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Pesticides and Ground Water State Management Plan Regulation; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152 and 156

[OPP–36190; FRL–4981–9]

RIN 2070–AC46

Pesticides and Ground Water State Management Plan Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule implements a key component of the Agency's 1991 *Pesticides and Ground Water Strategy*, and reflects many years of discussions and input from States and other stakeholders. Through the development and use of State Management Plans (SMPs), EPA is proposing to restrict the use of certain pesticides by providing States with the flexibility to protect the ground water in the most appropriate way for local conditions. This approach capitalizes on the most effective and efficient roles for State and Federal governments to collaborate in the protection of the nation's ground water resources. In this proposed rule, using the proposed SMP approach, EPA is proposing to restrict the legal sale and use of five pesticides that have been identified as either ''probable'' or ''possible'' human carcinogens--alachlor, atrazine, cyanazine, metolachlor, and simazine. Because of their potential to contaminate ground water, EPA has determined that these pesticides may cause unreasonable adverse effects on the environment in the absence of effective management measures provided by an SMP. The labels of these pesticides would be changed to require use in accordance with an EPA-approved SMP, after a period allowed for development and approval of these State plans. Incidentally, this proposed rule will also revise existing pesticide labeling regulations, in order to clarify general labeling requirements.

DATES: Written comments must be received on or before October 24, 1996.

ADDRESSES: Submit written comments, bearing the docket control number ''OPP–36190'' by mail to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Comments may be submitted by facsimile to (703) 305–5558. In person, bring comments to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number ''OPP–36190.'' No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit V. of this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Arden Calvert, Policy and Special Projects Staff (7501C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1113, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Telephone: (703) 305–7099, Fax: (703) 305–6244, e-mail: calvert.arden@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This document is organized into eight units. Unit I. describes the background and statutory basis for this proposed regulatory action. Unit II. describes the general considerations by which the Agency will decide to classify specific pesticides to be subject to State Management Plans (SMPs). Unit III. describes the content of SMPs as an ''other regulatory restriction'' pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(d). Unit IV. provides the risk and benefit determinations that are the basis for today's proposed rule, summarizing data on human health and environmental risks, ground-water contamination potential and benefits of the five pesticides subject to today's proposal. Unit V. provides further information on the public docket established for this proposed rule. Unit VI. describes referral to the U.S. Department of Agriculture and the Pesticides Scientific Advisory Panel. Unit VII. provides a list of references cited in today's proposal. Unit VIII. provides information on the Regulatory Impact Analysis provided for this proposed rule and other requirements.

Regulated Entities

Category	Examples of Regulated Entities
State Governments	States Developing Pesticide SMPs
Industry	Pesticide registrants; farmers and other commercial pesticide users

This table is not exhaustive, but is a guide to the entities EPA believes would be regulated by this action. Read carefully the contents of the rule to determine whether this rule applies to you.

I. Basis for Regulatory Action

A. Background

Ground-water resources are of vital importance to the United States. The quality of these resources affects the health of its citizens, the integrity of many of its ecosystems, and the vigor of its economy. Ironically, the variety of human activities made possible by healthy ecosystems and abundant clean water also threatens the continued viability of these resources.

Consequently, ground-water protection is a significant responsibility for EPA. In July 1991, the Agency set forth its ground-water protection goals and guiding principles in ''Protecting

the Nation's Ground Water: EPA's Strategy for the 1990's'' (Ref. 11). The centerpiece of Agency ground-water protection efforts is development of Comprehensive State Ground Water Protection Programs (CSGWPPs). These programs are designed to integrate all State and Federal efforts to protect ground water, increasing the efficiency and effectiveness of State and Federal resources. The CSGWPPs also mark a new direction in Federal/State cooperation: EPA supports voluntary State initiatives to harmonize diverse ground-water protection activities. Since the use of pesticides contributes significantly to the problem of ground-water contamination, one of the Agency's first efforts in developing CSGWPPs is the establishment of State Management Plans (SMPs) for certain pesticides.

A State Management Plan consists of 12 components that together:

(a) Describe the State's ground-water protection philosophy and goals, its authority and its organizational and resource basis for fulfilling its commitment to manage the pesticide's use.

(b) Detail the manner in which the State intends to carry out this commitment, using such measures as ground-water vulnerability assessments, ground-water monitoring, and direct management of pesticide use.

(c) Establish the State's commitments to develop and implement these provisions through a process of public participation, to make pesticide users aware of State management measures and to monitor the effectiveness of the Plan through the development of meaningful measurements of environmental results.

A pesticide State Management Plan is envisioned to be developed and implemented in the context of a State's CSGWPP, which outlines the State's overall ground-water protection approach. The additional benefits of coordinated implementation of a State's CSGWPP and its SMPs include: (1) More effective and consistent protection of the resource; (2) increased State control to target efforts towards highest priority protection; (3) more efficient use of limited program resources; and (4) reduced potential for ground-water protection activities to be at cross-purposes.

While EPA regards the creation of SMPs as a significant step in protecting ground water from pesticides, EPA will continue to act to reduce the risk of ground-water contamination in its ongoing national pesticide registration and reregistration efforts. EPA will continue to consider specific label provisions for individual pesticide products as it screens both new and existing uses of pesticides. These may include general advisory language (warning users of a pesticide's potential to contaminate ground water and advising caution in the circumstances of its use) or more specific constraints on the conditions of use, as the evidence of contamination potential warrants. It may also include classifying pesticides for use only by or under the supervision of a certified applicator, under ''conventional'' restricted-use classification authority (see section D. of this Unit). These alternative risk-mitigation measures are also part of EPA's consideration in proposing pesticides for SMPs (see Unit II. of this preamble).

The concept and development of pesticide SMPs is the direct outgrowth of extensive, collaborative work to produce a strategy for achieving ground-water protection by using and integrating all Federal and State pesticide regulatory authorities and resources. Beginning in 1986, with major public workshops EPA created an interactive process with other Federal agencies, State agricultural, environment and health agencies, the private sector, environmentalists, farmers and other pesticide users, and ground-water experts. The States in particular have taken an active and constructive role in addressing pesticide and ground-water issues and have moved ahead with many of the management approaches ultimately endorsed by the final Agency strategy for pesticides and ground water.

The Pesticides and Ground-Water Strategy (hereafter referred to as ''the Strategy'') was issued October 31, 1991 (Ref. 12). The Strategy describes the Agency's goals, policies, management programs, and regulatory approaches for protecting the nation's ground-water resources from risks of contamination by pesticides. The Strategy, and the 1988 proposed Strategy, characterize the breadth and seriousness of the potential problem of pesticides in ground water and the need for coordinated regulatory and nonregulatory initiatives to protect the resource (Ref. 7). Those interested in a more detailed discussion of the history, purpose, objectives, and policy are referred to the Strategy itself.

B. Goal

The Strategy articulated the Agency's goal for pesticides and ground water. In summary, the goal:

> is to *prevent contamination* of ground water resources resulting from the normal, registered use of pesticides that would cause unreasonable risks to human health and the environment by taking appropriate actions *where such risks may occur.* (Ref. 12, p 9, see also pp ES 6-7; emphasis added)

This goal highlights two important elements of EPA's pesticide and ground-water policy: pollution prevention and local action.

Delaying action until ground-water contamination occurs at significant levels and with a frequency sufficient to cause immediate concern is costly, and ultimately counterproductive. ''[G]round-water cleanup is extremely costly, and usually difficult and in some cases impossible to achieve and demonstrate'' (Ref. 12, p. 10; also, Ref. 11, p 5). In some cases, actual ground-water contamination may be virtually irreversible. Allowing contamination to reach a level that presents an immediate threat to human health or the environment forecloses prevention and necessitates remediation. Remediation is more costly, as well as more dangerous, than prudent action to anticipate and prevent harm.

The second element of the Agency goal is local action. Taking action locally, ''where such risks may occur,'' takes into account the highly variable factors affecting the potential for ground-water contamination. ''Ground water is a uniquely local resource due to the ease with which small sources can affect it, and the impact that use and hydrologic characteristics can have on its quality'' (Ref. 11).

There are several factors which generally influence whether pesticides will contaminate ground water: (1) The properties of the chemical itself (e.g., solubility in water, persistence, and mobility in the subsurface environment); (2) the characteristics of the site of use (e.g., soil type, depth to ground water, temperature, rainfall, and site-specific hydrological factors collectively denoted by the term, ''sensitivity''); (3) application practices, (e.g., the amount of pesticide per application, the frequency and method of applications); and (4) other agronomic practices associated with the pesticide use (e.g., irrigation or tillage practices).

The Agency believes that, as a general matter, the best method for addressing differences in sensitivity throughout the country is to tailor prevention measures in a given area to reflect the vulnerability of local ground water to contamination. This approach minimizes the complementary risks of over-regulating where ground water is not particularly vulnerable to contamination and of underprotecting highly vulnerable areas which might result from a solely ''national'' regulatory approach. It is expected to

result in an efficient regulation of pesticide use that will satisfy the pre-eminent objective of reducing or eliminating unreasonable risk with respect to ground water.

The Agency has further concluded that for pesticides which may pose an unreasonable risk, the States can appropriately take the lead in preventing unreasonable risk and protecting ground water through the management of pesticide use. State management of use can be based on local relative vulnerability of the ground-water resource, and where necessary, its use and value. A lead role for the States, consistent with overall Agency ground-water protection principles, acknowledges the traditional primacy of States in the management and protection of ground water as a natural resource; makes best use of expertise at the State level in local hydrogeology, soils, agronomic practices, climate, and pesticide use; and takes advantage of State and local understanding of population and land use trends that help to define the future use of ground-water resources.

C. SMP Start-up

State participation in pesticide-use management is a significant new step for many States, requiring substantial preparation. EPA has assisted this start-up in several ways, described more fully in the Strategy.

1. Since 1990, EPA has provided funds to States to help develop ''generic'' SMPs. In these ''generic'' SMPs, States prepare for development of pesticide-specific requirements by providing basic, generalized information for each of the required components of a pesticide-specific SMP. Generic SMPs give States an early opportunity to consider how they will design Plan components and build the capacity to implement them. Since Generic Plans have no legal force, EPA does not ''approve'' them, in the sense of conferring legal authority upon them; rather, States will submit Generic SMPs for review, comment and concurrence. Fifty-seven States and territories with primary enforcement authority for FIFRA use violations, as well as two Indian tribal authorities, have received funds and are proceeding with development of the generic SMPs. EPA has provided $35 million in grants for this purpose in the Fiscal Years 1990 to 1996. By June 1995, all 50 States had developed and submitted draft Generic Plans to EPA regions for early review and comment.

2. EPA published a *Guidance for Pesticides and Ground Water State Management Plans* with two appendices in December 1993 (Ref. 18, hereafter referred to as the Guidance). It provides practical instruction on how to develop both Generic and pesticide-specific SMPs. Much of the contents of the Guidance and the first Appendix anticipates the contents of today's proposed rule (see Unit II.C. of this preamble). These documents should be referred to for a more complete description of how EPA envisions SMPs will be developed, and what EPA envisions the level of protection will be.

3. As mentioned at the outset of this Unit, pesticide-specific SMPs are intended to operate as an integral part of CSGWPPs. Likewise, pesticide and ground-water protection measures tie into other EPA programs and grants dedicated to ground-water protection. Among the many related activities are: (a) The non-point source program under section 319 of the Clean Water Act; (b) Coastal Zone non-point source measures mandated by the Coastal Zone Management Act as amended in 1990; (c) the emerging ''watershed protection approach'' for implementing the Agency's Clean Water Act activities; (d) Wellhead Protection Programs and other drinking-water source-protection initiatives under the Safe Drinking Water Act (SDWA); and (e) Public Water System regulatory programs under SDWA, in particular, the establishment of Maximum Contaminant Levels (MCLs) and monitoring requirements for a variety of contaminants (including the five pesticides subject to today's proposed rule). For example, an SMP designed to deal with pesticide contamination risks could be integrated with a Well Head Protection Program in a rural community where pesticide use in nearby agricultural areas posed a threat to well field re-charge areas. The SMP would provide Federal and State authorities for pesticide regulation to complement and interact with the State's other water quality protection authorities to help achieve the goal of the Well Head Protection Program. A more detailed description of the variety of interlocking programs is provided in an October 1992 document prepared by EPA's Office of Pesticide Programs (OPP), ''Integrating EPA's Agriculture and Water Grant Programs.''

In addition, the Strategy detailed a variety of related Federal non-regulatory activities, including U.S. Department of Agriculture (USDA) research and the ongoing activities of the U.S. Geological Survey (USGS), as well as the connection between ground-water protection and the Agency's ongoing pesticide regulatory initiatives, such as encouraging the development of reduced-risk pesticides.

D. Statutory Authority

As a general matter, pesticides may not be sold, distributed, or used in the United States unless they are registered by EPA [FIFRA section 3(a)]. The standard for granting and maintaining a registration is found in FIFRA section 3(c)(5). Among other things, this section requires that the pesticide will perform its intended function without causing unreasonable adverse effects on the environment and that, when used in accordance with widespread and commonly recognized practice, will not cause unreasonable effects on the environment.

Further, FIFRA section 3(d) gives EPA authority to classify a pesticide for restricted use if EPA finds its use may cause unreasonable adverse effects on the environment. Specifically, FIFRA section 3 (d)(1)(C) [7 U.S.C. 136a(d)(1)(C)], provides:

> If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more such uses, or in accordance with widespread and commonly accepted practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, he shall classify the pesticide, or particular use or uses to which the determination applies, for restricted use.

In the event the Administrator makes such a determination, ''the pesticide shall be applied ... only by or under the direct supervision of a certified applicator, or *subject to such other restrictions as the Administrator may provide by regulation*'' (FIFRA section 3(d)(1)(C)(ii); emphasis added). An EPA-approved SMP would be such an ''other restriction.''

The basis for determining whether a pesticide warrants the ''additional regulatory restrictions'' referred to in section 3(d)(1)(C), is finding that the pesticide ''may generally cause ... unreasonable adverse effects ...'' without such additional restrictions. FIFRA section 2(bb) defines unreasonable adverse effects as ''any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide.'' Thus, one of the critical aspects of determining whether additional regulatory restrictions are necessary is an evaluation of the risks and benefits of the pesticide use. However, in finding a pesticide may cause unreasonable adverse effects, EPA will consider these risks and benefits in a manner that takes into account the considerable uncertainty surrounding both. Unit IV. of this preamble, as well

as the Regulatory Impact Analysis prepared for this proposed rule, describes the relative risks and benefits associated with the five pesticides proposed to be subject to SMPs, as well as the costs and benefits of State Management Plans as a regulatory measure.

Any restrictions imposed under FIFRA section 3(d) authority are fully enforceable under FIFRA. Section 12 (a)(2) of FIFRA specifically provides that it shall be unlawful (in subparagraph (F)):

> to distribute or sell, or make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 3(d) and any regulations thereunder.

Thus, once this rulemaking is final and EPA has approved the requirements and specifications that constitute a SMP, that SMP will be fully enforceable by Federal authorities. EPA will also require registrants to incorporate the restriction to use a pesticide according to the provisions of an EPA-approved State Plan as part of that pesticide's labeling. Thus SMP requirements would also be federally enforceable pursuant to section 12 (a)(2)(G), which makes it illegal ''to use any registered pesticide in a manner inconsistent with its labeling.''

II. Process for Selecting Pesticides for Restriction under SMPs

A. Determining Potential to Contaminate Ground Water

As described in Unit I. of this preamble, the Agency's goal for ground-water protection is to prevent contamination that would cause unreasonable risks. Prevention entails the need to act in anticipation of future environmental harm to ensure that this harm does not occur.

There are many uncertainties that limit the ability to quantify risks and benefits to any reasonable degree of accuracy. These stem in part from the circumstances pertaining to ground-water risks, and are discussed further in Unit IV. of this preamble. These and other impediments to national-level risk-benefit analysis were addressed in the development of the Strategy, and in fact were instrumental in the decision to favor the SMP approach in addressing serious pesticide ground-water risks. Prescribing SMPs for individual pesticides fits under EPA's regulatory authority to regulate beneficial but potentially risky substances well before the onset of unreasonable adverse effects. It also accommodates the uncertainties and variations which characterize groundwater risk assessment.

This judgement will be made consistent with the Agency's current regulatory procedures for classifying pesticides for restricted use. These procedures are contained in 40 CFR part 152, subpart I. They provide for EPA to impose restrictions other than limiting use to certified applicators if the Agency determines that:

> (a) Without such restrictions, the product when used in accordance with warnings, cautions and directions for use or in accordance with widespread and commonly recognized practices of use may cause unreasonable adverse effects on the environment; and
>
> (b) The decrease in risks as a result of restricted use would exceed the decrease in benefits as a result of restricted use. (40 CFR 152.171)

Subpart I also provides for restricting use to certified applicators and for other types of future restrictions, as authorized by FIFRA section 3(d)(1)(C). Unit III. of this preamble explains in further detail the distinction between such new ''other regulatory restrictions'' as this SMP requirement and the conventional restricted use of application only by or under the supervision of a certified applicator.

EPA will make such a determination to subject a pesticide to the requirements of an SMP through a weight of evidence analysis, taking into account the economic, social and environmental costs and benefits of the pesticide's use.

The first step in this weight-of-evidence approach is to characterize a pesticide's potential to contaminate ground water. Direct evidence of a pesticide's contamination potential includes its physical-chemical properties (e.g., leaching potential) and the circumstances, frequency and concentrations of known occurrence in ground water. In addition to the direct evidence of contamination potential, EPA will take into account information about use patterns and practices which may supplement the more direct evidence of contamination potential. Specifically, EPA will also consider: (a) The crops and sites on which a pesticide is registered for use; (b) the volume of pesticide used (on specific sites or crops, or in total) and the extent of the pesticide's use (in terms of rates and/or number of acres treated); and (c) the methods, timing, and rates of application of a pesticide.

EPA will also take into account the potential of any of a pesticide's by-products, metabolites or degradates, or any other component of a product associated with the pesticide, to reach ground water or to cause an adverse effect thereby, to the extent such substances have been identified and information about their potentials are known.

B. Determining Potential Risk

The second step is to compare the pesticide's potential to contaminate ground water to an indicator of unreasonable risk. In theory, a pesticide may have a ''potential to contaminate ground water'' but not an associated significant ''potential to cause adverse effects.'' The Ground-Water Reference Point is an important tool in determining whether this association exists. Ground-Water Reference Points are numerical indicators of the toxicity of a substance established by EPA, based on test data and other reliable health effects information. The concept of Ground-Water Reference Points was explicated in the July 1991 *Protecting the Nation's Ground Water: EPA's Strategy for the 1990's* (Ref. 11; in Part D, ''Agency Policy on EPA's Use of Quality Standards in Ground-Water Prevention and Remediation Activities'') and echoed in the Strategy (Ref. 12). Pursuant to these policies, EPA will use as reference points for specific substances any of the following: (1) Maximum Contaminant Levels (MCLs) established under the Safe Drinking Water Act, or (2) Health Advisories (where MCLs are not available for a substance), or (3) Water Quality Standards (where the concern is adverse effects to ecosystems affected by closely hydrologically linked surface waters) under the Clean Water Act. If such numbers are not available, reference points may be derived from the health effects literature where appropriate. In certain cases, the Agency policy (cited above) provides that Maximum Contaminant Level Goals (MCLGs) under the Safe Drinking Water Act may be used in order to comply with Federal statutory requirements; however, MCLGs are unlikely to be used in the context of any regulatory action the Agency might take under FIFRA.

In protecting ground water, the Agency takes the reference point as a benchmark that defines the failure of currently-implemented preventive measures (c.f., Ref. 11, p. 31: ''Reaching the ... appropriate reference point would be considered a failure of prevention.''). In the context of pesticides and ground water, a detection at or above the level established as the appropriate Ground-Water Reference Point for a pesticide ingredient would be considered a failure of measures to prevent unreasonable risk to human health or the environment associated with that ingredient. Known

or predicted levels of contamination can be compared to these reference points in order to gauge the relative risk of adverse effects. Reference points provide a means by which the Agency may assess and take into account the toxicity of ground-water contaminants, and thereby the implicit level of hazard and risk posed by particular contamination levels. Given the uncertainties regarding: (1) The actual level and extent of pesticide contamination in ground water; (2) the nature and degree of human exposure associated with such contamination; (3) either the levels or the mechanisms of pesticide occurrence that may affect ecosystems, habitats, or non-target biological organisms; and (4) the anticipated future levels of occurrence, exposure and associated hazard, it is problematic to make direct estimates of exposure, and hence estimates of risk, with satisfactory accuracy. Therefore, use of reference points to gauge the relative seriousness of detected pesticide contamination serves as a useful surrogate to direct estimates of exposure and risk.

It is theoretically possible to determine that a pesticide has the potential to contaminate ground water, but that it is unlikely to cause adverse effects. In practice, however, this distinction can often be difficult to sustain with reasonable certainty. First, there is often significant uncertainty about the levels and extent of current contamination. Ground water is not systematically monitored across the country. Ground waters susceptible to contamination by pesticides vary significantly in character, limiting the ability to generalize beyond ground-water monitoring sites. For ground water, models are not sufficiently reliable to predict future contamination. Second, any contamination of ground-water resources represents some tangible damage to its value as a resource to present, and especially future, generations. The Agency's pollution prevention philosophy clearly states the Agency's interest in protecting the resource from impairment. Hence, the Agency included in its Reference Point policy that, as a matter of policy (Ref. 11):

> Detection of a percentage of the reference point at an appropriate monitoring location would then be used to trigger consideration of additional action (e.g., additional monitoring, restricting, limiting use or banning the use of a pesticide).

As a matter of prudence, therefore, the Agency considers the ability to reach ground water, as indicated by physical and chemical properties, and detections at any level to be evidence of some potential to reach ground water at an unacceptable level.

C. Determining Appropriate Regulatory Action

After characterizing the pesticide's ground-water contamination potential and its associated health and environmental risk, EPA next considers the adequacy of current labeling safeguards. The Strategy describes this step (Ref. 12):

> If EPA has reasonable assurance from the evidence of a particular chemical's contamination potential that it would not cause 'unreasonable adverse effects on the environment' if used in accordance with the requirements of the label or under the conditions of restricted use [to certified applicators], then ...those national-level management measures [would be] the only measures necessary.

> However, if EPA cannot conclude from the available evidence that these measures would sufficiently reduce the risk of ground-water contamination, it could pursue either an approved SMP, ... or national cancellation if State Management Plans would not be adequate to prevent risks.

A judgement on the need for State management measures depends on the Agency's confidence in the effectiveness and efficacy of these uniform national labeling instructions relative to the protection anticipated from SMPs, present use practices and patterns, existing State risk-mitigation measures and other prospective Federal regulatory actions, including label changes and restricting use to certified applicators. When EPA has adequate confidence in the efficacy of such measures, it will conclude SMPs are unnecessary. The decision to prescribe SMPs is a judgement that national labeling limitations likely will not prevent the realization of a pesticide's ground-water contamination potential.

In considering whether to prescribe an SMP for a pesticide, EPA evaluates the benefits of continued pesticide use under the provisions of an SMP. The assessment of whether the reduced risk of ground-water contamination might justify the social and economic costs of the SMP is documented in a Regulatory Impact Assessment. The costs considered include both the expense of developing and implementing SMPs (e.g., direct costs) as well as the costs of foregone benefits (e.g., indirect costs). Indirect costs may include more expensive pest-control substitutes and the economic loss associated with less pest control. The Agency decides to establish the SMP restriction upon a reasoned determination that the benefits of regulatory action justify its costs, recognizing that some costs and benefits are difficult to quantify.

Finally, EPA also considers whether it is likely to take other, more stringent regulatory action such as cancellation of major products and/or uses of a particular pesticide. For instance, the Agency might conclude that a pesticide in Special Review poses an unreasonable risk for reasons different from and in addition to ground-water concerns, so that only cancellation of major products and/or uses would be appropriate. In that case, EPA would be inclined not to require the States to develop SMPs to manage uses that will soon be prohibited. On the other hand, EPA may both start a Special Review of a pesticide and propose the same pesticide for SMPs via rule making. There may be a need to provide the increased level of ground-water protection afforded by State Plans while the Special Review is conducted. As the Strategy explained, EPA may also use its cancellation authorities under FIFRA section 6 to establish SMPs. There are many possible outcomes of a Special Review besides the more stringent measure of cancellation. For example, the Agency is addressing the ground-water contamination potential of the pesticide aldicarb through a Special Review instituted in 1984, and thus is not including it in this proposed rule. EPA sees no inconsistency in pursuing both this proposed rule and the new Special Review for the triazines, initiated in November 1994.

D. Selection of Pesticides for Today's Rule

The Agency has selected five pesticides for regulation under SMPs: atrazine, simazine, cyanazine, alachlor and metolachlor. In selecting these five, the Agency evaluated the ground-water contamination potentials, hazards and uses of 20 currently registered pesticides that have been reported to occur most frequently in ground water, according to the available data compiled by EPA's Office of Pesticide Programs (Ref. 15) (see Table 1). This included the pesticide aldicarb, which was not considered for this proposed rule in light of its ongoing Special Review.

Table 1.—Currently-Registered Pesticides Considered for SMPs Because of Their Detection in Ground Water

Selected	Not selected at this time
Alachlor	Aldicarb
Atrazine	Bentazon
Cyanazine	Bromacil

Table 1.—Currently-Registered Pesticides Considered for SMPs Because of Their Detection in Ground Water—Continued

Selected	Not selected at this time
Metolachlor Simazine	Carbofuran DCPA (Dacthal) Dicamba Diazinon Lindane Picloram Methomyl Metribuzin Oxamyl Promoton 1,3-D (Telone II) 2,4-D

The five pesticides selected for this proposed rule, stand apart in the breadth, frequency, and magnitude of ground-water contamination. While Unit IV. of this preamble goes into the evidence in greater detail, each has been detected hundreds of times in many States. Each has been detected at levels exceeding their corresponding reference points in multiple locations or times, clearly exhibiting a capacity to contaminate ground water at concentrations exceeding health-based standards. All five are also associated with serious and irreversible toxicological effects, including carcinogenicity. One (alachlor) was classified as a B_2 (probable human) carcinogen by EPA, but is now considered to be not classified pending further review of scientific issues; the remaining four have been classified as C (possible human) carcinogens. These classifications are under review, as discussed later in this document.

