shall--

(a) (1) use only reliable statistically significant data regarding the dietary exposure to persons who have consumed the food for which the tolerance for the residue is proposed or is in effect.

(2) take into account all other tolerances in effect for the same pesticide chemical residue; and

(3) take into account all other sources (including drinking water if data demonstrating widespread or significant regional contamination in drinking water are available) of dietary exposure to be the level of exposure that would occur if--

(b) consider the exposure to be the level of exposure that would occur if--

(1) all the food, for which the tolerance for the pesticide chemical residue is proposed or in effect has amounts of the pesticide chemical residue equal to the

(a) Date - The Administrator may calculate dietary exposure to a food based on reliable data that provide the Administrator with a valid statistical basis to identify the percentage of the food in which the pesticide chemical residue actually occurs.

(b) Percentage - Such percentage shall be not less than the percentage of the food consumed in an appropriate locality identified by the Administrator, which percentage represents the highest level of exposure to such residue in the Philippines.

(c) Reevaluation - The Administrator shall reevaluate the determination under this Act every 2 years after the date of the determination. If under such a reevaluation, the Administrator finds that the determination is not justified the Administrator shall promptly issue a regulation requiring that the tolerance involved be set on the basis of the new determination.

Section 12. Tolerances. Population Covered. In determining if the dietary exposure to a pesticide chemical residue is negligible the Administrator shall evaluate the risk to

(a) infants of the age 0 to 1;

(b) children of the age 1 to 2;

(c) children of the age 2 to 3;

(d) children of the age 3 to 4;

(e) children of the age 4 to 5;

(d) children of the age 6 to 10;

(g) other population groups that have been identified by the Administrator to have special food consumption patterns or for which data are sufficient to demonstrate special food consumption patterns; and

(h) the entire population who

consume food with such pesticide chemical residue.

Section 13. Tolerances. Unavoidable Persistence. If a tolerance or an exemption from the requirement for a tolerance for a pesticide chemical is revoked and the Administrator finds the pesticide chemical residue will unavoidably persist in the environment and contaminate food the Administrator shall establish a new tolerance under Section 29 for the pesticide chemical residue. The level permitted by the tolerance shall not be greater than the lowest level that permits only such unavoidable levels to remain in food. The Administrator shall evaluate any such tolerance at least once a year to determine whether modification of such tolerance is necessary so that the tolerance provides only for the level of the pesticide chemical that is unavoidable.

Section 14. Tolerances Practical Method of Analysis

(a) General Rule - A tolerance for a pesticide chemical residue shall not be established or allowed to remain in effect unless the Administrator determines, after consultation with the Secretary that--

(1) there is a method for detecting and measuring the levels of such pesticide chemical residue in or on a food that will detect the residue at the level established by the tolerance and

(2) except as provided in clause (b) such method is the best available, practical method.

(b) Special Rule - If the Administrator determines that a practical method of analysis for a pesticide chemical residue is not available the Administrator shall identify the best available method that is designed to identify the lowest detectable amount of the pesticide chemical residue. The Administrator shall every 2 years after the date of the determination under this paragraph reevaluate the determination.

(c) Practical Method - A method shall be considered practical for purposes of this Act only if it is a multiresidue method that can be performed by the Secretary on a routine basis as part of surveillance and compliance sampling of foods for pesticide chemical residue with the personnel equipment and other resources available to the Secretary, or, if no multiresidue method is available only if it can be so performed by the Secretary.

Section 15. Tolerances. Consistent Application. The Administrator shall issue guidelines for the consistent application of the requirements in Sections 6 to 15.

Section 16. Exemptions Authority

(a) In General - The Administrator may promulgate regulations establishing or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue--

(1) in response to a petition filed under Section 22; or

(b) Expiration Date - Such a regulation may provide for an expiration date for the exemption.

Section 17. Exemption Standard Authority and Risk Standard

(a) Establishment - An exemption may be established for a pesticide chemical residue if such residue is not a human or animal carcinogen and otherwise presents no risk to

human health, including the health of individuals in the population groups set out in Section 13 from dietary exposure to such residue.

(b) Revocation - An exemption shall be revoked unless the residue is not a human or animal carcinogen and the residue does not present any risk to human health, including the health of individuals in the population groups set out in Section 13 from dietary exposure to such residue.

(c) Tolerance - No exemption may be established or allowed to remain in effect for a pesticide chemical residue for which there is in effect a tolerance.

