

registration or seek a new registration to address that future need.

IV. Background and Summary of Stakeholder Feedback

A. 1996 Section 18 Workshop to Streamline Emergency Exemption Process

In 1995, as part of an effort to streamline regulations, the Agency began a process to evaluate the emergency exemption regulations at 40 CFR part 166, and to formulate recommended changes to the operating procedures. As part of that effort, in November 1996, the Agency hosted a Section 18 Stakeholders Workshop to discuss possible regulatory changes to the Agency's section 18 process and receive stakeholder input. Participants of that meeting included representatives from State agencies responsible for pesticide oversight, chemical companies, and environmental and public interest groups. Participants voiced their concerns and identified suggestions for improving the emergency exemption process.

Although EPA scheduled the section 18 workshop prior to passage of the FQPA, in August 1996, the workshop was held shortly after the law was enacted. Because FQPA included new requirements affecting emergency exemptions, and was just 3 months old at the time of the workshop, the new law was of great interest to participants. Stakeholders at the workshop were deeply concerned that the new requirements of FQPA would hurt both the Agency's review time and approval rate for exemption requests, as well as increase the burden on applicants (primarily States) for information and documentation. Several of the recommendations raised in the workshop addressed these three concerns.

B. NASDA/AAPCO Initial Recommendations to EPA for Improvements

Subsequent to the November 1996 Section 18 Stakeholders Workshop, the National Association of State Departments of Agriculture (NASDA) and the Association of American Pest Control Officials (AAPCO) jointly sent a letter to EPA to provide recommendations for changes to the emergency exemption process. The letter referred to recommendations contained in a series of NASDA Proposed Resolutions. A copy of that letter and the Proposed Resolutions are available in the public docket for this Notice. The NASDA/AAPCO recommendations, which generally

summarized issues raised at the workshop, were:

1. Seek changes to current regulations which will allow EPA the flexibility to base decisions on crop yield as opposed to crop value (or profit loss) in situations where that is a better indicator of pest damage.

2. Provide States general guidance regarding the appropriate documentation of an "urgent, non-routine situation" and allow States to certify that the "urgent, non-routine situation" exists based on the guidance.

3. Implement a performance audit program to ensure compliance with the guidance and give States justification to resist pressure to certify an "urgent, non-routine situation" when it does not exist.

4. Delegate to the States authority to reissue the section 18 exemption for a second or third year, based on the State's confirmation/certification that the basis for an emergency continues to exist.

5. Actively support and coordinate regional section 18 requests.

6. Enter into discussions with the States to establish reasonable monitoring criteria and approaches for wildlife and endangered species.

7. Support specific exemptions for resistance management where there is documented scientific evidence of resistance to currently registered pesticides or where valid research demonstrates that a dynamic process of resistance is developing.

8. Amend 40 CFR 166.2 to include "reduced risk" as an acceptable basis for granting a section 18 exemption. The definition of "reduced risk," and the requirements for this request should allow States the ability to request a section 18 to allow for a pesticide use that will result in a lower potential for an adverse impact on human health or any other non-target species, including but not limited to, pest predators, pollinators, endangered species, and other organisms of special concern. Requests should be limited to only those situations where the "reduced risk" request will not result in additional risk to any aspect of the environment. Such requests should only be permitted where the proposed use is highly effective so that the potential for an increase in pesticide applications is extremely low.

The NASDA Proposed Resolutions also included recommendations concerning the establishment of time-limited tolerances for residues in food of pesticides used under emergency exemptions. Tolerances for pesticide uses under section 18 have already been addressed separately by EPA, as FQPA

required that the Agency publish a regulation to put in place a process for that purpose. Therefore, the NASDA/AAPCO recommendations concerning tolerances are not included in this discussion.

C. The Food Quality Protection Act and Evolution of the Emergency Exemption Program

FQPA included new requirements affecting emergency exemptions, as stated above. FQPA set a new safety standard, and, for the first time required time-limited tolerances for pesticide residues in food resulting from pesticide use under emergency exemptions. As a result of FQPA, each emergency exemption request must be evaluated based on the potential risk to human health and the environment, including the aggregate risk to the public from ingestion of treated food, pesticide residues in drinking water, and exposure to the pesticide in and around the home and other non-occupational settings.

Processing time for emergency exemption requests (days from receipt of request to decision) increased significantly in 1997, the first year after FQPA, as EPA developed methodology to implement section 18 under the new law. Due to the urgent nature of emergency exemption requests, the Agency worked very hard to streamline the process. Average processing time decreased to pre-FQPA rates in 1998, and has decreased each year since then. The average processing time for exemption requests reached an all-time low of 44 days in 2000, for the first time surpassing the Agency's goal of 50 days, and decreased again to 34 days in 2001.

The approval rate for exemption requests is similar to pre-FQPA levels. The number of exemption requests has increased sharply since 1996, as have the number of exemptions granted. EPA believes the burden on applicants to request any individual emergency exemption has not increased since the recommendations were made, and in some cases it has decreased. The Agency has worked hard to be flexible with applicants, to make full use of existing data, and to minimize documentation requirements where appropriate, with particular attention to issues raised in the NASDA/AAPCO recommendations. Although FQPA did not appreciably increase applicant burden in preparing any specific emergency exemption request, the Agency is always interested in improving and streamlining its processes.