ENVIRONMENTAL PROTECTION AGENCY

[OPP-38509; FRL-3846-4]

Existing Stocks of Pesticide Products; Statement of Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; statement of policy.

SUMMARY: This Statement summarizes the policies that will generally guide EPA in making individual decisions concerning whether, and under what conditions, the Agency will permit the continued sale, distribution, and use of existing stocks of pesticide products whose registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are amended, cancelled, or suspended. Although most of the policies reflected in this Statement have already been applied by the Agency on a case-by-case basis, EPA now intends to formalize these policies and is soliciting comments from interested persons. If, after reviewing any comments, EPA determines that changes to this Statement are warranted, the Agency will issue a revised Statement of Policy in the **Federal Register**.

DATES: The policies announced in this Statement are currently in effect. The Agency will review any comments on these policies received by the Agency on or before August 26, 1991. After reviewing such comments, the Agency may issue a revised Statement of Policy.

ADDRESSES: By mail, submit comments to: Public Docket and Freedom of Information Section, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. In person, deliver comments to: Rm. 246, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: By mail: Martha Lamont, Special Review and Reregistration Division (H7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. Office location and telephone number: Special Review Branch, rm. 31L3, Crystal Station 1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8033.

SUPPLEMENTARY INFORMATION: The general statement of policy on existing stocks of pesticide products whose registrations under FIFRA are amended, cancelled, or suspended follows.

GENERAL STATEMENT OF POLICY

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I. Application

This Statement of Policy applies to determinations the Agency will make concerning existing stocks of pesticide products whose registrations have been amended, cancelled, or suspended pursuant to sections 3, 4, or 6 of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA). This Statement also applies to existing stocks of products sold or distributed under a supplemental distributor agreement. It is the responsibility of the registrant to notify such distributors of any applicable existing stock provisions.

For purposes of this Statement, existing stocks are defined as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the action.

This Statement establishes general principles which the Agency generally will apply in determining whether and under what conditions to allow the sale and use of existing stocks. In general, if there are significant risk concerns associated with a cancelled pesticide, the Agency will make a case-by-case determination as to whether to allow the continued sale or use of existing stocks of the pesticide. The Agency will not allow continued sale, distribution, or use of such a pesticide unless the benefits associated with such sale, distribution, or use exceed the risks.

Where there are no significant risk concerns associated with the cancellation of a pesticide, the Agency will generally allow unlimited use of existing stocks, and unlimited sale by persons other than the registrant. A registrant will generally be allowed to continue to sell existing stocks for 1 year after the date cancellation is requested, or 1 year after the date the registrant has ceased to comply with the responsibilities that are placed upon registrants, whichever date is sooner.

This policy will be implemented on the date of publication of this notice. Because registrants were unaware of the policies contained in this notice, the Agency has decided to provide a 6-month "grace period" before certain aspects of this Policy become fully effective. Specifically, in cases where the Agency has not identified any significant risk concerns, the Agency will allow registrants of products cancelled on or before December 26, 1991 to continue to sell or distribute existing stocks at least until December 26, 1991, notwithstanding the fact that application of the policies set forth in this statement might result in a shorter existing stocks period or an outright prohibition against the sale or distribution by the registrant of any existing stocks.

II. Applicable Statutory Provisions

Under FIFRA section 3, a pesticide product must be registered with EPA before it may be sold or distributed in commerce. EPA may not register a pesticide unless, among other things, it first determines that the product and its use will not cause unreasonable adverse effects on the environment. Once a pesticide product is registered, FIFRA provides a number of different mechanisms for changing the status of a registration. These mechanisms can be grouped into three categories: Changes requested by a registrant; changes imposed by EPA for failure to comply with various obligations imposed upon registrants; and changes imposed by EPA because of a determination by the Agency that use of the pesticide product results in unreasonable adverse effects to man or the environment.

A registrant may request at any time, for any reason, to voluntarily cancel a registration (FIFRA section 6(f)) or to amend the terms and conditions of the registration, most frequently by amending the pesticide product label (FIFRA sections 3(f) and 6(f)). Voluntary amendments to registration can include, among other things, adding or deleting uses, increasing or decreasing application rates, changing the formulation of a pesticide, or changing the label language (such as changing directions for use, warning statements, etc.).

Other changes in registration status are the result of Agency action because of the failure of a registrant to fulfill

certain responsibilities adequately. Each registrant has a continuing obligation to ensure that its registered products comply with the standards for registration. Note that the the term "registration" includes reregistration (see FIFRA section 2(z)). As part of this obligation, a registrant may be required to submit to EPA additional information which the Agency considers necessary to support continued registration. See FIFRA section 3(c)(2)(B). Failure to submit information required by the Agency pursuant to section 3(c)(2)(B) may result in the suspension of a registration until the information is provided.

