

will also provide valuable information that will aid the Agency in developing and completing regulatory revisions related to these process improvements, which the Agency currently expects to propose in 2003.

*A. Which Emergency Exemptions will be Included in the Pilot?*

The pilot will be limited to emergency exemption applications for which the requested product is a pesticide previously identified by EPA as a reduced-risk pesticide, as discussed below. The pilot will only involve specific exemptions, and does not affect public health or quarantine exemptions. The pilot will begin with emergency exemptions for the 2003 growing season. As such, EPA will consider the two process improvements when it reviews eligible applications for emergency exemption for the 2003 growing season, including those applications that are currently pending final decision on and any applications received after April 16, 2003. The Agency recognizes that those applications currently under review by EPA that are eligible for the pilot, are not likely to include information that addresses the two improvements described in this Notice. In such cases, the Agency intends to work with the applicants to apply the pilot provisions where appropriate and desired by the applicant. It should be noted that at no time during the pilot is any applicant required to use the pilot provisions, even if eligible. Any applicant which chooses to forgo the pilot and use the established application process may do so.

EPA chose to focus the pilot on reduced-risk pesticides, a specific set of pesticide products which includes conventional pesticides which were registered under EPA's Reduced-Risk Pesticide Initiative, plus biological pesticides registered through the Biopesticides and Pollution Prevention Division (BPPD). The goal of the Reduced-Risk Pesticide Initiative and BPPD is to encourage the development, registration, and use of lower-risk pesticide products which would result in reduced risks to human health and the environment when compared to existing alternatives. A detailed description of reduced-risk pesticides may be found in Pesticide Regulation Notice 97-3, which is available in the public docket for this Notice. The reduced-risk determination for conventional pesticides is made by EPA for each use of a pesticide, particularly when compared to existing registered alternatives for that use. However, for use in implementation of the revised

practices under the pilot in this Notice, any active ingredient which is contained in at least one product registered under the Reduced-Risk Initiative, plus any biological pesticide, will be considered a reduced-risk active ingredient. Any product containing one or more of these active ingredients and no others will be eligible, while any product containing any other active ingredient will not be eligible for exemption under the pilot.

EPA has prepared a list of all reduced-risk active ingredients, as defined above, so that applicants and others may easily determine which emergency exemption requests may be eligible for consideration under the pilot for the revised approach for documentation of significant economic loss. The new economic loss approach under the pilot may be applied to any exemption request for a reduced-risk pesticide on this list. However, in order for exemptions to be eligible for re-certification of an emergency under the pilot, in addition to the restriction to reduced-risk pesticides, they must also meet the other criteria for candidacy for re-certification set forth in Unit V.B.1. Therefore, the Agency has prepared a second list of existing (*i.e.*, granted for use in 2002) exemptions that are eligible for re-certification. EPA has also prepared a guidance document for implementation of the revised practices under the pilot, which is intended to further aid applicants in preparing applications. The two lists for determining eligibility of exemptions under the pilot are appendices to the guidance document, which will be sent to the States and included in the public docket for this Notice.

*B. What Process Improvements are Being Piloted?*

Two potential improvements to the emergency exemption program will be tested through this limited pilot.

1. *Re-certification of emergency condition by applicants*—i. *What is our current practice?* EPA authorizes emergency exemptions (except quarantine exemptions) for no longer than 1 year. However, depending on the nature of the non-routine condition which caused the emergency, some exemptions may subsequently be granted again, 1 year at a time. Currently, EPA conducts a full review of an application for the first year of an exemption, to determine whether an emergency condition exists, to ensure the use will not result in unreasonable adverse effects to man or the environment, and, if the use will result in pesticide residues in food or feed, to make a safety finding consistent with

section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Applicants may submit an application for a subsequent year, in which case the Agency must again confirm the emergency condition and acceptability of the risk. For requests after the first year, the applicant again submits information to support the emergency finding, and EPA reevaluates the situation to determine, relative to the first year, whether: (1) The emergency condition has changed; (2) any alternative products have been newly registered for the use, or other effective pest control techniques are now available; (3) any changes have occurred in the status of the chemical's risk assessment; and (4) the requested use pattern has changed.

ii. *How will re-certification work under the pilot?* The first potential improvement that is part of the pilot will allow applicants for certain exemptions to re-certify in the application that the emergency conditions which initially qualified for an exemption continue to exist in the second and third years. Under the pilot, this re-certification by the applicant will serve as the basis for EPA's determination that an emergency condition continues to exist. An acceptable application which re-certifies the emergency will incorporate by reference all information submitted in a previous application or applications to document the initial emergency condition for which an exemption was granted previously. Eligible applications in years two and three may consist only of applicants' re-certification of the emergency condition, incorporation by reference of supporting materials, and specification of the pesticide application practices that growers would observe. Applicants would not need to submit new documentation that the emergency condition continues or the additional data elements generally required under 40 CFR 166.20.

EPA will apply specific criteria to determine whether an exemption request will be eligible for re-certification of the emergency condition by the applicant. All of the following criteria need to apply in order for EPA to consider an exemption as a candidate for re-certification of an emergency under the pilot:

1. EPA granted the same exemption the previous year, and it is the second or third year of the request by that applicant. The Agency determined that the situation the previous year satisfied requirements for an emergency condition (40 CFR 166.3(d)). A complete application will be required the first year of an exemption for a particular