All five are broad-spectrum herbicides with extensive agricultural uses. These similarities of use suggest that these five can be regulated together as a cluster. Since all raise significant ground-water concerns, dealing with them together also helps prevent creating unintended incentives to substitute ones under State-management constraints for those less stringently regulated. Analytic methods for ground-water monitoring of these compounds are available and in widespread use around the country. This fact, combined with the commonalities of use practices, will make it easier for States to develop coordinated monitoring programs for these five as a group.

Among the other candidates, several are known to have occurred in concentrations exceeding an MCL or Health Advisory Levels, but not as frequently as the pesticides selected. Furthermore, previous regulatory restrictions on use can be considered to have significantly reduced the risks of ground-water contamination for some of these candidates. One example is carbofuran, which has been detected over 4,100 times from 1980-1990 in 11 States, with 73 of those detections at levels over the current MCL of 40 micrograms per liter (µg/l) (Ref. 15). However, the vast preponderance of those detections (and all but one of those above the MCL) occurred in Suffolk County, New York, where all carbofuran use was banned in 1987. In addition, granular carbofuran products (which represent most of the chemical's prior use) have been phased out except for a few specialty uses. Other candidates on the list have had frequent occurrence in ground water, but neither as widely nor as frequently at high concentrations, as the five selected for this proposed rule.

EPA is proposing in today's rule to regulate those pesticides which in its judgement pose the greatest threat to ground water. The number of chemicals involved - five is a manageable number to ask States to manage; EPA hopes to facilitate State participation by designating only a manageable number of pesticides for SMPs at the outset.

III. State Management Plan Specifications, Development and Approval Procedure

A. Introduction

This document proposes adding a new subpart J to 40 CFR part 152, specifying SMPs as an ''other regulatory restriction'' authorized by FIFRA section 3(d).

Much of what SMPs will be and how they will work has been discussed in previous documents (e.g., the Strategy). In particular, this Unit of today's proposal follows closely the contents of EPA's Guidance (Ref. 18). The Guidance (with two Appendices) describes in detail EPA's expectations about the contents of an acceptable SMP, as well as the criteria and procedures EPA Regional Offices will use in deciding whether to accept or reject State Plans. Readers seeking more details on these subjects should refer to the Guidance. EPA intends generally to use the Guidance in reviewing State submissions, and to follow the provisions of the Guidance's Appendix A in review, approval, evaluation, amendment and (where necessary) revocation of State Management Plans. However, the Guidance is subject to revision; for example, the Agency fully expects to supplement the existing guidance in light of comments on today's proposed rule.

As explained in Unit I. of this preamble, State Management Plans are intended to complement CSGWPPs; as such, SMPs can be regarded as a program-specific subset of a CSGWPP. However, the requirements proposed here are specific to pesticide regulation under FIFRA, and so are somewhat more detailed than what is required under a completed CSGWPP as described in the 1992 Guidance. For example, under the Prevention component of SMPs (c.f., section 2(g) of this Unit, below), specific best management practices need to be listed and described for each pesticide. To meet SMP requirements efficiently, a State can extensively refer to portions of its CSGWPP, but the State also will need to build on the basic policies and approaches of the Comprehensive Program. Similarly, in the development of its CSGWPP, a State should ensure that aspects relevant to pesticides management are consistent with the requirements of an SMP. Because development of SMPs and CSGWPPs will occur at the same time in most States, the development of SMPs should not wait until a CSGWPP is completed. The Guidance on Pesticides and Ground Water State Management Plans describes the interrelationships of SMPs and CSGWPPs in greater detail (Ref. 18).

Several definitions of terms, applicable to this new subpart J, are proposed, in the new 40 CFR 152.183. The term ''ground water reference point'' (as discussed in Unit II.B. of this preamble) is defined for purposes of specifying the contents of an approveable SMP, and is consistent with the Agency's reference point policy. Two other terms are defined simply to facilitate reference to frequently referred concepts. The term ''Plan'' is defined as a shorthand term to refer to the SMP which is the subject of subpart J. In addition, ''State'' itself is defined to mean not only the 50 States, but also Puerto Rico, the District of Columbia, Guam and other territories and jurisdictions, plus Indian lands. This last category will be discussed in more detail below.

The proposed restriction itself is relatively simple and straightforward: a pesticide or pesticide product that is classified in this or a subsequent rulemaking may only be used in accordance with the provisions and requirements of an Agency-approved SMP, as of a specific date to be established by the rule. At that time, that pesticide or pesticide product may not be sold or used within a State without an Agency-approved Plan. These restrictions are the meaning of references to a pesticide being ''under,''

''subject to,'' ''classified for,'' ''designated for,'' or ''listed for'' SMPs.

The proposed ''restriction'' section (40 CFR 152.185) also contains some requirements on the registrants to amend the labeling of the products subject to SMPs, in order to notify users that use is now subject to the conditions of an approved SMP. Labeling provisions will be discussed in more detail in Unit III.G. of this preamble. Since the direct effect of this rule would be to limit the sale and use of the pesticide to States with approved SMPs, it would affect distribution and sale of these pesticides. Thus, distribution and sale of the pesticides subject to this rule with improper or obsolete labeling will be prohibited after the effective date of the rule.

The ''restriction'' will entail a specific label statement, as follows:

For use only in accordance with an EPA-approved State Management Plan (SMP) for ground-water protection. Sale and use are prohibited in States that do not have an EPA-approved State Management Plan.

This restriction would be effective 33 months after promulgation of this proposed rule as final. This period is designed to allow States to develop the Plans, EPA to review them, and registrants to change labels. Comments on the proper time frame for the effective date of SMPs are welcome; the Agency would especially value specific explanations of any procedural or legal constraints that States face in developing SMPs.

This restriction is a classification for restricted use pursuant to FIFRA section 3(d), but the classification does not automatically entail the restriction of use ''only by or under the supervision of a certified applicator.'' Conventionally, ''restricted use'' has come to mean exclusively this restriction to use by certified applicators, as specified in the Act. This disregards the possibility of more flexible meanings for ''other regulatory restrictions.'' Nonetheless, three of the five pesticides being proposed for SMPs today are already classified for restricted use in the conventional sense (one of which, atrazine, is explicitly classified for ground-water contamination concerns). Moreover, all five meet EPA's proposed criteria for considering a pesticide for restricted use classification because of ground-water concerns, as proposed May 13, 1991 (56 FR 22076). Therefore, EPA is interested in receiving comment on whether the Agency should simultaneously classify all of these pesticides for ''conventional'' restricted use due to ground-water concerns when it determines that they require an SMP. Such a procedure would oblige EPA to make a finding that the pesticide in question meets the criteria of 40 CFR 152.170, but such a finding could be made in this rulemaking for SMPs, since the Agency has laid out in this proposed rule an analysis of risks and benefits for these pesticides that could justify such a determination. EPA believes that such findings would be facilitated by the establishment of final ground-water restricted-use criteria.

The provisions, specifications, and requirements of these EPA-required State Plans do not replace, but add to existing or future national-level conditions of use, such as label directions for use, restrictions or precautions. Unless specifically provided, either in a final rule or in some action to amend a product's label, nothing in an SMP will supersede a national-level condition of registration. States may not supplant, override, or nullify a Federal label provision in developing an SMP proposal, or in implementing an EPA-approved SMP.

B. Overview of Application Approval Process

Section 152.187 of the proposed new subpart J sets out the procedures by which a State may submit, and EPA would approve, an SMP for each of the five pesticides covered in today's proposed rule.

1. *State submissions.* While § 152.187 provides that a State may submit a proposed Plan at any time, § 152.187 prohibits use of a pesticide or pesticides in question in States without an EPA-approved Plan after the effective date for the regulation. For practical purposes, then, a State would need an approved SMP in place by the date 33 months after the promulgation of the final rule, the proposed effective date of this regulation, in order that sale and use of the pesticide(s) in question continue within the State's borders.

States that intend to develop SMPs for any or all of the five pesticides in today's proposed rule will be required to submit proposed Plans for official EPA review within 2 years of the promulgation date. This would allow 9 months for EPA to review, consult and decide on approval of the State's submittal, and for States to prepare the implementation of the approved SMP on the effective date of the Federal restriction. States submitting Plans later than 2 years after promulgation of the rule would run a substantial risk that EPA will be unable to perform its review, and approve the Plan before the effective date of the regulation to enable the States to implement it at that time. As noted above, EPA welcomes comments on the feasibility of this proposed schedule.

In the interest of encouraging use of electronic information technology, EPA is proposing to require States submit their SMPs electronically (e.g., by disk) in an appropriate word processing format.

EPA would encourage States to submit SMPs for these five pesticides together, as a single package. While the SMP requirement imposed by this proposed regulation would be a condition of registration for each pesticide individually, EPA believes it is proper for States to combine their SMP submittals, at least for the five pesticides subject to this proposed rule. Combined submittals should be a resource savings for both EPA and the States, since these five pesticides are similar in use patterns and analytic methodologies. For practical purposes, large portions of Plans for individual pesticides can be expected to be substantially identical to each other (e.g., vulnerability assessments, monitoring sites), beyond the shared ''generic'' elements like philosophy and goals, legal authority, and resources. EPA would evaluate the adequacy of such joint SMPs together, as a cohesive multi-chemical Plan. However, EPA would retain the ability to selectively approve or disapprove Plans for individual pesticides covered by such a multi-chemical Plan, based on a judgement that the combined Plan is inadequate in some respect.

2. *EPA review, approval, or disapproval.* EPA intends to be flexible in its review of SMPs, recognizing that different approaches and philosophies can obtain the same environmental results. States will need to tailor prevention measures to local ground-water vulnerability, current and future use and value of ground water, pesticide use and agronomic characteristics and institutional characteristics. Appendix A of the Guidance describes in greater detail the internal process, including the general roles and responsibilities of EPA Headquarters and Regional Offices.

While the regulation specifies that ''the Administrator'' will make the determination whether a State submission is acceptable, it is the Agency's intention to delegate this authority to the Regional Administrator when the regulation is promulgated. The proposal as drafted requires States to submit their Plans to the appropriate EPA regional office. As the Guidance (Appendix A, p. 2-1) makes clear, EPA believes the Regional Administrator is the proper official to make this determination, given the proximity to the States and their particular

circumstances. In delegating approval authority to the Regional Administrator, EPA anticipates that only a limited Agency Headquarters role will be necessary. Headquarters will help assure overall national consistency among Regions by providing a forum to, for example, air issues which Regions believe may need additional clarification. It is EPA's assumption that such consultation will be particularly helpful in the beginning of SMP development and implementation; therefore, the Agency has established a regular schedule of regional/HQ consultation to facilitate regional review of initial Generic and pesticide-specific SMPs. After promulgation of the rule, Headquarters will continue to provide specific national policy guidance and technical assistance as the regions require.

The Guidance, in Appendix A (Chapters 2-4), envisions a two-step process for EPA review and approval or disapproval of proposed State Plans. The first step, a completeness review, is to ensure that the State has addressed all 12 components of an SMP, pursuant to the requirements set forth in § 152.190 of the proposed new subpart J. The second step, content review, is a more thorough examination of the SMP to determine whether it adequately addresses each of the 12 components of an SMP and therefore is likely to protect the ground-water resource from pesticide contamination.

As expressed in Appendix A of the Guidance, EPA expects that during the review and approval process there will be close and frequent interaction between the regions and the States to reach a mutually acceptable final Plan.

However, § 152.187(d) of the proposed rule does provide for the possibility of EPA disapproval of a State-submitted Plan. In content this section parallels the procedure EPA is proposing to revoke previously-approved SMPs (see § 152.195, discussed in F., below and Appendix A).

If the Regional review concludes that the State Plan is inadequate, either in completeness or in content, the Regional Lead Office would work with the State to address concerns before the effective date of the SMP restriction to prevent interruption of sale and use of the subject pesticide in the State. If the State fails to satisfy the Agency's concerns, the sale and use of the pesticide would be prohibited in the absence of EPA approval.

In the event the Region and State fail to reach agreement on an SMP, the Regional Administrator will notify the State Liaison and the officials directing the key State agencies in writing, indicating that EPA will not approve the State's Plan in its present form. This letter of notification will provide the State a last opportunity to satisfy the Regional Administrator's concerns and/or persuade the Regional Administrator that the State's proposal is adequate.

Even formal disapproval would not represent the end of a State's opportunity to develop a Plan. Since proposed § 152.187 provides that States may submit an SMP for regional consideration ''at any time,'' a State whose Plan or Plans have been disapproved would be free to revise and re-submit the Plan at its discretion.

Whether the Regional Administrator approves or disapproves a State's Plan, he or she will publish a formal notice of the decision in the Federal Register. As proposed, notice of the final decision to approve or disapprove is the only formal notice provided for by this regulation. In proposing this rule, EPA considered, but decided against, providing for formal public notice and opportunity for comment on the Regional Administrator's review of each State Plan. In making this decision, EPA in part relies on the requirement that the States must provide for public participation in SMP development to obtain EPA approval of such a Plan (see proposed § 152.190(j) of the regulatory text).

With this proposal, therefore, EPA states its belief that there is sufficient evidence of unreasonable adverse effects on the environment, within the meaning of FIFRA section 3(d)(1)(C)(ii), to warrant adoption of SMP's as an additional regulatory restriction. The Agency's basis for this proposed determination is set out in Unit IV. of this preamble.

Today's proposal, if finalized, would establish that there may be unreasonable adverse effects without the additional regulatory restriction of an SMP. The question then remains as to whether the particular Plan is adequate to prevent unreasonable adverse effects on the environment, or whether it is overly restrictive, i.e. whether a particular SMP adequately takes into account the social and environmental costs and benefits of the use of the pesticide. The State would consequently be able to develop and justify its SMP pursuant to the unreasonable adverse effects standard, as well as against the specific programmatic elements set out in this proposed rule.

EPA is also proposing procedures to assure adequate notice and opportunity to comment on whether a particular SMP satisfies the unreasonable adverse effects standard and the specific programmatic elements. Thus, States would be required to provide notice and opportunity to comment on these issues as part of its SMP implementation procedures. The State would have to respond to any comments and to justify its chosen approach in the administrative record developed to support the SMP. In deciding whether to approve or disapprove the SMP, EPA makes its final determination that unreasonable adverse effects may be present without additional State measures, relying on the record developed by the State during the SMP process, as well as on the record of this initial rulemaking establishing the SMP restriction.

3. *Indian lands.* It is EPA's intent in proposing this rule that no geographic area be excluded from coverage by an EPA-approved SMP upon the effective date of the regulation. To this end, Indian Tribal authorities will have the opportunity to develop Tribal SMPs in the event they wish to allow sale and use of these five pesticides on Indian lands under their jurisdiction. A few Indian lands have already received Federal financial assistance through FIFRA program grants to develop Generic SMPs. Indian tribes preparing SMPs would be subject to the same procedures and requirements that are described here for States.

However, Indian tribal authorities will not be required to develop Plans if they have no interest in allowing sale and use of the five pesticides within their jurisdiction. Furthermore, Indian tribal authorities that are interested in preserving sale and use of any of these five pesticides within their jurisdictions, but believe they are not able to commit the resources required to develop or implement a Plan, might be able to reach an agreement with an adjoining State authority to extend coverage of the State Plan to the Tribal lands. Such an agreement would have to be submitted to the pertinent EPA Regional Office for review.

C. Plan Requirements

An EPA-approved SMP will consist of 12 specific components, each developed in sufficient detail and scope to demonstrate the adequacy of the Plan. ''Adequacy,'' as generally used here and in the regulatory text, means that the content of, or commitment contained in, each component demonstrates that the general objective in establishing an SMP is met: preventing ground-water contamination by the pesticide or pesticides subject to this proposed rule, that may present adverse effects to human health and the environment. This entails an evaluation of the

adequacy of the State's proposal. A State's submission will not be satisfactory if it only provides a ''description'' of a provision, without regard to whether the provision represents adequate groundwater protection. Provisions cannot be merely ''adequately'' described; they must provide for successful implementation of ground-water protection. A Regional Administrator could disapprove a Plan on the basis of finding one or more of the components submitted will not fulfill the general objective for which EPA decided to make the pesticide subject to SMPs in the first place: the provision of State management measures that will prevent unreasonable adverse effects and protect the environmental integrity of the State's ground water.

Each State Plan, for each pesticide proposed for SMPs, must address each of the 12 components. These components are being proposed under the new 40 CFR 152.190. The proposed requirement that an acceptable SMP contain 12 components still gives a State a large degree of flexibility in managing the use of the pesticides subject to SMPs. While all 12 of these components will need to be discussed in an SMP, States will be allowed a substantial range of flexibility in the form and manner by which they propose to perform the functions contained in each component. This variability will reflect differences in State ground-water protection philosophies and regulatory approaches. Further, the Agency anticipates that the contents of State Plans will vary in extensiveness and detail according to the potential magnitude of the ground-water contamination threat. The Agency expects that in low-risk circumstances (e.g., a State in which a subject pesticide is not currently used, or in which use is limited to areas with a minimal risk of contamination), an acceptable SMP may need to be little more than an augmentation to a ''Generic'' SMP, showing how the State would move to a greater level of effort in the event the original low-risk circumstances change, or new evidence warrants. The Agency does not intend that a State will necessarily impose regulatory restrictions on every area of use or specific crop use pattern within a State involving a subject pesticide; if there is an appropriate basis for determining that an area or use site does not pose a significant risk of ground water contamination, the State's SMP might not require any change in user practices from the current Federal label. However, a State proposing such a position in its SMP would have to provide a reasoned basis for its conclusion that the risk of ground-water contamination for a particular geographic area or use site is such that further restriction is not required. EPA is prepared to accept this manner of variation among State plans; indeed, the need for this flexibility is the foundation of the entire SMP approach.

As a general matter, EPA Regional Administrators will evaluate each component individually and as each complements the other components. In many cases, the adequacy of a particular component's contents will depend in a material way on the contents of another component. Again, this approach is expected to give States a great deal of flexibility. A good example of this is the interrelationship between the ''monitoring,'' ''assessment,'' ''prevention'' and ''response'' components. States may differ in judging the relative efficacy of assessment methods for estimating the sensitivity of aquifers to contamination, versus ground-water monitoring. As a result, one State could put little emphasis on the assessment efforts, but compensate by placing a more substantial emphasis on monitoring. Another State could choose the opposite. Either approach could very well prove to be adequate. Still another State might view relying on either or both as deficient, and choose to emphasize prevention by imposing more stringent use-management measures more routinely. However, a State Plan that committed to a minimal effort in all three spheres could well be found to be inadequate. These interrelationships are discussed in more detail under the specific component headings in the Guidance. Thus, each Regional Administrator will be evaluating each component on its own merits, but also how all of the individual components work together to fulfill the ultimate objective of protecting ground water.

Furthermore, the Agency recognizes that certain elements of SMPs, particularly the vulnerability assessment and monitoring components (described below), entail extensive technical activities and substantial long-term resource commitments. One purpose in promoting the development of ''Generic'' SMPs is to provide for a head start in developing such technical capacity. However, the Agency does not expect that an acceptable SMP must in every instance have such components fully developed and in place at the time the State Plan is approved. Rather, an acceptable SMP may be at times one that provides an adequate, credible commitment and action plan to phase in such components in order to meet the State's ground-water protection goal specified in their SMP. Failure by the State to meet the commitments made in the SMP would result in EPA reconsidering the original decision to approve the SMP.

The Guidance, in chapter 3, describes EPA's expectations as to what an adequate State submission will entail. As a general rule, EPA will apply the criteria set forth in the Guidance in determining the adequacy of individual State plans. Obviously, guidance criteria are not intended to be as rigid as requirements established in regulations. However, a Plan is more likely to be acceptable if it conforms as much as possible to the provisions of chapter 3 of the Guidance. A State submission that fails to meet these criteria risks disapproval.

The Agency notes that, since State Management Plans are a new and evolving regulatory mechanism, the guidance for implementing Plans will also evolve. Thus, the Agency is likely to issue further clarifications to the Guidance as issues are raised by Regional Offices and States. For example, the comments that EPA receives in response to this proposed rule may be an important source for identifying such issues.

The following sections briefly describe each of the 12 mandatory components of an adequate State Management Plan being proposed in § 152.190.

1. *State's philosophy and goals toward protecting ground water.* Proposed § 152.190(a) would require that a Plan describe the State's philosophy and goals for protecting ground water. An acceptable plan must demonstrate that the State's goals and objectives are no less protective than EPA's goal of preventing unreasonable adverse effects to human health and the environment and to protect the environmental integrity of the nation's ground-water resources.

EPA's strategic approach emphasizes the prevention of contamination over remedial treatment. Further, it focuses priorities on sources of drinking water currently used, or reasonably expected to be, and ground water that is closely hydrologically connected to surface waters. While a State's goal must be no less protective than the Agency's, States will be free under the regulation as proposed to articulate its ground-water protection philosophy and goals in alternative form and language. In any case, a State submission, to be judged adequate, must include a statement that addresses both the ground waters to be

protected and the degree of protection to be achieved under the SMP.

2. *Roles and responsibilities of State Agencies.* State efforts to implement the Strategy will, out of necessity, require extensive coordination among State health, environment, agriculture, and water agencies. The SMP must include a description of the roles and responsibilities and coordination mechanisms of involved State agencies. For an SMP to be found adequate by EPA, it must satisfy six general provisions set forth in proposed § 152.190(b). For a further description of what these provisions entail, refer to pages 3-4 and 3-5 of the Guidance.

3. *Legal authority.* A State's ability to carry out prevention and response actions for pesticides in ground water is dependent on its legal authority to regulate pesticide use and protect ground water, to be provided pursuant to the provisions of proposed § 152.190(c). Regulatory authorities must be sufficient to accomplish the desired outcomes of the SMP. EPA will consider this component in parallel with the provisions of proposed § 152.190(i) on enforcement mechanisms. Descriptions of enforcement authorities provided in this component should be cross-referenced to that component as well. One suggestion is that the State provide a graphic ''crosswalk'' of legal, regulatory and enforcement authorities (e.g., a side-by-side comparison of SMP requirements as described in proposed § 152.190, and corresponding State authorities for implementing each requirement, modelled after what is currently provided for in the Public Water System program [40 CFR part 142.12(c)].

Under § 152.190(c), a State's plan must identify the specific legal authorities to be used in implementing the plan, to ensure that the State's submission is legally enforceable. Presently there is no provision that the State's chief legal officer be required to examine the submission, and be satisfied that the appropriate provisions of the plan are legally enforceable under State law. Several other EPA programs require a certification from the State Attorney General (or a designee) to ensure that there is sufficient legal authority to enforce provisions of the program. This approach provides further assurance that all of a State's rulemaking procedures have been followed, and that, as a result, the SMP is enforceable under State law. Such a step should reduce the likelihood that a legal challenge to the rule will not be sustained, and should entail a small resource requirement on the State. EPA is soliciting comment on whether the Agency should also require in the final rule that the State's submittal include such a certification.

4. *Resources.* A State's ability to carry out the commitments delineated in its SMP depends on the resources available to implement the program. Resources include technical expertise and personnel, physical and operational capabilities, and funding. Proposed § 152.190(d) requires that the SMP demonstrate that the necessary expertise is available and that there is an adequate match between revenues and proposed expenditures. This demonstration must:

i. Indicate what categories of personnel or technical expertise are necessary and available for implementation of the Plan.

ii. Include an estimate of the costs, both physical and operational, to develop and implement each element of the Plan.

iii. Disclose the current funding available for implementation of the program, existing and potential funding sources for the future, and a commitment to pursue additional funding if needed.

EPA will only be evaluating the adequacy of the resources specified in determining the adequacy of the overall Plan, and will not be judging the manner in which the State provides for those resources. However, EPA strongly encourages States to develop innovative means to finance and implement SMPs, such as user and/or sales fees, in order to reduce the burden on a State's general revenues. EPA will also explore ways of helping to shift some of the financial burden of implementing SMPs from the States to registrants, for example, in providing for concurrent National ground-water monitoring requirements.

5. *Basis for assessment and planning.* One of the fundamental principles in the Strategy is the tailoring of protection activities to the unique hydrogeologic settings, pesticide usage patterns, and agronomic practices of each State. The effectiveness of protection activities depends to a large extent on the degree to which vulnerable areas in need of protection can be accurately identified. Therefore, States must have an ongoing program that provides basic information on the occurrence, movement, and quality of ground water in relation to patterns of pesticide use. State Agencies of environment, water, agriculture, and health must all have the opportunity for input into this program. Pages 3-7 and 3-8 of the Guidance (supplemented by chapter 3 of the Guidance's Appendix B) describe in further detail the function and activities embodied by the term, ''assessment and planning.''

The component prescribed by the proposed § 152.190(e) is, for practical purposes, a description of the process by which a State will set priorities for prevention and response actions. In this component, the State will describe how it will assess ground-water vulnerability, use and value and how that assessment will be used: (a) To set priorities for protection activities; (b) to design and implement prevention and response measures; and (c) to determine the effectiveness of these measures and of the implementation of the overall Plan. An adequate SMP for these five pesticides must include a description of how the State will address vulnerability assessment on a sub-county level for the geographic area in which the State intends to allow continued use of the pesticides. EPA considers this level of geographic detail necessary in ground-water vulnerability assessment because it is generally held that current methods of vulnerability assessment are generally not capable of predicting the vulnerability of broader geographic areas, such as counties. It is widely held that the hydrogeologic factors which influence the sensitivity of particular ground waters vary within areas smaller than typical American counties. Distinguishing areas of different ground-water sensitivity must involve ''sub-county'' geographic units (see the Guidance and its Appendix B for further discussion of the basis for these opinions). It is also generally accepted that such assessments will entail a substantial level of effort. There is no standard definition of what the size or dimensions of a ''sub-county'' unit might be, other than the general observation that it is an area that is relatively homogenous with respect to the hydrogeologic characteristics that influence ground-water sensitivity.

