


FOURTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES)
First Regular Session)

7 JUL -3 19:13

SENATE

RECEIVED BY: 

Senate Bill No. 624


INTRODUCED BY SEN. JINGGOY EJERCITO ESTRADA

EXPLANATORY NOTE

The Constitution, under Article II 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.

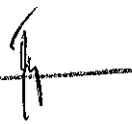
Considering the foregoing, the early passage of this proposed measure is earnestly solicited.


JINGGOY EJERCITO ESTRADA
Senator

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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***".

SEC 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.

SEC 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 use as a plant regulator, defoliant or desiccant;

(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 he product thereof;

(c) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant; and

- (d) in the case of a desiccant, and 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 dying 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 a pesticide chemical, regardless of whether the residue may be defected.
- (E) "Processed Food" means any food that has been subjected 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 RESIDUE

SEC 4. Requirement 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; and,
 - 2) an exemption for such residue is in effect under this Act and exemption such residue complies with such exemption.
- (b) Effect of a Tolerance or Exemption - While a tolerance or from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food shall not by reason of bearing or containing any amount of such residue be considered to be adulterated if such residue on such food complies with such tolerance or exemption.

SEC 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 the 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.

SEC 6. *Standard for Tolerance.* –

(a) General Rule –

- (1) a tolerance may be established 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;
 - (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.

SEC 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 on 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.

SEC 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 the 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.

SEC 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 one hundred (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 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.

SEC 10. *Tolerances, Nonthreshold 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 of 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 chemicals 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 is accordance with good manufacturing practice.

SEC 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 the same pesticide chemical residue; and
- (b) consider the exposure to be the level of exposure that would occur if

(1) all 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 tolerance proposed or in effect;

(2) all other sources of dietary exposure to such residue described in clause (a)(3) occur; and

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

SEC 12. *Tolerances, Special Exposure Rule.* –

(a) **Data** - 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 not be 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 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.

SEC 13. *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;

(f) 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 chemical residue.

SEC 14. *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

unavoidable 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 residue that is unavoidable.

SEC 15. *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 multi-residue method that can be performed by the Secretary on a routine basis as part of surveillance and compliance sampling of foods for pesticide chemical residues 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.

SEC 16. *Tolerances, Consistent Application.* The Administrator shall issue guidelines providing for the consistent application of the requirements in Sections 6 to 15.

SEC 17. *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 in response to a petition filed under Section 22;
- (b) Expiration Date - Such a regulation may provide for an expiration date for the exemption.

SEC 18. *Exemptions, 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 present 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.

SEC 19. *Exemptions, Exposure.* For purposes of Section 18, 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.

SEC 20. *Exemptions, Practical Methods of Analysis.* An exemption to 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 15.

SEC 21. *Exemptions, Consistent Application.* The Administrator shall issue guidelines providing for the consistent application of the requirements in Sections 17 to 20.

ARTICLE IV

PETITIONS AND ACTION ON THE INITIATIVE OF THE ADMINISTRATOR

SEC 22. *General Rule for Petitions.* Any person 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.

SEC 23. *Requirements for Petitions to Established a Tolerance Exemption*

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(A) Contents - A petition under Section 22 to established a tolerance or exemption for a pesticide chemical residue 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 due to any tolerance or exemption already granted for such residue; and
 2. the additional exposure to such residue that would result if he requested tolerance or exemption were granted;
- 2) a proposed tolerance for such residue, if a tolerance is proposed;
- 3) the name, chemical identity, and composition of the pesticide chemical that produces such residue;
- 4) reports of test 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 investigation;
- 5) data showing the amount, frequency, method, and time of application of such pesticide chemical;
- 6) reports of test 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 methods 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 Section 15 and 21;
 - 8) reports of investigations conducted on the effects 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 Sections 7, 8 and 9 all relevant data bearing on the physical or other technical effect the pesticide chemical involved is intended to have and the quantity of the pesticide chemical residue required to accomplish such effect; and
 - 10) such other data and information (including a sample of the pesticide chemical from 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 data.

SEC 24. *Action on Petitions, Notice.* -

- (a) In General - Within forty five (45) days of the filing of the petition under Section 22 for the establishment of a tolerance or an exemption, the Administrator shall determine if the petition complies with the requirements of Section 23. 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 23 (a)(1); and
 - (3) provide at least 30 days for comments on the petition .

SEC 25. *Action.* The Administrator shall within 270 days of the publication of a notice under Section 24 (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.

SEC 26. Action on Petition, Modification or Revocation. –

- (a) **Notice.** - Within forty five (45) days of the filing of a petition under Section 22 for the modification or revocation 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 270 days of publication of the notice under Section 24(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 and order denying the petition.

SEC 27. Actions on Petition Comments and Final Regulations. If the Administrator issues a proposed regulation under Section 25(b) or Section 26(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.

SEC 28. Action on Petition Priorities. The Administrator shall give priority to petitions for the establishment of a tolerance for a pesticide chemical residue that appears 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.

SEC 29. Action on Petition 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 final regulation.