In addition, registrants of pesticide products containing active ingredients first registered before November 1, 1984, must demonstrate, under FIFRA section 4, that their products meet the current standards for registration and should be reregistered. Failure to comply with certain provisions of section 4 can result in the cancellation or suspension of pesticide registrations. For example, registrations may be cancelled if a registrant fails to pay fees mandated by section 4(i) or fails to provide EPA with certain information during the early stages of the reregistration process (see FIFRA sections 4(d)(5), 4(e)(3) and 4(i)(7)(C)). Failure by registrants to supply other information required during reregistration may result in the suspension of registrations until the required information is provided to EPA (see, e.g., FIFRA sections 4(d)(6) and 4(f)(3)).

If a registration is a conditional registration, the Agency may also take action to cancel the registration pursuant to FIFRA section 6(e) if the registrant fails to meet any of the conditions imposed upon the product at the time of registration.

Finally, changes in the status of a registration may be mandated by EPA to assure that the product or its use does not result in unreasonable adverse effects on the environment. The Agency may reevaluate a pesticide at any time. If EPA determines that a pesticide product (without change in its terms of registration) no longer meets the standard for registration, the Agency may propose cancellation of the product under FIFRA section 6(b) or propose to classify the product for restricted use. Such Agency proposals may at times allow changes in the terms of registration (such as the deletion of particular uses or addition of specified protective measures) as alternatives to cancellation or change in classification. If the Agency determines that use may result not only in unreasonable adverse effects but in an "imminent hazard," EPA may initiate action to suspend the pesticide registration during the pendency of cancellation proceedings (FIFRA section 6(c)).

It is a violation of FIFRA section 12(a)(1)(A) to sell or distribute any pesticide that has been cancelled or suspended, except to the extent that sale or distribution is authorized by EPA. It is also a violation of FIFRA section 12(a)(2)(J) and (K) to violate the terms of a suspension or cancellation order. Thus, unless expressly permitted by the Agency, distribution or sale of existing stocks of cancelled or suspended pesticides is unlawful. Use of such existing stocks, on the other hand, is not unlawful unless specifically prohibited by the Agency in a cancellation or suspension order.

If a pesticide is cancelled under section 6(b) or section 6(e), FIFRA provides in section 6(a)(1) and (e) that the Administrator may permit the continued sale and use of existing stocks of the cancelled pesticide "to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of (FIFRA) and will not have unreasonable adverse effects on the environment." 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, in determining whether to permit distribution, sale, or use of existing stocks of pesticides cancelled under sections 6(b) or 6(e), EPA must apply the same risk/benefit considerations that are applicable to other Agency actions under FIFRA (except that such considerations would be limited to the context of allowing distribution, sale, or use of existing stocks).

FIFRA does not specify a standard for the Agency to apply in determining whether to allow the distribution, sale, and use of existing stocks of pesticide products cancelled voluntarily pursuant to FIFRA section 6(f) or for failure of the registrant to comply with the requirements of section 4. The Agency has decided to make existing stocks determinations with respect to products cancelled under sections 4 and 6(f) based upon whether distribution, sale, or use of existing stocks would be consistent with the purposes of FIFRA. In determining whether such distribution, sale, or use would be consistent with the purposes of FIFRA, the Agency will first determine whether there are any significant risk concerns associated with the cancelled product. If there are such risk concerns, the Agency will generally require a risk/benefit analysis before allowing the sale, distribution, or use of existing stocks. If there are no significant risk concerns, the Agency will generally not require a risk/benefit analysis before making an existing stocks determination.

In the case of suspension of pesticide registrations for failure to submit data, FIFRA has explicitly provided the Agency with broad discretion in the area of existing stocks. Section 3(c)(2)(B) provides that the Administrator may make such provisions for the sale and use of existing stocks of a pesticide whose registration is suspended for failure to submit data as EPA "deems appropriate."

As to existing stocks of pesticides that have had their registrations amended, the Agency generally considers sale or distribution of a pesticide bearing a label or containing a formula other than the label or formula currently approved by the Agency to be a violation of FIFRA section 12(a)(1)(B), (C), or (E). The Agency has, however, established regulations (at 40 CFR 152.130) which provide for the continued sale of a product bearing previously approved labeling for certain periods of time depending upon the nature of the amendment. These regulations do not apply to changes in composition. The Agency will treat sale and distribution of products containing a previously accepted formula that is different from the currently accepted formula in the manner described in unit III.C (Amendments of Registration) of this Policy Statement.

III. General Policies Applicable to All Existing Stocks

This Policy Statement contains the general policies that the Agency intends to apply in making determinations concerning the sale or use of existing stocks of pesticides, as defined in unit I (Application) of this statement. In any individual case, the Agency will consider additional factors if appropriate. To the extent that a particular action or cancellation can fit into more than one category discussed below, EPA will generally select the most restrictive existing stocks provision that may apply. Whenever an existing stocks provision is issued, the Agency reserves the right to amend that provision on its own initiative or at the request of any interested person (either by allowing additional time to sell or use stocks or by placing additional restrictions on the sale or use of existing

stocks) if later circumstances warrant. Finally, unless an existing stocks provision stipulates otherwise, any sale or use of existing stocks must be in accordance with the previously approved label and labeling on, or accompanying, the product.