While an adequate SMP must discuss what the State's approach to vulnerability assessment at the sub-county level will be, it must also discuss the limitations of its assessment techniques and how these limitations are taken into account in the design of prevention and response programs (see g. and h., below). For example, a State could describe in its submission for this component that it does not or cannot currently perform adequate vulnerability assessments to the desired level of detail, but then explain how the State will impose more restrictive pesticide use practices across a wider geographic area (e.g., an entire county where a pesticide might be used) so as to protect the most vulnerable ground waters within that area. In other words, if a State applies prevention measures

on broad regional or county-level designations, then sub-county level assessments may not be needed. However, the State should explain why the measures chosen are likely to be adequate to meet program goals. Conversely, if a State plan allows sub-county or farm-level distinctions in applying prevention measures, it should explain the basis for making such distinctions, and how protection goals will be met. EPA's expectations as to the adequacy of this component are further discussed in pages 3-8 through 3-10 of the Guidance.

6. *Monitoring.* Broadly defined, ''ground-water monitoring'' is the set of activities that provides chemical, physical, geological, biological, and other environmental data needed by environmental managers/decision-makers to assist in developing and implementing ground-water protection policies and programs. Ground-water monitoring is viewed as a continuum of activities ranging from defining background conditions, to defining the existence and extent of contamination, to defining the success of prevention and response measures and programs to protect the ground-water resource. The Guidance (in pages 3-10 to 3-11 and in Chapter 5 of Appendix B) discusses in further detail the dimensions of ground-water monitoring activities and their various functions in programs aimed at preventing pesticidal contamination of ground water.

An adequate SMP must describe the State's monitoring program for pesticides, the uses to which monitoring will be applied, and the parties responsible for various functions associated with monitoring. A current, approved State Quality Assurance Project Plan (QAPP), as described in chapter 5.4.2 of the Guidance's Appendix B, is a prerequisite for approval of an SMP. The provisions of such a plan will apply to data collected by the State as well as to any data collected by some other party on behalf of the State, for the purposes of performing the State's monitoring component. Such a quality assurance plan will provide sufficient assurance of the integrity of the data so as to preclude the applicability of the Agency's Good Laboratory Practices (GLP) regulations (40 CFR part 160). However, certain conceivable data collection activities (e.g., monitoring studies required by EPA as an adjunct to State monitoring, described in the next paragraph) could be subject to GLP Standards. The distinction would lie in: (1) Whether the monitoring activity is described in, referred to, or otherwise pursuant to, the monitoring component of the approved SMP; and (2) whether the monitoring activity directly relates to the maintenance of the Federal registration of the pesticide. For example, monitoring activities performed by a third party (e.g., a university) under the authority of the State's monitoring plan would be subject to QAPP provisions. Registrant monitoring directed by the State would similarly be subject to the State's QAPP. However, registrant monitoring performed either at EPA's behest or performed on the registrant's own initiative (but without State mandate or not at the State's behest) would be subject to EPA's GLP standards.

The essential criteria to determine the adequacy of the monitoring component of a State Plan are whether the State's monitoring effort is appropriate to achieve the purposes of the Plan, and whether the level, quality and extent of specific monitoring efforts provide a reasonable likelihood that contamination representing an unreasonable risk to the environment will not go undetected. As discussed earlier, the judgement of the adequacy of a monitoring component must be made in consideration of the stated goal of the Plan, and the contents and design of its constituent assessment and protection components. Further discussion of EPA's expectation of what constitutes an adequate monitoring component can be found in the Guidance (pages 3-11 through 3-13).

EPA assumes that monitoring activities will represent a significant portion of a State's resource investment in implementing its SMPs. Based on past State experience, EPA estimates in its Regulatory Impact Analysis for this proposed rule (see Unit V. of this preamble) that ground-water monitoring activities by themselves may constitute between 10 to 14 percent of the annualized State program costs. Furthermore, the costs of performing ground-water monitoring can be expected to vary widely across the country, inasmuch as the States are starting from different points in the degree of current monitoring. To help alleviate this resource requirement on the States, EPA is considering development of national-level requirements (pursuant to its data-call-in authorities under FIFRA section 3(c)(2)(B)) for additional ground-water monitoring from the registrants of these five pesticides. Such concurrent data-gathering requirements would be developed with reference to submitted State Plans, so that the ultimate requirement on the registrants would not be unduly burdensome and would be tailored to the strengths and weaknesses of actual SMPs. Such a requirement would also be designed to provide States the opportunity to review and comment on Federal specifications to the registrants, to ensure harmony with State intentions.

7. *Prevention actions.* The emphasis of EPA's *Pesticides and Ground-Water Strategy* is on prevention, and the core of an acceptable SMP will be its program of managing particular pesticide use in order to prevent contamination. Preventive management approaches may vary based on ground-water vulnerability and ground-water use and value, as well as social and economic factors. The actual measures employed may range from education of users, voluntary or mandatory best management practices, such as changes in application rates, methods and timing, all the way to use prohibitions in specific areas. As noted above, the Agency does not necessarily expect that SMPs will impose new restrictions on every use site or geographic area in which a pesticide is used in a State; if there is a reasonable basis for determining that risks for particular use sites or areas are not unreasonable, then little or no change from current label requirements may be needed.

Prevention measures may overlap with response measures at the point that pesticide contamination of ground water is detected. For example, when pesticides are detected, preventive actions can still be pursued to prevent further contamination. States may choose to combine their prevention and response discussions because of this overlap.

Appendix B: *Assessment, Prevention, Monitoring, and Response Components of Pesticides State Management Plans of the Guidance* identifies ground-water protection practices and methods for implementing prevention efforts that States may consider in the development of their prevention component. The methods described there are not considered an exclusive list of available options. The Agency fully expects some States to develop innovative measures to achieve their ground-water protection goals.

Because of the wide variety of possible approaches a State might adopt to fit a wide variety of local circumstances, proposed § 152.190(g) is worded very generally in order not to restrict the States' flexibility. While EPA is proposing that the rule provide for maximum flexibility in State program design, it acknowledges that other approaches are feasible. In recognition of this fact, EPA elsewhere in this preamble (see section D of this Unit) is requesting public comment on

alternative approaches to prevention program requirements.

The relation of these prevention programs to other risk-management measures will be an important consideration for the States in the development of SMPs. These SMPs are required to address the ground-water contamination potential of the five pesticides subject to today's rule. It happens, however, that these pesticides also represent a well-documented risk of surface water contamination, at least in some of their use-areas (see, for example, ''Triazines Water Resources Impact Analysis'' (Ref. 19)). Thus, an acceptable Plan for these pesticides must include consideration of whether specific measures employed by a State to protect ground water might elevate risks to surface water. For example, a Plan which would change a tillage practice to reduce pesticide infiltration of ground water may in some instances increase runoff to surface water. EPA therefore strongly encourages States to implement measures to protect surface water from pesticide contamination that is likely to impair water quality. Specifically, States should coordinate the development of preventive measures with measures under existing EPA programs, such as the Nonpoint Source, Coastal Zone Management, Wellhead Protection, and Comprehensive State Ground Water Protection Programs. Measures must also be coordinated with the USDA Soil Conservation Service's Compliance Conservation Plans.

As discussed in Unit IV.B. of this preamble, adverse ecological effects associated with these compounds are a concern, and a reason for proposing the compounds for SMPs. Because the ability to identify ground-water discharge to surface water is limited by resources and the current state of scientific knowledge, EPA will not disapprove out of hand any proposed State Plan that fails to specifically address ground water supporting surface water ecosystems in either the ''basis for assessment and planning,'' ''monitoring,'' ''prevention,'' or ''response'' components. However, States that are aware of specific bodies of water that receive a large percentage of their recharge from ground water are strongly encouraged to attempt to take this fact into account in designing the above components of their Plans. As in evaluating the adequacy of any and all the elements of State proposals, reviewing EPA regional offices will evaluate the adequacy of State measures to address such ''closely hydrologically connected'' ground waters on the basis of its own and the State's assessment of the State's vulnerability in this respect.

Similarly, if a State expects that a risk reduction measure will lead users to use alternative chemicals, then EPA encourages the State to consider whether the alternative chemicals will cause adverse effects to ground water, surface water, other areas of the environment, or other types of risk, such as risks to pesticide applicators. In other words, the State, in its Plan, should provide a reasonable assurance that the preventive measures it proposes to protect ground water are not likely to result in unreasonable adverse effects elsewhere in the environment as a consequence.

8. *Response to detections of pesticides*. This component will describe how the State plans to respond to contamination to ensure that reference points (MCLs, HAs, or State quality standards) will not be reached in ground water, and what actions the State will take in the event that the reference points are reached or exceeded. Response measures should be based on the State's ground-water philosophy and the assessment and monitoring components. Further, this component is closely tied to the requirements concerning prevention, which specify that an SMP must describe actions that the State will take initially in the absence of actual detection and those it will implement if the plan appears to be failing to protect ground water. SMPs should describe how the appropriate State agencies will be brought into remedial actions.

Response actions, such as increasing implementation of best management practices, and use restrictions or prohibitions, are the focus of this component, rather than remediation activities. Since FIFRA provides limited means for responding to contamination, however, States should increase efforts to coordinate enforcement and other response activities under a number of other Federal/State authorities. In addition, as in proposed § 152.190(g), States should coordinate response measures with measures under existing EPA programs, such as Nonpoint Source, Coastal Zone Management, Wellhead Protection, and Comprehensive State Ground Water Protection Programs. Appendix B of the Guidance presents a framework for assessing and responding to ground-water contamination by pesticides as well as suggested response alternatives. Again, EPA does not regard the Guidance as providing an exclusive list of options, since new information becomes available on a routine basis. For example, EPA is developing new guidance accompanying its new Hazardous Waste Identification Rule, defining ''best management practices'' (BMPs) for the treatment of contaminated media at remediation sites, in order to reduce the potential for cross-media contamination. Such ''BMP Guidance'' will help States reduce the possibility of incidental contamination of ground water at remediation sites. A review draft guidance document has been available since April 1996.

9. *Enforcement mechanisms*. To meet this requirement, the Plan must describe the State's enforcement capabilities, authorities, and compliance activities (e.g., inspections, technical support, penalty provision, etc.), if not already described pursuant to proposed § 152.190(c). The SMP also needs to identify the State agency with each enforcement authority and how coordination of enforcement capabilities will work to prevent and respond to contamination.

In addition, a Pesticide Plan must discuss the State's enforcement authorities and capabilities to monitor compliance with the specific measures included in the SMP, both those intended to protect ground water from contamination and response actions where contamination has already occurred. Further discussion of enforcement requirements can be found on pages 3-18 to 3-19 of the Guidance.

10. *Public awareness and participation*. Most government activities are subject to citizen involvement and review. An acceptable Plan must demonstrate that the public has opportunity to be involved in the process of Plan development and will be informed of significant Plan implementation activities. The Plan must address three different aspects of necessary public awareness and participation. The Plan must:

i. Describe the opportunities for public input regarding development of the Plan and decision-making in implementing it.

ii. Indicate how, when, and by whom the public will be informed of detections in ground water that are considered significant.

iii. Include a description of the process and means of communication by which the public will be made aware of important regulatory actions taken under the SMP. More discussion of public participation issues can be found on pages 3-19 to 3-20 of the Guidance. However, as discussed earlier in this unit, EPA expects that in fulfilling the first requirement, a State will at a minimum provide notice and opportunity to comment on whether the SMP under development satisfies the criteria for SMPs proposed in this rule,

including an opportunity to assess costs and benefits under the proposed SMP.

11. *Information dissemination.* The user is responsible for directly controlling the use of pesticides in the field. Therefore, an important part of any SMP must be the means by which ground-water protection measures and other Plan requirements are communicated to pesticide users as well as to appropriate industry groups and regulatory officials (proposed § 152.190(k)). Further discussion of this requirement is provided in the Guidance (pages 3-20 to 3-21).

12. *Records and reporting.* Documentation of a State's program not only serves as a source of data to share with EPA and other involved Federal and State agencies, but also provides a basis on which to assess the effectiveness of a State's prevention and response measures. An adequate SMP discussion of records and reporting will identify both management measures relating to the State's progress in implementing the Plan and environmental indicators of the effectiveness of the program. The Guidance provides a fuller description of the reporting requirements established by the new Subsection (l), particularly the key ''Biennial Report'' (pages 3-21 to 3-24). In addition, Chapter 5 of the Guidance's Appendix A provides a fuller discussion of the Biennial Report requirements pursuant to the provisions of this proposed rule for evaluation of EPA-approved Plans.

D. Evaluation of State Management Plan Implementation

Once in place, SMPs are a permanent condition of registration for the pesticide, for as long as the pesticide remains registered. Proposed § 152.191 of the new subpart J provides for EPA evaluation of State implementation of their Plans. Periodic evaluations of the implementation of SMPs will measure the State's progress towards its goals and commitments, determine the environmental effectiveness and the level of ground-water protection provided by the Plan, and ensure a minimum level of national consistency.

EPA will use the SMP Biennial Report required in proposed § 152.190(l)(2) to evaluate a State's effectiveness in protecting its ground-water resources from pesticide contamination. Both the general provisions for EPA's evaluation of approved SMPs and the Agency's expectations about the form and content of the Biennial Reports are described in greater detail in Chapter 5 of Appendix A of the Guidance. In specifying an evaluation requirement, EPA recognizes that States have a variety of evaluation methodologies and measures at their disposal.

E. Amendment of State Management Plans

Once in place, State Management Plans will have considerable built-in flexibility, in order to respond to a variety of circumstances. For instance, the response component entails a range of options for responding to contingencies triggered by pesticide detections in ground water; new information about pesticide usage patterns; and new information on ground-water vulnerability, use and value. Consequently, Plans will probably not need frequent revision and update. If the range of options in a given Plan turns out not to meet the State's needs, however, States may need to modify and update plans. States should consider revising SMPs:

- If EPA's periodic evaluation of the SMP determines that the provisions in a State's SMP are not adequately protecting the ground-water resource from pesticide contamination.
- If the statutory or regulatory framework for SMP development and implementation changes.
- If more comprehensive ground-water vulnerability assessments, additional monitoring methods, improved prevention technologies or new information concerning the risks posed by a pesticide become available and need to be accommodated in order to make the Plan more effective.
- If a State, through experience, finds substantially different, more effective ways to assess ground-water contamination, prevent or respond to contamination, or disseminate information.
- If changes in crops or crop production systems within the State are significant enough to require different pesticide management measures in order to manage risks to ground water.
- If roles and responsibilities of State agencies materially change.

Section 152.193 provides for the modification and update of SMPs under these circumstances.

Ordinarily, a State will submit needed amendments as part of the SMP Biennial Report. In an urgent case, a State may appeal for revision outside the biennial review process to the Regional Administrator. In addition, if the Regional Lead Office determines through the evaluation process that the SMP needs to be amended, then the Regional Administrator can initiate the amendment process by requesting that the State submit an SMP Update Report. Chapter 6 of the Guidance's Appendix A describes the process EPA envisions for the modification and update of approved SMPs.

F. Withdrawal of Approval of a State Management Plan

Section 152.195 of the proposed regulatory text provides for EPA withdrawal of its approval of existing State Plans under certain circumstances. Withdrawal of approval can begin when:

- The State fails to demonstrate that it is satisfactorily implementing the SMP as approved.
- The State's SMP is not protecting ground water from contamination above the ground-water reference point.
- The State fails to address deficiencies identified in the SMP Evaluation (per proposed § 152.191), by updating the SMP (per proposed § 152.193) and/or improving implementation of the SMP.

EPA envisions such revocation of a State's Plan to be generally a last resort. Before the withdrawal process commences, the State will have the opportunity to respond to EPA-identified deficiencies in its Pesticide SMPs through the SMP amendment process or by demonstrating to the Agency that the SMP is being satisfactorily implemented. Regions will work closely with individual State agencies or the State Liaison to assist the State in updating the plan or in addressing deficiencies or gaps in protection.

Withdrawal of approval of an SMP (as discussed in greater detail in the Guidance's Appendix A, Chapter 7) is a multi-step process. EPA would commence the withdrawal process by issuing a formal letter from the Regional Administrator (acting for the Administrator) to State officials responsible for implementing the Plan. The notice will include:

- A statement concerning the potential withdrawal of the SMP.
- A listing of the deficiencies of the SMP or a description of the failure of the Pesticide SMP to protect ground water.
- A brief summary of the events that led to the withdrawal notice, e.g., failure to respond to SMP's deficiencies in the Biennial Report and failure to update the SMP adequately.
- A time frame in which the State can respond to the deficiencies to stop the withdrawal process e.g., time frames for submitting an SMP Update Report, for improving implementation of the plan.

In the event this letter fails to elicit a satisfactory State response, EPA's next step is a second notice, announcing imminent publication of a Federal Register notice withdrawing EPA's

approval of the SMP. In the event this second letter does not elicit a satisfactory resolution, the final step is publication of a Notice of Withdrawal in the Federal Register. This withdrawal of EPA's approval will have the effect of prohibiting the sale and use of the pesticide in the State. Chapter 7 of the Guidance's Appendix A has a further description of the Agency and State roles and responsibilities in this process.

Proposed § 152.195 provides the State the opportunity to respond to EPA's initial decision to withdraw approval in at least two different ways. The State may respond in writing to the notice with a commitment to address the deficiencies in the SMP itself or in SMP implementation. In this case, the State must respond to the initial notice within 30 days of receiving it. However, the State may choose to appeal the EPA decision to initiate withdrawal. In that event, the State may request a meeting with the Regional Administrator (who will be the deciding official in these instances); that request must be made within 60 calendar days of the date of the initial notice. If the State does not respond to the initial notice within either of these time frames, or consultations pursuant to the initial notice fail to resolve EPA's concerns, the Region will take the next step of sending a second letter, and ultimately, of publishing a Federal Register notice.

In some instances EPA may find an SMP (or its implementation) is so deficient that further sale and use under its provisions would constitute an unreasonable risk to the environment. If so, the Regional Administrator may also prohibit sale and use of the pesticide during the withdrawal process if, in his or her judgement, continued use of the pesticide in the State under the conditions of the deficient SMP presents an unreasonable risk to human health or the environment. In this event, EPA would propose a temporary prohibition in a Federal Register notice, in addition to the letters to the States described above. This notice would explain the Regional Administrator's judgement that unreasonable risks to the environment may be present during the time required for correcting the deficiencies in the State's Plan, and solicit public comment on the impending prohibition. This Federal Register notice could be published simultaneously with the initial letter to the State, or at any time after that initial letter, in the event the Regional Administrator found an unreasonable risk to the environment was impending. After addressing any public comment, the Regional Administrator would implement the temporary prohibition. The prohibition of sale and use would remain in effect until the State and EPA reach agreement on how to address the SMP's deficiencies.

G. Label Changes

This regulation requires a change to the label of any pesticide subject to an SMP, so that users will be aware of their responsibility to use a product in accordance with the provisions and restrictions of an EPA-approved SMP. All products subject to an SMP must bear the following statement describing the SMP restriction itself:

> For use only in accordance with an EPA-approved State Management Plan (SMP) for ground-water protection. Sale and use are prohibited in States that do not have an EPA-approved State Management Plan.

Each State Plan will provide for other means, separate from the product label, to disseminate to pesticide users specific additional provisions, management measures and geographic restrictions. These State-specific information dissemination measures are intrinsic to the SMP in accordance with § 152.190(k) described above. However, additional information may be placed elsewhere on the label in order to direct users to appropriate State sources for more information, or to describe in more detail SMP requirements. Such information will not appear in the Restricted Use area of the front label, but preferably within the Directions for Use portion of the label.

In § 152.185(b) of the new subpart J, EPA proposes that registrants adhere to the same provisions for label changes, distribution and sale and advertising as apply to pesticides classified for conventional restricted use. In addition, registrants of pesticides classified for SMPs need to submit proposed labels specifying the SMP classification within 3 months of the effective date of the SMP provision.

An amended label containing the narrative restriction specified in this proposed rule must be submitted by each registrant of a product classified by this proposed rule to be subject to SMPs within 12 months of the publication of the final rule; and the amended label must be affixed to all products subject to this classification on the effective date for the rule.

EPA is proposing in this document to reorganize part 156, the regulation specifying labeling requirements for pesticides and devices. Part 156 is now organized so that paragraphs (a) through (j) of § 156.10 each describe one of nine specific components of a pesticide product label. EPA proposes that the last two paragraphs of § 156.10 become a separate subpart. EPA regards these as particularly important components. Specifically, the Agency is proposing to amend part 156: (1) By creating a new subpart G to encompass the existing paragraphs (i) and (j) of § 156.10; (2) redesignating paragraph (i) as two new sections, § § 156.120 and 156.121, within this new subpart G; and (3) creating new § § 156.135, 156.136 and 156.137 within this subpart G (from the previous paragraph (j)) to describe labeling pertaining to use classification, including both conventional restricted use to certified applicators and restriction to use under approved SMPs. The new label statement to accompany a product classified for SMPs is specified in the new proposed § 156.137(c)(2). As proposed, the SMP statement would appear under the ''Classification'' heading, because legally, an SMP is a form of classification pursuant to the ''other regulatory restrictions'' authority in FIFRA section 3(d).

H. Request for Comments

EPA is interested in receiving comments on all aspects of its proposed 40 CFR part 152 subpart J. For instance, is the effective date of 33 months after promulgation of the rule appropriate? Does it permit sufficient time for registrants to make the necessary label changes? Does it permit States sufficient time to develop Plans and EPA to review them before the restriction is effective? Does the proposed development, review and approval process provide sufficient public opportunity to comment on the contents of the Plan before its approval and implementation as a regulatory restriction? Has EPA properly specified the criteria which State Plans must meet? Has EPA provided sufficient mechanisms for appealing decisions to approve or disapprove Plans, and for evaluating, amending, and revoking Plans? Is two years a sufficient interval for EPA to require States to report on their implementation of SMPs? What further measures could be employed to encourage States to prepare Plans for pesticides with minor uses within their boundaries, so as to provide for their appropriate continued use? Should EPA concurrently develop National datagathering requirements to be applied to the registrants of the pesticides subject to SMPs, with the intent of easing States' ground-water monitoring burdens? If so, how should the Agency design such a requirement, i.e., balancing between helping the States with their monitoring efforts and not infringing on States' flexibility and

power to prescribe its own monitoring regimen? What further national-level resources (e.g., technical assistance from the USDA's Natural Resources Conservation Service) should be anticipated for supporting development of State Plans? Should EPA classify a pesticide for ''conventional'' restricted use classification at the same time it determines the pesticide must be subject to SMPs, in this or a subsequent rule? Should EPA propose a new form of labeling for pesticides classified for SMPs, to distinguish those pesticides from pesticides classified as ''conventional'' restricted use?

In addition to comments on issues like those described above, the Agency is interested in receiving comments on alternative approaches to the specification of State prevention-program components. Within the general framework of the SMP approach, there are many ways to specify how States will perform the duties of protecting ground water from contamination by pesticides. The approach being proposed today is in conformance with the previously published Guidance, which remains the Agency's preferred approach. EPA believes the approach developed in the Guidance provides for maximum flexibility in developing the means of ground-water protection, within the broad determination by the Agency that these pesticides warrant additional regulatory restriction. This flexibility, in turn, maximizes the opportunities for State initiative and effectiveness in tailoring its ground-water protection efforts.

At the same time, the balance between national consistency and State flexibility may be struck in numerous other ways, while still maintaining a fundamental partnership between EPA and the States. The Agency is pecifically soliciting comment on how to strike this balance, within the general consensus it believes exists on the existence of Federal and State roles. For instance, should EPA require an SMP to include regulatory action to prohibit use of the pesticide under SMPs in areas where contamination from current, legal use exceeds the reference point in current or reasonably expected sources of drinking water? If so, should EPA also require States to complete their identification of current and reasonably expected sources of drinking water (if States choose to make such a delineation) prior to Plan approval?

In addition, EPA is soliciting comment on whether it would be helpful for the Agency to provide more specific guidance to States (in the form of technical assistance, new guidance documents or amendments to the existing Guidance) on particular risk-reduction measures that may be appropriate to particular indications of present groundwater contamination. Such guidance would not be prescriptive (that is, codified in rulemaking), but rather reflect the best experience of EPA and the States in managing ground-water protection, as the States develop and implement SMPs. A State and EPA Region could benefit from the experience of others, with the cumulative effect of all States and Regions reaching a mutual understanding of what works best in general situations.

The Agency could be more specific in advance about certain prerequisites of an adequate SMP. For example, EPA might specify by regulation different ground-water contamination levels which would require State response. These levels would be based on the reference points specified in proposed § 152.198. A State would be free to specify in its Plan an array of risk-management measures it found appropriate to respond to such levels of contamination. In contrast, this regulation as presently fashioned only requires a State to describe its goals and response program elements in a manner that allows the Agency to evaluate their adequacy in relation to the adequacy of the other supporting Plan elements.

Under this alternative, proposed § 152.190(a) would require a Plan to establish, within its statement of philosophy and goals toward protecting ground water, its ground-water protection objectives in terms of EPA's reference point policy. This alternative would also change proposed § 152.190(h) to require SMP response-program elements to specify prospective risk-management measures in the event contamination is detected at or above EPA-specified contamination levels. For purposes of eliciting comment, EPA offers the following as appropriate levels: (a) 10 percent of a subject pesticide's ground-water reference point; (b) 50 percent of the ground-water reference point; and (c) 100 percent of the ground-water reference point. EPA would not pre-specify particular risk-management measures for these levels. However, whatever measures that a State does propose would be subject to the Agency's evaluation of its adequacy with respect to the fulfillment of the general objective of ''preventing unreasonable adverse effects ... and protecting the integrity of the ground-water resource.''

