

applicant, in order to establish the existence of the emergency. Re-certifications will not be accepted as the basis for an emergency after 3 years of an exemption to an applicant.

2. The emergency situation can reasonably be expected to continue for longer than 1 year. Examples of these include situations where a registered product relied upon by growers becomes permanently unavailable; expansion of a pest's range; and, documented loss of efficacy of a registered product. Situations which would not be expected to continue would include a temporary supply problem of a registered product; an isolated weather event; and a sporadic pest outbreak.

3. The exemption is not for a new chemical, a first food use, or for a chemical under Special Review. An exemption that is for a product containing an active ingredient which has never been contained in a product registered as a pesticide under section 3 of FIFRA, or has never been registered for a food use, has officially been placed under Special Review by the Agency, or has been the subject of a Notice of Intent to Cancel under FIFRA section 6, would not be considered for candidacy for re-certification of the emergency.

4. The requested pesticide is registered for another use and has been designated as "reduced-risk" by EPA for one or more uses. The reduced risk program is explained in PR Notice 97-3. This program offers pesticide manufacturers incentives for developing registration applications for pesticides which are less risky than the alternatives for a given pest problem. A committee of EPA scientists evaluates and selects pesticides and uses which are considered to be reduced risk.

Under the pilot, EPA will accept re-certifications of emergency conditions for exemptions which satisfy the eligibility criteria described above. It may not be clear to applicants whether some exemptions are eligible for re-certification. Since eligibility determinations must be made by the Agency, EPA has developed a list of emergency exemptions granted for use in 2002 that appear to be candidates for re-certification for the 2003 growing season. This list (included in the guidance document available in the public docket) is intended to help avoid an applicant's assumption that an exemption is eligible for re-certification of the emergency, when in fact it is not. EPA will attempt to include all appropriate candidates on this list. However, applicants may contact the Agency to request an eligibility determination for exemptions they

believe satisfy the criteria but which are not on the list.

For applications which are eligible and include a proper re-certification of the emergency condition, EPA will continue to assess whether the requested use poses a risk to human health or the environment that exceeds statutory and regulatory standards. If the risks posed by the requested use are determined to be unacceptable, the exemption request will be denied. However, when the emergency condition and requested use in an eligible year are the same as in the initial year of the exemption, EPA will only re-evaluate the situation to determine, relative to the first year, whether: (1) Any alternative products have been newly registered for the use; (2) any changes have occurred in the status of the chemical's risk assessment; and (3) the requested use pattern has changed. If an effective product has been registered for the requested use since the previous exemption was granted, then an emergency condition no longer exists. If the Agency has received new risk information since granting the previous exemption, then the risk will be re-evaluated. Likewise, if the request includes any change in the use pattern which may increase exposure (application rate, number of applications, type of application, pre-harvest interval, re-entry interval, total number of acres, and all other directions for use) then the risk will also be re-evaluated.

For eligible requests with applicant certification of a continuing emergency, if the three remaining review factors (product registrations, risk assessment status, and requested use pattern) have not changed, the Agency's review time is expected to be significantly reduced. In such cases, applicants are expected to benefit by expedited decisions, in addition to the reduced burden due to the certification of the emergency. Applicants will be permitted to modify the use pattern for the emergency program in an application in which they re-certify the emergency. However, EPA will need to determine whether, and how, such changes impact exposure and risk to human health or the environment. Therefore, these changes may undercut the ability of applicants to receive an expedited Agency decision. If the use pattern is the same as in the first year, applicants may include a separate certification that their requested use pattern has not changed in the re-certification year, and incorporate by reference all use pattern specifications submitted in a previous application or applications. This certification of an unchanged use

pattern will aid in expediting the Agency's decision.

If the Agency determines that there has been insufficient progress towards registration of the requested chemical on the requested crop, a request could be denied, consistent with current regulations and practice, regardless of eligibility for re-certification. Progress toward registration is determined for a pesticide-crop combination, whereas the year-count (first, second, third, etc.) in the eligibility cycle for re-certification would be determined separately for each applicant, and could often differ among applicants in a given year. Lack of progress towards registration would generally not cause denials during the first 3 years of exemptions for a chemical-crop combination. However, since some applicants may apply for the first time, in a year subsequent to the first request for a chemical-crop combination by another applicant, lack of progress towards registration could potentially interrupt the eligibility cycle for some applicants.

EPA is sensitive to emergency exemption requests being repeated for a number of years and requires that steps be taken to obtain a registration for the emergency use. Under this pilot for re-certifiable emergencies, EPA will not allow re-certification of emergencies for exemptions that have been granted for more than 3 years.

iii. *Why pilot this potential improvement?* Allowing applicants to re-certify the existence of an ongoing emergency condition for certain eligible exemption requests is expected to reduce the burden to both applicants and EPA as well as allow for quicker decisions. When an applicant certifies the continuation of the emergency condition and incorporates previously submitted materials by reference, a complete new application sufficient to characterize the situation in accordance with 40 CFR 166.20 will not be required. This will save applicants time and effort in gathering data and preparing their submissions. The Agency will save time and resources by not having to annually repeat the analyses that support the applicable requests. If no pesticides which can avert the emergency have been newly registered, and nothing has changed to affect the assessment of risk, then re-certification of an emergency will lead to significantly shorter Agency review, saving valuable time for those affected by the emergency.

EPA's experience indicates that emergency situations which continue after the initial year generally cause comparable losses in succeeding years. Therefore, with the certification of a