



# agriculture, forestry & fisheries

Department:  
Agriculture, forestry & fisheries  
**REPUBLIC OF SOUTH AFRICA**

## **EMERGENCY REGISTRATION PROTOCOL FOR AGRICULTURAL REMEDIES**

**Issued by the Registrar: Act No. 36 of 1947, Private Bag  
X343, Pretoria 0001, Republic of South Africa**

**Tel: +27 12 319 7000 / Fax: +27 12 319 7179**

**JULY 2018**

## DEFINITION OF TERMS

For the purpose of this document the following terms should be considered to mean: -

The Act	- The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).
Biologically similar	- A crop species within the same botanical genus or the same botanical family.
Crop protection industry	- The industry that imports, manufactures, supplies and distributes crop protection products and environmental health products (agricultural remedies).
Critical pest species	- Any indigenous or exotic living organism (plant, pathogen, micro-organism, macro-organism, vertebrate or invertebrate) that poses a high-risk threat to crop production or environmental health with devastating effects.
DAFF	- Department of Agriculture Forestry and Fisheries
Devastating	- A situation of near or total crop loss or market loss or disastrous human disease outbreak.
DoH	- Department of Health.
Emergency registration	- The registration of an agricultural remedy under the Act for a purpose that demands immediate action to protect a crop or environmental health situation from unforeseen, disastrous conditions emanating from an invasion or attack of any invasive or critical pest species. The registration could also be made if there are serious market trading issues that require protection of the South African exports necessitated by the importing countries requirement that may create a gap concerning agricultural remedies usage.
GAP	- Good Agricultural Practice.
Government agency	- An organ of state that is responsible for plant health or public health with a constitutional mandate to manage or protect such entities.
Grower association	- A group of crop producers that organized themselves as an association to promote the interest of said group in the agriculture and public arenas.
Invasive pest species	- Any exotic living organism (plant, pathogen, micro-organism, macro-organism, vertebrate or invertebrate) that is foreign to the South African biodiversity and has spread or has the potential to spread rapidly into a wide area of the country and poses a devastating threat to crop production or public health, or an indigenous living

organism (plant, pathogen, micro-organism, macro-organism, vertebrate or invertebrate) that rapidly becomes a potentially devastating pest to crop production or animal health.

- Key crop
  - A crop that is grown in South Africa that is supplying staple food or fiber, or is an important export crop.
- Niche crop
  - A crop that is grown in South Africa that is not paramount to the food security of the nation but fulfils a niche in the market and maintains livelihoods of many citizens.
- Phenotypical identification
  - Identification based on the visual appearance of the specimen.
- Public health
  - Any human health situation that may arise due to diseases carried or transmitted by disease vectors.
- Registrar
  - The Registrar of the Act.
- Registration holder
  - A natural or legal person as defined in Section 1 and regulated in Section 2 (a and b) of the general regulations for agricultural remedies published as Regulation No. R935 on 22 September 2006 or any amendment of said regulation thereafter, that holds registration(s) for agricultural remedies in South Africa under Act No. 36 of 1947.

## **Introduction**

Priority will only be given to applications which are of national importance and in cases where there are no existing registrations available. Registrations will be restricted to active ingredients or substances or new formulations containing active ingredients already approved or biological products already approved in South Africa for other purposes other than the emergency situation. Requests for the priority treatment of such applications have to be well motivated and enjoy the support of recognized organizations, such as., National Government Departments, Croplife SA, SABO, SANSOR, the Agricultural Research Council, grower organizations, provincial departments of agriculture, and local conservation bodies etc. If there are data gaps (efficacy and residues), the registration may be granted conditionally, provided the outstanding data is submitted within a reasonable time determined by the Registrar. The data requirements for any category of application made will be those already prescribed as per the guidelines published by the office of the Registrar. For any emergency registration request, any available local residues or monitoring data on a crop/commodity affected or any crop within a Codex Crop Grouping must be submitted. If there is no local residues/efficacy data available, any international residues data generated in climatic zones similar to the South African climatic conditions will be accepted provided the GAP and the formulation used is to that already approved in South Africa. If there is a Codex MRL standard published in the absence of a South African MRL, the Codex MRL or any other MRL set in a jurisdiction where the pest occurs should provisionally be proposed by the applicant for DAFF to then forward such proposals for the DoH consideration until such time it is subjected to a review when local residues data becomes available. For efficacy, the data extrapolation principle will be used in the absence of any local data on the new pest/disease or weed.

