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ENVIRONMENTAL PROTECTION AGENCY

40 CFR 162

(Docket No. OPP-30057)

CRITERIA AND PROCEDURES FOR SPECIAL REVIEWS OF PESTICIDES

AGENCY: Environmental Protection Agency (EPA or the Agency)

ACTION: Notice of Proposed Rulemaking

SUMMARY: The EPA proposes to revoke 40 CFR §162.11 (a) and (b) and to issue a new 40 CFR Part 154 in its place. Section 162.11 contains rules governing what is known as the "Rebuttable Presumption Against Registration" or RPAR process. These proposed amendments would revise both the substantive criteria under which EPA initiates review of pesticide products (leading to an ultimate determination of whether their use or uses pose unreasonable adverse effects to humans or the environment) and the procedures for the process. The proposed amendments are based primarily on changes made to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., by Congress in 1978 and on the experience acquired by EPA in regulating pesticides pursuant to the present section 162.11.

DATES: Comments should be received on or before (insert date 90 days after date of publication in the Federal Register).

ADDRESSES: Comments should be addressed to the Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Rm. E409, 401 M Street, SW., Washington, D.C. 20460. All comments should bear the identifying notation "OPP-30057." All comments will be available for public inspection from 8:30 a.m. to 4:00 p.m., Monday through Friday at EPA's Office of Document Control, Room E-409, 401 M Street, SW., Washington, D.C. 20460.

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I. Overview.

This proposed rulemaking is issued pursuant to sections 3, 6, and 25 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended ("FIFRA" or "the Act") (7 U.S.C. 136 et seq.). The preamble consists of five major parts. This first part is the Overview. The second part gives an historical background. The third part describes the change of the name from "RPAR" to "Special Review". The fourth part describes the proposed revisions to the risk criteria presently found in section 162.11. The fifth part describes the proposed revisions to the procedures of the Rebuttable Presumption Against Registration process. The preamble concludes with a request for comments.

Section 162.11 is entitled: "Criteria for determinations of unreasonable adverse effects" and is commonly known as EPA's Rebuttable Presumption Against Registration ("RPAR") process. Section 162.11 includes both the substantive criteria for initiating, and the procedures for conducting the public administrative reviews leading to determinations by EPA as to whether unreasonable adverse effects to humans or the environment exist or will be created as the result of some or all uses or prospective uses of a pesticide.

This document proposes to revise both the substantive criteria and the procedures of section 162.11. Furthermore, this document proposes to change the name of the RPAR process

to revise the criteria and procedures in response to (a) the requirements and legislative intent of Congress as expressed in the 1975 and 1978 revisions to FIFRA and (b) the Agency's own experiences gained after more than eight years of dealing with pesticide regulation under the present section 162.11.

The revisions to FIFRA in 1972, 1975, and 1978 will be discussed, by year, in the following section. However, the changes to the criteria and procedures which are proposed in this document are based especially on: (a) section 3(c)(8) of the 1978 revisions to FIFRA and (b) section 3(c)2(B) of the 1978 revisions to FIFRA. Regarding FIFRA section 3(c)(8), the 1978 Conference Report of the House and Senate directs the EPA to consider exposure to a pesticide before initiating the RPAR process (Conf. Rp. p. 21). Under this proposal, before a Special Review is initiated on a pesticide use the EPA would take into account actual or projected human or environmental exposures from that use. In effect, these proposed amendments would change several of the present initiating criteria from reliance primarily upon toxic effects found under laboratory conditions to criteria based on the assessment of actual or estimated risk in the environment.

Furthermore, the 1978 revisions to the FIFRA include section 3(c)(2)(B) which allows the Agency to require the registrants to generate and submit additional data to support

an existing registration. Prior to section 3(c)(2)(B) the Agency could obtain additional data only through its cancellation authority. Submission of data under section 3(c)(2)(B) can be enforced by suspension.

Since the inception of the RPAR review program in 1975, the Agency has accumulated experience in regulating pesticides suspected of causing health or environmental problems. The Agency's experience has led to concern over the amount of time and resources required to review each chemical and achieve a regulatory solution; the result has been a limited number of chemicals that could be processed each year. The length of time involved in the review of RPAR chemicals has been considerable. Review times have generally ranged from two to six years before a final resolution has been achieved.

The process needs to be made more efficient so that risk concerns from problem chemicals can be thoroughly reviewed and quickly resolved. The process must allow the Agency to respond more quickly to referral requests and, therefore, implement health and environmental protection measures sooner.

The Agency believes that the proposed changes to the RPAR criteria and procedures will achieve this goal by integrating legislative revisions with Agency experience. The legislative history of section 3(c)(8) directs the Agency to focus its time and resources on those chemicals that the environment, humans or animals are significantly exposed to and that pose unreasonable risks. When the available data are not adequate to eva-

luate risk and to make a decision, section 3(c)(2)(B) allows the Agency to require the registrant to submit additional data. Furthermore, the proposed revisions would insure that Agency resources are spent on the most significant chemicals, and assure public involvement in the Agency's decision-making and provide for peer review of data and issues when needed. Peer review would help to insure that: (a) action is taken on valid data or evidence; (b) the Agency knows whether the risks to health or the environment are significant; and (c) the Agency is provided with the most current thought and information in the field.

In summary, this document proposes certain changes to update and facilitate EPA's public interim administrative review process initiated when the Agency believes there are data or other significant evidence which raise prudent concerns that a use, or uses, of a pesticide cause or will cause an unreasonable risk to humans or to the environment, as defined and required by section 3(c)(8) of FIFRA. The sometimes rigid requirements of section 162.11 have not achieved the goal of speedy resolution of risk concerns. The EPA believes that these proposed amendments will aid the Agency in the future regulation of pesticides that may pose unreasonable adverse effects to humans or the environment and will implement

both the letter and the spirit of the statutory changes made by the Congress.

EPA believes that the goals of openness, speed, scientific accuracy, and candor will be achieved by the new procedures. This notice requests the submission of written comments, data and other evidence or argument from all interested persons concerning all issues raised by this rulemaking. By this notice, EPA intends to provide the public with full opportunity for discussion of all these issues and participation in the development of the final rule.

II. Historical Background.

A. The 1972 FIFRA (7 U.S.C. 136 et seq.).

In 1972, the FIFRA was significantly amended in scope and procedure with respect to the federal regulation of pesticides. Section 3(c)(5) of the FIFRA provides that the Administrator shall register a pesticide only if he determines that, among other things, "when used in accordance with widespread and commonly accepted practice it will not cause unreasonable adverse effects on the environment" (section 3(c)(5)(D)). Likewise, section 6(b) of the 1972 FIFRA authorizes the Administrator to cancel the registration of a pesticide if he determines that use of a product causes unreasonable adverse effects on the environment. "Unreasonable adverse effects on the environment," as used in both the registration and cancellation contexts, is defined by section 2(bb)

to mean "any unreasonable risk to man or the environment, taking into account the economic, social and environmental cost and benefits of the use of any pesticide." Furthermore, the 1972 legislation required that all previously registered pesticides be reviewed in light of possible adverse effects to health or the environment (FIFRA section 3(g)).

B. The 1975 Amendments to the FIFRA.

In 1975, Congress amended the FIFRA in two relevant respects. These changes required the Administrator to submit proposed cancellation actions or proposed changes in classification, under the FIFRA section 6, to the United States Department of Agriculture (USDA) and the Scientific Advisory Panel (SAP) for review prior to the initiation of hearings. These procedures were added to assure that the Agency complied with the section 6(b) cancellation criteria by looking at both risks and benefits prior to formal cancellation hearings.

First, the Administrator is required to submit a proposed action, along with an analysis of its impact on the agricultural economy, to the Secretary of Agriculture for review. This submission must occur at least 60 days prior to issuing the notice of final action. If the Secretary of Agriculture comments in writing on the proposed action and analysis within 30 days after receipt, the Administrator is required to publish both the Secretary's comments and the Administrator's

responses to these comments in the Federal Register, along with the notice activating the hearings rights of registrants and other adversely affected persons.

Second, the Administrator is required to submit certain proposed actions to the SAP for peer review. The Administrator is required to establish this review, pursuant to detailed procedures specified in the FIFRA section 25(d). Proposed cancellation actions are referred to the SAP for comment on "the impact on health and the environment of the action proposed..." (section 25(d)). The procedures governing the timing of submissions to the SAP and response to any comments received from the SAP are identical to the procedures governing review by the Secretary of Agriculture.

C. The 1978 Amendments to the FIFRA.

1. Section 3(c)(2)(B).

The Federal Pesticide Act of 1978 substantively amended the FIFRA. One significant 1978 addition that is relevant to this proposal is section 3(c)(2)(B). As previously mentioned, this section allows the Agency to require the registrants to submit additional data in support of an existing registration; prior to section 3(c)(2)(B) if the Agency needed more data in order to assess a possible hazard from a registered pesticide it had no express authority to do so.

2. Section 3(c)(8).

Another significant 1978 addition is FIFRA section 3(c)(8). The current oncogenicity and mutagenicity criteria for initiating RPAR reviews do not take exposure into account. Thus, section 162.11 technically requires the initiation of the RPAR process in some cases when the Agency may be convinced that exposures or risks are insignificant. Because of this perceived rigidity, Congress added section 3(c)(8). It provides:

> Interim Administrative Review. Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or the environment. Notice of the definition of the terms 'validated test' and 'other significant evidence' as used herein shall be published by the Administrator in the Federal Register.