Such a specification of program performance objectives would be consistent with the EPA's role under the Federal-State partnership, that of establishing uniform national policy goals and determining the overall regulatory approach. At the same time, States would be free to specify the means of meeting those performance objectives, subject to Agency review. One benefit of a more concrete specification would be the avoidance of misunderstandings between EPA and States: EPA would have stated more clearly what it will find acceptable (or unacceptable) in defining its requirements in this fashion. Another benefit would be greater assurance in the adequacy of a State's plan, since an approved Plan would clearly embrace a risk-management scheme tied to a uniform set of criteria for action. Regulation would be more protective insofar as all States would meet a minimum threshold of risk-management measures. This approach might also facilitate EPA review of Plans, by eliminating an additional interpretive step, that of determining whether the State proposal, in its unique form, conforms with EPA's expectations.

Finally, the Agency recognizes that some potentially affected parties have expressed concern that the proposed rule does not offer an opportunity to maintain use of a pesticide in the event a state does not have an approved SMP, for whatever reason. Therefore the Agency requests comment on whether there should be a default provision for stringent federal label requirements and/or conditions on the terms of registration for these pesticides that would allow continued use in lieu of an approved SMP.

Under this option, the Agency would specify in the final rule the national-level requirements that would apply to use of these pesticides in States without approved SMPs by the effective date. The Agency has established a model for such requirements. In 1994, the Agency granted a conditional registration for a new herbicide, acetochlor, for which the potential for ground water contamination is a concern. In that case, the Agency imposed a variety of restrictions on the use of acetochlor, including limiting application to certain soil types, prohibiting aerial application, and restricting use to certified applicators. In addition, the Agency required the registrant to conduct ground-water monitoring at a specified level of effort, and set triggers that would result in localized use prohibitions, and ultimately national cancellation of the registration if certain detection criteria are met. A copy of the specification of the terms and conditions of registration for pesticides containing acetochlor, which would

serve as the model for such specifications in the final rule, is available in the public docket for this rule. EPA notes that nothing in this proposal would preclude registrants themselves from proposing additional restrictions on the use of their product to the Agency, pursuant to FIFRA section 3(c)(5), in the event a State chose not to adopt an SMP. Consequently, this proposal leaves open to registrants the option of themselves devising suitable restrictions to prevent unreasonable adverse effects on the environment from use of these pesticides in the unlikely event that a State chooses not to develop an SMP, or that no SMP is approved.

The Agency would like comments on the following. Would a similar approach be appropriate for the SMP chemicals in the event a State elected not to develop an SMP for one or more of the chemicals? Should the default be available if a State did submit an SMP, but EPA did not approve it? What specific precautions and limitations on the label would provide adequate protection of ground water in the absence of an SMP? Is the Agency correct in proposing to use the specifications of the acetochlor registration as the basis of such national-level defaults, or are there specific provisions to be added or deleted? Should registrants be required to conduct monitoring, and if so, to what extent? If there is a registrant monitoring program, should States have a role in determining where and how monitoring is carried out? Should there be triggers for use prohibition in a State, or only in a local use area; if so, what should they be? What would the impact of this Federal alternative be on registrants and users? What would the effect of this alternative be on State development of SMPs and other ground water protection activities or programs?

IV. Risk and Benefit Determination

A. Chemical Background and Characteristics

1. *Uses*. The five candidates for SMPs proposed today are similar in many important respects. All five are broad-spectrum herbicides registered for use on a total of 100 different crops, including most of the major field crops grown in the United States (e.g., corn, sorghum, and wheat). Together, the five compounds are registered for another 31 non-crop and non-food uses including ornamental tree, plant, and grass sites. Atrazine, simazine and cyanazine are members of the *s*-triazine family of compounds, and are each used to control a variety of broadleaf weeds and grasses. Each is used for preplant, preemergence and postemergence weed control in crops. Alachlor and metolachlor are acetanilide compounds registered for pre-emergent control of broadleaf weeds and grasses.

EPA estimates that between 200 and 250 million pounds of the five herbicides, together, are used annually in the United States, which represents as much as one-half of total annual agricultural use of herbicides. Atrazine, alachlor, and metolachlor are currently ranked as the three highest-volume pesticides in use in the United States today, with cyanazine ranked fifth. Approximately 150 to 160 million pounds of active ingredient (a.i.) of these four pesticides are applied to just two field crops: corn and sorghum. Alachlor and metolachlor are also commonly applied to soybeans, with 20 to 30 percent of their annual use attributable to this crop. Remaining uses of these four herbicides, while representing a small fraction of their combined use, still represent several million pounds of active ingredient. For example, 1 to 2 million pounds of cyanazine are used annually on cotton; also, another substantial use of atrazine is on sugar cane.

Historically, use of atrazine was marked by a rapid rise in use on row crops through the 1960's, joined by a similar sharp rise in alachlor use from 1969 to 1974. At that time, use volumes of each leveled off at comparatively high levels (e.g., about 80 million pounds annually) as use of cyanazine, and then metolachlor, climbed. Through the 1980's, use volumes began to fluctuate, with use of the two older chemicals drifting down from combined uses of 170 to 190 million pounds per year to levels of 120 to 150 million pounds per year. These general declines were matched by corresponding increases in the other two. During the first half of this decade, this general trend continues, with the exception of a relatively sharp decline in alachlor, and a slightly earlier, but more-than-offsetting increase in metolachlor use.

Simazine stands as the exception to the rest of the candidates with respect to use. Only 3 to 5 million pounds of active ingredient are used in the United States annually. However, 1 to 2 million pounds (31 to 42 percent) of simazine is applied to corn, making it the principal use of simazine as well. Simazine's remaining uses include crops such as alfalfa, seed crops, fruits (apples, citrus, grapes, berries and stone fruits, among others) nuts and vegetables. Simazine is also registered for several terrestrial non-agricultural uses, as well as for aquatic uses (i.e., ornamental ponds).

2. *Other regulatory actions.* All five pesticides are subject to the reregistration requirements of the 1988 FIFRA Amendments. Reregistration of existing pesticide products entails the determination that they are eligible for reregistration because: (a) The data necessary to determine the pesticide's risk are substantially complete; and (b) these data indicate that the pesticide does not cause unreasonable adverse effects when the products are used according to label directions and restrictions. EPA publishes Reregistration Eligibility Documents (REDs), which summarize the studies reviewed and the findings reached. A RED for metolachlor has already been published (EPA 738-R-95-006, April 1995); a RED for alachlor is scheduled to be published in 1996. REDs for the three triazines are not expected before the conclusion of the triazines special review.

In addition to the scheduled reregistrations, four of these pesticides are in Special Review. One, alachlor, has been under Special Review since 1985. While EPA resolved substantial risk concerns about the use of alachlor in 1987, the Agency deferred action on whether the risks posed from alachlor in drinking water from contamination of ground water required regulatory action. EPA proposes to conclude review on these issues with the promulgation of this rule.

In November 1994, the Agency initiated Special Review (59 FR 60412, November 23, 1994) of the three triazine compounds - atrazine, simazine and cyanazine - subject to this rule. The Review will address the potential overall risks to human health and the environment posed by use of these three pesticides, particularly the carcinogenic risks from human exposure in drinking water, food, and through handling and application of products. Ground-water contamination is part of the concern in conducting the Special Review, but only part of the broader concerns addressed by it. Therefore, the Agency believes it is appropriate to carry out both regulatory proceedings for the triazines at this time.

B. Risk Assessment

1. *Adverse health effects*— a. *Toxicological endpoints of concern.* Toxicological endpoints of concern for these five compounds (and their metabolites) include carcinogenicity (all five compounds), developmental toxicity (atrazine and cyanazine), chronic blood and organ toxicity (cyanazine, simazine, alachlor, and metolachlor), and cardiotoxicity (atrazine). In the following discussion,

atrazine, simazine, and cyanazine are frequently referred to together as triazines, when the three compounds exhibit similar characteristics and effects.

EPA's Integrated Risk Information System (IRIS) summarizes the available information on the toxicological endpoints of concern for the five pesticides in today's proposed rule. IRIS data are available to the public in both printed and on-line form, and can be accessed by telephoning IRIS User Support at EPA's Center for Environmental Research Information in Cincinnati, Ohio; (513) 569–7254. The discussion below does not include a detailed review of studies showing relatively minor adverse effects, such as changes in average body weight or the rate of weight gain in developing animals. More extensive discussion of the evidence of adverse health effects for each of these pesticides has been presented in other documents, e.g., for metolachlor, in the recent Reregistration Eligibility Decision document and for the triazines, in the Federal Register notice announcing the initiation of the triazines Special Review. A more complete description of the toxicological evidence to support this rulemaking, drawn from these existing sources, is provided in the docket for this regulation.

All five compounds exhibit adverse effects in animals after long-term exposure, raising concern about chronic toxicity. For example, long-term (usually 2–years) feeding studies with the triazines typically show reduced rates of weight gain, and in some cases, hematological effects, such as reduced red-cell count. Treatment of pregnant animals with all of these compounds shows some developmental effects, such as reduced weight gain, or reduced litter size. In addition, a 1–year dog study with atrazine showed cardiac effects such as increased heart rate and irregular heartbeat. Although these are all adverse effects, they do not present the same level of concern as the evidence of cancer risk.

EPA had classified atrazine, simazine, cyanazine and metolachlor as Group C (possible human) carcinogens. EPA's Office of Pesticide Programs has assigned a numerical cancer potency coefficient, known as a $Q1^*$, to each of these chemicals as well (see Table 2 below).

The triazine compounds have an extremely close structural similarity and produce similar tumor profiles in animal bioassays, primarily malignant mammary tumors in female rats. In addition to animal study data, EPA has reviewed a number of epidemiology studies which suggest possible associations between triazine exposure and various human health effects, including ovarian cancer, non-Hodgkins lymphoma, and birth defects. All of the studies, however, had significant limitations, and the Agency does not consider any of the suggested health-effect associations to be established by currently available information.

Alachlor was classified as a B_2 (probable human) carcinogen by virtue of positive results in studies of both rats and mice. At this time, however, alachlor is considered to be not classified under the current agency system pending further review of scientific issues raised by the registrant. Metolachlor has limited evidence of liver carcinogenicity in animals.

The cancer classifications cited here are likely to change in the future for several reasons. First, EPA has recently proposed to revise its guidelines for the assessment of cancer risks. The new proposed guidelines were made available on April 16, 1996, for a 120–day public comment period. The issues raised during the comment period will then be presented to the Agency's Science Advisory Board. New guidelines are likely to become final in 1997. Among other things, the new guidelines may change the way the Agency weighs the various kinds of laboratory evidence used to identify carcinogenic potential.

In addition to changing guidelines, the registrants of the triazine and acetanilide herbicides have recently submitted new data which they believe should reduce concerns about human cancer risks for these compounds. It is not clear at this time how this new evidence will affect the Agency's risk assessment for these compounds, or how the evidence will be evaluated under the new guidelines. In any case, human cancer risk is not the only basis for the Agency's concern about these chemicals.

b. *Ground Water Reference Points.* Table 2 of this Unit displays the relevant summary toxicological data for these five compounds. The derivation of the Ground Water Reference Points shown in Table 2 is discussed below.

The Ground Water Reference Point for a compound is a representation of the compound's toxicity, expressed in units corresponding to environmental exposure. The Reference Point provides a means to assess the significance of known or anticipated concentrations that occur in ground water. As described in Unit II. of this preamble, the Agency normally will use MCLs established under the Safe Drinking Water Act (SDWA) as reference points. MCLs are derived from Maximum Contaminant Level Goals (MCLGs), which is that concentration, ''... at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety'' (SDWA section 1412(b)(4)). In most cases an MCLG is based on the Reference Dose (RfD) for the compound, to which standard conversion and uncertainty factors have been applied to account for anticipated drinking water exposure. For compounds classified as Group C carcinogens, EPA also applies a 10-fold uncertainty factor to provide for an additional margin of safety. The enforceable MCL, set simultaneously with the MCLG, is set ''as close to the [MCLG] as is feasible'' (Ibid). In the case of B_2 carcinogens, Agency policy has been to set the MCLG at zero. The corresponding MCL is then set at a finite level by evaluating the performance of feasible water treatment and analytic technology. More information on EPA's methodology for setting MCLs and MCLGs is available in the final rule which established MCLs for atrazine and alachlor (56 FR 3526, January 30, 1991).

The following Table 2 is a summary of the human health risk posed by these five chemicals:

TABLE 2.—SUMMARY OF HUMAN HEALTH RISK

	Ground Water Reference Point (µg/l)	Source (MCL, HAL, or other)	Reference Dose (RfD) (µg/kg/d)	Study/Endpoint[1]	Cancer Category	Q_1^* (1/mg/kg/d)
Atrazine	3	Final MCL	35[2]	Chronic Animal Study decreased body wt. gain; cardio-developmental toxicity	C	0.22
Simazine	4	Final MCL	5	Chronic Rodent Study (decreased body wt. gain hematological changes)	C	0.12

TABLE 2.—SUMMARY OF HUMAN HEALTH RISK—Continued

	Ground Water Reference Point (µg/l)	Source (MCL, HAL, or other)	Reference Dose (RfD) (µg/kg/d)	Study/Endpoint[1]	Cancer Category	Q_1^* (1/mg/kg/d)
Cyanazine	1	HA	2	Chronic Animal Study (decreased body wt. gain)	C	1.00
Alachlor	2	Final MCL	10	Sub-Chronic Dog Study (hematology)	*	0.08
Metolachlor	70	HA	100	Chronic Rodent Study	C	0.009

[1] This column refers to the study or toxicological endpoint which serves as the basis for the RFD listed in the column immediately to the left.
[2] The RfD for atrazine was revised in December 1992; the previous RfD (of 5 micrograms per kilogram per day) served as the basis for the current MCL displayed at left.

In the absence of MCLs, EPA will use a Health Advisory (HA) to establish Ground Water Reference Points. HA levels are established using the same methodology used for non-zero MCLGs. MCLs have been established for atrazine, simazine, and alachlor, and these are Ground Water Reference Points for these compounds. The Reference Points for cyanazine and metolachlor are based on HA levels.

In summary, the Agency feels that there is sufficient evidence to concluded that each of the five compounds addressed in today's rule may cause serious, irreversible adverse effects to the health of persons, if any of the compounds were present in drinking water at or above particular concentrations or at other concentrations for a prolonged period of time. In fact EPA has set drinking water standards for three of the compounds in this proposed rule, in order to prevent the onset of such effects as a result of drinking water in Public Water Systems (PWSs). The Agency has set Health Advisories for the other two compounds, in order to allow PWSs to evaluate and avert potential adverse effects to human health should these compounds be encountered. MCLs for these two compounds may also be developed at a later date.

2. *Environmental effects.* In addition to their potential for adverse human health effects, EPA is also concerned about the potential adverse effects of these compounds: (1) On specific non-target plants and animals, including the potential economic impact associated with adverse effects on both commercial crops and animals; and (2) on ecosystems as a whole.

EPA has far less specific data on the potential adverse ecological effects of these five compounds than for adverse health effects. However, both the chloro-triazines and the acetanilides inhibit photosynthesis in plants and may have phytotoxic effects to terrestrial and aquatic plants.

Of these chemicals, atrazine has been the most fully studied and characterized for environmental effects. In comparative laboratory acute toxicity testing, atrazine exhibits moderate toxicity to birds, mammals, fish, or aquatic invertebrates. Studies representing simulated field conditions have also been conducted. For aquatic plants, available information indicates that short-term exposure to relatively low levels of atrazine (for example, concentrations of approximately 20 µg/l) can produce phytotoxic effects from which plant populations will not recover. Information on simazine and cyanzine indicate that longer-term exposure at even lower levels, in the range of about 5 µg/l, can also inhibit plant reproduction.

Substantial risks can be anticipated from continuing off-target movement of these five compounds and consequent exposure of aquatic organisms and ecosystems. Contamination of ground water can be a mechanism of transport for these compounds to surface water, since ground water provides a significant source of recharge for many bodies of surface water. While it is difficult to segregate potential risks from the presence of these compounds in ground water from those that might result from other means of environmental transport such as runoff, the risks are real enough to be of concern.

In addition, there is a considerable body of monitoring data available on these five pesticides, primarily in the mid-western ''corn-belt'' States where they are most heavily used. These data demonstrate that residues of these five pesticides can be detected in both ground and surface waters in areas of heavy use, at levels which frequently approach, and sometimes exceed, the MCLs or HAs. (Data for ground-water occurrence are discussed in more detail below).

Thus, the Agency feels that there is sufficient evidence to infer that present environmental levels of these herbicides from various environmental transport mechanisms, including leaching to ground water, pose substantial risks to aquatic plant life, both in the form of outright phytotoxicity and in the longer-term and more subtle effect of inhibiting plant reproduction. If such effects occur in an aquatic environment, the effects on the ecosystem could be profound. Complete loss of habitats may occur. Even partial loss of food supply or protective cover can result in significant impacts on other aquatic organisms. Herbicides in the aquatic environment could destroy the food source for higher organisms, which may then starve. Herbicides may also reduce the amount of vegetation available for protective cover and the laying of eggs by aquatic species. Submerged aquatic vegetation is the nursery for commercial and recreational species. As such, drastic loss of submerged aquatic vegetation in rivers or estuaries is a serious environmental concern. Some experts believe that herbicide related ecosystem damage may already be occurring in locations such as the Chesapeake Bay and parts of the Mississippi delta.

EPA has drafted a Water Quality Criteria document for atrazine that proposes to establish a fish-protection level of 22.7 µg/l (measured as a 4–day average concentration over a 3–year period), below which ''freshwater aquatic animals and their uses should not be affected unacceptably ...,'' adding a peak 1–hour concentration limit of 571.9 µg/l (not to be exceeded more than an average of once in a 3–year period). For the protection of freshwater aquatic plants, atrazine concentrations should not exceed 2.0 µg/l for any 4–day period within a 3–year period.

The total risks of these five pesticides to aquatic ecosystems are beyond the scope of the regulatory action being proposed today. These ecological risks involve, in addition to contamination of ground water, contamination of surface water through many alternative routes, such as runoff through the unsaturated zone to a nearby water body.

Ground water SMPs cannot be expected to address all of these potential routes to surface water contamination that may occur as a result of the legal use of these five pesticides. However, certain use management measures implemented by States as part

of their ground-water Plans may provide some ancillary protection against such surface-water contamination. At a minimum, no SMP will be approved that contains a preventive measure that will clearly increase the likelihood that surface water will be adversely affected as a consequence (see Unit III.C.7. of this preamble, and Guidance, pp 3–15–6, Ref. 18).

3. *Ground water contamination potential*— a. *Persistence and mobility*. EPA requires that all pesticide registrants submit data on the physical and chemical characteristics of a pesticide in order to characterize its environmental fate. These data are generated through a battery of basic laboratory tests and limited field studies as specified in 40 CFR 158.290, otherwise known as the ''Subpart N'' Guidelines. Two important factors, known as persistence and mobility, are particularly relevant in predicting whether a substance has the potential to reach ground water.

Persistence refers to a substance's relative resistance to environmental processes which tend to break that substance down, and thus to the length of time that substance can exist in the environment. Persistence is generally measured as a half-life ($t_{1/2}$ or t_{50}), or the length of time in which 50 percent of an environmental concentration disappears as a result of transport or degradation. Mobility refers to the potential for an ingredient to move away from the point of application, and is typically represented by a substance's resistance to binding to soil or soil constituents. Measures such as the soil-water partition coefficient (kd) or the carbon-referenced sorption coefficient (Koc) are used to indicate a substance's binding potential.

A pesticide that is relatively persistent and mobile would tend to remain in the subsurface environment, be present at substantial fractions of the original environmental residue, and reach underlying aquifers relatively quickly. Together, persistence and mobility are referred to as a pesticide's leaching potential.

(i) Parent compounds. Table 3 of this Unit contains a summary of the persistence and mobility characteristics for the five pesticides subject to today's proposed rule. The Table shows chemical-specific values for the seven parameters that EPA uses to evaluate a pesticide's propensity to reach ground water. These values, generated from the combination of laboratory and field studies EPA requires for registration, are compared against the values (displayed in the Table) that EPA regards as indicative of leaching potential.

EPA proposed these values in a previous proposed rulemaking (see 56 FR 22076, May 13, 1991) as criteria indicating a reasonable potential for reaching ground water on a widespread basis, for purposes of considering a pesticide for restricted use classification. While EPA is not proposing to apply these criteria to determine whether a pesticide needs to be subject to an SMP, the Agency provides the information as evidence of the pesticides' leaching potential. As indicated in Table 3, all five pesticides display persistence and mobility characteristics exceeding the values EPA considers evidence of a propensity to leach. In the event EPA were to classify the pesticides for conventional restricted use independently of the regulatory action referred to above, the Agency believes that this evidence, combined with the detections of the parent compounds in ground water to date, would not only meet the EPA's final criteria for restricted use for ground-water concerns, it would establish that these pesticides could pose a serious hazard to the environment in the absence of the mitigation provided by restricted use classifications. Such evidence would be sufficient for EPA to propose restricted use classification for simazine and metolachlor, the two pesticides subject to today's proposed rule not now classified as such, under the existing regulations for restricted use classification (c.f., 40 CFR 152.170(d)).

As shown in Table 3 below, all five pesticides are resistant to chemical hydrolysis, indicating their likely environmental persistence. The term ''stable'' as used in Table 3 means the compound was observed to degrade more slowly than the rate of degradation specified as the critical value in the criteria column, i.e., a decrease of 10 percent or more in the tested concentration of a substance over 30 days duration of a hydrolysis test.

TABLE 3.— PERSISTENCE AND MOBILITY

(A value exceeding a criterion shown in Italic)

	Parameter	Criteria	Atrazine	Simazine	Cyanazine	Alachlor	Metolachlor
Persistence	Field dissipation half-life	> 21 days (3 wks), or	*60-120* days	*44-231* days	*6-181* days	11 days	*7-292* days
.....	Lab-derived aerobic soil metabolism half-life	> 21 days (3 wks), or	*146* days	*110* days	17 days	2-*3* weeks	*67* days
.....	Hydrolysis half-life	< 10% in 30 days, or	*stable* (pH 5,7,9)	*stable* (pH 5,7,9)	*148 days* (pH 5), *stable* (pH 7,9)	*stable* (pH 3,6,9)	*stable* (pH 5,7,9)
.....	Photolysis half-life (soil)	< 10% in 30 days	*> 30 days*	*> 30 days*	6 days	NA	8 days
Mobility	Soil adsorption: K_d	≤ 5 ml/g, or	*0.20 (sand)*	*4.31 (clay)*	*0.28-2.3*		*1.87 (clay)*
.....			*0.73 (loam)*	*0.65 (sand)*			*2.16 (sandy loam)*
.....			*0.79 (sandy loam)*	*1.27 (sandy loam)*		*0.62-8.13*	*0.108 (sand)*
.....			*2.45 (clay)*	*0.48 (loam)*			*0.77 (loam)*
.....	Soil adsorption ≤ K_{oc}	≤ 500 ml/g, or	*38 - 152*	*103 - 152*	*40 - 84*	*190 (est)*[1]	*22 - 110*

TABLE 3.— PERSISTENCE AND MOBILITY—Continued

(A value exceeding a criterion shown in Italic)

	Parameter	Criteria	Atrazine	Simazine	Cyanazine	Alachlor	Metolachlor
.....	Depth of leaching in field dissipation study	75 cm	NA[2]	NA[2]	45 cm	*122* cm	≥ *122* cm

[1] est = estimate.
[2] NA = Not Available (either not reported by the registrant or not required - waived - by EPA).

(ii) *Degradates.* In the case of all five of these pesticides, the leaching potential of metabolites and/or degradates are an additional concern. For example, since the 1980s investigators have reported detections of triazine degradates as well as the parent compounds in both ground and surface water. Alachlor and metolachlor also have various degradation products which may be mobile and persistent enough to leach.

b. *Occurrence of ground water contamination.* Registrants, States, the United States Geological Survey (USGS), and EPA's National Pesticide Survey are all sources of ground-water monitoring data (Refs. 10 and 14). In reviewing monitoring data, EPA's Office of Pesticide Programs (OPP) records occurrence in ground water as the number of discrete locations where a pesticide ingredient was detected at least once. Multiple detections at the same well over an interval of time from repeat sampling are not counted as separate detections in the main data collections cited below. EPA recognizes that this procedure could function to put wells with only a single detection from repeated sampling on an equal footing with wells in which occurrence is regularly found. Specified detection limits are a measure of the sensitivity of the analyses. Such sites are typically water-supply wells or, to a lesser extent, ground-water monitoring wells. OPP uses the term ''wells'' to refer to occurrence sites.

EPA's sources of ground-water data include: (1) The Pesticides in Ground Water Data Base (PGWDB), a data base containing the information described above, and periodically up-dated by OPP (Ref. 15); (2) EPA's National Pesticide Survey (NPS; Refs. 10 and 14), a statistically designed one-time survey of existing wells, including both community wells and rural domestic wells nationwide, (data not included in the PGWDB); (3) Monsanto's National Alachlor Well Water Survey (NAWWS) (Ref. 3)-this survey was limited to alachlor use areas, and sampling was limited to private rural domestic wells; (4) Ciba-Geigy (now Ciba Plant Protection) performed a Large-Scale Retrospective Ground-Water Study for Metolachlor in Four Areas of the U.S. (Ref. 2) with high metolachlor use and/or high vulnerability to contamination of ground water by pesticides; and (5) a number of State-initiated ground water monitoring programs. All of these information sources are described in greater detail in the ''Water Resources Impact Analysis for the Triazine Herbicides'' (Ref. 20). Tables 4 through 8 of this Unit summarize information developed from those sources.