Section 18. Exemptions Exposure For purposes of Section 17, in determining dietary exposure to a pesticide chemical residue the Administrator shall --

(a) use only reliable statistically significant data regarding the dietary exposure resulting from the consumption of the food for which the exemption for such residue is proposed or is in effect:

(b) take into account all other exemptions in effect for such residue and all other sources (including drinking water if data demonstrating widespread or significant regional contamination in drinking water are available) of dietary exposure to such residue; and

(c) consider the exposure to be the level of exposure that would occur if --

(1) all the food for which the tolerance for such residue is proposed or in effect has amounts of such residue equal to the tolerance proposed or in effect, respectively.

(2) all other sources of dietary exposure to such residue described in paragraph (b) occur; and

(3) human exposure to the pesticide chemical residue at the tolerance level occurs for a period equal to a lifetime.

Section 19. Exemptions Practical Methods of Analysis An Exemption for a pesticide chemical residue shall not be established or allowed to remain in effect unless the Administrator determines after consultation with the Secretary that there is a method for detecting and measuring the levels of such pesticide chemical residue on a food and that such method is the best available practical method as defined in Section 14.

Section 20. Exemptions Consistent Application The Administrator shall issue guidelines providing for the consistent application of the requirements in Section 7 to 20.

ARTICLE III

PETITIONS AND ACTION ON THE INITIATIVE OF THE ADMINISTRATOR

Section 21. General Rule for Petitions. Any persons may file with the Administrator a petition proposing the issuance of a regulation establishing, modifying, or revoking a tolerance or exemption for a pesticide chemical residue.

Section 22 Requirements for Petitions to Establish a Tolerance Exemption

(a) Contents - A petition under Section 21 to establish a tolerance or exemption for a pesticide chemical shall contain--

(1) an information summary of the petition and of the data, information and arguments submitted or cited in support of the petition including--

(A) a summary of the reports required under clause (4) respecting the safety of the pesticide chemical residue; and

(B) a characterization of--

(1) the exposure to the pesticide chemical residue to any tolerance or exemption already granted for such residue that would result if the requested tolerance or exemption were granted;

(2) a proposed tolerance for such residue, if a tolerance is proposed;

(3) the name chemical identify and composition of the pesticide chemical that produces such residue.

(4) reports of tests and investigations made with respect to the safety of such pesticide chemical including complete information as to the methods and controls used in conducting such tests and investigations;

(5) data showing the amount, frequency, method, and time of application of such pesticide chemical.

(6) reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on food when ready for sale to consumers including a description of the analytical method used;

(7) a description of methods for detecting and measuring the levels of such pesticide chemical residue in or on the food, which methods meet the requirements of Sections 15 and 20

(8) reports of investigations conducted on the effect of processing methods used to produce food on the level and identity of such pesticide chemical residue.

(9) if the petition is for a pesticide chemical residue that is described in effect the pesticide chemical involved is intended to have the quantity of the pesticide chemical residue required to accomplish such effects; and

(10) such other data and information (including a sample of the pesticide chemical form which the pesticide chemical residue is derived) as the Administrator may require to support the petition.

(b) Information Available to Administrator - If information or data required by this section are available to the Administrator the person submitting the petition may in lieu of submitting the information or data, cite the availability of the information or data.

Section 23 Actions on Petitions Notice.

(a) In General - Within 45 days of the filing of a petition under Section 21 for the establishment of a tolerance or an exemption the Administrator shall determine if the petition complies with the requirements of Section 22. If the Administrator finds requirements to be sufficiently complied with the Administrator shall publish a notice of the filing of the petition. If the Administrator determines that the petition does not comply with such requirements the Administrator shall notify the petitioner of such determination.

(b) Contents - A notice published under this section shall--

(1) announce the availability of a complete description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed;

(2) include the summary required by Section 22 (a) (1); and

(3) provide at least 30 days for comments on the petition.

Section 24. Action - The Administrator shall within 270 days of the publication of a notice under Section 23 (a) with respect to a petition, and after giving due consideration to the petition any comments on the petition and any other information available to the Administrator--

(a) issue a final regulation in accordance with the petition establishing a tolerance or exemption for the pesticide chemical residue;

(b) issue a proposed regulation establishing a tolerance or exemption for the pesticide chemical residue which tolerance or exemption is different from the tolerance or exemption requested in the petition; or

(c) issue an order denying the petition

Section 25 Actions on Petition, Modification or Revocation

(a) Notice - Within 45 days of a tolerance or exemption the Administrator shall publish a notice of the filing of the petition. Such notice shall contain the full petition or a summary of the petition and shall provide at least 30 days for comments on the petition.