The requirement that the Agency publish a notice in the Federal Register defining the terms "validated tests" and "other significant evidence" was satisfied on February 14, 1979, by the publication of a notice titled "Proposed Definitions of 'Validated Tests' and 'Other Significant Evidence.'" (44 FR 9626 February 14, 1979.) This document provided that the definition of these terms

shall be the definitions given to them in the Conference Report on the Federal Pesticide Act of 1978 (S. Rep. No. 94-1188, 95th Cong., 2d Sess. 35 (1978).1/

The legislative history of section 3(c)(8) makes it clear that Congress wanted the EPA to have some solid evidence of risk to humans or the environment in hand before initiating the lengthy and time-consuming RPAR process, and that the extent of human or environmental exposure to a pesticide should be considered when evaluating risk. The Conference Report of the House and Senate stated in pertinent part:

> Human exposure to pesticides through any medium or pathway is a central issue in evaluating the unreasonable adverse effects of pesticide products. Where this issue can be resolved without an RPAR being initiated, it shall be (Conf. Rp. p. 21).

Also, the Conference Report states that "[t]he Administrator should notify in writing the registrant of a pesticide product under Special Review of the exact scope and nature of any alleged unreasonable adverse effect on human health or the

1/ Those definitions are as follows: "The Administrator shall insure that the pesticide shall be subject to the RPAR process only on the basis of a validated test or other significant evidence (and not on the basis of unsubstantiated claims,) and that the term 'validated test' be defined as a test conducted and evaluated in a manner consistent with accepted scientific procedures, and that the term 'other scientific evidence,' be defined as evidence that relates to the uses of a pesticide and their adverse risk to man or to the environment. It is the intent of the conferees that 'other significant evidence' of adverse risk means factually significant information and is not to include evidence based only on misuse of the pesticide" (Conf. Rp. p. 20).

environment prior to initiating an interim public review" (Conf. Rp. p. 145). In the view of the Conferees, this notification should be a written, private communication between the Agency and the registrant (Conf. Rp. p. 71). Such notification is intended to give the registrants an opportunity to refute the Agency's findings in order to "... furnish a greater degree of protection for the property rights of pesticide registrants and ameliorate the indictment-like characteristics of the interim public review process" (Conf. Rp. p. 145).

Therefore, the Agency has followed a practice of notifying registrants by letters when it believes a pesticide will become the subject of a Notice of Rebuttable Presumption Against Registration. Typically, such letters have informed the registrant in general terms of the bases for the Agency's tentative conclusions.

The Agency's practice regarding such early notification has been consistent with Senator Leahy's statement on the Senate floor debate on consideration of the Conference Report regarding the 1978 revisions to the FIFRA:

> I wish to stress that this provision is not meant to permit extended private or closed negotiations. We want to protect rights of producers, but not circumvent established case law in regard to substantial questions of unreasonable adverse effects.
>
> Pesticide regulation is not the private business of the pesticide industry and the EPA. The conference report language affording affected pesticide producers an opportunity to respond to a "private communication" about

an impending RPAR is not intended to afford the registrant a protracted and secret discussion of risks and benefits with EPA. If the registrant discovers egregious errors in the studies to be cited by EPA in an RPAR, all parties are served by having this brought to EPA's attention. When, however, the registrant disputes the conclusions EPA may choose to draw from these experimental results, his views are of no greater relevance than those of any other person, and, indeed, because of his vested interest in the regulatory outcome, should be subject, along with the EPA interpretation, to public scrutiny. Therefore, "reasonable" time to respond to a private communication on an impending RPAR must take into account the interest of the public in participating in any risk-benefit evaluation that affects their health, and the need to consider that the public may remain exposed to the hazard the pesticide poses while the RPAR process is underway (cite to be provided).

D. The RPAR Process.

In its 1975 regulations implementing the registration provisions of the 1972 amendments, the Agency created a public administrative review process which has become known as the "Rebuttable Presumption Against Registration" or "RPAR" process. As mentioned previously, this process and the criteria that trigger it are found in 40 CFR 162.11. The process (a) was intended to provide an administrative mechanism for identifying pesticide uses which might pose substantial questions of safety, (b) was expected to provide an exchange of information between the Agency and interested persons on the question of whether a substantial question of safety in fact existed, (c) attempted to provide a forum for broad public participation during those steps, and (d) required initiation of formal adjudicatory proceedings under the FIFRA if the risk criteria were not rebutted.

Some of these criteria do not require the Agency to consider whether significant adverse effects result from the use of the pesticide; rather, they require the Agency to initiate the RPAR review on any pesticide that demonstrates the effect in animal studies. The regulations have not been amended since 1975.

1. Risk Criteria of the Current RPAR Process.

Presently, section 162.11 requires the Agency to initiate the RPAR process for a pesticide if it meets or exceeds any of the following criteria when used according to label directions:

(i) "Acute toxicity

(A) Hazard to Humans and Domestic Animals.

(1) Has an acute dermal LD50 of 40 mg/kg or less as formulated; or

(2) Has an acute dermal LD50 of 6 g/kg or less as diluted for use in the form of a mist or spray;

(3) Has an inhalation LC50 of 0.04 mg/liter or less as formulated.

(B) Hazard to Wildlife

(1) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels equal to or greater than the acute oral LD_{50} measured in mammalian test animals as specified in the Registration Guidelines.

(2) Occurs as a residue immediately following application in or on avian feed of an avian species, representative of the species likely to be exposed

to such feed in amounts equivalent to the average daily intake of such representative species, at levels equal to or greater than the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(3) Results in a maximum calculated concentration following direct application to a 6-inch layer of water more than 1/2 the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured on test animals specified in the Registration Guidelines.

(ii) Chronic Toxicity

(A) Induces oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation or dermal exposure; or induces mutagenic effects, as determined by multitest evidence.

(B) Produces any other chronic or delayed toxic effect in test animals at any dosage up to a level, as determined by the Administrator, which is substantially higher than that to which humans can reasonably be anticipated to be exposed, taking into account ample margins of safety; or

(C) Can reasonably be anticipated to result in significant local, regional, or national population reductions in non-target organisms, or fatality to members of endangered species.

(iii) Lack of Emergency Treatments

Has no known antidotal, palliative, or first aid treatments for amelioration of toxic effects in man resulting from a single exposure.

2. Stages of the Current RPAR Process.

The current RPAR process consists of several stages. First, the initial investigation phase involves a review of

the scientific studies that suggest that one or more of the RPAR criteria have been met or exceeded by the chemical in question. A validation of these studies is conducted by Agency scientists or by contractors. An extensive literature search is initiated in an attempt to identify all available health and environmental effects information. If health effects studies are found to be valid, an effort is made to gather and preliminarily assess readily available information on the exposure to the pesticide in question. The applicants or registrants of the pesticide are informed of the review and are offered the opportunity to submit additional information or comment.

The validated health effects studies, the literature search and the combination of this hazard information with information on use and routes of exposure produces the Agency's preliminary position on the potential risk of the pesticide. The document describing this position on risk is referred to as Position Document 1 (PD 1). A notice of the availability of the PD 1 and a formal Notice of Rebuttable Presumption Against Registration is published in the Federal Register. After a PD 1 is published, the public process begins.

Risks can be rebutted at this point in the RPAR process by interested parties submitting to the Agency; (1) proof that the study or studies upon which the presumption is based are not scientifically valid; or (2) proof that any actual risk can be reduced to levels where "unreasonable adverse effects" will not occur.

This phase of the process focuses on the gathering of additional information in the form of rebuttal comments, additional information on risk, and input from other agencies. For example, the United States Department of the Interior (USDI) provides information on the effects of pesticide use on endangered species.

In the event that the Agency concludes at this point that none of the risk criteria have been met with respect to one or more uses of the pesticide, the pesticide is returned to the normal registration process and the RPAR is terminated with regard to those uses. A second Position Document (PD 2) is drafted which describes the Agency's decision to support its regulatory action. The PD 2 ends the RPAR process for those uses.

When the rebuttal is not successful, a rebuttal assessment, risk assessment, benefits asessment, risk/benefit analysis and proposed regulatory position are presented in a document termed Position Document 2/3 (PD 2/3).

In the PD 2/3, the Agency attempts to examine the full range of regulatory options which are available under the law. These options range from full registration of specific uses to full cancellation. Within this range, the Agency has a variety of options involving labeling changes

and restricted use. 1/ Each option is examined in regard to its impact on the risks and benefits of each pesticide use. The recommended decision presents the best balance of risks and benefits in the interest of public health and the environment. A notice of the proposed determination and an announcement of the document's availability is published in the Federal Register.

As discussed earlier, the 1975 amendments to the FIFRA require that if the proposed decision (PD 2/3) proposes involuntary regulatory measures, it must be submitted to the Scientific Advisory Panel for review of its scientific basis and to the Secretary of Agriculture for comment. These comments, plus any industry or public comments on the proposed decision, are evaluated. The Agency's assessment of these comments and the final decision on the regulatory action are then announced in the Federal Register. The risk/benefit evaluation supporting the final decision is contained in the Position Document 4 (PD 4) which is available from the Agency on request.