(i) *Atrazine and triazine metabolites*—(a) *Atrazine parent.* The evidence of atrazine occurrence is summarized in Table 4 of this preamble. Atrazine was the third most often detected of all currently registered pesticides in OPP's Pesticides in Ground Water Data Base, after aldicarb (and its metabolites) and carbofuran (and also after two banned pesticides, EDB and DBCP).

Atrazine was found in the National Pesticide Survey, as shown in Table 4, and in the Monsanto NAWWS Survey. In particular, in the latter, atrazine was the most frequently found pesticide, estimated to be present in 12 percent of wells in the alachlor use area. The study estimated that concentrations will exceed the MCL of 3 µg/l in 0.1 percent of the wells in the alachlor use area.

(b) *Chloro-triazine degradates and other triazine occurrence.* There are fewer data on degradates in ground water than for the parent triazines; cyanazine and simazine degradates in particular are rarely looked for. The Pesticides in Ground Water Data Base contains detections of two chloro degradates of atrazine at concentrations of 0.05 to 2.86 µg/l. The NPS analyzed for only one degradation product of atrazine (desethyl atrazine) and the detection limit for that product was relatively high (2.2 µg/l); the NAWWS did not analyze samples for degradation products of atrazine or the other triazines at all. Two of the three major chloro-triazine degradates of atrazine were analytes in Iowa's SWRL study, the results of which are shown in Table 4. The Wisconsin Rural Well Study provided significant information on the occurrence of atrazine degradates. Almost 92 percent of wells that were resampled in phase 2 of the study contained a combination of parent and degradate residues. Overall, degradates found in the Wisconsin Rural Well Survey accounted for 67 percent of total triazine residues.

Results of a recent USGS study of herbicides and nitrates in near-surface aquifers in the mid-continent United States (Kolpin, et. al., 1994) reported that desethyl atrazine was the most frequently reported compound (18.1 percent of wells), followed by atrazine (17.4 percent), and desisopropyl atrazine (5.7 percent). The detection of total residues was 25 percent more than the detection of atrazine alone. This study differs from the NPS and NAWWS studies in that it sampled ambient ground water, not just ground water used as a source of drinking water.

Finally, the advent of new analytic techniques such as the rapid, highly sensitive and relatively cheap detection methods based on enzyme-linked immunosorbant assay (ELISA), has allowed monitoring studies of ''total triazine'' levels. While typically employed as a ''screen,'' with detections subsequently analyzed by conventional methods to identify and quantitate specific compounds, the PGWDB contains reports of one State's findings of undifferentiated ''total triazine'' occurrence. In 1990, Ohio reported monitoring at 863 sites, with 48 detections at concentrations ranging from 0.1 to 5 µg/l (Baker, et. al., ''Nitrate and Pesticides in Private Wells of Ohio: A State Atlas,'' Heidelberg College, (Ongoing)).

(ii) *Simazine.* The evidence of simazine occurrence in ground water is summarized in Table 5 of this preamble. Simazine was the eighth most often detected pesticide in OPP's Pesticides in Ground Water Data Base and the sixth most frequently detected of the currently registered analytes. In Kolpin, et. al. (1994) simazine residues were detected in 1.0 percent of the wells sampled in the mid-continental U.S.

(iii) *Cyanazine.* Less monitoring data exist for cyanazine in ground water than for atrazine and simazine. Table 6

summarizes data on monitoring results for cyanazine. Cyanazine was the 15th most often detected pesticide in OPP's Pesticides in Ground Water Data Base, with detections in 15 out of 27 States in which samples were collected. Additionally, cyanazine has been reported to be found at concentrations greater than 0.1 g/l (or 10 percent of its reference point of 1 µg/l) in more than 80 additional wells in 12 States.

No detections were reported in the NPS; however, the minimum detection limit in that study was 2.4 µg/l whereas the likely MCL for cyanazine is 1 µg/l. NAWWS estimates that detectable levels of cyanazine are expected to occur in 0.3 percent of rural domestic wells in counties where alachlor is used. As is the case for simazine, this may not be a good national estimate of cyanazine occurrence because the use areas of cyanazine and alachlor may not closely coincide. The detection limit for cyanazine in this study was 0.1 µg/l; whereas the detection limit for the other 4 analytes was 0.03 µg/l. This higher detection limit undoubtedly reduced the number of observed positives. No estimate was given for cyanazine concentrations that exceed 1 µg/l. NAWWS did not analyze water samples for degradation products of cyanazine. Cyanazine was not an analyte in the Ciba-Geigy Large-Scale Retrospective Ground-Water Study. As regards State surveys, cyanazine was the 5th most frequently detected pesticide in Iowa's SWRL study (of the 27 pesticide analytes). Cyanazine was not an analyte in the Wisconsin study and no confirmed detections of cyanazine are reported in the California database. Cyanazine was detected in 0.7 percent of the wells sampled in the USGS study by Kolpin et. al. (1994).

(iv) *Alachlor (and metabolites).* Table 7 of this preamble summarizes the information available to the Agency regarding alachlor occurrence in ground water. Alachlor is the seventh most often found pesticide in the Pesticides in Ground Water Database, with only aldicarb (and its metabolites), carbofuran, atrazine and oxamyl among the currently registered pesticides detected more often. In addition, alachlor has been reported to be found at concentrations greater than 0.2 µg/l (or 10 percent of its reference point) in more than 350 wells in 21 States.

The NPS estimated that 3,140 (or <0.1 percent) rural domestic wells contained alachlor at levels above the Reference Point of 2 µg/l. There were no detections of alachlor in community water system wells. The NAWWS estimated that alachlor occurs in approximately 1 percent of rural wells throughout its use area. Less than half of these detections are at levels exceeding 0.2 µg/l (or 10 percent of the MCL). Alachlor is estimated to occur at levels exceeding its 2 µg/l MCL in 0.02 percent (or approximately 1200 wells) of the 6 million rural wells in the alachlor use area. There were no degradation products analyzed in either the NPS or the NAWWS. Alachlor residues were detected in 1.7 percent of the wells sampled by USGS (c.f., Kolpin, 1994). The State survey results are summarized in Table 7. In addition, several investigators (including USGS) have reported finding a major metabolite of alachlor, t-sulfonic acid in ground-water samples (c.f., Ref. 3).

(v) *Metolachlor.* Metolachlor was the 12th most often found pesticide in the OPP Pesticides in Ground Water Database (see Table 8). Metolachlor was also reportedly found at concentrations exceeding 7 µg/l (or 10 percent of its reference point) in 19 wells across 6 States. NAWWS estimates that metolachlor has a detection frequency near 1 percent in the surveyed ''alachlor use area.'' Less than half of the metolachlor detections are at levels exceeding 0.2 µg/L. The average detection limit was 0.03 µg/L.

Results from the Ciba large-scale retrospective study of metolachlor indicate that metolachlor was detected in 89 of 920 samples (or 10 percent), and 39 of 240 wells (or 16 percent). The screening level was 0.1 µg/l. Detections ranged from 0.1 to 88 µg/l with half of these detections at concentrations of 0.1 to 0.5 µg/l. None of the detections in this study exceeded the Health Advisory (HA) of 70 µg/l. USGS (Kolpin, 1994) reported that 2.7 percent of the wells sampled in the mid-continental United States contained metolachlor residues. The following five tables (Tables 4 through 8) summarize the data on occurrence for each of the five pesticides.

TABLE 4.—ATRAZINE OCCURRENCE IN GROUND WATER

Atrazine (Rf. Pt. = 3 µg/l)	Data Source					
	PGWDB	NPS	NAWWS	State Surveys		
				IA: SWRL	WI: RWS	CA: WID
# of Wells Sampled	26,909 (in 40 states)	1,349 (566 PWS, 783 private)	1,430 (in 89 counties)	686	2,200/236	6286 (in 53 counties)
Frequency & Distribution of Detections (# of wells).	1,512 (in 32 states)[2]	NA	166	NA	603/200 (143-208)[1,2]	111 (in 21 counties)
Frequency & Distribution of Wells > Rf. Pt..	172 (in 22 states)	NA	2	NA	NA/15 (56)[1,2]	0
Range of Detected Concentrations (in µg/l).	trace-1500	trace - 7.0	≤0.1 - 6.72	0.13 - 6.61	0.10 - 16.0	0.1 - 0.19
Estimated Occurrence Rate (Statistical Surveys only; Confidence interval ranges in parens).	NA	Among CSWs: 1.7% (0.5-2.9%); Private wells: 0.7% (0.1-2.0%)	12%	4.4%(2.8-5.9) 3.5% [3] ..... 3.5%[4]	NA	NA
Estimated Number of Wells with measurable residues (Statistical Surveys only; Confidence interval ranges in parens).	NA	Among CSWs: 1570 (420-2710); Private wells: 70,800 (13,300-214,000)	720,000	NA	NA	NA

TABLE 4.—ATRAZINE OCCURRENCE IN GROUND WATER—Continued

Atrazine (Rf. Pt. = 3 μg/l)	Data Source					
	PGWDB	NPS	NAWWS	State Surveys		
				IA: SWRL	WI: RWS	CA: WID
Estimated Occurrence Rates & # of wells with concentrations > Rf. Pt. (Statistical Surveys only).	NA	< 0.1% Private wells < 9,450 Private wells	0.1%; 8,400 private wells	NA	NA	0
Detection Limit (μg/l)	Various	0.12	0.025	0.13	0.1	Various

[1] Results of both Phase I and II Studies shown; Phase I (immunoassay) results shown first, separatefrom Phase II with a slash (/).
[2] There are additional chloro-metabolite detections reported in PGWDB, but the majority of samples and detections occur within the IA:SWRL study. Des-ethyl atrazine reported in 27 sites in Indiana and Iowa; des-isopropyl atrazine reported in 24 sites in Indiana and Iowa.
[3] Desethyl atrazine (a chloro-metabolite).
[4] Desisopropyl atrazine (a chlorinated metabolite).

TABLE 5.—SIMAZINE OCCURRENCE IN GROUND WATER

Simazine(Rf. Pt. = 4 μg/l)	DATA SOURCE			
	PGWDB	NPS	NAWWS	State Surveys
				CA: WID
# of Wells Sampled	22,374 (30 states)	*	*	6,752 (55 counties)
Frequency & Distribution of Detections (ι of wells).	486 in 19 states	NA	23	308 (9 counties)
Frequency & Distribution of wells > Rf. Pt.	36 in 12 states	NA	1	0
Range of Detected Concentrations (μg/l)	trace - 67	trace - 1	< 0.15 - 8.36	0.1-2.4
Estimated Occurrence Rate (Statistical Surveys only).	NA	For CSWs: 1.1% (0.4-2.7%) private wells: 0.2% (< 0.1 - 1.3%)	Private wells: 1.6%	
Estimated Number of Wells with measurable residues (Statistical Surveys only).	NA	For PWSs: 1,080 (350 - 2540) private wells: 25,100 (590 - 141,000)	96,000 private wells	
Estimated Occurrence Rates & # of Wells with concentrations ≤ Rf. Pt. (Statistical Surveys only).	NA	< 0.1 % < 9,450 private wells	NA	
Detection Limit (μg/l)	Various	0.38	0.025	Various

TABLE 6.—CYANAZINE OCCURRENCE IN GROUND WATER

Cyanazine (Rf. Pt. = 1 μg/l)	DATA SOURCE				
	PGWDB	NPS	NAWWS	State Surveys	
				IA: SWRL	CA: WID
# of Wells Sampled	7,468 (in 27 states)	*	*	686	871 (in 24 counties)
Frequency & Distribution of Detections (ι of Wells).	155 in 15 states	NA	NA	NA	0
Frequency & Distribution of Wells ≤ Rf. Pt..	22 in 9 states	NA	0	0	0
Range of Detected Concentrations (μg/l).	trace -29.0	0	< 0.45	0.14 - 0.84	0
Estimated Occurrence Rate (Statistical Surveys only).	NA	< 0.1%	0.3% (private wells)	1.2% (private wells)	NA
Estimated Number of Wells with measurable residues (Statistical Surveys only).	NA	< 9,450 private wells	18,000 private wells	NA	NA
Estimated Occurrence Rates & # of Wells with concentrations > Rf. Pt. (Statistical Surveys only).	NA	< 0.1%	0	NA	NA
Detection Limit (μg/l)	Various	2.4	0.1	0.12	Various

TABLE 7.—ALACHLOR OCCURRENCE IN GROUND WATER

Alachlor (Rf. Pt. = 2 μg/l)	DATA SOURCE				
	PGWDB	NPS	NAWWS	State Surveys	
				IA: SWRL	CA: WID
# of Wells Sampled	26,856 (in 35 states)	*	*	686	2,009 (34 counties)
Frequency & Distribution of Detections (ι of Wells).	543 (in 25 states)	*	28	NA	1
Frequency & Distribution of Wells > Rf. Pt..	101 (in 16 states)	*	NA		1
Range of Detection Concentrations (μg/l).	trace - 3,000	4.2	< 0.15 - 6.19	0.02 - 4.76	9.0
Estimated Occurrence Rate (Statistical Surveys only).	NA	< 0.1% (< 0.1 - 1.0%) - private wells	0.8% - private wells	1.2% (0.4 - 2.0%)	NA
Estimated Number of Wells with measurable residues (Statistical Surveys only).	NA	3,140 (1 - 101,000) private wells	48,000 private wells		NA
Estimated Occurrence Rates & # of Wells with concentrations ≤ Rf. Pt. (Statistical Surveys only).	NA	< 0.1% (<0.1 - 1.0%); 3,140 (1 - 101,000) private wells	0.02%; 1200 private wells		Various
Detection Limit (μg/l)	Various	0.50	0.025	0.02	

TABLE 8.—METOLACHLOR OCCURRENCE IN GROUND WATER

Metolachlor (Rf. Pt. = 70 μg/l)	DATA SOURCE				
	PGWDB	NPS	NAWWS	State Surveys	
				IA: SWRL	CA: WID
# of Wells Sampled	22,255 (in 29 states)	*	240 (in 4 states)	686	107 (10 counties)
Frequency & Distribution of Detections (# of Wells).	213 (in 20 states)	*	39 (in 4 states)	NA	0
Frequency & Distribution of Wells > Rf. Pt..	3 (in 3 states)	0	0	NA	0
Range of Detection Concentrations (μg/l).	0 - 157	0.20 - 3.81	0.1 - 88.0	0.04 -9.00	0
Estimated Occurrence Rate (Statistical Surveys only).	NA	1.0% (private wells)	16% (private wells)	1.5% (0.6-2.4%)-private wells	NA
Estimated Number of Wells with measurable residues (Statistical Surveys only).	NA	60,000 private wells	NA	NA	NA
Detection Limit (μg/l)	Various	0.025	0.1	0.04	Various

Legend (for Tables 4-8) Data in Tables include data on identifiable metabolites, shown in italics. Specific degradate compounds identified by footnote. Numbers in parentheses in rows displaying estimates for statistical surveys are 95% confidence intervals for a given estimate. Studies, surveys, and reports containing the information summarized in Table, denoted by abbreviations as explained below:

PGWDB = Pesticides in Ground Water Data Base (as summarized in Ref. 15), which also includes the data reported in the ''state surveys'' in this Table - thus, ''detections'' as reported in each column are not additive (although the PGWDB does not include the detections from the NPS, NAWWS or Ciba statistical studies).

NPS = National Pesticide Survey, Phase I Report (Ref. 10); also Phase II Report (Ref. 14). Data may be displayed reporting separate results for community-supply wells (CSWs), serving public community water systems and rural, private wells. The two categories were selected for sampling according to different stratification schemes.

NAWWS = National Alachlor Well Water Survey (as summarized in Refs. 3 and 4); note that estimates of occurrence rates listed in the Table under the ''NAWWS'' column apply only to rural private water wells in the ''alachlor use area'' as defined in the NAWWS design; ascribing Study's occurrence rates nationally would overstate prospective occurrence. However, the projected number of wells and/or population exposed take that limitation into account.

Ciba = Large-scale Retrospective G.W. Monitoring Study (for metolachlor only; Ref. 2).

IA: SWRL= Iowa State-Wide Rural Water Survey (1990); note that specified occurrence rates in the Table apply to estimated occurrence in the State of Iowa only.

WI: RWS = Wisconsin Rural Well Survey (1990).

CA: WID = California Well Inventory Database (annual reports; data contained in Ref. 15).

NA = Not applicable or unavailable.

Trace = Detection below a specified detection limit.

* = See Table 4.

c. *Conclusions—Ground water contamination potential.* The five pesticides selected in today's proposed rule exhibit persistence and mobility characteristics that suggest the capacity to reach ground water on a widespread basis. This potential is confirmed by the record of occurrence produced from ground-water monitoring efforts. Each of the five has been detected hundreds of times in many States, indicating the breadth and magnitude of ground-water contamination potential. Moreover, each has been detected at concentrations exceeding its respective reference point in multiple locations, in different States, and across a variety of hydrologic and geologic conditions. This, and the fact that many more detected concentrations of each are within one order of magnitude (i.e., 10 percent or more) of each reference point, confirms that each pesticide exhibits the capacity to reach ground water at concentrations exceeding health-based standards. To EPA's knowledge, point sources do not explain the range and number of these occurrences. All five can be reasonably expected to contaminate ground water at or above their respective reference points. EPA has reached the tentative conclusion from this data that continued use of these pesticides without further controls and protective measures constitutes a clear risk of continued ground-water contamination.

4. *Risk conclusions.* In summary, EPA concludes that exposure from these pesticides may present the potential for adverse human health and environmental effects associated with exposure from these five pesticides.

These five, while they may differ among themselves in the frequency and severity of prior detections in ground water, entail a significant number of detections in multiple States. Among currently registered pesticides, only these five and aldicarb, which is being addressed by other regulatory means, have been detected above their respective reference points in three States or more. Second, these five share a substantial overlap in use sites and crops, such that each pesticide could represent a significant alternative to the use of one or more of the others. This latter circumstance plays a significant role in EPA's decision to subject all five to SMPs. Leaving one or more of these free from State management measures might constitute an incentive for users to substitute that pesticide for one of those subject to SMPs. EPA's analysis of the contamination potential of these pesticides suggests that such a course might only increase the occurrence of the excluded pesticide(s) to a frequency and severity that would rival that observed for atrazine and alachlor. The practical effect of such an exclusion might be to worsen the overall quality of the ground-water resource.

EPA has also considered the potential impact associated with the increased use of substitute pesticides that may result from reduced use of the five under consideration here. This issue includes two separate considerations. The first is the possibility that increased ground-water contamination will result from increased use of substitute

pesticides not subject to SMPs. EPA acknowledges that there is a likelihood that other pesticides will be used in substitution for these five in cases where State measures constrain triazine and acetanilide use. EPA has analyzed the likelihood for such substitutions in its Regulatory Impact Analysis (see Unit VIII. of this preamble); in this analysis the Agency has identified the likely substitute pesticides for a substantial variety of crops and other uses. Only a few of the prospective substitutes exhibit similar persistence and mobility characteristics; upon closer examination, moreover, it is unlikely that any of the prospective substitutes exhibit as severe a potential for ground-water contamination as these five candidates. None of the prospective substitutes have been detected in ground water to the extent and frequency as these five. Given the substantial evidence summarized in here that these five are the largest ground-water contamination risks of any pesticides in current use, EPA concludes that it is has no reason to anticipate that increased use of substitutes will result in a greater risk to ground water for the foreseeable future.

The other consideration is that the increased use of substitutes might indirectly increase net risks, because of greater risks through other routes of exposure, such as dietary and worker exposures. This is a considerably more complex question. EPA believes that these risks will not measurably rise because of the use of anticipated substitutes. EPA reaches this conclusion, considering: (1) There will be comparatively little substitution of use of these pesticides with potentially more dangerous alternatives (at least compared to an outright cancellation), since EPA's analysis of impacts concludes that State measures will permit substantial continuing use of the five pesticides in question; and (2) none of the anticipated substitutes pose particularly elevated risks for these other exposure routes at reasonably expected increased levels of use. EPA has confidence that none of the substitutes are particularly more toxic, overall and in relation to particular endpoints, than the five pesticides in question. For example, none of the prospective substitutes are in Special Review, for health concerns as the triazines are.

a. *Metabolites*. At this time EPA does not intend to require that State Plans provide for monitoring degradates of these five pesticides. However, EPA would like comments on: (1) Whether it should require State submissions to address selected metabolites of toxicological concern; (2) what specific metabolites should be addressed by SMPs; and (3) what specific SMP provisions should apply to the metabolites.

The Agency notes that relatively inexpensive screening methods are available for all five of the parent compounds, and for many of their metabolites. Thus, a State may choose to include degradates in their monitoring plan, as some already do. Moreover, if additional information about some or all of these degradates raises concerns in the future, EPA may revisit this issue. The availability of practical analytical methods would be an important consideration in asking States to include degradates in their monitoring plan.

C. Costs and Benefits

The following section completes EPA's proposed determination that the five pesticides may present an unreasonable risk to the environment without additional management measures to reduce the chances of their contamination of ground-water resources, by evaluating the risks represented by that contamination potential in light of the social and economic costs that SMPs represent. Costs and benefits under consideration are conceived on the broadest, most inclusive fashion (i.e., beyond the direct costs of the SMPs envisioned by this proposed rule and the benefits of averting human health risks represented by ground-water contamination). The remainder of this section summarizes the data, analysis and conclusions contained in the Agency's draft Regulatory Impact Analysis (RIA) prepared for this rule pursuant to Executive Order 12866 (see Unit VIII. of this preamble). Those interested in a more detailed analysis of costs and benefits should refer to that document.

The assessment of risks and benefits associated with the decision to make these five pesticides subject to SMPs as a regulatory requirement takes into account the Agency's policy objective of prevention, i.e., to act in order to avert reasonably expected adverse effects to human health or the environment before they may occur. EPA must exercise its judgement on the basis of an analysis of the respective costs and benefits of regulatory action in a manner that takes into account the considerable uncertainty surrounding both. This entails acting on the basis of less tangible evidence of risk and considerable degree of uncertainty about both existing and future ground water contamination and its consequences, and taking considerable allowance of these uncertainties. It also entails weighing a detailed and quantified analysis of costs against an array of prospective benefits, many of which are difficult to describe in quantitative terms. Such a comparison, between what appear to be tangible costs and more intangible benefits, presents well-recognized analytic difficulties. Care must be taken not to let the quantified factors override consideration of important qualitative factors. In other words, SMPs will be justified based on a reasoned determination that the benefits (generally conceived and including elements difficult to quantify) justify the cost impacts associated with SMPs.

In developing the Strategy (Ref. 12) EPA evaluated a range of available regulatory options in addition to the State Management Plan approach. Specifically, EPA compared three general approaches in a companion document to the Strategy, the ''Pesticides and Ground-Water Strategy: A Survey of Potential Benefits'' (February 1991; Ref. 13). This analysis is discussed in Unit IV.D., of this preamble.

In the interests of presenting as full and honest a characterization of risk and benefit as possible, the Agency will also point out: (1) The relative magnitude of uncertainty regarding the true value of a quantity or attribute that EPA is estimating in its analysis; and (2) the reasons for believing that any specific estimate or characterization may overstate or understate the true value of such a quantity or attribute.

1. *Costs*. EPA identifies four general areas where some level of adverse economic impact (i.e., both direct and indirect costs) could result from regulatory action in response to ground water concerns. Federal program costs are the attributable costs of developing and justifying regulatory action regarding ground-water protection, including the assembly and evaluation of ground-water risk data, as well as expenditures relating to implementation of protection measures. Current expenditures include the cost of ongoing regulatory and risk assessment activities pertaining to ground-water protection in the pesticides program and grants to State pesticide programs to help sustain the cost of ground-water protection activities and, in particular, the development of ''generic'' SMPs.

EPA program costs are subdivided into headquarters (HQ) program costs and regional costs. As should be evident from the description in Unit II. of this preamble, the larger portion of EPA's effort will reside with the Regions. EPA estimated its regional-program costs by estimating a per-SMP average level of

effort and multiplying by the expected number of State Plans that are currently anticipated for these five pesticides. EPA's analysis is calculated on the expectation that 236 Plans will be submitted. This translates into an annualized cost of $1.1 million for regional activities. EPA estimates its annual HQ program costs will range approximately from $413,300 to $437,000 (in current dollars) for the first 3 years after promulgating this rule, with costs decreasing to an average of $160,600 annually thereafter.

The margin of uncertainty for EPA's estimate is relatively small (mostly reflecting the relatively small dollar estimate) and relatively insignificant with regard to its potential impact on EPA's decision. It is difficult to determine whether EPA's estimate tends to understate or overstate the likely actual value of Federal costs, in part since a substantial proportion of the costs are part of ongoing regulatory activities. However, any error in EPA's estimate (because of these uncertainties) is probably more likely to understate the estimate slightly.

State program costs are the estimated State expenditures for implementing Federal ground-water protection actions. These include the costs of developing five pesticide-specific SMPs and of implementing and enforcing elements of approved Plans and represent a substantial level of expenditure.

Because the scale of State Management Plans is contingent upon pesticide usage and aquifer sensitivity—which will vary not only between States but also within a given State—the costs of developing, implementing, and enforcing SMPs are particularly difficult to generalize. In calculating the costs of SMPs, it is reasonable to assume that costs will vary directly with the scale of a State's plan. Finally, several additional factors will influence the eventual costs of a State's plan. These include: the risk mitigation options available to State planners; the role of coordination between State agencies and other governmental bodies; the shifting of costs to registrants; and technological innovations that may lead to decreasing costs over time. States have reported (in the process of developing ''generic'' SMPs) a broad range of anticipated costs (from as little as $17,000, to write a generic plan to over $1 million, counting in full the conduct of vulnerability assessments, ground-water monitoring and data base management), corroborating the assumption of variable State costs.