(b) Action - The Administrator shall within 270 days of the publication of the notice under Section 23(a) and after giving due consideration to the petition, any comments on the petition, and any other information available to the Administrator--

(1) issue a final regulation in accordance with the petition modifying or revoking a tolerance or exemption for the pesticide chemical residue;

(2) issue a proposed regulation modifying or revoking a tolerance or exemption for the pesticide chemical residue which tolerance or exemption is different from the modification or revocation requested in the petition; or

(3) issue an order denying the petition

Section 26 Actions on Petition Comments and Final Regulations. If the Administrator issues a proposed regulation under Section 24(b) or Section 25(b)(2), the Administrator shall allow at least 30 days for comments on such proposed regulations. The Administrator shall issue a final decision within 180 days of the date of the publication of the proposed regulations.

Section 27. Actions on Petition, Priorities. The Administrator shall give priority to petitions for the establishment of a tolerance for a pesticide chemical residue that appear to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

Section 28. Actions on Petitions Action on the Initiatives by the Administrator.

(a) General Rule - Upon his own initiative the Administrator may issue a final regulation establishing, modifying or revoking a tolerance or exemption for a pesticide chemical residue.

(b) Notice - Before issuing a final regulation under paragraph (a), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 30 days for public comment on the proposed regulation unless the Administrator finds that it would be contrary to the public interest to issue the notice and provide the period and states the reasons for the finding in the notice of the final regulation.

Section 29 Actions on Petition Effective Date

(a) General Rule - Except as provided in paragraph (b), a final regulation issued under Sections 23, 24, 25, 26, 27 and 28 shall take effect upon publication.

(b) Delay -

(1) General Rule - If a regulation issued under Section 23, 24, 25, 26, 27 and 28 revokes or modifies a tolerance for a pesticide chemical residue or revokes an exemption for a pesticide chemical residue, the Administrator may, delay the effective day of the regulation to permit the tolerance or exemption to remain in effect at the level in effect immediately before such regulation is issued only --

(A) for foods that on the date of the publication of the regulation contain such pesticide chemical residue in an amount that is not more than the amount that could legally be applied on the date the Administrator under Sections 24, 25, 26, 27, 28 and 29; and

(B) if dietary exposure to the pesticide chemical residue in or on the foods described in clause (A) meets the negligible risk standard prescribed by Section 6 during the period of delay of the effective date.

(2) Period of Delay - If the Administrator finds that delay of the effective date of such a revocation or modification is consistent with the public health, the Administrator may delay such date under Section 5, for each type of food that contains such pesticide chemical residue, for the period that is required for such food to be sold to consumers in the course of the usual practice for persons engaged in the production, processing, transportation, storage, and distribution of the of food.

Section 30. Actions on Petitions Special Data Requirements.

(a) Determination of Inadequate Data - The Administrator shall take the action described in Sections 5 to 16 if a tolerance or exemption is in effect for a pesticide chemical residue and the Administrator determines that data contained in the petition, which had been submitted, under Section 21 for establishment of the tolerance or exemption under this Act are not adequate to support the continuation of such tolerance or exemption because--

(1) based on the data contained in the petition and other data available to the Administrator, the Administrator determines that dietary exposure to such pesticide chemical residue may present a risk to human health that is greater than the standard prescribed by Section 6 to 15 and Section 18, 19 and 20; or

(2) the data contained in the petition are insufficient requirements of Sections 6 to 15 or Section 18, 19 and 20 or the requirements of Section 22.

(b) Action by Administrator - When the Administrator makes the determination described in paragraph (a) with respect to a tolerance or exemption for a pesticide chemical residue; the Administrator shall--

(1) within 30 days of a determination under Section 4, initiate an action under Section 28 to modify or revoke the tolerance or exemption so that the tolerance or exemption meets the standard prescribed by Sections 6 to 15 or Sections 18, 19 and 20 and within 1 year of such determination issue a final regulation to complete such action; and

(2) within 30 days of the date of a determination under Section 4(a)(2), require the submission of data to support--

(A) the existing tolerance or exemption; or

(B) a new tolerance or exemption for such residue, that meets the standard prescribed by Section 6 to 15 or Sections 18, 19 and 20.

Section 31. Action on Petition, Special Data Requirements Deadlines. Except as provided in Section 34 if an order is issued under Section 30 with respect to a tolerance or exemption and a deadline in the order is not met, the tolerance or exemption is revoked, effective 45 days after the date the deadline is not met. Immediately after such deadline is not met the Administrator shall publish a notice of the revocation.