1/ Restricted use pesticides are those pesticides with uses that are limited to certified applicators or persons under their supervision, or subject to other regulatory restrictions which might be imposed by regulation. The term "certified applicator" refers to an individual certified under section 4 of the FIFRA. Although the Agency was given the authority in 1972 to have restricted use pesticides, the criteria necessary to classify pesticides for restricted use was not established until 1975.

III. The Change of the Name.

Over a period of years, registrants have commented that the term "Rebuttable Presumption Against Registration" implies that the risks posed by a product subject to an RPAR review are not justified by the benefits of the product's use. These comments point out that, at the time the Agency determines that a risk criterion has been met or exceeded, there had not been an assessment of the benefits of the product under review. As a result, many registrants have expressed concern that governments of foreign countries and members of the public may misinterpret the meaning of an "RPAR" notice.

The Agency recognizes that the presumption that arises upon initiation of an RPAR review or Special Review is that one of three types of notices--a notice of denial of registration under FIFRA section 3(c)(6), a notice of intention to cancel a registration under section 6(b)(1), or a notice of intent to hold a hearing under section 6(b)(2)--will be issued for each pesticide or pesticide use under review, unless specific information is eventually brought forward to rebut the presumption. The procedural device of a rebuttable presumption reflects that under the FIFRA it is the registrant who must satisfy the ultimate burden of establishing that the risks posed by his product are reasonable in light of the

benefits it provides. It is not intended as a statement of an Agency conclusion that the pesticide poses an unreasonable risk. However, the Agency agrees that the public and others may misinterpret the ongoing review as indicating that the Agency has determined that registration of a pesticide or pesticide use should be cancelled or denied.

Accordingly, to avoid any misinterpretations resulting from the term "Rebuttable Presumption Against Registration," the Agency proposes to refer to its in-depth review of the risks and benefits posed by a pesticide use as a "Special Review." This description distinguishes the process from the routine reviews that the Agency conducts in making most registration and reregistration determinations, but it does not connote an Agency conclusion that a pesticide use presents or will present an unreasonable risk to the environment. The term "Special Review" is intended instead to indicate that the use of a pesticide may pose a significant risk, and, therefore, the Agency will perform an in-depth review of the risks and benefits of the pesticide use before deciding what regulatory action, if any, is appropriate.

IV. Proposed Changes to the Risk Criteria.

A. Introduction.

As discussed above, the risk criteria issued in 40 CFR 162.11 in 1975 were intended to identify pesticides which might pose significant risks and, therefore, might require regulatory action. When one or more of the risk criteria

were met or exceeded, the RPAR process was intended to provide a brief period for comments by interested parties, and to propose and then finalize a regulatory decision within a short period of time.

The Agency has encountered problems in attempting to apply or interpret the criteria. These problems include criteria based on toxicity without considering exposure and unclear or impractical criteria.

First, the existing criteria are narrow or unrealistic since several of the criteria are based on toxicity demonstrated in laboratory tests (i.e., the acute oral, dermal and inhalation criteria, and the oncogenicity and mutagenicity criteria) without considering whether exposure to humans or other nontarget species is high enough to pose an unreasonable risk. Illustratively, the criteria for acute effects to wildlife focus on laboratory test results and a theoretical concentration of a pesticide in food or water which might exceed a defined toxicity level, rather than considering the exposure of wildlife to a pesticide. As a result of initiating the RPAR process on criteria based only on toxicological effects, the Agency has discovered during RPAR reviews that either these studies or the exposure data were inadequate for estimating potential risks.

Second, some of the risk criteria are unclear or have been

impractical to apply. For example, the criterion for mutagenic effects requires "multi-test evidence." However, it has not been clear as to what evidence of mutagenicity would raise a concern.

The proposed changes to the risk criteria address these two problems by assuring the sufficiency of exposure, as well as toxicity information, prior to evaluating the significance of the risk posed by the use of a pesticide.

B. Exposure Information.

Many different types of exposure information may be taken into consideration when determining the sufficiency of the exposure information. Among these are:

1. chemical characteristics measured in the laboratory or derived from other chemicals with similar structures;
2. predicted mobility in soil;
3. parameters used to predict absorption through the skin or gastrointestinal tract;
4. production volume;
5. location of use (soil characteristics, etc.);
6. persistence;
7. actual or expected presence in the food chain of humans or wildlife; and

8. estimates of the number of people exposed through occupation, diet, or water consumption.

In addition, the amount of exposure information which the Agency determines to be sufficient to investigate risk may depend upon the toxicity or uses of the chemical at issue. The Conference Report of the House and Senate on the 1978 amendments to the FIFRA stated:

> In determining whether there is more than minimal exposure, the toxic properties of the chemical should be considered. In some cases, low levels of exposure in a purely quantitative sense will, nonetheless, because of the serious toxicity of the chemical, raise prudent concerns about the safety of the chemical (Conf. Rp. p. 71).

A very toxic chemical would be assessed differently than a less toxic chemical; a chemical used on food crops would be assessed differently than a chemical used only on non-crop lands. Also, the the amount of data which is sufficient may vary according to the volume of use or whether the uses are minor or major.

Also, the Agency may have sufficient exposure information as a result of using "surrogate" data. Surrogate exposure data are data regarding similar chemicals from which the Agency may extrapolate if data are not available for the chemical under review (45 FR 42858). In such cases, the Agency will proceed without waiting for exposure data on the chemical under review.

The Agency may determine that additional exposure information is necessary. In such cases, the Agency will require under FIFRA

section 3(c)(2)(B) that the registrant submit this information.

C. Exposure as a Basis for Assessing Risk.

Usually, the Agency evaluates the sufficiency of exposure information in order to determine significance of risk after validated toxicity data indicate an effect to health or the environment. However, in some cases, the Agency will further investigate to determine the significance of risk from concerns originally raised from exposure information. One such case would be when groundwater is found to be contaminated by a pesticide.

Groundwater provides 45% of the United States drinking water supply. Therefore, contamination of groundwater by pesticides could result in widespread exposure to large populations. The ability for some pesticides to persist without significant degradation in soil or groundwater, the mobility of groundwater (and waterborne residues) throughout an aquifer, and the extreme heterogeniety of soil and aquifer characteristics in the United States, makes it difficult to predict what level or duration of groundwater contamination at a given site may result from use of a pesticide at the same or a different site. Evidence of relatively localized levels of pesticide contamination of groundwater should be treated as warnings of more widespread, future contamination. In addition, groundwater once contaminated cannot be easily decontaminated; thus, there is a considerable potential that groundwater contamination will continue long after actions have been taken to restrict application of the pesticide.

Therefore, if the Agency finds any pesticide in groundwater or if the Agency has data indicating the presence of a pesticide in groundwater, the Agency will investigate further to determine if there is a significant risk. If essential toxicity or environmental fate data are not available, registrants will be required to submit the data under the FIFRA section 3(c)(2)(B). The Agency will evaluate the available data in regard to levels and extent of ground water contamination, the likelihood of more extensive groundwater contamination (both present and future), environmental fate and transport, and toxic effects in order to determine whether a Special Review should be initiated. The mere presence of a pesticide in groundwater will not be a basis for initiating a Special Review, but the Agency evaluation of known contamination together with estimated current and future contaminantion at toxicologically significant levels may provide the basis for initiating a Special Review.

The Agency's Office of Pesticide Programs (OPP) discussed toxicity assessment for drinking water contamination in a document prepared by OPP for the FIFRA Scientific Advisory Panel (SAP) in June 1983. This document states the following:

> Contamination of any drinking water by pesticides is undesirable, but may be unavoidable. Depending on the level found, however, regulatory action or a public health concern may or may not be warranted. In order to assess the significance of pesticides in ground water, EPA proposes to extend the concept of the acceptable daily intake (ADI), used in the establishment of food tolerances, as a benchmark for the assessment of potential hazard. The ADI has been defined as follows: "The daily exposure level of a pesticide residue which, during the entire lifetime of man, appears to be without appreciable risk on the basis of all facts known at the time.

> The ADI is expressed in milligrams of the pesticide, as it appears in the diet, per kilogram of body weight per day (mg/kg bw/day). 'Without appreciable risk' is taken to mean the practical certainty that injury will not result even after a lifetime of exposure...The ADI is based on a rigorous evaluation of animal studies and, in rare cases, human data. Although in most cases the ADI will be based on a chronic feeding study, other studies such as a multigeneration reproduction study may also be used to set an ADI."

In determining whether to initiate a Special Review, the Agency will consider, among other things, the levels of contamination found in groundwater relative to drinking water standards and health advisories.

The presence of a pesticide in groundwater is one example of an exposure concern that would cause the Agency to further investigate to determine if there is a significant risk. Other examples include the presence of unanticipated pesticide residues in consumer products and the presence of indoor pesticide residues from domestic uses.