A. Cancelled Pesticides

In determining what existing stocks provision is appropriate with respect to a pesticide whose registration has been cancelled, the Agency generally will base its determination on the total circumstances affecting the cancelled registration. The actual mechanism triggering cancellation will not always be the controlling factor. Instead, the Agency generally will focus on three factors: (1) Whether there are significant potential risks which raise a question as to whether the use of the cancelled pesticide results in unreasonable adverse effects on man or the environment (this category consists primarily of cancellations where the registration is the subject of a notice of intent to cancel issued pursuant to section 6(b) or a special review initiated pursuant to 40 CFR part 154); (2) whether the registrant of the cancelled pesticide has failed to meet an obligation of registration (such as payment of fees under section 4, or submission of data required under section 3(c)(2)(B), 3(c)(7), or (4); and (3) whether the Agency has taken some regulatory position with respect to the cancelled registration (such as issuance of a Registration Standard, Label Improvement Program, or a document describing the reregistration status of a pesticide or active ingredient). Consideration of these factors in a particular case may suggest differing provisions for the sale, distribution, or use of existing stocks. In such situations, the Agency generally will apply the most restrictive existing stocks provision to the cancelled product.

1. *Cancellations where the Agency has identified particular risk concerns.* Whenever a pesticide registration is cancelled, the Agency will determine whether there are significant potential risk concerns associated with the use of the pesticide. If there are such concerns, the Agency generally will make a case-by-case determination as to whether to allow continued distribution, sale, or use of existing stocks of the cancelled pesticide. This likely will be the case whether a product is cancelled by Agency mandate after issuance of a risk-based notice of intent to cancel, whether the product is cancelled because of the registrant's failure to comply with the reregistration requirements of section 4, or whether the cancellation was requested voluntarily by the registrant.

In most cases, the Agency will not permit continued distribution, sale, or use of existing stocks of a cancelled pesticide raising risk concerns unless it can be demonstrated that the social, economic, and environmental benefits associated with such distribution, sale, or use exceed the social, economic, and environmental risks. A risk/benefit analysis for existing stocks purposes is somewhat different from the analysis that is performed by the Agency in determining whether or not to cancel a registration. In making existing stocks determinations, the Agency may consider any or all of the following criteria, to the extent that information is provided or available:

a. The quantity of existing stocks at each level of the market (i.e., in possession of registrants, distributors, retailers, end-users, etc.)

b. The risks resulting from the use of such stocks. The examination of risk may take into account the limited nature of use of existing stocks where relevant (such as where limited use might result in a level of exposure that may not result in much risk). In many cases, however, it may turn out that the risks posed by use of existing stocks will be similar or identical to the risks posed by continued registration (such as, for example, where the risk is primarily an acute risk from single exposure). In assessing the risks posed by use of existing stocks, the Agency will, to the extent possible, also consider the risks posed by likely alternatives (if any).

c. The benefits resulting from the use of such stocks. In considering the benefits of existing stocks, the Agency may consider the short-term problems (if any) in switching to alternatives, including the length of time before which such alternatives could be available to retailers and users and any hardships that might be presented to users before alternatives are available. The consideration of benefits may also include (insofar as it affects existing stocks) the type of analysis of benefits that the Agency performs in its other risk/benefit analyses (i.e., whether alternatives are available, how any such alternatives compare in terms of cost and efficacy, and what the economic effects to the user will be if the cancelled product is unavailable).

d. The dollar amount users and others have already spent on existing stocks (which would be lost if distribution, sale, or use were not permitted).

e. The risks and costs of disposal or alternative disposition of the pesticide if distribution, sale, or use are not permitted. The Agency may assess whether existing stocks could be used for other purposes. If disposal appears likely, the Agency may consider relevant aspects of disposal, including the nature, feasibility, and cost of proper disposal of the cancelled product.

f. The practicality of implementing restrictions on distribution, sale, or use of existing stocks. For instance, it may be that in some circumstances the Agency would allow continued use of a product because the product could not, as a practical matter, be retrieved.

In addition to the factors listed above, the Agency may consider any other information relevant to either the risks posed by, or the benefits resulting from, the sale and use of existing stocks.

In performing a risk/benefit analysis the Agency will consider all information and/or comments from registrants and interested persons regarding existing stocks that are received in response to public documents that the Agency issues in the course of its regulatory process. For example, where an active ingredient is in special review, the Agency will often issue a Preliminary Determination (position document (PD) 2/3) and request public comment on all proposed regulatory actions. Where a registrant's request for voluntary cancellation is received prior to initiation of special review, but while one is under consideration, the Agency will publish a notice in the **Federal Register** acknowledging receipt of the request and may solicit public comments regarding existing stocks provisions.