EPA made some critical simplifying assumptions in developing its cost estimates: (1) That ''States'' (including territories and some Indian tribal authorities) would develop and submit State Plans for all or most of the five pesticides in question before the effective date of the rule; (2) that the Plans would represent an adequate level of protection, i.e., would be approved by EPA; (3) that some States would be obliged to develop SMPs that entailed extensive protection programs for one or more of the five pesticides, that others would have to develop Plans with some additional protection and that still others would have to do little more than minor amendments to their ''generic'' SMPs to provide for future use of any of the five chemicals (based on an analysis of the current use patterns of the five pesticides); (4) that virtually all States would submit Plans that would consolidate the activities related to any and all pesticides as much as possible, so that substantial costs in ground-water vulnerability assessment and monitoring, for example, would be shared and not duplicated among individual-pesticide proposals - a reasonable assumption in this case, considering in particular the common use areas among these five candidates and their concentration in areas of high-intensity field-crop agriculture that would otherwise be of high State concern in any case; and (5) that the mix of ''extensive'' and less-extensive State Plans would entail a level of effort that could be estimated on the basis of a ''model'' SMP activity, that could in turn be extrapolated from analysis of existing State programs, ''generic'' SMP submissions and the requirements of pesticide-specific SMPs embodied here in today's proposed rule and in the Agency's Guidance. The Agency regards this last assumption as particularly conservative, since the Agency expects that a significant number of actual Plans will turn out to be of the less-extensive variety. Pricing every Plan on the basis of a ''model'' Plan will significantly overstate the true costs, since the Agency constructed the ''model'' to represent a relatively extensive level of effort.

EPA developed its aggregate State-cost estimate by means of using an existing State plan (Wisconsin's) as a model or surrogate for individual State plans. Wisconsin's program was chosen as representative for several reasons; its ability and readiness to share its data on program development and costs; and its exemplary nature (in terms of level and extent of commitment and exercise of risk-management measures). Furthermore, Wisconsin falls into the range of moderate vulnerability as measured by several macro-level ground-water vulnerability indices. However, this latter circumstance is in itself not the consummate proof of Wisconsin's representativeness (or even adequate characterization of Wisconsin's relative ground-water sensitivity), since State situations in terms of vulnerability are so diverse as to preclude the classification of any State as ''average.'' Finally, EPA did not view the Wisconsin program as the maximum effort a State might have to exert: not only has the program dealt primarily with a few, particular pesticides, but it terms of general ground-water contamination risk, Wisconsin may not represent the greatest degree of vulnerability.

EPA, in its analysis, took into account both the one-time costs of a Wisconsin-type program (annualized over either a 5– or 10–year period) and estimated annual incremental costs to arrive at a range of estimated annual State expenditures. One reason for using Wisconsin's experience as a model is the fact that it has performed some of the initial activities necessary to implement an SMP, enabling the Agency to model such activities as the establishment of pesticide usage surveys, vulnerability assessment, soil susceptibility mapping, other data base creation, monitoring (establishing and sampling sites), maintenance of records, personnel, public awareness and education, and other miscellaneous costs of plan development.

EPA estimates State programs on the average may annually cost in the range of $250,000 to $750,000 during the first several years of implementation, with $500,000 as the average annual cost. Successive SMPs required by the Agency will undoubtedly require less new effort by the States, so that incremental costs would be expected to decline over the long run. EPA took this expectation into account in its estimate of State program costs, projecting that each State, in developing multiple SMPs for these five pesticides, would incur some economies by developing Plans with common elements. Therefore, national costs were calculated by positing one per-SMP cost estimate ($500,000) for a single Plan, and fractional estimates for accompanying Plans. Calculated on this basis, if States and territories were to implement a total of 236 SMPs (EPA's current estimate of States' intentions), their total annual cost of implementing this regulation would be $ 59.9 million.

The Agency wishes to emphasize that the use of a ''model'' level of effort, based largely on one State's experience, is for purposes of estimating the costs

and benefits of this proposed rule. The analysis is not meant to represent pre-conceptions about the contents of State submissions. State Plans could depart substantially from the details presented in the ''model.'' Such differences could be caused by the State's particular situation (varying in size, ground-water vulnerability, and pesticide use patterns from the model) or by an innovative approach that EPA has not anticipated. These Plans would be found adequate to the extent States could demonstrate to the satisfaction of the reviewing Region that they assure adequate protection. At the same time, the Agency believes that it has projected the particulars of the ''model'' Plan in a manner that depicts the kind of effort necessary to meet the objectives of this proposed rule. To that extent, EPA offers the State-cost analysis as a reasonable basis for evaluating the cost and benefit of this rule.

Moreover, the Agency wishes to emphasize that the estimate of $59.9 million is the annual average of aggregate State costs over a 10–year period. As such, it represents: (1) The amortization of high one-time costs, such as drilling monitoring wells or performing baseline vulnerability assessments; and (2) several years of operation of fully-developed, mature State programs. Under no circumstances should the figure be construed to be the immediate, first- (or even second-) year costs the States will incur. As stated in Unit III. of this proposed rule, EPA anticipates that States can be expected to have to phase in ''capital'' elements of an SMP (e.g., the development of monitoring and vulnerability assessment activities).

EPA's assumption of broad State participation (that all States will develop Plans for most of the five pesticides, and that many will develop Plans for all five) may appear to be particularly tenuous, since there is no compulsion on the States to develop such Plans, beyond the loss of the legal use of a pesticide within the State. The consequences of error in this assumption are two-fold with respect to estimating costs: (1) EPA's estimate of State costs may overestimate actual State costs, because the Agency has over-estimated State participation; but (2) in that event, EPA's estimate of user impacts might be low. Since the absence of an acceptable SMP would result in prohibition of a pesticide's use in a State, more user impacts may result than EPA has estimated. The fact that the effects of error in this assumption are at least potentially offsetting reduces the Agency's concern.

EPA has confidence in the validity of assuming maximum State participation, however. First, the Agency believes the States have strong incentive to avoid these increased impacts to its own users by developing Plans. This belief is bolstered by the strong evidence of the States' interest in assuming the responsibility for managing pesticide use to protect ground water (for example, the near-universal acceptance of grants and development of ''generic'' SMPs). At the same time, EPA has little alternative to such an assumption. EPA does not have any basis for estimating which or how many States might fail to implement plans, beyond current informal communications between EPA regions and the States. Finally, it seems reasonable to assume the States least likely to participate are those with the least incentive to do so (i.e., those with little or no current or projected use of the pesticides), so that their non-participation would have comparatively little effect on current use (and consequently little user impact).

Among the other sources of EPA's uncertainty of its estimate are the inherent variation in the size and level of agricultural activity across States, and the anticipated variation in State approaches, ground-water protection objectives and the like. EPA does not believe the margin of uncertainty in its estimate exceeds the magnitude of the estimates. Among the reasons for believing EPA's estimate underestimates the true impact of regulatory action are unanticipated difficulties or obstacles in State implementation of its requirements (such as unanticipated non-compliance, necessitating substantially more enforcement activities), as well as those considerations described above. In addition, EPA has not taken into account potential increased costs of Federal-State enforcement of sale/use prohibitions for those States that fail to develop Plans. For the reasons explained above in describing the assumptions, EPA does not anticipate many States will not develop approveable Plans for all five pesticides. For those few cases that may arise it is EPA's expectation that enforcement and compliance costs will be minimal, since part of the reason for State disinterest in developing SMPs for these pesticides will be their insignificant use in the State. Among the reasons for anticipating that EPA's estimate overstates the true level of State expenditures would be the deliberate conservatism in pricing aggregate State costs on the basis of a ''model'' Plan that represents substantial effort, limiting the estimate of economies-of-scale achieved by developing multiple SMPs and the possibilities for innovations in ground-water assessment and monitoring techniques (particularly the latter).

Registrant (or pesticide-industry) impacts are those that would be the direct result of regulatory action, apart from any anticipated loss of income from reduced use of the products attributable to regulatory restriction. Attributable costs would include: (1) The lost revenue associated with decreased use of the products, caused by State risk-management measures; (2) the costs of increased technical assistance (such as ground-water monitoring) and outreach to users that the registrants might provide, to help them ascertain and follow the new, applicable State management measures or other safeguards on the chemicals' continued use; and (3) the direct costs of relabeling and compliance with the administrative provisions of this proposed rule. The first category, lost revenue, was calculated as a function of likely State actions, which in turn are represented as three scenarios of differing regulatory stringency. Projected annual lost revenues for a ''medium impact'' scenario was calculated to be $33.6 million. Using current sales figures from the major registrants of these five pesticides, this figure represents an estimated 0.06 percent decrease in total sales, and a 0.48 percent decrease in pesticide-product sales for these registrants. The estimated costs in the second category are those that are incremental to ongoing ground-water monitoring, technical assistance or outreach efforts the registrants now perform with regards to ground-water protection. They are estimated to be in the range of $3.1 to 12.7 million annually, conceived as substantial new ground-water monitoring activities performed in addition to State efforts. These costs can also be attributed to the possible new ground-water monitoring requirements that EPA may prescribe on registrants concurrently with State development of SMPs (see Unit III. of this preamble). While EPA has not committed to the development of such requirements at this time, the Agency nevertheless includes a cost estimate for the activity in the interests of not underestimating costs. Uncertainties include EPA's actual specification of those requirements, the level of effort represented by that specification, the identification of further technical-assistance activities and their delineation from ongoing regulatory efforts.

By far the most substantial impact (in terms of relative magnitude) is anticipated to be impacts on agricultural

and non-agricultural users, and associated indirect impacts of reduced consumer benefits. These impacts pertain to the changes caused by regulatory restrictions in use of pesticides and the consequent changes in agricultural (and other economic) productivity and expenditures. In addition to being the largest component of cost, its magnitude is the most uncertain and difficult to estimate. Estimating these impacts entails an econometric analysis with consideration of a multitude of cascading secondary effects across geographic regions and economic sectors and with estimated impacts expressed through a variety of economic measures. These difficulties are compounded by the necessary consideration of the combined behavior changes of perhaps a million affected farmers and other users, the normal uncertainties in the agricultural sector (the effect of weather, etc.) and the like.

EPA attempted to anticipate as many of these interactions and uncertainties as possible by using a widely used multi-sector, multi-regional econometric computer simulation model called AGSIM. The analysis was performed to take into account not only regional variations in commodity supply and production (i.e., varying responses to changes in per-acre yields, variable costs, and prices) but also the present and projected influences of farm policy elements (e.g., Federal price-support and conservation programs, Federal monetary policy, etc). These measures aggregate into separate (and additive) dollar estimates of the combined impact to the agricultural-production sectors (expressed as the change in net agricultural production and income) and the consequent decrease in domestic-consumer benefits (sometimes referred to as ''surplus value,'' or the amount of additional consumer expenditures to maintain the same standard of living as reflected in the ''baseline'' conditions, prior to a regulatory action).

In order to estimate impacts it is necessary to estimate certain effects of the SMPs and use these as inputs to the econometric model. Specifically, a critical task was to estimate how State risk-management measures would influence: (1) The acreage where these five pesticides are used; (2) yield impacts; and (3) input (i.e., pesticide-chemical) cost impacts. Thus, SMP impacts on users are estimated by a matrix of combinations of these three factors (taking the availability of non-SMP pesticide substitutes into account) and the consequent change in crop yield and price. The critical measure of impact is the reduced treated acreage associated with State risk-management measures. These values must be regarded as a proxy for the variety of potential effects that SMPs may have on agricultural practices. They are not intended to represent a forecast of actual State practices, but rather a surrogate measure of their potential effect on agricultural practices.

These estimates were made by consultation with a variety of sources. Affected acreage was identified by the use of a Ground-water Vulnerability Index for Pesticides designed by Robert Kellogg of USDA's Soil Conservation Service. A percentage of these affected acres was assumed to be subject to either restricted or prohibited use under State Management Plans; this percentage varied according to impact scenario and was based upon the 1992 Wisconsin Atrazine Rule. EPA tried to account for the considerable uncertainty about the impact of State management measures by positing a variety of reduced-use scenarios across the principal use areas of these five pesticides. EPA believes the most-likely estimate of user impacts rests with its medium-impact scenario, but has provided companion low- and high-impact scenarios for comparison. The Regulatory Impact Analysis accompanying this proposal provides a fuller explanation of EPA's estimates and the methodology used to derive them. The SMP-use restrictions have the anticipated effect of lowering expected yields and pesticide input costs. Restrictions on application rates lower pesticide input costs since total usage declines; use prohibitions also lower costs since the cost of alternative pesticides are less than that of the SMP pesticides. Crop producers are actually expected to be better off in terms of net crop revenues as a result of such restrictions, due to the combination of increased prices obtained for affected commodities and reduced input costs. Increased commodity prices are predicted due to reduced acreage planted, which in turn, decreases the total supply of a particular commodity. However, increased prices resulting from reduced supply are a net negative impact to the economy overall, in the form of reduced consumer surplus value.

At the same time, increased feed crop (corn, soybean, sorghum) prices raise input costs for livestock producers. Coupled with stagnant or declining demand for livestock products, increased input costs negatively impact livestock returns in this analysis by reducing livestock revenues. Because the reduction in livestock returns is estimated to be greater than the increase in crop returns, net impacts to the U.S. agricultural sector are negative, but relatively minor (-$1 million to -$11 million, across the three scenarios).

Correspondingly, indirect impacts, in the form of reduced consumer benefits, are estimated to be in the range of $242 to $254 million.

While the absolute magnitude of such impacts appear to be substantial, in relative terms such impacts are moderate. Relative to the economic value of U.S. field corn production ($16 to $23 billion), such impacts are small. For example, the SMP-use restrictions are anticipated to lower U.S. field corn production by about 1 percent, leading to a potential 1.1 percent increase in market prices. Such impacts would have a *de minimis* effect on the Gross Domestic Product. Average annual consumer expenditures and food prices would change less than $1.00 per person (from $0.94 to $0.98) as a result of these impacts. Individual farmer income in the aggregate would also change little, but regional effects of greater magnitudes (both positive and negative) could occur.

This range of projected impacts compares to impacts of $ 3.6 billion or more in combined user costs and reduced consumer benefits, associated with either outright cancellation of the five pesticides (plus aldicarb, which had minimal costs associated with its management) or more stringent, nationwide use restrictions, as estimated by Taylor, et al. in 1991, using a similar econometric approach.

EPA's method for estimating user impacts, like its projection of State-program costs, relies on some key simplifying assumptions: (1) A degree of regulatory restriction will translate into a discrete (and predictable) level of decreased (or alternative) pesticide use, resulting in predictable adverse effects to agricultural production and the other relevant economic effects summarized above; and (2) the scenarios vary (predictably) in the degree of regulatory restriction they represent, and this difference can be expressed in terms of the cropped acreage subject to reduced, substituted or eliminated pesticide use. Among the reasons for anticipating that EPA's estimate understates the true potential impact of ground-water protection measures are: (1) That the analysis pertains only to uses on field crops (which, however, represent over 90 percent of the combined current use of these five), overlooking the potential impact on fruit and vegetable crops; and (2) that EPA assumes all States will participate, so that no greater restrictions on use will ensue from the fact that State inaction causes a

complete curb on use. However, EPA has equal or greater reason to believe its estimate overstates the actual potential impact; chief among these is faith in the States' ability to develop a variety of innovative management measures that will minimize the disruption in crop production caused by ground-water safeguards. State resourcefulness in developing new approaches will undoubtedly outrun the Agency's present expectations. It is already clear, for instance, that States will emphasize measures that will enhance the sustainability of agricultural production simultaneously with ground-water protection, preserving much of the necessary use of the pesticides in question. Also, inevitable improvements in ground-water monitoring and vulnerability-assessment techniques will enable states to ''fine-tune'' necessary restrictions to a degree EPA cannot yet anticipate in its estimate. In addition, in developing its estimates of crop yield losses, EPA did not take into account the considerable promise that is subsequently emerging in the areas of integrated pest management and other reduced-use strategies.

In summary, it needs to be stated that in distinguishing the various costs that may be attributable to Federal regulatory action for purposes of weighing the costs and benefits of any action, EPA did not attempt to assess the reasonable likelihood that a particular category of parties would actually incur the costs. For example, the boundaries between ''State'' and ''registrant'' costs may be considerably more blurred than our analysis would suggest. A variety of activities attributed to the States in managing the use of a pesticide subject to an SMP rule (including those involving substantial levels of effort, such as ground-water monitoring or user education and outreach), for example, could in practice be either performed (in part or in whole) or paid for (either directly or through State imposition of fees) by the registrants. Likewise, some of the activities identified by EPA as ''registrant costs,'' e.g., the provision of increased user training and technical assistance, could be expected to be performed often at the behest of State agencies pursuant to their Plans. Accrual of expenditures accurately to the various parties was of less importance to EPA in making this analysis than was concern for the projection of overall level of effort and expenditure attributable to this rule.

2. *Benefits*. Chapter 7 of the RIA contains the Agency's appraisal of the potential benefits associated with establishing SMPs for these five pesticides. This appraisal begins by cataloging the different kinds of values associated with protecting ground water as a natural resource. These values are categorized in terms of their various services as a resource. This categorization follows a recent Agency conceptual framework for assessing the economic value of ground-water protection in evaluating regulatory impacts (Ref. 19). Each of these service values, (associated with two general functions of ground water: both as a source of water stock and as a discharge to surface water supplies) may be subject to a variety of economic valuation techniques. Since these categories generally involve the value of the resource in terms of its economic use, other categories of value recognized by natural-resources economists must also be acknowledged: the so-called altruistic, bequest, and existence values (sometimes referred collectively as ''non-use value'') associated with protecting a natural resource per se.

In general, however, the benefits of SMPs will accrue from the reduced levels of ground-water contamination, by substances associated with adverse human and/or environmental effects, that result from the regulatory safeguards required by the individual Plans. It is the presence of this contamination that jeopardizes any and all of the use and non-use values under consideration.

In order to perform a reasonable quantitative analysis of benefits, accurate and reliable estimation of exposure levels (both existing and projected, and in the case of the latter, projected for a number of different regulatory options) are critical. Unfortunately, reliable estimation of ground-water contamination occurrence is among the most difficult and uncertain issues with regards to ground-water concerns. Past and current efforts at ground-water monitoring have not been of a sufficient level and frequency to give adequate assurance that the Agency knows the levels of occurrence of pesticide contamination of ground water, either of the specific pesticides addressed in this proposed rule or of pesticides in general.

The United States Department of Interior, in comments submitted to EPA regarding the proposed Ground Water Restricted Use Rule (in 56 FR 22076, referred to in Unit I. of this preamble), characterized the state of knowledge associated with the nation's ground-water monitoring efforts as follows: ''Given shortcomings in national ground-water monitoring efforts, it is highly unlikely that all locations of all contaminants in ground water have been determined.'' [July 5, 1991 letter from Jonathan P. Deason, Director, Office of Environmental Affairs; exhibit 7 in OPP comment file no. 36172]. While not necessarily reflecting the views of EPA, these comments are testimony to the limitations associated with the evidence of contamination from current ground-water monitoring results, particularly the substantial likelihood of under-estimating the present and future level of exposure. Other methods of estimating prospective occurrence, such as projections from data on the leaching potential, volume and location of use of a pesticide or projections using environmental-fate-and-transport models, have even greater limitations (see, for example, National Resource Council, ''Ground Water Vulnerability Assessment,'' NAS Press, 1993, for a fuller description of the strengths and weaknesses of various ground-water analytic techniques).

The consequences of this potential under-measurement of present ground-water contamination has another dimension. Since known ground-water contamination is particularly localized, it is characterized by the incidence of limited ''hot spots'' of high concentrations. Occurrence of ground-water contamination is unevenly distributed, due to the variety of hydrologic and topographic factors. Locations of high concentrations of pesticides (and a corresponding high risk of potential adverse effects) in ground water are dispersed unevenly across the country. The overall profile of the risks associated with pesticides in ground water, then is one of large numbers of people at relatively low risk, punctuated with ''hot spots'' of higher risk. The risk concentrated in these ''hot spots'' are likely to exceed national average risks, but are difficult to characterize using aggregate occurrence estimates. This unevenness in the distribution of risk levels raises concerns regarding ''environmental equity,'' to the extent that effects are disproportionately high and adverse, which the Agency is committed to take into account as a matter of policy.

Finally, it should be noted that taking the next step of quantifying human health risk by combining population exposure figures with some benchmark of toxicity associated with a unit quantity of exposure, is hampered by limited methodologies for quantifying hazard. At present, the Agency customarily confines hazard quantification to carcinogenicity (e.g., projecting ''number of cancer cases avoided''), while the possible consequences of other toxicological endpoints cannot usually be presented with the same appearance of precision.

Despite the limitations on available evidence and methodologies discussed above, as a matter of illustration the Agency has presented in the RIA a number of different estimates of nationwide human exposure to these five pesticides in drinking water using ground-water sources. These alternatives represent different data sources and estimation methods. Three of these data sources have been referenced earlier in Unit IV. of this preamble: the Pesticides in Ground Water Data Base, the National Pesticide Survey and the National Alachlor Water Well Survey. Another estimate is based on the application of a modeling procedure, i.e., the application of an environmental-fate model using assumed values for prevailing hydrogeological conditions across all local areas where corn pesticides are used. This estimate is provided in a yet-unpublished Agency analysis of the cumulative risks and benefits of a host of pesticides frequently used on corn, a so-called ''corn cluster'' analysis. A copy of this analysis is available in the public docket for this rule-making.

The Agency presents these alternative estimates without making a judgement that one estimate is superior to another, or that any (or all, considered collectively) can be considered a reliable estimate of nationwide exposure and hence, national risk. Three of the four analyses provide estimates of both: (1) the number of individuals exposed to any measurable concentration of these five pesticides (or, in the case of the NPS, a surrogate estimate of ''total pesticide'' exposure); and (2) the number of individuals exposed to concentrations at or above health-based ground water reference points. The model-based estimate also estimates total population with any exposure, but offers a calculation of baseline cancer and non-cancer risk in place of the number of individuals exposed above reference points.

It is notable that when viewed together, there is a wide variation in central-tendency estimates of population exposed among the studies, as well as considerable uncertainty surrounding each estimate, taken individually and together. For example, best estimates derived from the available statistically-based studies of total population exposed to any concentration of the five pesticides, from domestic wells alone, range from a few hundred thousand to as many as 5 million. Estimates from the non-statistically based Pesticides in Ground Water Data Base, which does not differentiate private and public well occurrence, range to more than 20 million. More importantly, the estimated numbers exposed to high concentrations range from nearly none to one-half million people or more; taking estimates of random error into account, the number exposed above health-based standards could theoretically also be as high as 20 million. Estimates from the Data Base for this subset run as high as 2.84 million people.

In addition, each of the four estimations discussed has specific shortcomings which need to be recognized before relying on any estimate, considered either individually or together, as a credible basis for estimating the benefits of the rule. Some of the problems to be aware of with these studies are: (1) Most fail to account for the entire nationwide exposure potential, leaving out parts of the total exposed population (e.g., those drinking from community water systems); (2) not every data source addresses precisely the five pesticides in question; (3) most are based on limited and imperfect monitoring data (i.e., data from surveys with design flaws, or data that are not statistically based), and the modeling exercise is not based on monitoring results at all; (4) all of them measure or estimate the frequency and concentration of well contamination and not human exposure per se, which means that certain unverified assumptions were made regarding the numbers of people drinking well water to produce population-exposure estimates; and (5) they all produce estimates that are highly uncertain, for example, with the potential for random error (among the statistically designed studies) represented by 95 percent confidence intervals ranging from zero to the hundreds of thousands. One method (based on the PGWDB) is based on a larger amount of well water sampling, but such sampling is not statistically based, so no estimate of the degree of expected random error in the estimate is possible.

Given the wide range of divergent estimates, and the significant limitations on their reliability, the Agency cannot reasonably identify a single ''best estimate'' of prevailing exposure to the SMP pesticides in ground water. The Agency believes that the evidence of substantial contamination of ground-water-based drinking water supplies, indicated by the data summarized in Unit IV. of this preamble, provides reason to believe: (1) That many individuals (running up to the thousands, or even hundreds of thousands) are or will be consuming ground water contaminated by one or more of these pesticides at levels above health-based standards, in the absence of effective, localized risk-reduction measures as envisioned in SMPs; and (2) that many more individuals (running into the millions) are or will be consuming ground water with at least detectable levels of contamination. While concern tends to focus on the former subset, SMPs can be expected to substantially reduce the exposure to the larger population as well. The Agency further believes that the potential health risk represented by this magnitude of occurrence/exposure bears a reasonable relation to the magnitude of the economic impacts discussed in the section above.

The uncertainty surrounding the actual levels of individual exposure makes it very difficult to take the next step, that is, combining indications of toxicological potency with the estimates of exposure to obtain an estimate of human health risk. Where the particular study cited presents no estimates of population risk associated with the estimated exposure, the Agency has not developed any subsequent estimates. However, one of the studies (the modeling-based analysis associated with the Corn Cluster) offers both estimates of cancer and non-cancer population risks. The analysis suggests that these five pesticides together represent about 0.4 excess cancer cases per year, given a 3–meter depth of ground water as a drinking water source. The preponderance of this risk comes from one chemical alone, atrazine. The analysis arrives at an estimate of maximum individual cancer risk at this depth of 2×10^{-4}. To put the magnitude of this risk into perspective, as a measure of risk in hotspots, is to note that it is roughly twice as great as the incremental lifetime risk that this analysis estimates for the dietary pathway, about 8×10^{-5} for an individual of average exposure. A less conservative assumption that a 1 meter depth is representative of ground water recharge leads to an estimate of about 5 statistical cancers a year, with a corresponding estimate of maximum individual cancer risk of 3×10^{-3}, or nearly 40 times the average dietary estimate stated earlier. However, given that neither estimate can be regarded as a direct representation of ground-water exposure (since the model only simulates the loading to ground water via percolation through crop root zones), the Agency regards neither estimate as authoritative. In particular, the Agency has reason to believe the 3 meter estimate understates ground-water occurrence, based on the Agency's

experience with controlled field-scale studies, and describes this experience in Chapter 7 of the RIA. In addition, it is very likely that the cluster analysis underestimates the risk posed by pesticides other than atrazine. Specifically, risks presented by alachlor and simazine should be only slightly less than that of atrazine, based on the monitoring record.

