The Agency determined that a total of 397 potential active ingredients were in Toxicity Category 3 or 4 for at least one of the following guideline studies: oral, inhalation, dermal, skin irritation, and eve irritation. After this initial screening, 109 of the 397 active ingredients whose end-use products would have REIs greater than 12 hours were excluded, resulting in 287 potential candidates. The REI's of these 109 active ingredients were set utilizing chemical specific data via the registration, reregistration, or special review process. The remaining 287 active ingredients were then screened to determine if both the dermal toxicity and eye irritation tests resulted in Toxicity Category 3 or 4, and the results of the sensitization/hypersensitization test were negative. Candidates failing to meet this criteria were excluded from consideration. This screen reduced the number to 88 active ingredients. From this group of 88 active ingredients, an additional 13 were excluded for subchronic, developmental, reproductive, mutagenicity, or carcinogenicity concerns, or if the registration was not supported currently. This resulted in 75 active ingredients as potential candidates for REI reduction to 4 hours.

Some active ingredients are not included on the list in Attachment A because they have been the subject of a reregistration eligibility document (RED), in which the Agency concluded that a 12 hour REI was necessary to protect workers. These active ingredients would not be eligible for reduced REIs through the notification process outlined in the PRN. It should be noted that WPS does not apply to pheromones utilized in insect traps and will not be included in the PRN.

VI. Agency Determination for Adding Active Ingredients To Candidate List

If a registrant believes an active ingredient meets the criteria set forth in Part IV of the PR Notice, and that products containing that active ingredient should be eligible for a reduced REI through the notification process, the registrant should contact Judy Smith in Certification, Training and Occupational Safety Branch, Field Operations Division (7506C), 401 M St., SW., Washington DC 20460, before August 31, 1995. If a registrant or other party has information or data indicating that an active ingredient should not be on the candidate list, the registrant must notify the Agency before August 31, 1995. To be considered for a reduced REI, the active ingredient must meet the criteria outlined in the PRN, based upon studies determined by the Agency to be

acceptable. The registrant would be required to submit the studies [or cite their MRID numbers and provide copies of Agency reviews that confirm that the criteria are met]. For additional information on this issue, registrants should contact Judy Smith (703–305–7666) as early in the comment period as possible.

VII. Procedures for Determining Eligibility of End-Use Products

If the active ingredient(s) is included on Attachment A, the registrant must evaluate the product to determine if the EP is eligible for REI reduction. To be acceptable, the following criteria must be met. The registrant must certify to the Agency that the EP meets all of the criteria outlined below:

- 1. The registrant has submitted or cited studies for the EP on acute dermal toxicity, primary skin irritation, primary eye irritation and skin sensitization (or hypersensitivity if the product contains a microbial or biochemical active ingredient). The Agency need not have completed these study reviews.
- a. The registrant must cite the MRID numbers for all studies submitted.
- b. If EPA has permitted the use of studies performed on a substantially similar EP to fulfill the acute toxicity data requirements, the registrant must submit proof that EPA has approved the use of these studies.
- c. If EPA has waived a data requirement for one or more of the required studies, the registrant must submit proof that the data were waived.
- d. If all studies on the EP have not been submitted, cited, or waived, the REI may not be reduced for the end-use product at this time.
- 2. Based on the acute toxicity studies, the product is in Toxicity category III or IV.
- 3. Based on the sensitization or hypersensitivity studies, the product is not a sensitizer or there have been no reports of hypersensitivity.
- 4. The registrant has no data indicating, and is not aware of, adverse health effects associated with the EP, i.e., carcinogenicity, mutagenicity, developmental effects, reproductive effects.
- 5. The registrant is not aware and has not been informed of incident information (illness or injury reports) that are "definitely" or "probably" (as defined by the California Incident Reporting System) related to postapplication exposures to the product.

VIII. Procedure for Notification/ Certification

A. Notification Statement

For each product that qualifies for the notification procedures, the registrant would be required to submit:

- 1. An Application for Registration (EPA Form 8570–1), identified as a notification under this PRN.
- 2. Three copies of a revised label, clearly marked to highlight the revised REI.
- 3. The information required to demonstrate that the product is eligible for the reduced REI.
- 4. The following certification statement:

I certify that this notification is consistent with the provisions of PR Notice 95–x and that no other changes have been made to the labeling or the confidential statement of formula of this product.

I further understand that if this notification is not consistent with the terms of PR Notice 95–x, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. I understand that the Agency may direct a change in the REI of a product subject to this notice if the Agency determines that a change is appropriate, and that products may be subject to regulatory and enforcement action if the appropriate changes are not made.

B.Final Printed Labeling

For each product, final printed labeling must be submitted either as part of the notification or separately in accordance with PR Notice 82–2, before the product may be distributed or sold.

IX. Sale and Distribution

After the PRN is issued and once the registrant has submitted the information and certification specified in Unit VIII, the registrant would be able to sell or distribute products bearing the registrant-certified revised labeling that was submitted to the Agency.

X. Permitted Relabeling of Product in Channels of Trade

After the PRN is issued, registrants revising their labeling to reduce an interim REI from 12 hours to 4 hours may revise labeling of products through stickering or full relabeling. Stickering, or full relabeling, may occur at sites where product is not under direct registrant control (such as distribution or retail sites), by any person the registrant designates, and without registration of the site as a pesticide producing establishment. The registrant, however, retains full responsibility for ensuring that such labeling modifications are carried out correctly.