D. Risk Assessment.

When the Agency determines that there is sufficient exposure and effects information on a chemical, a risk assessment will be performed for the appropriate route(s) of exposure. Risk assessment has been defined as:

> ...the characterization of the potential adverse health effects of human exposures to environmental hazards. Risk assessments include several elements: description of the potential adverse health effects based on an evaluation of

results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgments as to the number and characteristics of persons exposed at various intensities and durations; and summary judgments on the existence and overall magnitude of the characterization of the uncertainties inherent in the process of inferring risk. 3/

The possible components in risk assessment, have been described as follows:

> Risk assessment can be divided into four major steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. A risk assessment might stop with the first step, hazard identification, if no adverse effect is found or if an agency elects to take regulatory action without further analysis, for reasons of policy or statutory mandate.
>
> Of the four steps, hazard identification is the most easily recognized in the actions of regulatory agencies. It is defined here as the process of determining whether exposure to an agent can cause an increase in the incidence of a health condition (cancer, birth defect, etc). It involves characterizing the nature and strength of the evidence of causation. Although the question of whether a substance causes cancer or other adverse health effects is theoretically a yes-no question, there are few chemicals on which the human data are definitive. Therefore, the question is often restated in terms of effects in laboratory animals or other test systems, e.g., "Does the agent induce cancer in test animals?" Positive answers to such questions are typically taken as evidence that an agent may pose a cancer risk for any exposed humans. Information from short-term in vitro tests and on structural similarity to known chemical hazards may also be considered.
>
> Dose-response assessment is the process of characterizing the relation between the dose of an agent administered or received and the incidence of an

3/ National Academy of Sciences. Committee on the Institutional Means for Assessment of Risks to Public Health. Risk Assessment in the Federal Government: Managing the Process. NAS-NRC, p.18, 1983

adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent. It takes account of intensity of exposure, age pattern of exposure, and possibly other variables that might affect response, such as sex, lifestyle, and other modifying factors. A dose-response assessment usually requires extrapolation from high to low dose and extrapolation from animals to humans. A dose-response assessment should describe and justify the methods of extrapolation used to predict incidence and should characterize the statistical and biologic uncertainties in these methods.

Exposure assessment is the process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment. In its most complete form, it describes the magnitude, duration, schedule, and route of exposure; the size, nature, and classes of the human populations exposed; and the uncertainties in all estimates. Exposure assessment is often used to identify feasible prospective control options and to predict the effects of available control technologies on exposure.

Risk characterization is the process of estimating the incidence of a health effect under the various conditions of human exposure described in exposure assessment. It is performed by combining the exposure and dose-response assessments. The summary effects of the uncertainties in the preceding steps are described in this step. 4/

Although scientific assumptions may be made in performing risk assessments, when common parameters are applied to many chemicals, the Agency can compare the potential risks associated with the use of each of a number of chemicals. Therefore, risk asssments can assist the Agency in ranking or prioritizing chemicals for review. As a result, Agency resources can be directed to those chemicals presenting the greatest potential risk. The Agency will perform risk assessments as expeditiously as possible so that any significant risk

4/ Ibid pp. 19-20

to the public can be defined and announced quickly. Further, in order to avoid replacement of one pesticide with another whose risk may be equal or greater, the Agency will generally attempt to review the risks and benefits of all alternative pesticides in the same use category of a candidate for Special Review.

E. The Proposed Criteria Revisions.

The following sets forth revisions in the risk criteria (the standards for initiating a Special Review of pesticide uses). Proposed §154.4 includes criteria for the initiation of a Special Review based upon (1) acute toxicity to humans or domestic animals (§154.4(a)); (2) the potential of adverse chronic effects in humans (§154.4(b)); (3) mutagenicity (§154.4(c)); (4) hazards to non-target wildlife (§154.4(d)); (5) separate criteria for hazards to threatened or endangered species (§§154.4(e) and (f)); and (6) an "other adverse effects" criterion which would permit the Agency to initiate a Special Review in circumstances wherein the other criteria have not been met (§154.4(g)). The revised criteria would require the Agency to evaluate not only toxicity data, but also actual and potential exposure information, prior to initiating a Special Review.

1. Acute Toxicity to Humans or Domestic Animals.

Instead of the present numerical criteria that trigger the RPAR process, EPA believes that the acute toxicity risk criterion for initiating a Special Review [162.11(a)(3)(i)(A)] should be revised to read:

> the use of a pesticide... may pose a risk of serious acute injury to humans or domestic animals.

This proposed change to the risk criterion for acute toxic effects is intended to remedy the fact that the present criterion does not consider exposure; the present criterion does not consider whether humans or domestic animals will actually be exposed to amounts of the pesticide high enough to induce the effect observed in laboratory tests. The proposed criterion would consider exposure, whether based on observed effects under conditions of use, simulated field tests, or reliable estimates.

2. Oncogenic, Teratogenic, Fetotoxic, Reproductive, and Other Chronic or Delayed Toxic Effects.

EPA believes the current risk criteria for initiating a Special Review pertaining to oncogenicity [162.11(a)(3)(ii)(A)] or other chronic or delayed toxic effects [162.11(a)(3)(ii)(B)] should be combined and revised to read:

> the use of a pesticide... may pose a risk of inducing in humans an oncogenic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect, which risk is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk, based upon;
>
> (a) the effects demonstrated in humans or experimental animals,
>
> (b) the known or predicted levels of exposure of various groups of humans, and
>
> (c) the use of appropriate methods of evaluating data and relating such data to human risk.

Under this proposed criterion, the Agency would determine, from the body of available evidence, whether the pesticide use may pose a risk of inducing in humans an oncogenic,

teratogenic, fetotoxic, or reproductive effect, or another type of serious chronic or delayed toxic effect. Mutagenic risks would be covered under a separate risk criterion.

The changes in this criterion are intended to improve the current criteria by requiring that exposure information be considered as an integral part of the decision to initiate a Special Review, as is the legislative intent of the FIFRA section 3(c)(8). The Agency will determine the degree to which humans would be exposed and whether adequate data exist to estimate risk. The Agency would evaluate the quality of the data available and determine whether the data would support a regulatory action on the pesticide of concern.

3. Mutagenic Effects.

EPA believes that the unique character of mutagenic effects justifies establishing a separate risk criterion for such effects. This criterion for initiating a Special Review is as follows:

> the use of a pesticide... may pose a risk of inducing a mutagenic effect in humans, based upon effects demonstrated;
>
> (a) in one or more appropriate test systems, if there is sufficient evidence that the test substance or its metabolites will reach mammalian germinal cells, or
>
> (b) in epidemiological or other data indicating mutagenic effects in humans,
>
> unless, in either case, the potential exposure of human populations is sufficiently low that significant mutagenic risk to humans is not likely to occur.

The changes reflected in the proposed criterion are intended to eliminate the ambiguity of the existing criterion [162.11(a)(3)(ii)(A)] and to give better guidance as to the kinds of mutagenic effects which might cause concern. The existing criterion states that "multitest evidence" is required to initiate a Special Review. However, this criterion does not indicate the kinds of mutagenicity tests that might indicate a hazard to man. Furthermore, it seems to preclude action based on one study.

The proposed criterion could be satisfied in either of two ways. First, if the Administrator concluded from the results of appropriate testing that the test substance causes changes in genetic material and, also, that it will reach mammalian germinal cells, the Special Review process would be initiated, unless the Administrator also determined that the exposure or potential for exposure to human populations is insufficient to result in significant risk. The term "germinal cells" is intended to encompass reproductive cells in all stages of development. Some mutagenic test systems provide evidence that the test substance has the ability to cause changes in genetic material and can reach mammalian germinal cells. By providing evidence of mutations directly in the offspring of mammalian test species, these test systems can produce results strongly indicative of the ability to induce heritable changes in human populations. Therefore, it

is possible that one such test system, properly administered, could suffice for the purposes of this criterion, provided that there is actual or potential exposure to human populations. In other risk determinations, evidence of potential mutagenicity would consist of results from test systems that are, of themselves, less indicative of the ability to cause mutations in human populations. In such instances, relatively more evidence would be necessary to cause the Administrator to conclude that genetic change will occur and that mammalian germinal cells will come into contact with the test substance.

Second, the criterion could be satisfied by direct evidence of heritable genetic change in human populations. Although the capability does not exist currently, the Agency believes that epidemiological studies may provide this evidence in the future.

4. Hazard to Wildlife.

The Agency believes that the criteria in 162.11(a)(3)(i)(B) pertaining to acute effects on mammals, birds, and aquatic organisms and the criterion in 162.11(a)(3)(ii)(C) regarding wildlife population reduction should be condensed into one criterion, except that separate criteria for endangered species are warranted (discussed below). This criterion for initiating a Special Review should be revised to read:

> the use of a pesticide... may result in residues of the pesticide product or its ingredients, impurities, metabolites or other degradation products in the environment of nontarget organisms at levels which:

> equal or exceed concentrations acutely or chronically toxic to such organisms, or which produce adverse reproductive effects in such organisms,
>
> as determined from tests conducted on representative species or from other appropriate data.

The Agency has had difficulty in implementing the existing criterion. The present acute toxicity criteria for wildlife are based solely on a theoretical calculation of residue on animal or bird feed or in an aquatic organism's immediate habitat (e.g., a 6-inch layer of water). The present criteria are met if the theoretical residue exceeds a toxicity level determined by laboratory tests (e.g., LD_{50}, LC_{50}). However, this set of criteria does not consider the concentrations that wildlife in the natural environment are actually or likely to be exposed to. The proposed criterion requires that actual or expected concentrations of a pesticide in the environment meet or exceed acute or chronic toxicity levels for an organism.