Section 32. Action on Petition. Special Data Requirements Extension of Request

(a) Request - Any person may request the Administrator to issue an order to extend the deadline established under Section 30(d) before expiration of the deadline.

(b) Grant of Request - The Administrator may grant such a request only if--

(1) the person submitting the request notified the Administrator pursuant to Section 32(a) in compliance with the deadline established under Section 30(c); and

(2) the Administrator finds that extraordinary circumstances beyond the control of such person prevented such persons from submitting the required data.

(c) Extension - If the Administrator issues an order extending a deadline--

(1) the Administrator may extend the deadline for a period no longer than such times as is necessary for such person to submit the data; and

(2) the Administrator shall establish a new deadline in accordance with Section 32(d)

(d) Delay - If a tolerance or exemption is revoked under Section 30(b)(1), the Administrator may delay the effective date under Section 29(b)

(e) Evaluation of Data - Within 90 days of the date of the receipt of data under Section 30, the Administrator shall evaluate such data and determine whether action is required under Section 28 with respect to the tolerance or exemption for the pesticide chemical residue for which the data were submitted so that such tolerance meets the negligible risk standard prescribed under Sections 6 to 15 or Sections 18, 19 and 20. If

the Administrator determines that action under Section 29 is required, the Administrator shall complete such action within 1 year of the date of such determination.

Section 33. *Confidentiality of Data.* Data submitted to the Administrator in support of a petition under Section 22, which data have not previously been made available to the public without restriction shall upon request of the petitioner be considered as entitled to confidential treatment by the Administrator until publication of a regulation or order under Sections 24 to 28 in response to the petition unless disclosure of such data is required by Section 24(a)(B) or Section 36 is allowed by Section 35.

Section 34. *Confidential of Data Disclosure.* Data that are entitled to confidential treatment under Section 34 until publication of a regulation or order under Sections 24 to 28 may be revealed to --

(a) either House of Congress or any committee or subcommittee of such House to the extent of matter within the jurisdiction of the committee or subcommittee;

(b) any officer or employee of the State in connection with the official duties of such officer or employee under any law for the protection of health or the environment or for specific law enforcement purposes; or

(c) any officer or employee of the State in connection with the official duties of such officer or employee under any law of the State for the protection of health or the environment of for specific law enforcement purposes; or

(d) contractors with the State authorized by the Administrator to examine such data in the carrying out of contracts under such statutes under such security requirements as the Administrator may provide.

Section 35. Access to Data in Support of Petition, General Rule

(a) *Public Access* - If data in support of a petition, shall provide, in accordance with this subsection, public access to health and safety data that are submitted or cited in support of such petition.

(b) *Request* - To obtain access to such data a person shall not later than 30 days after the publication under Section 24 of a notice of the filing of a petition, send by certified mail to the Administrator and to the petitioner a request for such access and the affirmation required by Section 37.

(c) *Grant of Request* - The Administrator shall grant such request unless, within 15 days after the receipt by the Administrator of such request and affirmation, the petitioner submits to the Administrator an objection to the request asserting that the affirmation is inaccurate and other reasons for the objection.

(d) *Objection* - If an objection to a request is submitted to the Administrator within such 15-day period the Administrator shall resolve such objection within 5 days after receipt of the objection. If the Administrator determines to grant the request, access shall not be permitted until 5 days after the petitioner making the objection has been notified.

(e) *Denial of Request* - If access to data is denied, comments on the petition for which such data were submitted or cited shall be filed within 30 days after the decision of the Administrator denying access.

Section 36. Access to Data in Support of Petition Restriction

(a) Affirmation - Data referred to in Section 34 may be made available only to a person who provides an affirmation (and such supporting evidence as the Administrator may require) that-

(1) states that the person is not engaged in and is neither employed by nor acting (directly or indirectly) on behalf of any other person or affiliate of a person engaged in the production, sale, or distribution of a pesticide chemical;

(2) identifies any business, employer, or other person, if any, on whose behalf the person is requesting access to the data; and

(3) states that the person will not intentionally or recklessly violate this section.

(b) Affiliate - For purposes of this paragraph, an affiliate of a person is a person who directly or indirectly, through one or more intermediaries, controls or is controlled by or is under common control with the other person.

Section 37. Access to Data in Support of Petition Comments.