The Agency is not attempting to authoritatively quantify the risks of ground-water contamination by these five pesticides, nor to monetize the value of avoiding these risks. The Agency believes such estimates are difficult to support scientifically, under these circumstances. The Agency solicits comment on the reliability of risk estimates that may be developed from these exposure estimates cited above, or from other sources.

Beyond the difficulties of characterizing the magnitude of potential human exposure to these pesticides in drinking water, absent the risk reduction afforded by SMPs, there remains the question of how effective SMPs will be in reducing that risk. The main impediment to the evaluation of SMPs' prospective effectiveness is the fact that individual SMP provisions remain to be set. However, even making some assumptions as to the general features of future SMPs, there remains the problem of estimating ground-water contamination occurrences. As mentioned earlier, present levels of ground-water monitoring are inadequate to gauge the levels of overall ground-water contamination with confidence. Alternatives to monitoring, e.g., environmental fate models, are not yet developed to provide an adequate substitute to monitoring results.

However, what little evidence is available to the Agency appears to support the conclusion that the risk-management measures contained in SMPs are likely to be effective in reducing the occurrence of ground-water contamination. The most reasonable approach to assessing the prospective effectiveness of SMPs is to consider the closest existing analogue to SMPs, i.e., the performance of existing State-imposed localized risk-reduction measures. Very few such analogues presently exist, but there is recent information that the Wisconsin atrazine use restrictions referred to earlier have resulted in an overall reduction in atrazine concentrations in contaminated wells.

In 1995, the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) conducted an extensive analysis of atrazine and its metabolites in drinking water wells located within risk-management areas imposed by the Department beginning in 1992, which had been previously monitored (Ref. 22). Seventy-six (84 percent) of 90 wells sampled in 1995 declined in total atrazine concentration, and 16 percent increased. For the 76 wells that decreased in concentration, levels decreased an average of 2.5 parts per billion (ppb). While the re-sampling of these wells generally occurred in one time period, from June to September 1995, the study compares these results to a baseline sampling frame that varies for each well. Each well was sampled with varying frequency across a period that spans from March 1990 to September 1994. Relative to the State standard, 57 percent of a slightly larger universe of 111 wells (encompassing the 90 cited above) are now below 3 ppb (with an average concentration of 1.4 ppb). The 43 percent of wells still above the 3 ppb standard had an average concentration of 5.9 ppb. The overall average concentration for the 111 wells is 3.3 ppb. While the report attributes the reductions in contamination to the use reductions, it was less able to explain the reasons for the occasional increases. However, the report mentions several plausible reasons, including the possibility that these wells are deeper (and so experienced higher levels of contamination from pre-controlled atrazine use later than the norm), or are located in more recently designated areas, or were affected by continued illegal use or spills near the wells. These are in addition to the common-sense explanations, i.e., the natural variability in sample results over time and/or metabolite contributions from non-prohibited triazine use in the areas (because atrazine, simazine, and cyanazine have some common degradation by-products that will be detected by first-round analytic methods). These data provide some evidence that state risk-reduction measures seem to have a beneficial effect, reducing both the number of occurrences of pesticide contamination in affected areas and the level of that contamination.

In addition to health effects, the Agency believes that the possibility of resource effects need to be acknowledged and considered in the decision whether to exact further regulatory protection for these pesticides. There are two major considerations. First is the adverse effect to ecosystems linked to ground-water sources. The scientific basis for estimating such things as the location, frequency, and duration of sensitive-ecosystem exposure to such ground-water contamination is less developed than even the limited information discussed above for human exposure. At the same time, the risk of ecological adverse effects is certainly a real possibility, and should not be discounted merely out of lack of currently available scientific means of ascertaining it. Second, there is an even more inestimable, but nonetheless relevant, concern over the intrinsic or future value of ground water as a resource, as free of man-made pollution as may be practicable. Studies that estimate ''willingness to pay'' based on survey methodologies have suggested proxy values of substantial magnitude, which if extrapolated to national scale, amount to billions of dollars, but the estimates from this controversial approach have uncertain applicability. One can hypothesize a threshold willingness to pay commensurate to the estimated costs of this proposed rule, which would compare favorably to the results of previous studies. Specifically, if an estimated 5 to 8 million potentially-affected households (an estimated 15 to 20 million potentially exposed individuals divided by the national-average per household population of 2.64) were willing to spend between $47 to $63 annually, these sums would be commensurate with the $356 million projected cost of the SMP rule. EPA believes that these estimates are well within the range of expectations, but only a carefully conducted survey, expressly clarifying the expected risk-reductions specifically associated with SMPs, could confirm these expectations. Likewise, prevention is a value that EPA subscribes to because the costs of prevention can be expected to be much lower than the costs of remediating contaminated ground water when and if it occurs.

The fact that the dimensions of risk and the effect of risk-reduction efforts are both highly uncertain dictates a policy to proceed cautiously and with maximum flexibility. The Agency believes the prudent course in the face of the uncertainties presented by pesticidal ground-water contamination is to take positive action that avoids irrevocable national policy courses at the outset that might lead to programmatic dead-ends. The Agency believes this is the essence of the SMP approach, and that this is the most practical policy course from among the regulatory alternatives.

EPA therefore recognizes the lack of information necessary to calculate quantifiable benefits that may be associated with the SMP approach. However, the States, in electing to participate, will have made a practical

evaluation of both the real and intangible benefits of ground-water protection measures, and their participation will represent the choice for prevention over remediation. These States will have evaluated the benefits of participating relative to their respective environmental policy philosophy and goals and on the State economies depending upon pesticide use.

D. Risk-Benefit Conclusions

Based on the information currently available, it is EPA's reasoned determination that the benefits of preventing ground-water contamination by these five pesticides justify the expected costs of implementing preventive measures through the SMP approach, and further, that the SMP approach appears to be the most cost-effective of the means available for protecting ground water.

EPA believes that the level and nature of protection to be afforded by SMPs is appropriate to the magnitude and character of contamination potential indicated by the evidence. In developing the SMP approach in cooperation with a broad spectrum of interested parties from the public and private sectors, there was much discussion of the alternative approach of having EPA impose national-level risk-reduction measures, such as labeling or use restricted to certified applicators. That alternative is discussed in Unit III. of this preamble and is being offered for comment in this proposal. The Agency wishes to point out, however, several factors which led EPA to propose the SMP approach rather than the national-level restrictions approach.

The main issue is whether label changes alone, or in combination with restricted use classification, and perhaps additional requirements placed on the registrants would be sufficient to address the risks of ground-water contamination. The evidence of each of the five pesticides' ground-water contamination risks suggests no particular, specific circumstances causing such contamination. The evidence of present ground-water contamination is so broad and general that it is unlikely that a pesticide user could readily identify a specific condition that would, to a high degree of certainty, cause the pesticide to contaminate ground water. Consequently, it seems questionable whether clear and simple label instructions could be developed that would adequately identify conditions for a user to avoid such that ground water risks would be significantly reduced or eliminated. Many ground water experts, including EPA staff, believe that reliable neutralization of the risks requires a knowledge of technical, site-specific factors that most pesticide users cannot reasonably be expected to possess. Furthermore, as a matter of policy, EPA believes that the users of pesticide products should not be given the burden of interpreting label instructions that are either unreasonably complex or technical, or are uncertain to achieve their purpose. The training associated with classification for restricted use may alleviate some of this concern, but would not address the issue of whether label restrictions would actually work.

If this alternative approach were to include monitoring requirements to demonstrate effectiveness, and use prohibitions if specific detection triggers were met, then this approach might well end up being substantially more onerous to both users and registrants than SMPs. The Agency is requesting detailed comments on this alternative from all potentially affected parties.

In considering the issue of national-level labeling measures, EPA has taken into consideration the fact that new risk-reduction measures have recently been in effect for atrazine (since 1992) which are intended to reduce the pesticide's contamination potential for both surface and ground water. These measures include label changes providing for the deletion of certain non-crop uses including highway and railroad rights-of-way, reduction of the rates of application for remaining crop uses and the imposition of set-backs (non-application zones) for wells and bodies of water, prohibiting use and mixing/loading within specified distances from surface waters and drinking water wells. These measures have not been in place long enough for EPA to discern any positive effect on the ground-water contamination potential of this pesticide. However, when EPA agreed to these risk-reduction proposals (which were voluntary measures proposed by the registrant), it made clear that additional measures would have to be considered. Furthermore, the Agency is taking into account the voluntary phase-out and eventual cancellation of cyanazine, announced in August 1995 (see 1., below). Finally, EPA is anticipating that all the pesticides ultimately subject to SMPs will also be classified for ''conventional'' restricted use, that is, restricted to use by or under the direct supervision of a certified applicator.

In the Strategy EPA committed to considering existing State and local measures in making its regulatory decisions about pesticides with ground-water concerns. To EPA's knowledge, a total of 10 States have or are working on some kind of independent restriction for one or more pesticides with ground-water concerns. However, not all of these apply to the five pesticides discussed here. Another 12 States have some authority to impose such restrictions, but have heretofore not employed it. From a national perspective, this level of effort appears to be inadequate to address the extent and character of ground-water contamination potential associated with these five pesticides. It appears that, in the main, States are anticipating that this proposed rule requiring pesticide-specific SMPs will serve as the framework for their own efforts in this regard.

Finally, it is EPA's belief and expectation that SMPs should sufficiently reduce the risks associated with the ground-water contamination potential of these five pesticides, so that full cancellation of use based on ground-water concerns alone is not likely to be necessary. While the potential risks represented by these five are substantial and warrant the imposition of effective preventive measures, the measures to be taken by the States should be adequate to mitigate the risks.

A remaining issue is whether the risks associated with ground water may combine with other routes of exposure for any of these five pesticides to constitute an unreasonable risk and thus warrant cancellation. EPA customarily uses the Special Review procedure to determine whether the combination of different routes of exposures represents unreasonable risks. Alachlor and cyanazine have been subject to Special Reviews in the past, and the three triazine active ingredients (atrazine, simazine, and cyanazine) have just recently begun Special Review. Any or all of these five may be subject to this further consideration in the future. In such Special Reviews, EPA will take into account the level of risk-reduction expected to be afforded by SMPs in making an evaluation of the pesticides' overall risk to human health and the environment.

1. *Cyanazine special review.* The recent agreement between the Agency and DuPont Agricultural Products, the principal registrant of cyanazine in the United States, to phase out and eventually terminate sale and use of cyanazine, affects this proposed rule. On August 4, 1995, DuPont signed an agreement with EPA whereby DuPont will amend its registration to: (1) Reduce the maximum use rates on cyanazine labels in four increments,

from 1997 to 1999; (2) cease production and sale at the end of 1999; and (3) prohibit all uses of cyanazine by the end of the year 2002. This arrangement will resolve the Agency's concerns with respect to cyanazine in its Special Review of the three triazines. EPA will soon publish its termination of the cyanazine Special Review. However, EPA will proceed with proposing cyanazine to be subject to SMPs in this rule, for several reasons. First, until the Special Review is officially terminated and the registrant's voluntary actions go into effect, the ground-water risks enumerated in this notice will remain, warranting at least proposed regulatory action. Second, even when the agreement is implemented, the phase-out schedule provides for a brief interval during which cyanazine may be used in States that would need SMPs. Third, the Agency is concerned with the possibility that cyanazine could be registered at some future date as a completely new pesticide. In that event, it is the Agency's judgement at this time that the present evidence of the pesticide's severe contamination potential requires that any such future use needs to be subject to SMPs.

It may be EPA's judgement in considering a final SMP rule that cyanazine's eventual cancellation will be sufficient to address the Agency's ground-water concerns; if so, it may choose to issue a final rule for only four of the pesticides proposed today. In any event, the Agency wishes to emphasize that the fact that cyanazine use will terminate soon after the effective date of the SMP restriction will be taken into account when EPA evaluates State submissions. EPA does not anticipate that State Plans for cyanazine will have to be as extensive or detailed as for pesticides whose uses are expected to continue indefinitely.

2. *Alachlor Special Review*. In 1985, EPA initiated a Special Review of Alachlor (50 FR 1115, January 9, 1985). As noted above, alachlor was classified as a B_2 (probable human) carcinogen, and the carcinogenicity potential has been quantified, although the classification is now under review. EPA concluded the Special Review of alachlor (52 FR 49480, December 31, 1987), after taking the following actions to reduce risk for workers: EPA classified alachlor for restricted use by certified applicators; prohibited aerial application using human flaggers; and required persons applying alachlor to 300 or more acres per year to use mechanical transfer systems for mixing and loading alachlor. In addition to these regulatory actions, however, EPA deferred action on whether the risks posed from alachlor in drinking water from contamination of ground water required regulatory action. EPA concluded that the further evaluation of the ground-water risks would offer an appropriate occasion to revisit the overall risks and benefits of alachlor (including dietary risks) on a crop-by-crop basis to determine whether the risk benefit balance had changed to a degree requiring regulatory action.

Since 1987, Monsanto has submitted the National Alachlor Well Water Survey (NAWWS) and review has been completed. EPA's concerns with respect to continuing ground-water risks are evident in its proposal to classify alachlor for SMPs in this proposed rule. In addition, EPA has reviewed recent trends in usage and percent of crop treated with alachlor and determined it is not necessary to revisit the risk/benefit determination of alachlor on a crop-by-crop basis. The dietary risks posed by alachlor were in the 10^{-6} range at the time the Special Review was concluded and have declined further since then.

EPA has determined that the remaining Special Review concern about alachlor in ground-water is adequately addressed by the actions proposed in today's document. Thus, EPA concludes that the concerns deferred by the Special Review will have been addressed with promulgation of this proposed rule and no further action related to the Special Review of alachlor will be necessary upon this proposed rule's promulgation. In a separate notice, EPA will announce the cessation of the alachlor special review.

E . Analysis of Regulatory Options

In developing the Strategy EPA evaluated a range of available regulatory options in addition to the SMP approach. Specifically, EPA compared three general approaches in a companion document to the Strategy, the ''Pesticides and Ground-Water Strategy: A Survey of Potential Benefits'' (Ref. 13). In supporting the comparative advantages of the SMP approach, this document compared it to the option of a projected extension of current national-level risk-reduction measures, and another of full cancellation of a problem pesticide. Both options were regarded as establishing the extremes of potentially effective and reasonably feasible alternatives to the SMP approach.

The first alternative to SMPs was construed to permit significant levels of ground-water contamination before milder forms of regulatory action (e.g., label changes or restricted use) would be considered. In other words, the option constituted a non-prevention-oriented approach that, although contrary to Agency policy, constituted a conceivable approach to the problem of pesticide contamination of ground water. The option relied to a considerable degree upon remediation of projected contamination sites to address the problem; as such, it was tantamount to addressing the problem of pesticides in ground water through other environmental statutes, especially the Safe Drinking Water and Superfund (CERCLA) Acts. Consequently, the costs of remediation, and, by extension, the costs associated with degradation of ground water as a natural resource, were construed to be a larger component of this option's cost impacts than any other. While these impacts were not directly monetized in EPA's 1991 analysis (for the same considerations discussed in Unit IV.C. of this preamble), by indirect analysis EPA concluded that the ''status quo'' option would bear considerably higher societal-cost impacts than the SMP approach. Moreover, such an approach would be unacceptable on policy grounds, representing insufficient commitment to a preventive approach. This policy preference, of course, in part reflects EPA's discomfort about the ability to correct (much less correctly estimate the price of) ground-water contamination once it occurs. EPA's view is that such ground-water contamination may be in many circumstances practically irreversible, based in part on the economics of remedial action (where millions of dollars can be spent for uncertain results at a single site).

Likewise, outright cancellation of one or more pesticides that might represent a substantial risk via ground water stands to entail far higher societal costs than other regulatory alternatives, such as SMPs. As the Taylor analysis (Ref. 5) indicates, the magnitude of user and consumer impacts associated with cancellation of these five pesticides dwarf those that might be associated with SMPs. Taking into account the additional administrative and technical program costs associated with the SMP approach (that would not be necessary if the pesticides were canceled instead), the SMP approach still appears to represent the most cost-effective approach. While absolute cancellation may provide a degree of greater surety that ground-water contamination will be averted (and in that way affords greater benefits), it is unlikely that the incremental gain in surety justifies the enormous difference in economic impact between the two options.

F. Request for Comments

EPA is interested in receiving comments on its determination of the risks and benefits associated with its proposal to classify these five pesticides as subject to SMPs. EPA in particular invites all interested persons to submit further information concerning the risks and benefits (with respect to ground-water contamination, its prevention and any ancillary issues) associated with the use of atrazine, simazine, cyanazine, alachlor, and metolachlor, as discussed in this proposed rule. EPA would like comments on its estimate of the economic impacts of the proposed rule. For instance, has the Agency sufficiently addressed the indirect costs, such as those associated with minor use sites (e.g., fruits, nuts, and turf)? Of particular interest would be suggestions for how to improve both: (1) The estimate of present/future risks posed by these five pesticides in ground water absent further risk-reduction measures like SMPs; and (2) the estimate of environmental results likely to be achieved by SMPs.

V. Public Docket

A record has been established for this rulemaking under docket number OPP–36190 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

VI. Notification to Secretary of Agriculture and the Scientific Advisory Panel

As provided in 40 CFR 153.31(b), EPA has transmitted copies of this Notice and the Regulatory Impact Analysis, to the Secretary of Agriculture and the Scientific Advisory Panel for comment, prior to today's publication. In the process of reviewing the proposed regulation USDA has raised a number of concerns that the Agency has addressed in the text of the proposal. Among those concerns are the effects on minor uses, the potential for *de facto* cancellations with the States' failure to have an approved Plan, possible costs incurred by USDA programs, the need for an appropriate balancing of risks and benefits in the development and approval of SMPs, and the most appropriate statutory authority for taking regulatory action. USDA looks forward to a full public consideration of these and other critical issues in the promulgation of the final regulation. In particular, USDA urges the Agency to adopt a streamlined process which examines a broad range of possible alternatives for efficiently mitigating the environmental impacts while preserving sound agricultural production. The Panel had no written comments.

VII. References

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VIII. Regulatory Assessment Requirements

A. Executive Order 12866

Pursuant to Executive Order 12866 (58 FR 51735, October 4, 1993), it has been determined that this is a ''significant regulatory action'' because it may result in an annual effect of $100 million or more. This action was therefore submitted to the Office of Management and Budget (OMB) for review, and any comments or changes made during that review have been documented in the public record.

In addition, the Agency has conducted an economic analysis of the potential impacts associated with this proposed action, which is included in a Regulatory Impact Analysis' document prepared for this regulation. A copy of this analysis, which is discussed in Unit IV. of this preamble, is also included in the public record.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), EPA has determined that this regulatory action does not impose any adverse economic impacts on small entities.

An analysis of the prospective impacts of this proposed rule on small States, pesticide distributors, and agricultural producers was prepared as part of the Agency's economic analysis for this proposed action, which is summarized in Unit IV. of this preamble. This analysis is included in a Regulatory Impact Analysis' document, a copy of which is included in the public record for this action. This information is also being forwarded to the Chief Counsel for Advocacy of the Small Business Administration. Any comments regarding the economic impacts that this proposed regulatory action may impose on small entities should be submitted to the Agency at the address listed above.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (EPA ICR No. 1771.01) and a copy may be obtained from Sandy Farmer, OPPE Regulatory Information Division; U.S. Environmental Protection Agency (2136); 401 M St., SW.; Washington, DC 20460, by calling (202) 260–2740, or by sending an e-mail request to: farmer.sandy@epamail.epa.gov.

For PRA purposes, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Development and implementation of pesticide SMPs entails the collection of various sorts of information. In particular, States will need to create and/or gather information to conduct ground water vulnerability assessments, including data on agronomic practices (e.g., pesticide use, cropping patterns) and aquifer sensitivity; the States will either gather the data themselves or require third parties (users and/or pesticide registrants) to report the data. States will then use this data to assess the vulnerability of ground water to the pesticides requiring Pesticide SMPs. In addition, States may need to develop and/or maintain ground-water monitoring efforts, or expand their existing efforts to gather chemical, physical, geological, biological, and other environmental data. This data will be necessary to support Pesticide SMP activities such as determining ground water levels, analyzing the existence and extent of contamination, and evaluating the effectiveness of management measures. Furthermore, once Pesticide SMPs are approved by EPA, States will need to submit an SMP Biennial Report every 2 years beginning 2 years from the EPA approval date and continuing every 2 years thereafter. The SMP Biennial Report will provide a basis for measuring States' progress toward protection of ground water resources from pesticide contamination. The commitment to develop and report such information is a mandatory component of SMPs.

The total annual burden for the information collection related activities associated with this proposed action is estimated to average 412,560 hours per year for all respondents, including State (and territorial) government, and private parties. The per respondent burden (i.e., burden for each State, territory, or private party divided by the number of States, territories and tribal authorities expected to submit SMPs) is expected to average 7,367 hours per year. First year burden is estimated to be a total of 673,083 hours, with 12,1019 hours per respondent. The total annual costs for the information collection related activities associated with this proposed action is estimated to average $18,043,080 per year for all respondents, with an annual estimated cost of $322,198 per year for each respondent. First year start-up costs are expected to be $22,395,865, with an estimated $399,926 cost per respondent.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, OPPE Regulatory Information Division, U.S. Environmental Protection Agency (2136), 401 M St., SW., Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Comments related to these estimates may be submitted to the address listed in the ADDRESSES unit anytime during the comment period for the proposed action. However, since OMB is required to make a decision concerning the proposed collection between 30 and 60 days after June 26, 1996, a comment to OMB is best assured of having its full effect if OMB receives it by July 26, 1996. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

D. Unfunded Mandates Reform Act and Executive Order 12875

Pursuant to Title II of the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4), EPA has determined that this regulatory action contains a Federal mandate that may result in expenditures of $100 million or more for State, local and tribal governments, in the aggregate, or to the private sector in any 1–year. Accordingly, EPA has prepared the following description of the intergovernmental consultation under UMRA, and Executive Order 12875 (58 FR 58093, October 28, 1993), entitled ''Enhancing the Intergovernmental Partnership.'' The basis for EPA's determination is contained in the economic analysis accompanying this rule, which is included in the public record for this action and summarized in Unit IV. of this preamble.

UMRA requires that such a rule be accompanied by a statement that, among other things, documents that the rule is the least costly, most cost-effective or least burdensome alternative that achieves the regulatory objective. In the absence of such documentation, UMRA

provides that the head of the promulgating Agency may otherwise provide in the statement an explanation of why the least burdensome approach was not adopted or is inconsistent with law. The discussion in part E of Unit IV of this preamble describes the Agency's analysis of regulatory options. As this discussion, and the earlier analysis cited therein (c.f., Ref. 13) indicates, the Agency believes that this proposed action is the most cost-effective and least burdensome alternative to the alternatives considered in the development of the Pesticides and Ground-Water Strategy (Ref. 12), developed as the groundwork for today's proposed rule. A particularly advantageous feature of the chosen option is that it allows States to determine the most appropriate approach for preventing unreasonable adverse effects within their individual States. The practical alternatives are a choice between different kinds of Federally mandated restrictions, either national standards and/or risk-reduction measures (principally in the form of label changes) or outright cancellations of use. The principal disadvantage of both is that they can not take State specific issues into consideration, and so can be anticipated to increase the loss of economic benefits associated with the pesticides' use, relative to the impacts of SMPs. National-level measures are potentially less certain of meeting the regulatory objective, that is, of achieving the goal of preventing unreasonable levels of ground-water contamination. This greater uncertainty is caused by the relative inability to tailor risk-management measures, proceeding instead on a ''lowest common denominator'' approach. Still another conceivable (but unanalyzed) option is doing nothing at the Federal level, leaving the potential for ground-water contamination to be addressed, if at all, by voluntary action and/or independent State action. This alternative was not analyzed because it clearly failed to meet the regulatory objective. Such an option that freely permits contamination would entail no direct regulatory costs, but the far larger reduction in the value of the resource must be compared to the more conventional economic impacts.

The statement required by UMRA also requires a summary description of State/local/Tribal governmental input in the rule's development. Prior consultation with State and Tribal authorities has been extensive. The Pesticides and Ground Water Strategy development process began with a major public workshop held in 1986 in Coolfont, West Virginia. State Agriculture, Environment and Health agencies were among the participants. A second public workshop was held at Coolfont during the summer of 1987, also with similar participation. Beyond the Strategy, State regulatory officials were involved in the development of the subsequent Guidance beginning in 1989, when EPA sponsored working sessions to determine how best to guide the process of managing pesticide use to protect the ground water resource. Two week long sessions were held in Fredericksburg, Virginia during October and November of 1989. These sessions were actual working sessions to develop the document that today is the SMP guidance document. Between five and seven States participated in each session. Drafts of the guidance document were shared with all 50 State Lead Agencies for Pesticides, EPA Regional Offices, and other Federal agencies.

During development of the proposed rule, many issues were discussed with the Water Quality Working Committee Group of the State FIFRA Issues Research and Evaluation Group (SFIREG) on which eight State Lead Agencies sit. This group meets three times per year with OPP to discuss water quality issues and this forum was used extensively in the early stages of development of the proposed rule.

The proposed regulation itself has been provided as an initial draft twice to EPA's 10 regional offices and all 50 states for review and comment, in addition to the SFIREG Water Quality Committee and to SFIREG's parent body, the American Association of Pesticide Control Officials (AAPCO). The first round of review in fall 1994 elicited 38 written comments from State and Tribal agencies; the second round in spring 1995 elicited 18 further comments. As a result of each round of review, the draft proposed rule was modified. These written comments are in the public record and were considered in the development of the proposed rule. Virtually all of the principal State comments and concerns are reflected in the discussion in Unit III of this preamble, and in the request for comments accompanying that Unit.