5. Hazard to Threatened or Endangered Species.

In order to bring the Agency criteria into compliance with the Endangered Species Act of 1973, the Agency believes that the applicable part of 162.11(a)(3)(ii)(C) should be revised to read:

> the use of a pesticide... may pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973, as amended, or

> may result in the destruction or other adverse modification of any habitat designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act as a critical habitat for any such endangered or threatened species.

The proposed criteria would consider whether the habitat of any endangered or threatened species might be adversely affected by pesticides. The Endangered Species Act of 1973 requires the Agency to consult with the Secretary of Interior or the Secretary of Commerce on these issues. Therefore, these proposed revisions would make the criteria consistent with the Agency's obligations under the Act.

6. Other Adverse Effects.

In order to be able to consider risks to man or the environment which may not be covered by the preceding risk criteria, the Agency believes that the following criterion should be added:

> the use of a pesticide...may otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, or environmental benefits that justify initial or continued registration.

While the existing 162.11 criteria are intended to define most hazards which might constitute unreasonable adverse effects, they may not encompass all possible types of hazard to man or the environment.

The proposed criterion would enable the Agency to initiate the Special Review process for potentially serious effects which do not meet or exceed the other risk criteria. An

example of such an effect might be the potential for an acutely toxic pesticide to contaminate groundwater despite label restrictions specifically prescribed to avoid such contamination. By proceeding through the Special Review process the need to immediately initiate formal hearings, which are resource-intensive for all involved parties, could be avoided; the Agency could choose the procedure which best protects health and the environment while using resources efficiently.

7. Lack of Emergency Treatments.

The proposed regulation deletes the existing criterion in 162.11(a)(3)(iii), which addresses the lack of a known treatment to ameliorate toxic effects in man resulting from a single exposure. The Agency recognizes that for many pesticide products it is not possible to specify an effective environment which may not be covered by the preceding risk antidote for accidental poisoning. Accordingly, the determination the Agency considers to be important for the Special Review process is whether the lack of an effective antidotal treatment poses a significant risk to health, given the particular packaging, labeling, methods of application, and characteristics of the product. If such a risk does exist, the Agency would investigate the feasibility of various regulatory alternatives to reduce the risk to acceptable levels. The proposed criterion for acute toxicity above would apply to risks of serious acute injury resulting from

product toxicity, whether or not the risks result from lack of an effective antidote. Consequently, the Agency believes that a separate criterion is no longer necessary.

V. Proposed Procedural Changes to the RPAR Process.

As mentioned previously, the 1972 legislation required that all previously registered pesticides on the U.S. market be reregistered. This involved the review of approximately 35,000 pesticide formulations. The extensive reviews and documentation associated with the reregistration review of all these pesticide formulations would have been extremely costly. In response to this problem, the 1978 amendments to the FIFRA allowed a generic registration standards program to be created. The approximately 35,000 active registrations can be covered by approximately 600 Registration Standards, each representing a single active ingredient. These approximately 600 active ingredients have been grouped into 48 "clusters", and these clusters have been ranked for review. The manner in which the review priority of these clusters was set, and a more detailed explanation of the cluster concept is set forth in a Federal Register notice published November 14, 1980 (45 FR 75488).

As part of the Registration Standard program, data on the toxicology, chemistry, environmental effects, and environmental fate of an active ingredient are reviewed for all formulations of that active ingredient. The Registration Standard will summarize these data and present any risk concerns identified during the review; in fact, most risk concerns that are identified occur during reregistration reviews.

However, risk concerns may also be identified from reviews conducted outside the reregistraton process. Such reviews may result from new applications for registration or from information submitted by individuals, research or educational institutions.

A. Registrant Notification.

When the Agency concludes tentatively that effects data, together with preliminary information on exposure, indicate that a risk criterion may have been met, registrants will receive private notification that the Agency is considering issuing a Notice of Special Review (see §154.14 and II.C.2. in this preamble). Although this notification is private, a docket will be established which will record this notification and all related information. After the decision is made whether to issue a Notice of Special Review, this notification and information will be available to the public (see §154.20 and V.D. in this preamble).

The registrant notification would consist of the toxic effects findings, the route(s) of exposure, and general information concerning the assumed level of exposure. The registrant would have 30 days from the receipt of notification to dispute in writing the validity of the Agency's conclusions or to present in writing any information in response to this notification.

B. Current Benefits Review (CBR).

After the Agency has determined the validity of a study or evidence which indicates a hazardous effect to health or the environment from the use of a pesticide a Current Benefits Review (CBR) would be initiated on the chemical. Such a review can be completed in approximately 90 days. Therefore, the Agency would have a preliminary benefits profile for the chemical at approximately the same time the risk assessment is being evaluated.

However, benefits information would not be relied on to decide whether or not to initiate a Special Review. A benefits profile will help the Agency decide whether to allow a pesticide use which has an indicated risk to continue while data and reviews are being developed. Also, a preliminary benefits profile would aid the Agency in developing a realistic regulatory position and in developing early regulatory options.

Furthermore, a benefits profile early in the process would aid the Agency in knowing where to focus a more detailed benefits analysis. Such an analysis would be initiated if a significant risk is found to be associated with a specific pesticide use or uses. However, a full benefits evaluation may not be undertaken unless cancellation is being considered as a possible regulatory action for a pesticide use or uses.

C. Significance of Risk - Decision Whether to Initiate a Special Review

Following notification to the registrants of the Agency's concerns, if the Agency determines that a significant risk is not associated with a pesticide use or uses, a Federal Register notice will be issued which explains the Agency's previous risk concerns, gives the basis for the Agency's tentative determination that there is not a significant risk associated with a use or uses of a pesticide, announces the availability of the Registration Standard or, for reviews conducted outside the reregistration process, the availability of an Agency support document, and solicits public comment on the Agency determination (see §154.16). Following a public comment period, the Agency will issue a final determination on whether a significant risk may be associated with a pesticide use or uses.

If a significant risk is associated with a pesticide use or uses, a Notice of Special Review will be issued in the Federal Register for the pesticide use or uses of concern. This notice will announce: the Agency's risk concerns and reasons for the determination of a significant risk; the assumptions and data used in the analyses; the nature and strength of the conclusions; and the availability of the Registration Standard or Agency support document. The notice

will, also, solicit public comment and request additional information on the chemical (see §154.18). If a public meeting has been planned for these risk issues, this notice will announce such a meeting; these meetings may include presentations before the SAP. As a rule, the time allowed for public comment during any part of the review will be flexible, depending on the complexity of the issues.

The major steps and decision points that would usually lead to an initiation of a Special Review, as well as those that would usually comprise the Special Review process, itself, are outlined in Table 1. However, the Agency may, at any time after initiating a Special Review, conduct the review without going through all or any of the steps described below, or the Agency may issue a notice of intent to cancel or suspend a pesticide or any uses thereof without first conducting a Special Review.

Reviews conducted for a new registration application may result in a Special Review risk criterion being met. When this occurs a risk/benefit analysis will be performed by the Agency. After this analysis is made, the Agency will tentatively decide whether to register any of these new pesticide uses. The Agency's proposed decision and rationale will be presented to the public for review and comment before a final decision is made.

D. Administrative Record.

After a Special Review is initiated, the Agency will establish an administrative record, which will contain the information and analyses on which the Agency bases its determinations, as well as copies of all public notices, written comments, and transcripts from public meetings. All documents, in the administrative record except those which may not lawfully be disclosed, will be available for public inspection.

E. The Special Review Process.

1. Public Discussions.

After the Notice of Special Review has been issued, additional information is gathered and analyzed on effects, exposure, and benefits from a pesticide. The Agency will promote open discussions with environmental groups, registrants, and other interested parties. The discussions will focus on the chemical at issue and possible ways to reduce its potential risk to health or the environment. These discussions may be conducted in small groups, or the Agency may choose to hold informal, public meetings. This period of discussions may vary in length, depending on the complexity of the issues.

The registrants may agree to voluntarily take action to reduce risks. Among those actions which could reduce potential effects or exposure are changing the use patterns, lowering application rates, requiring protective clothing or respirators for applicators, label warnings, changing production methods, etc. In addition, the registrant may offer to cancel certain uses.

When assessing voluntary actions or any regulatory option, the Agency must take many factors into consideration. Obviously, voluntary actions will only have merit if it can be shown that such actions would reduce risk to "acceptable" levels. The Current Benefits Review generated earlier on the pesticide at issue may have contributed to the Agency's basis for regulatory options, since alternative pesticides would have been identified and the possibility of substituting alternative pesticides taken into consideration. Another consideration will be the enforceability of any regulatory action. For example, the Agency must consider if protective clothing requirements are enforceable or likely to be complied with in a given situation.

Some discussions with the registrants must be private. The confidentiality of certain production and use information is protected by law. However, these meetings will be announced and summarized in a public docket; therefore, any other interested party can request a meeting with the Agency on the same topic. Furthermore, to the extent possible without violating confidential business information, any issues discussed or other information presented in these meetings will be made available in the public docket.

If, as a result of discussions, the Agency determines that the registrants are able to reduce the risks to acceptable levels, a Notice of Preliminary Determination will be published in the Federal Register which identifies the Agency's previous

risk concerns with the pesticide, explains how the Agency feels these concerns can be resolved, and gives the basis for the Agency's proposed regulatory decision (see §154.28(a)(2)). This notice will solicit public comments on the Agency's position and proposed resolution. After the public comment period, the Agency will review and evaluate public comments before announcing its final regulatory decision (see §154.33). Therefore, the public will have full access to and play a vital role in the decision making process.