(a) General Rule - Data supporting a petition may be made available under Section 38 to a person only for the purpose of permitting the person to comment to the Administrator on such petition. Such comments may reasonably quote data submitted to the Administrator. No person, including the Administrator, may make such comments public before the decision of the Administrator on the petition for which such data were submitted or after such decision if the petition is denied.

(b) Restrictions - A person who obtains data (directly or indirectly) under Section 36 may not publish, copy, or transfer the data to any other person to obtain approval to sell, manufacture, or distribute a pesticide chemical anywhere in the world.

Section 38. Access to Data in Support of Petition, Procedure.

(a) In General- Data made available may be examined at an office of the Department of Environment and Natural Resources or an appropriate State agency under the conditions prescribed by this Article and may not be removed from such office.

(b) Record - The Administrator shall maintain a record of the persons who inspect data. A copy of such record shall be sent on request to the person who submitted the data.

(c) Basis for Comments - Once access to data supporting a petition is granted, the data may be examined and notes may be taken for use in developing comments on the petition. Such comments on the petition shall be filed within 60 days after the decision of the Administrator granting access, unless the comment period is extended by the Administrator.

Section 39. Access to Data After Decision. When the Administrator takes final action on a petition submitted under Section 21 or on the initiative of the Administrator under Section 28, the Administrator shall make available to the public the administrative record of the decision, including the data relied upon for the decision.

Section 40 Existing Pesticide Chemical Residues. Pesticide Chemical Residues Under Regulations establishing tolerances for pesticide chemical residues under this Article or exemptions for pesticide chemical residues under this Article on or before the

date of the enactment of this Act shall be deemed to be tolerances or exemptions issued under this Act and shall be subject to modification or revocation.

Section 41. Generally Recognized as Safe Pesticide Chemical Residues, General Rule. Pesticide chemical residues that do not have tolerances or exemptions from tolerances under this Act because the residues are generally recognized as safe under this Act shall, until the expiration of the period prescribed by Section 45, not be considered unsafe solely because the chemicals do not have such a tolerance or exemption.

Section 42 Generally Recognized as Safe Pesticide Chemical Residues, List Not later than 90 days after of the enactment of this Act, the Administrator shall --

(a) publish a list of all pesticide chemical residues that the Administrator has determined are generally recognized, on the day before the date of the enactment of this Act as safe under this Act;

(b) require, by regulation, that any person who before the date of the enactment of this Act, distributed in commerce as a pesticide chemical, a pesticide chemical that is not on the list described in paragraph (a), and that such person determined is generally recognized as safe under this Act, shall--

(1) report to the Administrator the identify of such pesticide chemical; and

(2) report to the Administrator the data that supports the claim that the pesticide chemical is so safe.

Section 43 Generally Recognized as Safe Pesticide Chemical Residues, Determination of the Administrator. Not later than 270 days after the enactment of this Act, the Administrator shall determine if each pesticide chemical reported to the Administrator in accordance with Section 42 is generally recognized subject to modification or revocation.

Section 44. Food and Drug Administration Monitoring of Pesticide Chemical Residues.

(a) Sampling - The Secretary shall conduct surveillance and compliance sampling of food for pesticide chemical residues to determine if the pesticide chemical residues are in compliance with this Act. In carrying out this paragraph, the Secretary shall give priority to foods that contain pesticide chemical residues included in a notice under paragraph (b).

(b) Notification - The Administrator shall notify the Secretary of the pesticide chemical residues that the Administrator determines, in the administration of this section--

(1) are above the standard prescribed by Section 6; or

(2) are not above such standard but that may under certain circumstances reach or exceed such standard.

Section 45. Fees. The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the functions of the Administrator under this Act. Under such regulations, the performance of the services or other functions of the Administrator under this section may be conditioned upon the payment of such fees. Such regulations

may further provide that the continuation in effect of a tolerance or exemption shall be conditioned upon the payment of an annual fee and for waiver or refund of fees in whole or in part when, in the judgment of the Administrator, such waiver or refund is equitable and not contrary to the purposes of this Article.

Section 46. Judicial Review. Any person (including a person without an economic interest) who may be adversely affected by a final regulation or order issued may obtain judicial review of such regulation or order by filing a petition requesting that the regulation or order be set aside in whole or in part in the Court of Appeals within 60 days after publication of the regulation or order.

Section 47. Judicial Review, Review of Data

(a) In General- Any person (including a person without economic interest) may obtain judicial review, of the adequacy of the data made available by the Administrator under Section 41 to support the issuance of a tolerance or exemption for a pesticide chemical residue, by filing a petition for the review of data in the Court of Appeals.