All other UMRA requirements for the accompanying statement to a ''significant regulatory action,'' e.g., descriptions of statutory authority, anticipated costs and benefits, compliance costs, are contained throughout this preamble, in the appropriate headings.

E. Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities. As related throughout this document, the approach the Agency is proposing to address the problem of pesticides in ground water is based on a full appreciation of the localized nature of the problem, and this approach strives to be the most effective strategy for localized protection of the ground-water resource. As the Strategy highlights, alternatives to effective local-level risk reduction measures (e.g., national-level regulation or no regulatory protection) are considered likely to either over-regulate pesticide use (causing undue economic hardship to affected parties) or under-protect (increasing the risk of various adverse health and environmental effects to specific parties).

List of Subjects

40 CFR Part 152

Environmental protection, Administrative practice and procedure, Pesticides and pest, Reporting and recordkeeping requirements.

40 CFR Part 156

Environmental protection, Labeling, Occupational safety and health, Pesticides and pest, Reporting and recordkeeping requirements.

Dated: June 19, 1996.

Carol M. Browner,

Administrator.

Therefore, 40 CFR chapter I, is proposed to be amended as follows:

1. In Part 152:

PART 152 —[AMENDED]

a. The authority citation for part 152 would continue to read as follows:

Authority: 7 U.S.C. 136-136y; Subpart U is also issued under 31 U.S.C. 9701.

b. By adding a new subpart J to part 152, to read as follows:

Subpart J—Ground-Water State Management Plans

Sec.

152.180 Applicability.
152.183 Definitions.
152.185 Restriction.
152.187 Submission and approval of ground-water State Management Plans.
152.190 Specifications and requirements of a ground-water State Management Plan.
152.191 Evaluation of State Management Plan Implementation.
152.193 Amendment of State Management Plans.

152.195 Withdrawal of approval of a State Management Plan.
152.198 Pesticides classified for restricted use subject to a ground water State Management Plan.

Subpart J—Ground-Water State Management Plans

§ 152.180 Applicability.

This subpart applies to any pesticide or pesticide product designated to be subject to the requirements and provisions of ground-water State Management Plans by means of a Restricted Use Classification.

§ 152.183 Definitions.

In addition to the definitions in § 152.3, the following terms also apply to this subpart:

Ground Water Reference Point means an environmental concentration of a pesticide ingredient based on any of the following:

(1) Maximum Contaminant Levels (MCLs) established under the Safe Drinking Water Act; or

(2) Health Advisories (where MCLs are not available for a substance); or

(3) Water Quality Standards (where the ingredient poses adverse effects to ecosystems affected by closely hydrologically linked surface waters) under the Clean Water Act.

Plan means a State Management Plan developed for the purpose of managing the use of a pesticide in order to prevent unreasonable risks of ground water contamination.

State means each of the 50 States, Puerto Rico, the U.S. Virgin Islands, the District of Columbia, Guam, American Samoa and other Pacific Island Territories of the United States, as well as Indian Lands under Tribal jurisdiction.

§ 152.185 Restriction.

(a) *Restriction*. A pesticide or pesticide product classified for restricted use subject to a State Management Plan may be used only in accordance with the provisions and requirements of an Agency-approved State Management Plan, after a date 33 months from the date the pesticide or product is so classified. Such a pesticide or pesticide product may not be sold or used after that date within the boundaries of a State without an Agency-approved State Management Plan.

(b) *Labeling*. (1) Upon classification of a pesticide for restricted use, subject to ground-water State Management Plans, each registrant of a product subject to that classification shall, within 12 months after the date of that classification by final Agency rule, submit for such product:

(i) A copy of the labeling amended to include the statement specified in § 156.137(a)(2)(ii) of this chapter.

(ii) A statement that the registrant will comply with the labeling requirements prescribed by the Agency by the effective date of this rule. The Agency will regard such statement to be a report under the Act. The Agency may deny registration or initiate cancellation proceedings if a registrant fails to comply with the timetables established in this section.

(2) A product whose labeling bears directions for end use and that has been classified as subject to ground-water State Management Plans must be labeled in accordance with the requirements of § 156.10 of this chapter after the effective date of the restriction.

(c) *Distribution and sale of classified products*. No product with a use classified for restricted use, subject to ground-water State Management Plans, may be distributed or sold by a retailer or other person after the effective date of the restriction, unless the product bears a label or labeling which contains the terms of the classification and otherwise complies with paragraph (b)(2) of this section.

§ 152.187 Submission and approval of ground-water State Management Plans.

If any State, at any time after the classification of a pesticide or pesticide product to be subject to State Management Plans by final rule, wishes to establish a ground-water State Management Plan for such a pesticide or pesticide product, that State shall submit a proposed Plan for that purpose to the Administrator. The Administrator will approve the Plan submitted by any State if, in the Administrator's judgement, the Plan meets the requirements of § 152.190.

(a) *Schedule*. A State that wishes to implement a Plan on the effective date of the State Management Plan restriction shall submit a proposed Plan, along with the administrative record accompanying development of the proposed Plan to the appropriate EPA region under 40 CFR 1.7, before a date 24 months from the date a pesticide or product is classified. The submission shall include an electronic file in Wordperfect 5.1 or higher or ASCII for all material. The Administrator will review such submittals and approve or disapprove Plans within 9 months of receipt of a complete submittal.

(b) *Review*. Upon receipt of a proposed State Plan submitted for EPA approval, the Administrator or a designee will first review the proposed Plan to determine that all requirements as provided in § 152.190 have been addressed. Upon completion of this review, the Administrator will notify the State in writing of the initial determination of the completeness of the submission. In the event that the Administrator determines that the submission fails to address all requirements, the Administrator will request the State revise its submission to provide the missing components. Once the Administrator is satisfied that the submission is complete, full evaluation of the submission will proceed.

(c) *Approval*. Upon completion of the review of the submission, if the Administrator finds that the Plan meets the requirements of § 152.190, then the Administrator will publish a Notice of Approval in the Federal Register and a letter of notification to the State official designated as State Liaison, pursuant to § 152.190(b), informing of the approval.

(d) *Disapproval*. If, after completion of the review of the submission, the Administrator finds that the submission fails to meet the requirements of § 152.190, the Administrator shall notify the State Liaison by letter that EPA will not approve the Plan as submitted, and specifying the deficiencies in the Plan that prevent its approval. If, after further consultation, the Administrator still finds that the submission fails to meet the requirements, the Administrator will publish a notice in the Federal Register announcing the disapproval of the Plan and including the reasons for finding the Plan inadequate pursuant to § 152.190. In this event, sale or use in the State of the pesticide that is the subject of the Plan shall be prohibited 33 months after the promulgation of a rule classifying the pesticide as subject to a ground-water State Management Plan.

§ 152.190 Specifications and requirements of a ground-water State Management Plan.

The Administrator shall approve the State Management Plan submitted by any State, or any modification thereof, if in the Administrator's judgement, the Plan fulfills the following requirements.

(a) *State's philosophy and goals toward protecting ground water*. An acceptable Plan must, to the satisfaction of the Administrator, contain a description of the State's ground-water protection philosophy and goals regarding pesticide management, including an explanation how its philosophy and goals will be no less protective than EPA's goal of preventing adverse effects to human health and the environment and protecting the environmental integrity of the nation's ground water.

(b) *Roles and responsibilities of State agencies.* An acceptable Plan must, to the satisfaction of the Administrator:

(1) Identify and describe both the general responsibility of, and the specific technical and administrative tasks to be performed by, each participating agency responsible for the development and implementation (including enforcement) of the Plan, including a description of how the State agencies intend to use the programs and expertise of Federal agencies in carrying out the Plan.

(2) Identify a Liaison who will serve as a single contact point for all formal communications concerning the Plan process between EPA and the State, including responsibility for the transmittal and receipt of official correspondence and information.

(3) Describe the coordination mechanisms between all participating State agencies, local entities, and appropriate Federal agencies.

(4) Describe how local governments are included in activities under the Plan. When local governments have authority to address State ground-water-related objectives and priorities, the State must demonstrate that program coordination, guidance, or oversight is provided.

(5) Contain official concurrences from the directors of all State agencies with responsibilities under the Plan stating their agreement with the Plan, and their commitment to carry out their responsibilities under the Plan.

(6) Discuss any relevant inter-State multi-jurisdictional coordination, including how any multi-jurisdictional issues will be resolved for purposes of implementing the Plan.

(c) *Legal authority.* An acceptable Plan must, to the satisfaction of the Administrator:

(1) Contain regulatory authorities that are sufficient to accomplish the objectives of the Plan, established in paragraph (a) of this section.

(2) Specify the legal authorities of the State to implement the Plan successfully and specify the State's authority to impose preventive measures, its remedial action authority and its compliance and enforcement authorities, citing all relevant State laws and regulations and including Federal legislation, regulations and program delegation, available to the State.

(3) Identify the specific authorities that will be used to carry out the specific commitments made in the Plan. The State must specifically identify the authority to conduct or require others to conduct monitoring, prohibit use in specific areas, close public wells, or supply or require others to supply alternative sources of water, where such actions are elements of the Plan, must be identified.

(d) *Resources.* An acceptable Plan must, to the satisfaction of the Administrator, demonstrate there are adequate resources available to implement and enforce the program. Resources include technical expertise and personnel, physical and operational capabilities, and funding. The Plan must demonstrate there is an adequate match between revenues and proposed expenditures and that the necessary expertise is available.

(e) *Basis for assessment and planning.* An acceptable Plan must, to the satisfaction of the Administrator, specify the State's approach and activities to assess vulnerability for the geographic area in which the State intends to allow pesticide use, identifying the sources of all such data. The State shall specifically describe the State's available pesticide use data (e.g., geographic use and application rates) and how it will be factored into assessing vulnerability.

(f) *Monitoring.* An acceptable Plan must, to the satisfaction of the Administrator, demonstrate that monitoring activities (including ground-water monitoring) performed pursuant to the Plan are appropriate for the purposes of the Plan, with assurances that the activities will be carried out adequately. Specifically, an acceptable Plan must identify and describe key elements of the monitoring program, including the scope and objective (in relation to the purposes of the Plan) of such monitoring, design and justification (including the number of sites to be sampled, the number of samples to be taken and the frequency of sampling) of such monitoring, monitoring protocols, quality assurance/quality control, sampling methodology, analytical methods, and analytes. Such description must make clear how the placement of monitoring sites relates to the State's priorities for protecting ground water, and will allow evaluation of the effectiveness of prevention and response measures specified in paragraphs (g) and (h) of this section. Monitoring performed for the purpose of fulfilling this requirement must be performed in accordance with an EPA-approved Quality Assurance Project Plan (as described in Chapter 5.4.2 of Appendix B, ''Assessment, Prevention, Monitoring and Response Components of State Management Plans,'' to the Guidance for Pesticides and State Management Plans (EPA 735-B-93-005c, February 1994). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Copies may be inspected at the above address or at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC. Good Laboratory Practice Standards (40 CFR part 160) do not apply to monitoring performed for the purpose of fulfilling this requirement.

(g) *Prevention actions.* An acceptable Plan must, to the satisfaction of the Administrator, specify the actions a State will take to manage the use of the pesticide classified for use subject to the Plan, to fulfill the State's goals and principles enunciated pursuant to paragraph (a) of this section and will otherwise prevent unreasonable adverse effects to human health and protect the environmental integrity of the nation's ground-water resources.

(h) *Response to detections of pesticides.* An acceptable Plan must, in the judgement of the Administrator, adequately specify the measures that the State will take (and the circumstances under which the State will take them) to respond to contamination so that Ground Water Reference Points are not reached, and specify the actions the State will take in the event Reference Points are met or exceeded. This description must be presented in the form of a general corrective response scheme, illustrating the State's capacity for timely, coordinated response to contamination.

(i) *Enforcement mechanisms.* An acceptable Plan must, to the satisfaction of the Administrator, demonstrate that the State's enforcement authorities and capabilities are adequate to implement and to monitor compliance with the specific measures included in the Plan, describing authorities and capabilities that are intended to protect ground water from contamination and response actions where contamination has already occurred. Enforcement authority must be identified by the State, and the roles and responsibilities of each State agency must be defined, including how coordination of enforcement capabilities within agencies will work to prevent and respond to contamination.

(j) *Public awareness and participation.* An acceptable Plan must, to the satisfaction of the Administrator, demonstrate that there is notice and opportunity for public comment within the process of Plan development, and will be informed of significant Plan

implementation activities. This demonstration must:

(1) Describe the public role regarding development of the Plan and decision-making in implementing the Plan, and identify or describe existing legal requirements within the State that would ensure public participation in the process (i.e., an Administrative Procedure Act requiring notice and comment, etc.). If no such legal requirements exist within the State, the Plan must describe any other public participation process that the State uses in the development of the Plan.

(2) The Plan must also specify the level of detection in ground water that is considered by the State to be of such significance that the State will inform the public. Indicate how, when, and by whom the public will be informed of detections in ground water that are considered significant, providing for, at a minimum:

(i) The notification of any well owner of any detections in ground water; and

(ii) The notification of all users of any detections above the reference point.

(3) Include a description of the process and means of communication by which the public will be made aware of important regulatory actions taken under the Plan.

(k) *Information dissemination.* An adequate Plan must, to the satisfaction of the Administrator, describe the means by which measures prescribed pursuant to the Plan will be communicated to pesticide users and all other interested parties. A plan must:

(1) Describe how information regarding prevention measures (e.g., use limitations and precautions) will be relayed to the appropriate audiences.

(2) Describe how pesticide users will be trained or educated in how to comply with requirements of applying a pesticide where use is governed by the Plan.

(3) Identify the targeted parties and discuss how information will be relayed.

(4) Explain why the information dissemination approach is appropriate for the type of contamination prevention actions being employed, and the education and/or awareness of the targeted audience is required.

(5) Describe how information will be updated as requirements change. Such discussion should include the form these updates will take and the distribution methods. The Plan should also discuss any existing mechanisms (i.e., Memoranda of Understanding, cooperative agreements, etc.) between the State and other entities that will be involved in this effort.

(l) *Records and reporting.* An adequate Plan must, to the satisfaction of the Administrator:

(1) Include a commitment by the State to maintain essential records relating to Plan implementation for a period of at least 6 years. The information maintained must include, but is not limited to, records on any monitoring or sampling conducted, results of analyses, issuance of permits, types and numbers of enforcement actions taken, records of any site-specific regulatory actions, and administrative actions. The State must commit to promptly make available to the Agency, upon request, records related to the development or implementation of the Plan.

(2) Commit to developing and submitting to the appropriate Regional Office a Plan Biennial Report, as described in § 152.191(a), and to report any significant findings to the appropriate Agency Regional Office.

(3) Commit to submitting with each report to EPA a signed certification, worded as follows:

> I certify under penalty of law that I have personally examined and am familiar with the information submitted herein and based on my inquiry of those individuals immediately responsible for obtaining the information, I believe the submitted information is true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment. See 18 U.S.C. section 1001 and 7 U.S.C. section 136).

§ 152.191 Evaluation of State Management Plan Implementation.

Any State Management Plan approved under § 152.190 shall be subject to periodic evaluations of its implementation by the Agency, in order to assure implementation of the Plan consistent with its goals and commitments, to determine the environmental effectiveness and the level of ground-water protection provided by the Plan, and to ensure a minimum level of national consistency.

(a) *Biennial Report.* A Biennial Report, as described in § 152.190 (l)(2), must be developed and submitted by the State in order to maintain Agency approval, and will be used by the Agency and by State officials to evaluate a State's effectiveness in protecting its ground-water resources from pesticide contamination. The State shall prepare the Biennial Report according to the provisions of Chapter 5 of Appendix A, ''Review, Approval and Evaluation of State Plans,'' to the Guidance for Pesticides and State Management Plans (EPA 735-B-93-005b, February 1994).

(b) *Evaluation reporting requirements.* The Biennial Report must be approved by State officials directing the key State agencies that play a role in implementing the Plan. The Biennial Report must be submitted in October of alternate years, starting in October [of the year 4 years after date of publication of the final rule] to the appropriate Agency Regional Office. The State may submit a single Biennial Report in the event it implements Plans for more than one classified pesticide. In that event, the report must include programmatic and environmental evaluations addressing each approved Plan. States will also submit a programmatic and an environmental evaluation that addresses any progress made in implementing the Plan.

§ 152.193 Amendment of State Management Plans.

(a) The State will amend an approved Plan as part of the Biennial Report required under § 152.191(a) when:

(1) The evaluation performed pursuant to § 152.191 demonstrates that the provisions in the Plan do not adequately protect the ground-water resource from pesticide contamination.

(2) A change in the legal (statutory or regulatory) and enforcement framework for Plan development and implementation necessitates a change in the Plan.

(3) A State, through experience, finds more effective ways to assess ground-water contamination, to prevent and respond to contamination, and to educate affected parties or disseminate information.

(4) Changes in pesticide management measures or approaches become necessary as a result of significant changes in crops or crop production systems and technologies within the State.

(5) Roles and responsibilities of State agencies involved in the implementation of the Plan change so as to necessitate a change in the Plan.

(b) If a State is aware that an amendment is needed, then that amendment should be submitted as part of the Plan Biennial Report. In addition, if the Regional Office that is the recipient of that Report determines through the evaluation process that the Plan needs to be updated, then the Regional Administrator of that region, or a designee, can initiate the updating process by requesting that the State submit a Plan Update Report. In every case, the Update Report must include:

(1) A description of the proposed changes in the Plan.

(2) An explanation of why the changes are necessary.

(3) An analysis of the impact the changes will have on the other

components of the Plan, the implementation of the Plan and the protection of the resource.

(4) If changes will affect pesticide users, a description of how users will be alerted to the changes in the Plan.

(5) Concurrences by all officials directing the key State agencies.

(6) If changes are significant, a description of how the State received public input on changes to the Plan, and the administrative record developed in the course of changing the Plan. Amendments to Plans must be concurred or approved by the Regional Administrator.

§ 152.195 Withdrawal of approval of a State Management Plan.

(a) If, in the judgement of the Administrator or a designee, either:

(1) A State fails to demonstrate that it is satisfactorily implementing the Plan; or

(2) A State's Plan is not protecting ground water from contamination at or above ground water reference points (as specified in § 152.198); or

(3) A State fails to address deficiencies identified by the Plan evaluation through updating the Plan and/or improving implementation of the Plan; or

(4) A State fails to submit a biennial report;

he or she shall notify the designated State Liaison, named pursuant to § 152.190(b), and relevant State administrators of the Agency's concerns. In that event, the State will have 90 days to respond to these deficiencies in its Pesticide Plans, either through the Plan updating process or by demonstrating to the Region that the Plan is being satisfactorily implemented.

(b)(1) If the Administrator determines that the State has failed to address the deficiencies identified by the Agency or has failed to correct the deficiencies, the Administrator shall notify the officials directing the key State agencies involved in implementing the Plan and the designated State Liaison by letter that withdrawal of Agency approval is being considered. The notice will include:

(i) A statement concerning the potential withdrawal of Agency approval of the Plan.

(ii) A listing of the deficiencies of the Plan or a description of the failure of the Plan or its implementation to protect ground water.

(iii) A brief summary of the events that led to the withdrawal notice.

(iv) Dates by which the State can respond to the deficiencies to stop the withdrawal process.

(2) The State must respond to the notice within 30 days of receipt of the notice in writing with a commitment to address the deficiencies in the Plan itself or in its implementation. If the State disagrees with the judgement or the findings of the Administrator in the initial notice described in paragraph (b) of this section, the State may request to meet with the Administrator within 60 calendar days from the time the EPA Administrator sends the letter of potential withdrawal to the Administrators of the key State agencies.

(3) If, in the Administrator's judgement, continued use of the pesticide within the State presents unreasonable adverse effects on the environment because of the deficiencies cited pursuant to paragraph (b)(1) of this section, the Administrator may prohibit further sale and use of the pesticide in the State until the Agency and the State reach an agreement on how to address the Plan's deficiencies. Such a prohibition shall be published in a Federal Register notice describing the basis for the Administrator's findings, and soliciting comment thereon. After addressing any public comment, the Administrator may take final action temporarily prohibiting use of the pesticide in the State.

(c) If the State does not respond to the notice that withdrawal of approval is being considered or fails to address the deficiencies identified in the notice to the satisfaction of the Administrator, the Administrator will send a formal letter to the officials directing the key State agencies and the State Liaison indicating that EPA is publishing a Federal Register Notice proposing to withdraw the Pesticide Plan. In the event the State does not respond to this notice, the Administrator will publish a Federal Register Notice to provide an opportunity for public comment on withdrawal of the Plan. After addressing any public comments, the Region will publish a Notice of Withdrawal in the Federal Register and prohibit the sale and use of the pesticide in the State.

(d) Upon publication of the final Notice of Withdrawal in the Federal Register, sale and use of the pesticide within the boundaries of the State will be prohibited.

§ 152.198 Pesticides classified for restricted use subject to a ground water State Management Plan.

Pesticide products containing the active ingredients listed in the table to this section, with the corresponding Ground Water Reference Points specified are classified for restricted use, to be subject to the provisions and requirements of an EPA-approved State Management Plan.

Active Ingredient	CAS Number	Ground Water Reference Point
Alachlor	15972-60-8	2 µg/l
Atrazine	1912-24-9	3 µg/l
Cyanazine	21725-46-2	1 µg/l
Metolachlor	51218-45-2	70 µg/l
Simazine	122-34-9	4 µg/l

2. In Part 156:

PART 156—[AMENDED]

a. The authority citation for part 156 continues to read as follows:

Authority: 7 U.S.C. 136-136y.

b. In § 156.10, by revising paragraphs (a)(1)(viii) and (a)(1)(ix) and removing paragraph (i) to read as follows:

§ 156.10 Labeling Requirements

(a) * * *

(1) * * *

(viii) The directions for use as prescribed in subpart G of this part; and

(ix) The use classification(s) as prescribed in subpart G of this part.

* * * * *

c. By adding a new subpart G to part 156 to read as follows:

Subpart G—Directions for Use

Sec.
156.120 General requirements.
156.121 Contents of directions for use.
156.135 Statements of use classification.
156.136 General use statements.
[Reserved]
156.137 Restricted use statements.

Subpart G—Directions for Use

156.120 General requirements.

(a) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(b) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(1) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag.

(2) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as ''See directions in the enclosed circular.''

(3) The Administrator determines that it is not necessary for such directions to appear on the label.

(c) *Exceptions to requirement for direction for use*—(1) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(i) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(ii) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes.

(iii) The product will not come into the hands of the general public except after incorporation into finished products.

(iv) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(i) The label clearly states that the product is for use only by physicians or veterinarians.

(ii) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(iii) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(3) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(i) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes.

(ii) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved.

(iii) The product as finally manufactured, formulated, mixed, or repackaged is registered.

(iv) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

156.121 Contents of directions of general use.

The directions for use shall include the following, under the headings ''Directions for Use'':

(a) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading ''Directions for Use.''

(b) Immediately below the statement of use classification, the statement ''It is a violation of Federal law to use this product in a manner inconsistent with its labeling.''

(c) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(d) The target pest(s) associated with each site.

(e) The dosage rate associated with each site and pest.

(f) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(g) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(h) Worker protection statements meeting the requirements of subpart K of this part.

(i) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR part 165. These instructions shall be grouped and appear under the heading ''Storage and Disposal.'' This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(j) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(1) Required intervals between application and harvest of food or feed crops.

(2) Rotational crop restrictions.

(3) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(4) [Reserved]

(5) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(6) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

§ 156.135 Statements of use classification.

(a) *Requirement.* Each product bearing one or more uses that has been classified for restricted use must bear a classification statement on the label of the product, and also in any supplemental labeling that accompanies the product in sale or distribution. A product that bears only unclassified uses as described in § 152.160 or uses classified for general use is not required to bear any classification statement. Restricted use statements are set out in § 156.137.

(b) *Products bearing mixed classified uses.* A product for which some uses are not classified, and other uses are classified for general use or for restricted use must have a separate registration for uses that are restricted, except that a product bearing restricted uses may also bear unclassified or general uses in addition to the restricted uses. A product bearing mixed restricted uses and other uses is considered a restricted use product.

(c) *Placement of classification statements.* (1) Statements of restricted use classification must be located at the top of the front panel of the label (the ''Restricted Use'' area), and in a similarly prominent location in supplemental labeling. No other label statements shall appear above the restricted use statements, and no other statements than those prescribed by the

Agency shall appear in the restricted use area of the label.

(2) The restricted use statements shall be distinguished from surrounding label text by suitable means, such as white space or a box around the statements. The words ''Restricted Use Pesticide'' shall appear in a type size at least that of the signal word prescribed by § 156.10(h)(1)(iv).

§ 156.136 General use statements. [Reserved]

§ 156.137 Restricted use statements.

(a) A product that is classified for restricted use must bear, on the front panel in accordance with § 156.135(c), the statements in paragraphs (a)(1) and (a)(2) of this section.

(1) The phrase, ''Restricted Use Pesticide.''

(2) Immediately below the phrase ''Restricted Use Pesticide,'' a statement of the reason for the restricted use classification. This statement will describe the characteristic of the pesticide, its formulation, or its use pattern, that is the basis for the classification. These characteristics include acute or chronic toxicity, environmental fate (biodegradability, leaching potential, etc.), or non-target organism toxicity. The Agency will prescribe the nature and wording of the statement.

(i) A product that is restricted to use by certified applicators (for example, pesticides and uses listed in § 152.170) must bear the statement, ''For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.''

(ii) A product that is classified for restricted use subject to a ground-water State Management Plan (SMP) under subpart J of part 152 of this chapter must bear the statement, ''For use only in accordance with an EPA-approved State Management Plan for ground-water protection. Sale and use are prohibited in States that do not have an EPA-approved State Management Plan.''

(b) The Agency may develop and require a label statement different from, or in addition to, those described in paragraphs (b)(1) and (b)(2) of this section, for any product classified for ''restricted use.''

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