Following a final regulatory decision any Registration Standard which had been completed for the chemical will be amended to reflect that decision. The Registration Standard will discuss the previous risk concerns and how these concerns were resolved.

Moreover, to help prevent these discussions from becoming unnecessarily drawn out, approximately 90 days after these discussions begin, the Agency will determine whether to continue these discussions to seek voluntary resolutions or, instead, propose imposition of involuntary regulatory measures. Such involuntary restrictions include cancellation, denial of registration, or change of classification.

2. Preliminary Determinations.

When registrants are unable, or unwilling, to voluntarily amend the terms and conditions of registration in a manner that

would lessen sufficiently any risks resulting from the uses of the pesticide, the Agency will prepare to take action to cancel, suspend or amend the terms and conditions of registration to eliminate any unreasonable adverse effects associated with the use of the pesticide.

The Agency's proposed action will include an analysis of the benefits of each use of the pesticide, considering the availability and cost of alternative control methods. Also, this analysis will determine the effects of the proposed action on production and prices of agricultural commodities, retail food prices, and the agricultural economy.

The USDA may be requested to participate in development of the analysis by responding to specific questions, augmenting the Agency's economic information previously summarized in the Current Benefits Review, or generating a benefits analysis targeted to specific uses. All potential sources of data will be explored in an attempt to provide a fully definitive assessment of the effects the proposed action will have on pesticide uses, commodity markets, consumers, communities, and national economic activity.

In accordance with statutory requirements, the Agency will conduct a risk/benefit analysis to determine whether the use of the pesticide causes "unreasonable adverse effects" on health or the environment prior to issuing a proposed notice of intent to cancel, suspend, or deny registration for certain or all uses of the pesticide. The Agency's proposed action

will be announced in the Federal Register in a Notice of Preliminary Determination (see §154.28).

3. Review and Comment on Preliminary Determination.

As required by section 25(d) of the FIFRA, the Agency will submit the proposed action to the Scientific Advisory Panel (SAP) for comments on the scientific basis of the proposed action (see §154.28(b)). The Panel's review would be conducted in accordance with the peer review notice published in December 1981 (40 CFR 61502) regarding corroborative scientific review. At the same time, as required by section 6(b) of the FIFRA, the Agency will submit the proposed action to the United States Department of Agriculture (USDA) for comment on the benefits issues and agricultural impacts (see §154.28(b)). As specified in sections 6(b) and 25(d) of the FIFRA, the USDA and the SAP will have at least 30 days to provide comments to the Agency. During this period, the Agency will also solicit comments from the public.

4. Final Determination.

The Agency will evaluate all comments received from the USDA, the SAP, and the public to the proposed action and consider whether the proposal should be modified prior to issuance as a final action. The Agency will evaluate comments and revise the proposed action where appropriate. A Notice of Final Determination will be issued in the Federal Register announcing the final action (see §154.33). As required by the FIFRA, the notice will include comments received from

the SAP and the USDA and the Agency's responses to these comments. The final action will be implemented after issuance in the Federal Register, unless an affected party requests that an administrative hearing be held according to procedures set forth in 40 CFR Part 164.

VI. Request for Comments.

The Agency encourages and solicits public comment on this proposed rule. Comments are sought on all aspects of the proposed criteria and the proposed process, but, in particular, the Agency seeks comments on:

1. The Agency is especially concerned with groundwater contamination, as well as surface water contamination, by pesticides. Groundwater contamination may expose large populations, is very difficult to clean up, and may indicate more widespread, future contamination. Therefore, the Agency has considered establishing a specific risk criterion for the initiation of a Special Review when groundwater is found to be contaminated by pesticides. The proposal does not include a specific criterion because the Agency believes the other criteria provide an adequate basis for initiating a Special Review to address groundwater contamination, and no specific criterion is necessary. In addition, the Agency emphasizes its concerns regarding groundwater contamination in the preamble; such contamination will cause the Agency to further investigate the significance of risk (see IV.C.).

However, the Agency solicits comments on the appropriateness of establishing a specific criterion for groundwater

contamination by pesticides and solicits suggested language for such a criterion.

2. Should the Agency omit the Notice of Special Review and, instead, make the first public notice the Notice of Preliminary Determination? Issuance of a Notice of Special Review will raise public concerns over the continued use of a pesticide, before the Agency has determined what actions, if any, are necessary to reduce the risks associated with use of the pesticide. If the Agency's first public notice was the Notice of Preliminary Determination, the public would be better informed of the potential risk and, at the same time, the means to reduce the risk. In addition, elimination of the Notice of Special Review would conserve Agency resources that would be required to develop the Notice of Special Review and analyze all comments submitted in response to it.

On the other hand, elimination of the Notice of Special Review will delay public notification of potential adverse effects associated with the use of a pesticide. Furthermore, because the public was not involved earlier, the Notice of Preliminary Determination may lack significant information that might have been provided in response to the Notice of Special Review. Moreover, in those instances where the Agency's concerns would have been resolved through voluntary actions by registrants, the Agency will have needlessly spent resources to develop an in-depth benefits analysis, a use-by-use risk/benefit determination, an analysis of regulatory options for reducing the risks associated with each use, and the Notice of Preliminary Determination.

VII. Statutory Review.

In accordance with the FIFRA sec. 25(a), this proposal was submitted to the U.S. Department of Agriculture for comments.

(To Reader: Discussion will be added here after USDA comments are received.)

Copies were also supplied to the Committee on Agriculture of the U.S. House of Representatives and the Committee on Agriculture, Forestry and Nutrition of the U.S. Senate for comment.

(To Reader: Discussion will be added here after any Committee comments are received.)

VIII. Regulatory Review Requirements.

A. Executive Order 12291.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this proposal is not a major regulation as defined by Executive Order 12291.

This proposed rule was submitted to the Office of Management and Budget (OMB) for review, as required by Executive Order 12291. Any comments from OMB to EPA and any EPA response to those comments are available for public inspection at the Document Control Office. E-107, 401 M St. S.W., Washington, D.C. 20460 from 8 a.m. to 4 p.m. Monday through Friday, except legal holidays.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, (15 U.S.C. 601, Pub. L. 96-354, Sept. 19, 1980), EPA hereby certifies that this proposed rule, if promulgated, would not have a significant impact on a substantial number of small entities. EPA has concluded that the number of pesticide registrants subject to an RPAR review would not be increased as a consequence of the promulgation of the revisions proposed here, and that the review criteria and procedures would not have any disproportionate effect on those pesticide registrants that can be classified as small entities under the Act.

C. Paperwork Reduction Act

This proposal contains no information collection requests. Therefore, the Paperwork Reduction Act does not apply.

