

the useful life of the essential registered pesticide and ultimately limit the need for more emergency exemptions. The potential improvement would take a more preventive approach to resistance management.

Under such an approach, EPA could review applications and look for all four of the following criteria before approving an emergency exemption request for resistance management:

i. Pest resistance is developing or has developed to the registered pesticide product. Claims that a pest is developing or has developed resistance to a pesticide should be documented by scientific evidence. The applicant would submit the best readily available information which supports their case. Because acceptable techniques for verifying resistance vary considerably for the numerous crop-pest-pesticide combinations, EPA determinations on sufficiency of documentation would be made on a case-by-case, weight-of-the-evidence basis. Resistance development would be documented through field studies, references to field studies, or loss of ability to control the pest in the field and confirmed to be due to pest resistance in commercial plantings or other actual use conditions such as in greenhouses.

Typically, documentation of a decrease in susceptibility to a pesticide would involve collections of pest samples from fields suspected of containing high frequencies of resistant pests, and laboratory bioassay would be conducted to estimate the frequency of resistant individuals and the degree of resistance. Field tests would be conducted to assess the degree to which the laboratory resistant bioassay reflects loss of efficacy under typical treatment conditions in the field. Because resistance developed or measured under laboratory or other non-field conditions may not accurately reflect conditions in normal use situations, the applicant would need to demonstrate that the data presented can substitute for field conditions. That is, the laboratory bioassay must have relevance to the field such that individuals shown to be resistant in the laboratory bioassay actually do contribute to a substantial loss of efficacy under the treatment conditions of the field. The data should reflect numerous susceptibility estimates within single locations and multiple locations to confirm resistance and account for within-field variability. The geographic extent of resistant populations should be described.

The applicant could present evidence on previously reported resistance incidences that are substantially similar to the pest situation under

consideration, as well as a rationale for why resistance is anticipated.

Applicable situations include those where resistance has been documented, either in the U.S. or outside the U.S., for the same pest species or related pest species, similar pesticide use patterns, and comparable climatic conditions. Documentation of comparable situations should also include evidence that the loss of efficacy was not due to misapplication, weather, or other effects not due to resistance. Documented field failures due to pest resistance outside the U.S. and/or laboratory or non-commercial greenhouse experiments could also be included to substantiate resistance in the same or closely related pest species. However, evidence should be presented to justify the use of related pest species, since even closely related pest species may have a different genetic potential to develop resistance.

Information should be provided on the genetic, biological (biotic and behavioral), and operational (chemical and application technology) characteristics that influenced the selection of resistance. Evidence should be provided that indicates the typical number and frequency of pesticide applications, and rate of application used, and host, and why the target pest is likely to develop or has developed resistance at the requested and/or reported site(s), country, county, State, or region. The applicant must also discuss what has been done to manage resistance to the existing registered alternatives and why the requested pesticide is essential to managing pest resistance. This information is important for understanding the basis of resistance and choosing appropriate strategies to manage it.

ii. The registered chemical to which resistance is developing is considered essential for the management of the pest(s) in the particular crop. The pesticide to which resistance is developing should be a registered pesticide which serves as the standard treatment, is critical for obtaining control of the emergency pest, and for which suitable registered alternatives are lacking. If the registered pesticide is used only rarely, the likelihood of resistance developing is generally greatly reduced. Applicants would be asked to document that the pest is one which occurs regularly in the subject crop and State, and is capable of causing a significant economic loss (see Unit V.B.) if no effective control were available. This criterion would ensure that, while addressing resistance proactively by preventing future emergency conditions before they occur, the scope of these exemptions would

not include those for which an actual emergency would never occur.

iii. The request is for only one chemical, which is in a different class, or has a different mode of action, from the registered chemical to which resistance is developing. Applicants would be asked to provide evidence to demonstrate that the requested chemical has a different mode/mechanism of action, metabolic effect, behavioral response, target enzyme, or target life stage from the available effective registered pesticides. Evidence should also be presented regarding whether the requested pesticide may result in unintended pesticide exposure in non-target pests, if available. Pesticide Registration Notice 2001-5, available in the public docket for this Notice and on the Internet at http://www.epa.gov/opppmsd1/PR_Notices/pr2001-5.pdf, describes the Agency's voluntary policy toward resistance management based on mode of action. The Appendices of that document provide the mode of action classification of all of the available registered active ingredients for insecticides, miticides, acaricides, fungicides, bactericides, and herbicides for agricultural uses.

iv. The applicant has a credible approach to managing the development of resistance using both the requested chemical and the chemical to which resistance is developing. The applicant would be asked to include various pest management strategies to reduce selection pressure to not only the requested pesticide, but also the registered alternatives that still may have utility. When available, the applicant should also include supplemental control measures for reducing selection pressure, especially those of a non-chemical nature (e.g., biocontrol, scouting, cultural practices, crop rotation, and use of a pest forecasting system). Management tactics might also include biological and ecological factors that influence pest migration, dispersion, or overwintering, for example. Management strategies should consider all useful information on the stability and inheritance of resistance (cross- and multiple resistance) and relevant information on pest ecology, biology, and toxicology.

3. *Why is this potential improvement being considered?* EPA believes that granting emergency exemptions on the basis of resistance management is a proactive approach for addressing the development of resistance in its early stages, thereby preventing significant economic losses before they occur. Availability of an additional pesticide for resistance management may reduce the likelihood of the common scenario