If registrants or others indicate that there is an interest in the continued sale or use of existing stocks of cancelled pesticides raising risk concerns, and if information is provided to the Agency to support such distribution, sale, or use, the Agency will generally conduct an analysis of the risks and benefits of the distribution, sale, and use of existing stocks. If information is not provided to the Agency or no interest in continued sale, distribution, or use is expressed to the Agency, the Agency will generally not conduct a risk/benefit analysis and will not permit any sale, distribution, or use of existing stocks.

While a risk/benefit analysis will be an important factor in the Agency's determination of whether or not to allow distribution, sale, and use of existing stocks of cancelled pesticides raising risk concerns, the Agency must also determine that further distribution, sale, or use would be consistent with the purposes of FIFRA. There may be unusual circumstances where the Agency will place restrictions on the distribution, sale, and use of existing

stocks beyond those limits otherwise identified in a risk/benefit analysis (e.g., to prevent stockpiling by distributors and users).

In addition, in determining whether distribution, sale, or use of existing stocks would be consistent with the purposes of the Act, the Agency will generally look at the circumstances surrounding the cancellation. If a cancellation is the result of a final Agency action after a special review and a hearing pursuant to section 6(b), the Agency is unlikely to allow continued sale or distribution (and quite possibly, use) of the cancelled pesticide. In such circumstances, registrants, other distributors, and users of the pesticide have had ample notice of the Agency's intentions and sufficient time to take appropriate steps accordingly (such as to procure alternatives, not stockpile large quantities of the pesticide involved, use up stocks already on hand, etc.). On the other hand, where a voluntary cancellation occurs well before the Agency could take final action (i.e., prior to the completion of a special review or in lieu of a hearing under section 6(b)), the Agency may take into consideration the shorter period of notice sellers and users may have had before cancellation, the degree to which the registrant's actions accelerated the removal of the pesticide from the market, and whether the cancellation would have occurred at all without an existing stocks provision.

In a special review situation, the Agency will publish its final determination on whether to allow any sale, distribution, or use of existing stocks of cancelled pesticides, and if so, what conditions to place on such sale, distribution, or use, as part of the Final Determination (PD 4) and any other documents the Agency may issue either with or subsequent to the issuance of the PD 4 (such as notices of intent to cancel, cancellation orders, etc.). If a chemical raising a risk concern is cancelled without issuance of a Notice of Final Determination at the conclusion of a special review, the Agency will include a final existing stocks determination in a cancellation order. Existing stocks determinations contained in cancellation orders will be enforced under section 12(a)(2)(K) or 12(a)(1)(A) of FIFRA.

The Agency may allow the continued sale, distribution, and use of existing stocks of a voluntarily cancelled product raising risk concerns without performing a risk/benefit analysis if similar products with substantial share of the market remain on the market. For example, if a registration raising risk concerns is cancelled voluntarily, the Agency may examine whether the cancelled registration comprises a significant share of the market for the particular active ingredient and use pattern, and the circumstances surrounding the cancellation. If the cancelled registration does not comprise a significant share of the market, a prohibition on existing stocks would not be likely to significantly reduce environmental risks, because similar products would continue to be sold and used. Further, the Agency believes that it makes sense to encourage the early, voluntary cancellation of registrations when risk concerns arise.

If such an early cancellation is truly voluntary (i.e., the registration is not facing imminent cancellation or suspension), the Agency may allow the registrant to sell and distribute existing stocks for 1 year without performing a detailed risk/benefit analysis, and may allow other persons to distribute, sell, and use existing stocks until the stocks are exhausted. The Agency does not believe it should penalize registrants, distributors, or users in cases where a registrant voluntarily cancels a registration before other registrants are compelled to do so. Moreover, it is unlikely that a detailed risk/benefit analysis would yield a different result; so long as similar registrations comprising a predominant share of the market remain, it is unlikely that distribution, sale, or use of existing stocks of a relatively small volume of cancelled product would significantly (if at all) increase the risk of any unreasonable adverse effect on the environment.

On the other hand, if registrations constituting a dominant share of the market are cancelled, and the Agency does not believe that the remaining registrants can fill the previous demand for the product, the Agency will generally not allow continued sale, distribution, or use of existing stocks unless a risk/benefit analysis supporting such sale, distribution, or use is performed.

In cases where the Agency allows continued sale and use of existing stocks of cancelled products raising risk concerns because of the continuing nature of other registrations, it should be understood that the existing stocks allowance may be amended if the conditions concerning the registrations of the remaining products change. (The Agency in all cases reserves the right to amend existing stocks provisions where appropriate.) If other registrations are cancelled or amended during an existing stocks period for a voluntarily cancelled product, and the Agency establishes restrictions on existing stocks of these other registrations or requires relabeling of product made prior to the amendment, the Agency will likely impose similar restrictions on the existing stocks of the earlier voluntarily cancelled registration.

2. *Cancellations where a registrant has failed to comply with an obligation of registration.* This category consists of cancellations where the Agency does not have significant risk concerns with respect to the cancelled pesticide, but where the registrant has failed to respond appropriately to an obligation of registration. In these situations, the Agency has no particular reason to believe that continued distribution, sale, or use of the cancelled product would result in unreasonable adverse effects on the environment.

