Section 24(c) of FIFRA – Special Local Need Label

“State”-granted registration of a new end use pesticide (or added use to a currently registered product) for an existing or pending pest problem.

States are required to file the 24(c) with the U.S. Environmental Agency (EPA) who oversees the program. EPA has 90 days to deny, during which time the use may occur. Should EPA deny, distribution of the 24(c) and new use must stop immediately.

The following conditions apply:

- A federally registered pesticide a) is not available in the state for the desired site(s) to adequately control the target pest(s), or b) cannot be applied without causing unacceptable risks to human health or the environment, or c) is necessary to maintain resistance management, or d) could be replaced by a formulation that poses less risk to man or the environment.

- A new use pattern is required that is a) not similar to any registered use of the same or similar product. Examples: new method/timing of application; new crop/site/rate.

- Specific new use of a product needed (other uses may be federally or state suspended).

Process:

1. Request for a Special Local Need label is sent to the registrant typically from growers and academia (i.e. university extension agents).

2. If the registrant is willing to support the request, the following will be provided to state pesticide registration agency: established tolerance for the proposed use (if applicable); draft SLN label and registrant’s letter of support. Assurance that product will be available to the growers for term of emergency is required.

3. In addition to the above, many states will require product performance data (efficacy and plant tolerance) and a letter of support from local researchers and/or grower groups. The state must confirm that no unreasonable adverse effects on humans or the environment may result from proposed use.

4. Once the state agency approves the label, they assign it a unique SLN registration number and inform the registrant of approval. Expiration dates vary across the states (1-5 years).

5. States are required to file the 24(c) with (EPA) who oversees the program. EPA has 90 days to deny during which time the use may occur. Should EPA deny, distribution of the 24(c) and the new use must stop immediately.

For additional guidance on any of the above, check with the regulatory team. Federal and state policy is always subject to regulation changes.
Section 18 of FIFRA – Emergency Exemptions

Approved “federal” registration of a pesticide for a limited time for “emergency,” crisis, or non-routine situation exists. These may be requested either by state or federal agencies (i.e., USDA, USDI), but must be approved by EPA.

The following conditions apply:
- When there are no alternatives to control a pest problem which impact production of agricultural goods.
- The pesticide is federally registered (exceptions can be granted for crisis exemptions as defined below).
- Uses are requested for a limited time only (typically 1 year), but EPA may renew if the emergency continues.

Process
1. Request for a Section 18 is sent to the registrant directly from the state pesticide regulatory agency following awareness of a growing pest threat to a state commodity.
2. If the registrant is willing to support the request, the following will be provided to the state pesticide registration agency: established tolerance for the proposed use (if applicable); draft Section 18 label, efficacy data (where required) and registrant’s letter of support. Assurance that product will be available to the growers for term of emergency is required.
3. The state agency will submit their application to EPA which includes nature and scope of emergency (i.e. economic loss to state growers, potential adverse effects to man or the environment and 5 year crop history of crop production costs vs yields).
4. If the state need is determined to be immediate, the state has authority to declare a Crisis Exemption which allows the “unregistered use” for a consecutive 15 days.
5. The state must notify EPA of declaration of a Crisis Exemption. EPA may allow extending days under the declared Crisis Exemption until they can make their decision for the Section 18.

For additional guidance on any of the above, check with the regulatory team. Federal and state policy is always subject to regulation changes.
Section 2(ee) of FIFRA – Product Bulletin Recommendations

Company (registrant) recommendation beyond the use direction or label claims on a pesticide label. A product bulletin is neither “labeling” nor “supplemental labeling” and must not be attached to the product container, or accompany the product at any time. FIFRA section 2(ee) bulletins may be distributed by extension personnel, industry representatives, at the point of sale, displayed (i.e., trade shows) with the product, or downloaded off the Internet, provided the bulletin is factually correct and conforms to the restrictions of section 2 (ee).

The following disclaimer must appear on all FIFRA Section 2(ee) literature: “This recommendation is made as permitted under FIFRA Section 2(ee) and has not been submitted to or approved by the EPA”.

**Because these are not enforceable, registrant assumes all liability for the recommended use.

The following conditions apply:

- Use at any dosage, concentration, or frequency less than specified on the labeling, unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency.
- Use against any target pest not specified on the labeling to a target crop already on the registered container label (unless EPA has required that the pesticide may only be used on specific pests or has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment).
- Methods of application not prohibited on the Section 3 label (or the labeling specifically states that the product may be applied only by the methods specified on the label).
- Mixtures with fertilizer or another pesticide not prohibited on the Section 3 label.

FIFRA Section 2(ee) Recommendations must not:

- Add a crop/site or expand an existing crop/site
- Increase the dosage, concentration or frequency of application
- Decrease pre-harvest interval or interval between applications
- Alter the timing of applications
- Add chemigation

For additional guidance on any of the above, check with the regulatory team. Federal and state policy is always subject to regulation changes.