IX. LIST OF SUBJECTS IN 40 CFR PART 162

Intergovernmental relations

Packaging and containers

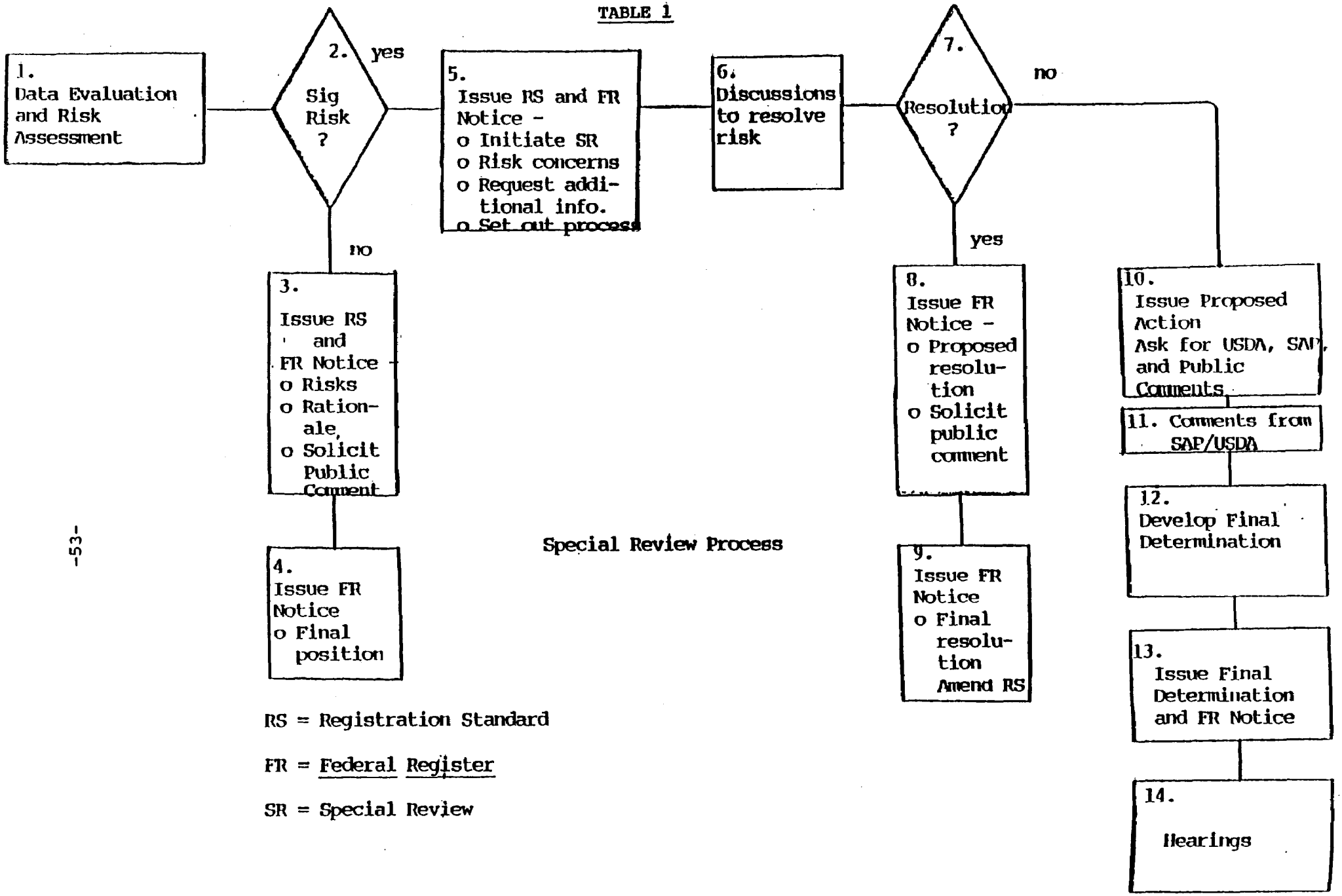
Pesticides and pests

Administrative practices and procedures

Dated: _____

_____
William D. Ruckelshaus
Administrator

TABLE 1



Special Review Process

RS = Registration Standard

FR = Federal Register

SR = Special Review

For the reasons set out in the Preamble, it is proposed that Title 40 of Code of Federal Regulations be amended by removing paragraphs (a) and (b) of §162.11, and by adding a new Part 154 to read as follows:

TITLE, CONTENTS, ETC.

§154.1 Special Review Process: Purpose and Scope

(a) Purpose. The purpose of the special review process is to help the Agency determine whether to initiate procedures to cancel or deny registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment, in accordance with sections 3(c)(6) and 6 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The process is intended to insure that the Agency assesses risks that may be posed by pesticides, and the benefits of use of those pesticides, in an open and responsive manner. The issuance of a Notice of Special Review means that the Agency has determined that one or more uses of a pesticide may pose significant risks and that, following completion of the special review process, the Agency expects to initiate formal proceedings seeking to cancel, deny, or require modifications to the registration of the product(s) in question unless it has been shown during the special review that the Agency's initial determination was erroneous, that the risks can be reduced to acceptable levels without the need for formal proceedings, or that the benefits of the pesticide's use outweigh the risks.

(b) Scope. This part sets forth the substantive standards for initiating a special review of a pesticide product and the procedures for initiating and conducting the special review.

(c) Alternative procedures. The Agency expressly reserves the authority to use alternative procedures for conducting special reviews, or to initiate cancellation or denial proceedings without first conducting a special review. If the Agency decides to use alternative procedures for conducting a special review in a specific case, it will publish a notice in the Federal Register describing the procedures to be used and why the Agency has determined that use of such procedures is in the public interest.

§154.2 Definitions

(a) Except as otherwise defined in this section, terms defined in section 2 of FIFRA or in Part 152 shall have the same definitions for purposes of this part.

(b) The term "pesticide use" means a use of a pesticide (described in terms of the application site and other applicable identifying factors) that is included in the labeling of a pesticide product which is registered, or for which an application for registration is pending, and the terms and conditions (or proposed terms and conditions) of registration for the use.

(c) The term "validated test" means a test determined by the Agency to have been conducted and evaluated in a manner consistent with accepted scientific procedures.

(d) The term "other significant evidence" means factually significant information other than a validated test.

(e) The term "Administrator" means the Administrator of the Environmental Protection Agency or any officer or employee thereof to whom authority has been delegated to act for the Administrator.

(f) "Terms and conditions of registration" means the terms and conditions governing lawful sale, distribution and use approved in conjunction with registration, including labeling, use classification, composition, and packaging.

(g) The term "interested person" means an applicant, registrant, pesticide user, environmental or labor group, or other person interested in pesticide regulation.

(h) The term "Act" or "FIFRA" means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 USC §136 et seq.

§154.3 Burden of persuasion in determinations under this part.

In making determinations under this Part the Administrator shall be guided by the principle that the burden of persuasion that a pesticide product is entitled to registration or continued registration for any particular use or under any particular set of terms and conditions of registration is always on the proponent(s) of registration.

§154.4 Criteria for Initiation of Special Review

The Administrator may conduct a special review of a pesticide use if he determines, based on a validated test or other significant evidence, that the use of the pesticide (taking into account the ingredients, impurities, metabolites, and degradation products of the pesticide):

(a) May pose a risk of serious acute injury to humans or domestic animals;

(b) May pose a risk of inducing in humans an oncogenic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect, which risk is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk, based upon:

(1) effects demonstrated in humans or experimental animals;

(2) known or predicted levels of exposure of various groups of humans; and

(3) the use of appropriate methods of evaluating data and relating such data to human risk.

(c) May pose a risk of inducing a mutagenic effect in humans, based upon effects demonstrated:

(1) in one or more appropriate test systems, if there is sufficient evidence that the test substance or its metabolites will reach mammalian germinal cells, or

(2) in epidemiological or other data indicating mutagenic effects in humans,

unless in either case the potential exposure of human populations is sufficiently low that significant mutagenic risk to humans is not likely to occur;

(d) May result in residues in the environment of non-target organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms, or which produce adverse reproductive effects in such organisms, as determined from tests conducted on representative species or from other appropriate data;

(e) May pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973, as amended;

(f) May result in the destruction or other adverse modification of any habitat designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act as a critical habitat for any endangered or threatened species; or

(g) May otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, or environmental benefits that justify initial or continued registration.

§154.10 Petitions to Begin the Special Review Process. The Administrator may evaluate a pesticide use under the criteria of §154.4 either on his own initiative, or at the suggestion of any interested person.

§154.14 Preliminary Notification to Registrant(s) and Applicant(s) for Registration.

(a) Preliminary Notification. If the Administrator determines that one or more of the criteria for initiating a special review may have been met, he shall send written notice by certified mail to the affected registrant(s) and applicant(s) setting forth his determination and a general description of the information which supports it.

(b) Comment Opportunity. Registrant(s) and applicant(s) may submit written comments in response to the Administrator's notice. Only written comments received by the Agency within a period specified in the notice, which period will not exceed thirty (30) days after receipt of the notice, will be considered by the Agency in deciding whether the first public notice should be issued under §154.16 or under §154.18(c).

§154.16 Proposed Decision Not to Start a Special Review. If the Administrator proposes not to initiate a special review after having given notice under §154.14, he shall publish in the Federal Register his proposal and the supporting reasons, and shall invite public comment on his proposal within a period generally not less than thirty (30) days. A notice under §154.18(b) may not be published unless it has been preceded by a notice under this section. A proposal under this section shall not be based on the benefits of use of a pesticide product.

§154.18 Public Announcement of Final Decision Whether To Initiate a Special Review.

(a) The Administrator shall evaluate the available information and the comments received in response to the notice under §154.14 and any notice issued under §154.16, and shall publish a notice under paragraph (b) or (c) of this section.

(b) If the Administrator determines not to initiate a special review, he shall publish his decision in the Federal Register with a statement of reasons.

(c) If the Administrator determines that one or more of the risk criteria set forth in §154.4 have been satisfied, the Agency shall publish a notice in the Federal Register which shall include:

(1) identification of the pesticide uses for which a special review has been initiated and an identification of the criteria which have been satisfied;

(2) a brief discussion of the Agency's reasons for determining that the criteria have been satisfied;

(3) a statement indicating that EPA has established a docket for the administrative record of the special review, the contents of the docket, the location of the docket, and the times during which the administrative record will be available for inspection and copying;

(4) an invitation to all interested persons to submit further information concerning the risks and benefits associated with each use of the pesticide subject to the special review;

(5) a brief description of the special review process and a statement that registrants and applicants bear an affirmative burden of supporting registration of a pesticide product; and

(6) a date by which information in response to the Agency's request for further information must be submitted.

(d) In his discretion, the Administrator may request that the Scientific Advisory Panel hold a public meeting to review the scientific issues related to the special review.

§154.20 Administrative Record of the Special Review

(a) Establishment of the administrative record. When the Agency first publicly announces that it is conducting a special review of a pesticide, it shall establish an administrative record of documents concerning the special review.

(b) Contents of the administrative record. The administrative record shall contain:

(1) the Notice of Special Review, any Notice of Preliminary Determination, and any Notice of Final Determination;

(2) any notice issued under §154.14 or §154.16;

(3) any documents referred to by the Agency in those notices as relied upon by the Agency;

(4) copies of all written comments responding to any notice furnished under §154.14 or §154.16 or submitted at any time during the special review process;

(5) any written response to the Notice of Preliminary Determination from the Secretary of Agriculture or the Scientific Advisory Panel;

(6) a transcript of all public meetings held by the Scientific Advisory Panel or conducted by the Agency for the purpose of gathering information; and

(7) memoranda summarizing meetings concerning the special review, as specified by §154.22.