If a cancellation is not triggered by section 6(b) or 6(e) of FIFRA, the Agency is not required to perform a risk/benefit analysis before determining whether to allow continued sale, distribution, or use of existing stocks. Unless there are significant risk concerns associated with the cancelled pesticide, the Agency generally does not intend to perform such an analysis. Even where a cancellation is triggered by section 6(b) or 6(e), the Agency generally intends to make existing stocks decisions for cancelled products without performing a detailed risk/benefit analysis if there are no significant risk concerns associated with the cancelled pesticide. EPA believes it would be a poor use of resources to perform such an analysis when the Agency is not aware of any risk/benefit considerations that would serve as a basis for cancelling a registration. The Agency believes it highly unlikely that any analysis of risks and benefits of products not raising significant risk concerns would result in prohibition of distribution, sale, or use of existing stocks.

EPA does, however, believe that where registrants of cancelled products have failed to comply with requirements of registration, the nature of noncompliance with the particular obligation involved should be taken into account in determining whether distribution, sale, or use of existing stocks would be consistent with the purposes of FIFRA. Since such noncompliance does not itself raise concerns of unreasonable adverse effects on the environment, EPA will generally allow persons other than the registrant to continue to distribute, sell, or use stocks of cancelled products in this category until such stocks are exhausted (although the Agency may

place some restrictions on sale or use if inventories are not exhausted in a reasonable period of time). In the case of the noncompliant registrant, however, EPA will generally apply the policies set forth below in determining whether to allow continued sale and distribution. Those policies would generally prohibit a registrant from selling or distributing existing stocks more than 1 year from the date the registrant first failed to comply with an obligation of registration.

In any given case, multiple existing stocks dates might apply if a registrant has failed to comply with more than one obligation of registration. In such circumstances, the most restrictive date will generally apply, regardless of the triggering mechanism for cancellation. For example, if a registrant of a cancelled product failed to pay a maintenance fee due on March 1, 1990, and a reregistration fee due on June 1, 1990, the registrant would likely not be allowed to sell or distribute any existing stocks of the product after March 1, 1991 (regardless of whether the product was actually cancelled for failure to pay maintenance fees or reregistration fees).

a. *Failure to pay maintenance fees.* FIFRA section 4(i)(5) requires all registrants to pay annually by March 1st certain maintenance fees for registrations. Failure to pay such fees may result in the cancellation of a registration by order without a hearing (although the cancellation itself does not become effective until the Agency issues the cancellation order). If a maintenance fee is not paid for any given year, the Agency will generally not allow a registrant to continue to sell or distribute existing stock of a cancelled product for more than 1 year after the date when payment to support the cancelled registration was due, regardless of when the actual cancellation occurs. For example, if a registrant fails to pay a maintenance fee due March 1, 1991, to support a particular registration, and the registration is later cancelled, the Agency will generally not allow that registrant to sell or distribute existing stocks of the pesticide after March 1, 1992.

b. *Failure to pay reregistration fees.* FIFRA section 4(i) also requires some registrants to pay a reregistration fee (either in one or two deposits). This fee is to be apportioned among the applicable registrants on the basis of market share information that registrants are required to submit to the Agency. Failure to submit market share information or to pay an appropriate fee can lead to cancellation of a registration by order without a hearing (FIFRA section 4(i)(7)(C)). If a registrant fails to pay the appropriate reregistration fee or submit the required market share information, and an applicable product is later cancelled, a registrant will generally not be allowed to sell or distribute existing stocks of the cancelled product more than 1 year after the date the market share data or fee were due.

c. *Failure to file information during reregistration.* FIFRA section 4 establishes a five-phased process for reregistration activities. If a registrant elects to pursue reregistration, a registrant may have to commit to supply, and then supply, information to the Agency during Phases 2, 3, 4, and 5 (sections 4(d), (e), (f), and (g)). Failure to provide appropriate commitments or information can result in suspension or cancellation of a registration. If a registrant fails to comply fully with any particular phase of reregistration, and an affected product is later cancelled, the Agency will generally not allow a registrant to sell or distribute existing stocks of the cancelled product more than 1 year after the date that a registrant commitment for that particular product was due. For example, if an initial Phase 3 response is due from a registrant on July 24, 1991, the registrant fails to submit an adequate response, and the product is later cancelled, the Agency will generally not allow the registrant to sell existing stocks of the product after July 24, 1992.

Registrants will not be penalized for voluntarily cancelling a product at the beginning of any particular phase of reregistration (i.e., a registrant who cancels as of the commitment date will have a full year from the commitment date to sell or distribute existing stocks). Noncompliance in any phase, however, will generally be treated as if the registrant had requested voluntary cancellation at the beginning of the phase.