NB: The emergency registration call will remain open for a period of twelve months and thereafter all applications submitted after a year will be treated as normal applications if there products approved already within such a period. If there are no products registered, then the Registrar will make a second call.

## PROTOCOL

### 1. Classification of emergency situations.

Pest or disease situations that warrant emergency registration of agricultural remedies:

- a. An invasive pest or disease species:
  - i. is imminently threatening a key crop or public health for the first time ever in South Africa where it is expected to have a devastating effect if it invades such crop or establishes itself in public health; or
  - ii. rapidly invaded a key crop or public health for the first time ever in South Africa; or
  - iii. is imminently threatening a niche crop for the first time ever in in South Africa in which crop it is expected to have a devastating effect it if invades such crop; or
  - iv. rapidly invaded a niche crop for the first time ever in South Africa; and
    1. for which no agricultural remedy is registered at the time of the imminent threat or the invasion of the invasive species for the management thereof; or
    2. for which agricultural remedies are registered that fail to effectively control the pest species according to the original registration application efficacy data; and failure to control the pest species must have been verified by at least two independent agriculture research scientists.
  
- b. A critical pest or disease species:
  - i. is imminently threatening a key crop or public health for the first time ever in South Africa where it is expected to have a devastating effect if it invades such crop or establishes itself in public health; or
  - ii. rapidly invaded a key crop or public health for the first time ever in South Africa; or
  - iii. is imminently threatening a niche crop for the first time ever in in South Africa in which crop it is expected to have a devastating effect it if invades such crop; or
  - iv. rapidly invaded a niche crop for the first time ever in South Africa; and
    1. for which no agricultural remedy is registered at the time of the imminent threat or the invasion of the critical pest in the crop or public health for the management thereof; or
    2. for which agricultural remedies are registered that fail to effectively control the pest species according to the original registration application efficacy data; and failure to control the pest species must have been verified by at least two independent agriculture research scientists (for crop pests) or two independent public health research scientists (for public heath pests).
  
- c. Environmental conditions:
  - i. environmental conditions that would make the crop more susceptible to pest/diseases or also resulting in phenological events which may require a plant growth regulator.
  - ii. become conducive to a high risk of premature bud formation, premature petal drop, premature fruit set, premature fruit fall, premature fruit/crop ripening or any other unusual fruit/crop damage; or

- iii. may result in pest or disease invasion following conditions described above; and
  - 1. for which no agricultural remedy is registered at the time of such conditions to manage the results of such conditions and resultant pest or disease invasion; or
  - 2. for which agricultural remedies are registered that fail to effectively control the pest species according to the original registration application efficacy data; and failure to control the pest species must have been verified by at least two independent agriculture research scientists.

## **2. Motivation for emergency registration.**

Demonstration of need for emergency registration of agricultural remedies.

- a. Growers associations and/or government agencies must demonstrate that the invasive or critical pest species is imminently threatening or has invaded a crop or crops or public health situation by or the environmental conditions have affected the crop.
  - i. offering scientifically validated pest species identification by means of consulting species experts for phenotypical identification, or genotyping, or breeding/cultivation in controlled environments to assist with phenotypical identification;
  - ii. the nature of the threat i.e. situations as described in paragraphs 1 a – c above;
  - iii. the potential crop losses in tonnage or financial terms, or serious threat to food security or health risk to the public if the pest remains unchallenged or uncontrolled.
  - iv. trading partners new regulatory requirements in the form of World Trade Organization (WTO) Notifications or through published regulations etc.

## **3. Notification of emergency situation.**

- a. A notification of an emergency situation must be prepared and submitted to the Registrar who will then share with CropLife SA and SA Biological Products Association by the -
  - i. grower association in the case of pest invasion in crop production; or
  - ii. government agency in the case of public health pest invasion.
- b. The notification shall be verified by the Registrar in consultation with other government departments and agencies and CropLife SA and SA Biological Products Association. Once verified it shall be published on the DAFF website and CropLife SA website and SA Biological Products Association website to inform registration holders of the need to participate in identifying and applying for emergency registration for agricultural remedies to manage the pest species.