SEC 30. *Action on Petition Effective Date.* -

- (a) General Rule - Except as provided in paragraph (b), a final regulation issued under Section 24, 25, 26, 27, 28 and 29 shall take effect upon publication.

- (b) Delay -

- (1) General Rule - If a regulation issued under Section 24, 25, 26, 27, 28 and 29 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 in 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 acted under Section 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 under 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 type of food.

SEC 31. *Actions on Petition, 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 22 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 Sections 6 to 15 and Sections 18, 19 and 20; or
 - (2) the data contained in the petition are insufficient requirements of Section 23
- (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 29 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 Sections 6 to 15 or Sections 18, 19 and 20.

SEC 32. Action on Petition, Special Data Requirements, Submission of Required Data. - When the Administrator requires the submission of data under Section 31(b)(2), the Administrator shall publish an order –

- (a) requiring one or more interested persons to notify the administrator that such person will submit the required data;
- (b) describing the type of data required to be submitted;
- (c) describing the reports required to be made during and after the collection of the data; and
- (d) establishing deadlines for the actions described in paragraphs (a) and (c).

SEC 33. Action on Petition, Special Data Requirements, Deadlines. Except as provided in Section 34, if an order is issued under Section 32 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.

SEC 34. Action of 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 32(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 32(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 time 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 revoke under Section 31(b)(1), the Administrator may delay the effective date under Section 30(b);
- (e) Evaluation of Data - within 90 days of the date of the receipt of data under Section 32 the Administrator shall evaluate such data and determine whether action is required under Section 29 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.

SEC 35. 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)(Z)(B) or Section 36 is allowed by Section 35.

SEC 36. *Confidentiality 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 sub-committee 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 employees 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 or 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.

SEC 37. *Access to Data in Support of Petition, General Rule.* -

- (a) **Public Access** - If data in support of a petition are submitted to the Administrator, the Administrator before acting on such 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 thirty (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 that access has been granted.
- (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.

SEC 38. *Access to Data In Support Of Petition, Restriction.* -

- (a) Affirmation - Data referred to in Section 37 may be made available only to 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 of 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.

SEC 39. *Access To Data In Support of Petition, Comments.* -

- (a) General Rule. - Data supporting a petition may be made available under Section 36 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 publicly 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.

SEC 40. *Access to Data in Support of Petition, Procedure.* –

- (a) In General - Data made available under Section 36 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 sixty (60) days after the decision of the Administrator granting access, unless the comment period is extended by the Administrator.

SEC 41. *Access to Data After Decision.* When the Administrator takes final action on a petition submitted under Section 22 or on the initiative of the Administrator under Section 29, the Administrator shall make available to the public the Administrative record of the decision, including the data relied upon for the decision.

SEC 42. *Existing Pesticide Chemical Residues; Pesticides Chemical Residues Under Regulations.* 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 under Sections 22 to 33.

SEC 43. *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.

SEC 44. *Generally Recognized as Safe Pesticide Chemical Residues, List.* Not later than ninety (90) days after the date 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 identity of such pesticide chemical; and
 - (2) report to the Administrator the data that supports the claim that the pesticide chemical is so safe.

SEC 45. *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 44 is generally recognized as safe. If the Administrator determines, by order, that such pesticide chemical is generally recognized as safe, the residue of such pesticide chemical shall be considered a pesticide chemical residue subject to modification or revocation under Sections 22 to 33.

SEC 46. *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.

SEC 47. *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.

SEC 48. *Judicial Review.* Any person (including a person without an economic interest) who may be adversely affected by a final regulation or order issued under Sections 24, 29, 33, 43, 44 and 45 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.

SEC 49. *Judicial 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 Sections 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.

SEC 50. *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.

SEC 51. *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 CHEMICALS, RESIDUE TOLERANCES AND EXEMPTIONS

SEC 52. *Evaluation.* Within one (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.

SEC 53. *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 52, 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 one (1) year of the date of such finding, modify or revoke the tolerance.

SEC 54. *Insufficient Data, General Rule, Submission of Data.* If, with respect to any pesticide chemical residue that is evaluated under Section 52, the Administrator determines that the data are insufficient to determine whether the tolerance or exemption meets the prescribed requirements, the Administrator shall establish a schedule for the submission of data in accordance with the prescribed requirements.

SEC 55. *Insufficient Data, Determinations.* The Administrator shall -

- (a) within two (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 four (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 six (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 seven (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 IV REVIEW OF EXISTING METHODS OF ANALYSIS

SEC 56. *Procedure* -

- (a) **Determination** - Within one hundred eighty (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 three (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.

SEC 57. *Fees.* - The Administrator shall by regulation require the payment of such fees as will in the aggregate judgment of the Administrator, sufficiently supplement over a reasonable term to provide, equip and maintain an adequate system for the implementation of this Act.

SEC 58. *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.

SEC 59. *Repealing Clause.* Any law, presidential decree or issuances, 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.

SEC 60. *Effectivity Clause.* This Act shall take effect fifteen (15) days after the publication in at least two (2) newspapers of general circulation.

Approved,