Agency policy with respect to existing stocks of suspended products that failed to comply with the requirements of reregistration are discussed later in this document.

d. *Failure to comply with the terms of a conditional registration.* FIFRA section 3(c)(7) allows the Agency to issue registrations before all applicable supporting data are provided. Such registrations, however, are conditional upon submission of the missing data in a timely manner (and upon compliance with any other conditions contained in the registration at the time of issuance). Failure to comply with the terms of a conditional registration can lead to issuance of a notice of intent to cancel under section 6(e).

Where a conditional registration is cancelled (and the Agency has not identified significant risk concerns), the Agency will base its existing stocks decision on the nature of any conditions that have not been met by the registrant. For purposes of this analysis, conditions of registration can be categorized as "general" conditions or "specific" conditions. A general condition, frequently applied to conditional registrations issued pursuant to FIFRA section 3(c)(7)(A) (i.e., registrations issued to products that are identical or substantially similar in chemical composition and use to one or more existing registered products), requires a registrant to submit required data when all other registrants of the similar product are required to do so. Such a general condition neither establishes specific data requirements nor specific dates; the condition is generally triggered by issuance of a data call-in notice. On the other hand, some conditional registrations, particularly those issued pursuant to FIFRA section 3(c)(7)(B) and (C) (i.e., conditional registrations of products containing new chemicals or bearing significant new uses), contain conditions requiring the submission of specified studies or information by specified dates. Where data requirements and submission dates are specifically identified in the conditional registration, such requirements are considered "specific" conditions.

The Agency will treat the failure to comply with a general condition of a conditional registration in the same manner as a failure by a registrant to comply with the terms of any other data call-in. If a registrant of a conditional registration with a general condition to submit data upon request does not thereafter submit data after issuance of a data call-in, and the registration is cancelled for any reason, the registrant would generally be allowed to continue to sell or distribute existing stocks for 1 year after either the day the 90-day response to the data call-in was due or the date at which the registrant ceased to remain in compliance with the terms of the data call-in, whichever date is later. (See unit III.A.3 below).

On the other hand, if a registrant of a conditional registration fails to comply with a specific condition identified at the time the registration was issued, the Agency does not believe it is generally appropriate to allow any sale and use of existing stocks if the registration is cancelled. Accordingly, the Agency does

not anticipate allowing a registrant to sell or distribute existing stocks of cancelled products that were conditionally registered if the registrant fails to demonstrate compliance with any specific requirements set forth in the conditional registration.

3. *Cancellation of products while subject to data call-in notices under section 3(c)(2)(B).* Section 3(c)(2)(B) allows the Agency to require data from registrants. Registrants are required to make an initial response to data call-in notices in 90 days, and thereafter to submit the required data in accordance with the schedule established by the Agency. Failure to respond appropriately can result in the suspension of any registration subject to the data call-in.

Similar to reregistration, data call-in notices require a commitment from a registrant to supply data, and the timely submission of data, to maintain an active registration. Accordingly, the Agency will generally not allow registrants to sell existing stocks of cancelled products more than 1 year after the date a 90-day response to a data call-in notice is due unless the registrant remains in compliance with the terms of the notice. For example, if a registrant commits to submit a 3-year study and the product registration is thereafter cancelled upon request by the registrant pursuant to section 6(f) 9 months after the 90-day response date, sale and distribution of existing stocks by the registrant will be permitted for no more than 3 months (1 year from the 90-day response date). However, if a product subject to a data call-in is cancelled and the registrant can demonstrate full compliance with the requirements of the data call-in up to a certain date, the Agency will likely allow the registrant to continue to sell and distribute existing stocks for 1 year from the date that compliance ended. For example, if the registrant had contracted with a lab to perform a 3-year study, the lab had commenced work, and the registrant instructed the lab to cease work 6 months later, the registrant would generally be allowed to sell and distribute existing stocks of cancelled products for 1 year from the date the lab was asked to cease work on the required study. The Agency will generally allow persons other than the registrant to continue to distribute, sell, or use stocks of cancelled products in this category until such stocks are exhausted (although the Agency may place restrictions if such stocks are not exhausted in a reasonable time).

The preceding discussion assumes that data generated under the data call-in have not disclosed significant potential risks associated with the product. Registrants should be advised that voluntary cancellation of a product during a data call-in response period does not excuse the registrant from compliance with the requirements of FIFRA section 6(a)(2) to report to the Administrator any information regarding unreasonable adverse effects on the environment.

4. *Cancellation of registrations subject to reregistration requirements and label improvement programs.* In the case of a registration subject to a Label Improvement Program (LIP) or determination resulting from decisions made during reregistration, the Agency has determined that the registration of the product may continue, provided that certain changes are made to the terms of registration (generally involving the product label). If a product subject to an LIP or reregistration requirement is cancelled, whether voluntarily or upon action by the Agency (e.g., for failure to pay fees), the Agency will generally not allow a registrant or any other person to sell or distribute existing stocks unless such sale or distribution is consistent with the terms of the LIP or reregistration determination.