#### 4. Identification of agricultural remedies.

Identification of candidate agricultural remedies for the management of the pest.

- a. **Crop pests.** Grower associations and/or government agencies must engage registration holders of agricultural remedies and collectively identify those agricultural remedies that are potential candidates for emergency registration to manage the pest/disease, based on –
  - i. their South African registrations on the pest in other biologically similar crops (if it is a critical local pest); or
  - ii. their South African registrations on the pest in other crops (if the pest is a critical local pest and if biologically similar crops have not yet been affected); or
  - iii. their South African registrations for biologically similar pests on the crop(s) (if it is a local critical pest or an invasive pest species);
  - iv. their South African registrations on biologically similar pests in biologically similar crops (if it is an invasive species that is related to other local pests that are found on biologically similar crops); or
  - v. their South African registrations on the crop(s) with projected evidence (extrapolated from scientifically verified efficacy data from other countries) that it should be effective against the pest/disease (if no biologically similar local critical pest/disease exists); or
  - vi. their registrations on the pest in the same or similar crops in other countries with autonomous regulatory systems and with a South African registration of some or other manner; and
  - vii. its acceptability as an agricultural remedy that will meet the residue requirements for the crop for local consumption and for export purposes if the crop is destined for export.
  
- b. **Public health pests.** Government agencies through the office of the Registrar must engage registration holders of agricultural remedies and collectively select those agricultural remedies that are potential candidates for emergency registration to manage the pest based on –
  - i. their South African registrations for biologically similar pests; or
  - ii. their registrations in other countries with sound regulatory systems for the pest and its local registration for any other pest in public health or crop protection.

**Note that an application for emergency registration will only be accepted for the crop and associated pest as identified in paragraph 2. Such application will not be extended or extrapolated to include other crops for which registered agricultural remedies exist for the identified pest species.**

#### 5. Application for emergency registration.

- a. The registration holder of a candidate agricultural remedy must apply for emergency registration to the Registrar, with the following documentation:
  - i. completed application forms with proof of payment for emergency registration application as per the Government Gazette regulation for registration fees; plus
  - ii. preliminary supporting data i.e. efficacy/residues

- iii. label with the appropriate amendments to accommodate the emergency registration;
- iv. letter from the grower association or government agency in support of the application; plus
- v. proof of registration details for from any foreign country where such a product may already be registered for the purposes as detailed in paragraph 3 a vi if such registration exists; plus
- vi. demonstration for the need for emergency registration application as detailed in paragraph 2; plus
- vii. a written undertaking by the grower/ manufactures/ distributors/ manufacture's associations and/or government agency advising producers/farmers to only use the product once registered as per the emergency registration (in which case should be a label extension) and to manage residues on crops; plus
- viii. a framework drafted by the registration holder for field trials as may be specified by the Registrar to support a full registration of the agricultural remedy with appropriate efficacy data. Such field trial data must be submitted to the Registrar within three years after registration.

#### **6. Granting conditional emergency registration.**

The Registrar will grant emergency registration as per an applicant's application if he is satisfied that the applicant meets all the requirements and may impose certain conditions namely that –

- a. the applicant shall submit acceptable trial data within three years to prove that the agricultural remedy performed as claimed or as expected; and
- b. the applicant shall submit data to demonstrate that the agricultural remedy does not exceed the South African maximum residue limits for the active ingredient(s) as stipulated in the government gazette regulations for residues on edible crops; and
- c. the applicant shall submit a statement that the use of the agricultural remedy has not resulted in undue risk human health and the environment;
  - i. should the applicant become aware of exceedance of maximum residue limits or undue risk to human health and the environment, the applicant shall immediately inform the Registrar in writing of such situations upon which the Registrar will institute appropriate remedial action;
- d. the applicant shall submit an interim progress report or monitoring data on such trials and generated data after twelve months.

#### **Important notes.**

1. No emergency registration applications will be accepted for active ingredients, biological agents or combinations of active ingredients that are not yet registered in South Africa.
2. No emergency registration applications will be accepted for existing pests for which agricultural remedies are registered in existing crops or public health situations with proven efficacy.
3. No emergency registration applications will be accepted for minor crops in which pests are not considered to be devastating.



## EMERGENCY REGISTRATION FLOW DIAGRAM