(b) Scope of Review - Review in a proceeding initiated under the preceding section shall be limited to whether the data under review are adequate to demonstrate that the tolerance or exemption supported by such data meets the standards required by Section 6 or Section 18, 19 and 20 and interpreted by the guidelines issued under Section 16 or 21.

(c) Burden of Proof. In any such proceeding the Administrator shall have the burden of proof on all issues.

Section 48. Judicial Review, Court Responsibility. In any action seeking judicial review of actions under this Act, the court shall have the principal responsibility for deciding issues of law.

Section 49. Judicial Review, Attorney's Fees. Any petitioner who prevails in a proceeding brought under this Act shall be entitled to recover reasonable attorney's fees and expenses (including expert witness fees).

ARTICLE III EVALUATION OF EXISTING PESTICIDE CHEMICAL RESIDUE TOLERANCES AND EXEMPTIONS

Section 50. Evaluation. Within 1 year of the date of the enactment of this Act, the Administrator shall for each pesticide chemical residue that has a tolerance or exemption in effect, evaluate all available data with respect to the safety of such pesticide chemical residue and the nature and amount of such residue remaining in or on foods and determine if--

(a) the tolerance or exemption meets the requirements under this Act;

(b) the tolerance or exemption does not meet such requirements; or

(c) the data are insufficient to determine if the tolerance or exemption meets such requirements.

Section 51. Sufficient Data.

(a) *Acceptable Risk Data* - If, with respect to any pesticide chemical residue that is evaluated under Section 4, the Administrator finds that data for the pesticide chemical residue are sufficient to determine that the requirements for tolerance or exemption for the pesticide chemical residue are met, the Administrator shall publish such finding.

(b) *Unacceptable Risk Data* - If, with respect to any pesticide chemical residue that is evaluated under Section 50, the Administrator finds that data for the pesticide chemical residue are sufficient to determine that the tolerance or exemption for the pesticide chemical residue does not meet the required standard, the Administrator shall within 1 year of the date of such finding, modify or revoke the tolerance.

Section 52. *Insufficient Data, General Rule, Submission of Data.* If, with respect to any pesticide chemical residue that is evaluated under Section 50, the Administrator determines that the data are insufficient to determine whether the tolerance or exemption meets the prescribed requirement, the Administrator shall establish a schedule for the submission of data in accordance with the prescribed requirements.

Section 53. *Insufficient Data, Determinations* The Administrator shall--

(a) within 2 years of the date of the enactment of this Act, make such a determination respecting a tolerance or exemption standard for at least 30 percent of the tolerances or exemptions in effect for pesticide chemical residues in existence on such date;

(b) within 4 years of the date of the enactment of this Act, make such a determination for at least 60 percent of the tolerances or exemptions in effect for pesticide chemical residues in existence on such date.

(c) within 6 years of the date of the enactment of this Act, make such a determination for at least 90 percent of the tolerances or exemptions in effect for pesticide chemical residues in existence on such date; and

(d) within 7 years of the date of the enactment of this Act, make such a determination for 100 percent of the tolerances or exemptions in effect for pesticide chemical residues in existence on such date.

ARTICLE 1V REVIEW OF EXISTING METHODS OF ANALYSIS

Section 54. *Procedure*

(a) *Determination* - Within 180 days of the date of the enactment of this Act, the Administrator shall determine, for each method of detecting and measuring levels of pesticide chemical residues, whether the prescribed requirements have been met.

(b) *Notice* - The Administrator shall issue a notice identifying each pesticide chemical for which there is such a method that does not meet such requirements. Any such method that does not meet such requirements within 3 years of the date of the issuance of the notice.

(c) *Revocation* - If upon the expiration of such 3-year period, a method does not meet such requirements, then any tolerance or exemption in effect for the pesticide chemical residue subject to such method shall be considered revoked.

Section 55. Fees. The Administrator shall by regulation require the payment of such fees as well in the aggregate in the judge of the Administrator, sufficiently supplement over a reasonable term to provide, equip, and maintain an adequate system for the implementation of this Act.

Section 56 Separability Clause. If any provision, or part hereof, is held invalid or unconstitutional, the remainder of the law or the provision not otherwise affected shall remain valid and subsisting.

Section 57 Repealing Clause. Any law, presidential decree, or issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent with, the provisions of this Act is hereby repealed modified or amended accordingly.

Section 58. Effectivity Clause. This Act shall take effect then (15) days after the publication in at least two (2) newspapers of general circulation.

Approved,