For example, if an LIP states that registrants may not sell or distribute a product after January 1, 1992, without a certain label change and states that other persons may not sell or distribute product without the new label after January 1, 1994, and a product subject to the LIP is voluntarily cancelled on July 1, 1991, the registrant of the cancelled product will not be allowed to sell or distribute existing stocks of the cancelled product after January 1, 1992, unless the existing stocks are relabeled to be in compliance with the LIP. Similarly, no other persons would likely be allowed to sell or distribute existing stocks of the cancelled product after January 1, 1994, unless the stocks were in compliance with the terms of the LIP.

5. *Other voluntary cancellations.* If a registrant requests to voluntarily cancel a registration where the Agency has identified no particular risk concerns, the registrant has complied with all applicable conditions of reregistration, conditional registration, and data call-ins, and the registration is not subject to a Registration Standard, Label Improvement Program, or reregistration decision, the Agency will generally permit a registrant to sell or distribute existing stocks for 1 year after the cancellation request was received. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted.

B. Suspended Pesticides

FIFRA provides for two different types of suspension. Under section 6(c), EPA may suspend a pesticide registration if use of the pesticide results in an imminent hazard. Under section 3(c)(2)(B), EPA may suspend a registration if a registrant fails to submit required data to the Agency in a timely fashion. Section 4(d)(6) and 4(f)(3) provide for suspensions pursuant to section 3(c)(2)(B) if registrants fail to make timely progress of data development to meet commitments for data submission, tests are not initiated within 1 year after issuance of a Phase 4 data call-in notice, or data are not submitted by the due date.

Where a pesticide is suspended because of an imminent hazard, EPA will apply the policies applicable to cancellations where the Agency has identified significant risk concerns. The Agency is highly unlikely to allow significant sale, distribution, or use of pesticides suspended because of imminent hazard concerns.

Where a pesticide is suspended because of failure to comply with the provisions of a data call-in or reregistration requirement, the Agency will generally not allow the registrant to sell or distribute any existing stocks during the pendency of the suspension. Registrants who sell or distribute a pesticide which has been suspended under FIFRA section 3(c)(2)(B) will be in violation of FIFRA section 12(a)(2)(J). Unlike imminent hazard suspensions, the Agency does not anticipate generally placing restrictions on the sale, distribution, or use of existing stocks by persons other than the registrant where a pesticide is suspended because of failure to comply with the provisions of a data call-in or reregistration requirement unless risk concerns were identified.

C. Amendments of Registrations

The Agency has promulgated regulations (at 40 CFR 152.130) dealing with the sale or distribution of products bearing labeling other than the labeling currently approved by the Agency. Section 152.130(c) of the CFR states that the Agency will "normally" allow registrants to sell products bearing old labeling for 18 months after Agency approval of a revised label and allow others to sell products bearing the old label until all such products are sold, if the product labeling is amended "on the initiative of the registrant." Section 152.130(d) goes on to say that if a

revision is the result of a Registration Standard, Label Improvement Program, or notice concluding a Special Review, the Agency may establish alternate dates after which product sold by a registrant, or sold by others, must bear currently approved labeling.

The regulations do not address the issue of time periods for sale of products bearing a different composition or packaging from that currently approved by the Agency. The Agency believes that if the composition or packaging is required to be changed by the Agency, the policies expressed below concerning label changes should apply. However, if the composition or packaging of a product is changed by a registrant voluntarily, the Agency will generally allow registrants to sell or distribute product for 18 months after the Agency approves the change; other persons will generally be allowed to sell product using the old composition or packaging until all such product is sold.

Changes in labeling made at the behest of the Agency are covered by paragraph (d) rather than paragraph (c) of 40 CFR 152.130. Thus, if label changes are imposed in a document issued during Phase 5 of reregistration (under FIFRA section 4(g)(2)(A)) or if label revisions (or other changes) are in part attributable to concerns that the product may pose unreasonable adverse effects without the change, the Agency may impose appropriate restrictions on the sale or distribution of products not only by the registrant but by others in the distribution chain as well ("channels of trade" dates).

The Agency believes that, although such channels of trade dates may be relatively lengthy, they are necessary to effective enforcement, serving as a form of "closure" on old labeling. In the Agency's enforcement experience, products bearing old labels can be found in channels of trade far longer than foreseen. Besides enforcement difficulties, lack of an absolute cutoff point for needed label changes prolongs inconsistency among similar products, leading to confusion among users as to what label instructions are correct. More importantly, the lack of a channels of trade date creates uncertainty that product labels actually represent current and protective standards. Under FIFRA, the assurance of risk reduction depends heavily on expectations that labeling instructions will be followed. Uncertainty that such compliance is occurring and inconsistency among labels can frustrate efforts by both the Agency and registrants to effect real and consistent risk reduction. Accordingly, in each label change either imposed by the Agency, or attributed in part to risk concerns under review by the Agency, EPA intends to impose both a date for introduction of new labeling into channels of trade (a registrant sale and distribution date), and a date for removing old labeling from channels of trade. Except in the case of labeling changes imposed through Special Review, EPA is unlikely to impose restrictions upon use of product bearing old labeling.