(c) Access to the Administrative Record.

(1) The administrative record shall be available for public inspection during normal business hours of the Agency at a place or places designated by the Administrator, and an index of its contents shall be prepared, kept current, and made available to the public on request.

(2) Information contained in the administrative record shall not be disclosed to the public to the extent that section 10 of the Act or other statute prohibits its disclosure.

§ 154.21 Comment opportunity.

After issuance of a Notice of Special Review that applies to a use of a pesticide product (or category of products), any person may submit to the Agency any information, argument, or both, pertinent to:

(a) Whether the use of a pesticide product satisfies any of the §154.4 risk criteria, with respect to the composition, labeling, packaging, and restrictions on use of the product as currently registrered;

(b) Whether the use of a pesticide product would satisfy any of the §152.4 risk criteria if its composition, labeling, packaging, and restrictions on use were approved in accordance with an application for registration or amended registration pending before the Agency (see also §154.22(b));

(c) Whether any risks posed by the use or proposed use of the product that satisfy the §154.4 risk criteria are unreasonable, taking into account the economic, social, and environmental costs and benefits of the use of the product; or

(d) What regulatory action, if any, the Agency should take with respect to the use of the product.

§154.22 Meetings with Interested Persons.

(a) Any interested person may ask to meet with Agency officials to discuss factual information available to the Agency, to present any factual information, to respond to presentations by other persons, or to discuss what regulatory actions should be taken regarding a pesticide which is or may be the subject of a special review. If the Agency holds such meetings concerning a use of a pesticide product, the Agency will prepare and file in the administrative record a memorandum of such meetings. The memorandum shall identify the meeting participants and describe all significant positions taken and facts set forth. Any written materials presented at the meeting shall be attached to the memorandum. The Agency will file the memorandum promptly after the meeting is held.

(b) Meetings described in paragraph (a) of this section may include meetings held after issuance of a Notice of Special Review with any registrant who proposes to change voluntarily the composition, packaging, labeling, or other terms and conditions of registration of his pesticide product in a way which he believes

would reduce the risks of use of the product so that it would no longer meet or exceed the risk criteria of §154.4. Meetings for this purpose will be most helpful and productive for both registrants and the Agency if they are requested by registrants shortly after the issuance of the Notice of Special Review.

(c) The Agency shall prepare an index of such meetings for each pesticide under special review and shall provide that index to any interested person upon request.

(d) While the Agency may meet with persons interested in its decisions insofar as practicable and as time permits, the Agency will not grant preferential access for its decision-making process to any particular group.

§154.24 Informal Public Hearings During a Special Review.

(a) Timing. At any time after issuance of a Notice of Special Review and prior to issuance of a Notice of Final Determination, the Administrator may conduct an informal public hearing to gather relevant information or otherwise assist Agency decision-making.

(b) Federal Register Notice. The Administrator shall publish advance notice in the Federal Register of any informal public hearing held under this section. The notice shall contain the following information:

(1) the time, date, and place of the hearing;

(2) a brief description of the procedures governing participation in the hearing by interested persons; and

(3) the issues to be considered at the hearing.

(c) Transcript. A verbatim transcript of the hearing shall be prepared and filed in the administrative record.

§154.28 Notice of Preliminary Determination.

The Administrator shall prepare a Notice of Preliminary Determination after the close of the comment period on a Notice of Special Review.

(a) Contents of Notice. The Notice of Preliminary Determination shall respond to all significant comments submitted in response to the Notice of Special Review. For each use of a pesticide product that was the subject of the Notice of Special Review, the Notice of Preliminary Determination shall also include, as appropriate:

(1) a determination whether the use satisfies any of the risk criteria set forth in §154.4, and a discussion of the reasons for the determination;

(2) a determination of whether any changes in the composition, packaging, labeling, or restrictions on use of a pesticide product that were proposed in an application for new or amended registration submitted after issuance of the Notice of Special Review would reduce the risk so that the use no longer would satisfy any of the risk criteria in §154.4;

(3) if the use satisfies any of the risk criteria set forth in §154.4, a determination of whether the adverse effects posed by the use are unreasonable, taking into account the economic, social, and environmental costs and benefits of the use of the product, and a discussion of reasons for the determination;

(4) if the use is determined to pose an unreasonable adverse effect, a statement of the regulatory action, if any,

which the Agency intends to initiate with respect to the use, and a discussion of the reasons for initiating that regulatory action;

(5) a statement that the Administrator is requesting comments from the Secretary of Agriculture and the Scientific Advisory Panel on the notices and analysis specified in paragraph (b) of this section, and that the notices and analyses are available on request;

(6) instructions to interested persons on how to submit comments (including the deadline for submission of comments); and

(7) the location of the administrative record (see §154.20) and the times during which the administrative record will be available for inspection and copying.

(b) Referral to Secretary of Agriculture and Scientific Advisory Panel. If the Administrator proposes to cancel, deny, or change the classification of the registration of a pesticide product which is the subject of a special review, or to hold a hearing under FIFRA section 6(b)(2) on whether to take any of those actions, he shall:

(1) prepare a proposed form of a Notice of Intent to Cancel, a Notice of Intent to Deny Registration, a Notice of Intent to Hold a Hearing, and/or a Notice of Intent to Change Classification, as appropriate;

(2) prepare an Agricultural Impact Analysis, analyzing the impact of the proposed action on production and prices of agricultural commodities, retail food prices, and otherwise on the

agricultural economy;

(3) send the proposed notices and analysis to the Secretary of Agriculture and the Scientific Advisory Panel for comment, as provided by the Act; and

(4) send the Notice of Preliminary Determination and the other notices and analysis prepared under this section to all registrants and applicants for registration of products that are subjects of the special review.

(c) Publication. The Agency shall publish the Notice of Preliminary Determination in the Federal Register.

§154.33 Notice of Final Determination.

(a) Publication and notice to registrants and applicants. The Administrator shall prepare a Notice of Final Determination after the close of the comment period on a Notice of Preliminary Determination. As necessary, the Administrator shall also prepare Notices of Intent to Cancel, Notices of Denial, Notices of Intent to Hold a Hearing under FIFRA §6(b)(2), or Notice of Intent to Change Classification.

(b) Contents. The Notice of Final Determination shall include:

(1) For each pesticide use subject to the Notice of Preliminary Determination, the Agency's final determination with respect to each use, along with a discussion of the reasons for the determination;

(2) Any comments submitted by the Secretary of Agriculture or the Scientific Advisory Panel, and the responses of the Administrator to these comments;

(3) The response of the Administrator to any significant public comments submitted on the Notice of Preliminary Determination; and

(4) Instructions to registrants, applicants for registration, and other interested persons concerning the procedures which will be used to implement any regulatory action which the Administrator has decided upon, including instructions concerning how to request hearings, if hearings are available as of right under the Act or have been made available by the

Administrator under the Act.

(c) Publication and Notification of Registrants and Applicants. The Notice of Final Determination and any Notice of Intent to Cancel, Notice of Denial, Notice of Intent to Hold a Hearing, or Notice of Intent to Change Classification shall be published in the Federal Register. If the Administrator issues a Notice of Intent to Cancel, Notice of Denial, Notice of Intent to Hold a Hearing, or Notice of Intent to Change Classification, such notice, along with the Notice of Final Determination, also shall be sent by certified mail to all affected registrants and applicants.

§154.40 Finality of Determinations.

(a) The Administrator will not approve an application for registration or amended registration of a pesticide product except by use of the procedures specified in subsection (c), if:

(1) The application proposes registration of a product for a use which earlier had been the subject of a notice under §154.14(a); and

(2) After the Administrator issued the notice, he determined not to initiate a special review, because of a proposal by an applicant for registration or amended registration to change the terms and conditions of registration of the product in a way which would reduce the risk sufficiently to eliminate the need for a special review; and

(3) The application for registration or amended registration now proposes that the terms and conditions which served as the basis of the earlier determination be eliminated, or be modified in a way which might increase the risk which was the subject of the notice under §154.14(a).

(b) The Administrator will not approve an application for registration or amended registration of a pesticide product without notice, opportunity for comment, and issuance of a final determination, as specified in subsection (c), if:

(1) The application proposes registration of a product for a use which earlier had been the subject of a Notice of Special Review issued under § 154.18; and

(2) After the Administrator issued that Notice, he determined not to issue a notice under FIFRA section 3(c)(6) or 6(b) because of a proposal by an applicant for registration or amended registration to change the terms and conditions of registration of the product in a way which would reduce the risk sufficiently to eliminate the need for issuance of a notice under FIFRA section 3(c)(6) or 6(b); and

(3) The application for registration or amended registration now proposes that the terms and conditions of registration which served as the basis for the earlier determination now be eliminated or be modified in a way which might increase the risk which was the subject of the Notice of Special Review.

(c) An application to which paragraph (a) or (b) of this section applies may not be approved until:

(1) the Administrator publishes a notice in the Federal Register which describes why the application is subject to the provisions of this section, states that the Administrator proposes to approve the application and his reasons therefor, solicits public comment on whether the application should be approved, and provides a period not less than 30 days for comments to be submitted; and

(2) if any substantive comments are submitted in response to the notice, the Administrator publishes a second notice in the Federal Register responding to the comments.