The exact restrictions that the Agency may impose will, of course, depend upon the particular circumstances involved. Nonetheless, the Agency can identify certain principles it generally will apply to label changes directed by the Agency. Label changes directed by the Agency are currently imposed under three specific activities:

1. *The Special Review Process.* Special reviews often culminate in an Agency determination that use of the pesticide without labeling changes would cause unreasonable adverse effects. Also, registrants of pesticides in special review may propose label changes prior to the conclusion of a special review to reduce the risks that are the focus of the review. When label changes are approved in such situations, existing stocks provisions will be determined on a case-by-case basis. In determining what provisions are appropriate, the Agency may consider any or all of the following factors:

a. The nature of the risk posed by the pesticide.

b. The nature of the labeling change required.

c. Whether an amendment to effect the labeling change was submitted in a timely manner.

d. The potential adverse effects associated with continued sale of product not bearing the revised labeling.

e. The volume and location of affected products in the distribution chain.

f. The feasibility, expense, and effectiveness of either requiring relabeling of existing stocks, or of restricting sale and distribution of product not bearing the revised labeling.

2. *Reregistration of current products.* Under FIFRA section 4(g), Phase 5 of the reregistration scheme requires that products containing active ingredients first registered before November 1, 1984, be reregistered. The Agency anticipates that labeling changes (amendments) will likely be required upon issuance of a document stating the Agency's determination of the reregistrability of an active ingredient under FIFRA section 4(g)(2)(A). This Reregistration Eligibility Document (RED) will ask for label changes to be submitted within one of two timeframes—normal or expedited.

In the first instance, the reregistration process envisioned in Phase 5 will normally encompass changes in labeling, composition, or packaging. These changes will be of a more routine nature, or will depend upon the development of product-specific data, such as acute toxicity or efficacy data. Dates for submission of labeling, timeframes for Agency review of labeling changes, and existing stocks provisions will be specified in the RED. Generally, submission of labeling changes will be required 8 months from the date of submission of the RED, and Agency review will be completed 6 months following submission. Registrants will generally be permitted to sell or distribute products bearing old labeling (or composition or packaging) for 1 year after the timeframe established in the RED for Agency approval, and persons other than registrants will generally be permitted to sell or distribute those products for an additional 24 months. Thus, existing stocks dates for sale and distribution of products bearing old labeling will generally be 26 months from the date of issuance of the RED for registrants and 50 months from the date of issuance of the RED for persons other than registrants.

In the second instance, the Agency may require expedited labeling changes if it has significant concerns about the risks of the active ingredient that do not warrant placing it into the Special Review process, but that labeling changes could mitigate. Although EPA believes this situation will be rare, nonetheless the significance of Agency concerns will dictate early submission and review of labeling, and relatively short existing stocks provisions. Existing stocks timeframes will be established case-by-case, depending on the number of products involved, the number of label changes needed, and other factors.

3. *The Label Improvement Program (LIP).* An LIP provides a framework for upgrading labeling that is unconnected with reregistration, and can be initiated at any time that circumstances warrant. The LIP was established to provide a mechanism for the Agency to target a particular labeling problem or a group of products having a common label element and to implement a labeling solution uniformly for all affected products. In that respect it should be viewed as neither active ingredient-specific nor product-specific, but rather "problem-specific." Fundamental to this approach is that the program does not depend upon the development or

interpretation of data, such as is required for reregistration. With such a cross-cutting but focussed approach, the LIP generally endeavors to impose labeling requirements that can be specified exactly or with a minimum of variability. Although labeling may be required to be submitted and reviewed in a LIP, EPA's preferred approach is to obtain agreement via certification that registrants will make the changes. Thus, registrants can rapidly begin implementing the changes in products they distribute and sell. EPA anticipates that any submission of labeling or certification would be required in a comparatively short time after issuance of the LIP. Unless the LIP is a singularly complex one or involves large numbers of products or registrants, submissions of labeling or certifications will normally be required within 3 months. Registrants will generally be allowed to sell or distribute products bearing old labeling for 1 year after issuance of the LIP and persons other than registrants for 3 years after issuance of the LIP.

The Agency acknowledges the impact multiple and frequent required label changes have in escalating registrant costs, potentially disrupting the distribution chain, and creating user confusion. EPA will make every effort to consolidate labeling efforts resulting from reregistration with those that may be under way from LIPs or from parallel regulatory activities.

Interested persons are invited to sumbit written comments on this notice of statement of policy on or before December 26, 1991. Comments must bear a notation indicating the document control number, (OPP–38509). Written comments should be addressed to the Public Docket and Freedom of Information Section, Field Operations Division, at the address given above.

Dated: June 17, 1991.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 91–14958 Filed 6–25–91; 8:45 am]

BILLING CODE 6560–50–F