## General Information

A. All agricultural pesticide[1] products used in the cultivation of plants intended for sale must be registered with the Singapore Food Agency (SFA). These include pesticide-containing biostimulant/fertilizer/soil conditioner. Pesticide products for other purposes, including export, and industrial, public hygiene, landscaping and household uses, do not require registration with SFA. Pesticides used for the formulation of pesticide products also do not require registration with SFA.

B. Any person who manufactures, imports, distributes, supplies or sells any pesticide products and who is conducting business in Singapore which is registered under the Business Names Registration Act 2014, or any company incorporated under the Companies Act, may apply for the registration of pesticide products for use in the agricultural farms in Singapore.

C. Before applying for registration of a pesticide product with SFA, applicants are required to check whether the import of the pesticide for local use is allowed by the following agencies:

   i) Pollution Control Department (PCD) of the National Environment Agency (NEA) for import, export and sale of chemical pesticides that are listed as hazardous substances

   ii) Plant Health Services of the National Parks Board (NParks) for import of biological pesticides

D. If applicants are dealing with pesticides that are listed in the Environmental Protection and Management Act (EPMA), a copy of the Hazardous Substances Licence issued by the PCD/NEA must accompany the application.

E. Applicants are required to complete an application form that is available on SFA website: http://www.sfa.gov.sg/. Each application form is for the registration of one pesticide product only. Separate forms should be submitted for each additional application.

F. A softcopy registration dossier including a duly signed application form has to be submitted in a CD to the Food Regulatory Management, SFA at 52 Jurong Gateway Road, #14-01, Singapore 608550. The application is valid for one year upon receipt of the application.

G. Applicants are required to ensure that their dossier is complete before submission to ensure that the dossier has all the data requirements mentioned in this guideline. Incomplete submissions will not be considered.

### Payment for registration fee

H. The registration fee is $465 per product (non-refundable). Applicants can make payment via AXS, GIRO or electronically via the SFA website once the application has been received and an invoice has been sent to the registered company address. Please visit the SFA website for more information on the modes of payment.

[1] A pesticide is defined under the Control of Plants Act as any substance or mixture of substances prepared or used for preventing, destroying, repelling or mitigating any pest and any substance or mixture of substances prepared or used as a plant regulator, defoliant or dessicant.

**Dossier requirements**

I. Applicants must provide the following information in the registration dossier: -

1) A copy of the applicant's NRIC/Passport (for new applicants only)

2) A copy of an up-to-date "Instant Information (Business Profile)" printout from the Registry of Company and Business (not required if same as previous application)

3) A copy of the Hazardous Substances Licence (if applicable)

4) A proposed dual language pesticide product label containing the following information: -

a) the trade name or the brand name under which the pesticide product is to be sold or supplied

b) the composition of the pesticide product and the chemical name of every constituent, whether active or inert; include name/identity of hazardous co-formulants that contribute to the classification of the formulated product if any.

c) the type of formulation of the pesticide product

d) the type of crop in the cultivation of which the pesticide product may be used or applied

e) the directions for the use of the pesticide product together with the safety measures to be taken when applying the product and resistance management measures

f) the re-entry periods into the area after spraying

g) in the case of a pesticide product to be used on food crops, the recommended interval before the last application of the pesticide product and the harvest of the crop

h) the relevant hazard and caution statements and graphic symbols recommended by the WHO/FAO Hazard Classification Code

i) the antidote to the pesticide product, if any, and first aid instructions in case of poisoning by the pesticide

j) the storage conditions of pesticide product

k) the disposal method for the formulation and its containers

l) the net weight and volume of the pesticide product in the container in which it is sold or supplied

m) the name and address of the Singapore company that has registered the pesticide product with SFA.

Applicant has to ensure that the information provided on the label of a pesticide product including use advice is accurate and reliable.

5) Data/Information (in English language) to be included in the dossier:

- For **Chemical/ Biochemical** pesticides and biostimulant/fertilizer/soil conditioner that contains these pesticides- refer to Annex 1
- For **Microbial** pesticides and biostimulant/fertilizer/soil conditioner that contains these pesticides- refer to Annex 2

*Additional information pertaining to Annexes 1 and 2:*

- It is the applicant's responsibility to ensure product's efficacy and to present adequate and accurate information to support product's uses on the label including the rates, frequencies of use and application equipment stated on the label.

- For efficacy information, applicant can choose to submit any published information, overseas data assessments or valid scientific arguments in lieu of efficacy field trial.

- Submission of efficacy trial report is no longer mandatory. However, applicant would still need to assure themselves through testing that their products are efficacious. SFA reserves the right to ask for efficacy field trial reports on a case-by-case basis.

- Efficacy trial report if submitted, should be in English language and conducted in accordance to the principles of good experimental practice and international standards. Efficacy trials should be conducted on crops that are grown locally and under similar tropical climatic conditions. Efficacy trial reports should include raw data and statistical results as well as information such as spraying volume and rates.

- For acute oral and dermal toxicities, toxicity tests should be carried out for formulated products intended for registration. If the tests are carried out on the active ingredients in the formulation, calculations according to the "WHO Recommended Classification of Pesticides by Hazard" should be shown in the submission.

- Experimental tests carried out to support the registration of a pesticide product must be done in ISO/GLP accredited laboratories or institutions, and in accordance to the principles of good experimental practice and international standards.

- Published reports or data must be properly referenced and submitted together with the dossier.

J. When a complete dossier is received, the dossier will be sent to a technical committee for evaluation. SFA reserves the right to ask for additional information for areas that need further evaluation.

K. Applicant may be asked to submit the following samples:
   - 0.25 g of **analytical standard active ingredient** together with the COA and MSDS; and/or 2 ml of the **formulated product**

L. Applicant is required to ensure that the pesticide products conform to relevant FAO or WHO specifications.

**Upon approval**

M. Once a pesticide product is approved, a Certificate of Pesticide Registration with the registration number will be issued to the registrant. The registration takes effect from the date stated in the certificate.

N. The registrant is required to comply with the labeling requirements listed in para I(4) and print the registration number on the pesticide product's label. Any non-compliance under rule 10(1) of the Control of Plants (registration of Pesticides) Rules may result in cancellation of a registration.

O. It is the responsibility of the registrant to ensure the safety, efficacy and quality of the product.

P. SFA reserves the right to cancel the registration if the product is no longer commercially available to the agricultural farms.

## Annex 1: Data Requirements for Chemical/Biochemical[2] Pesticides

| | | Data Requirements |
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| **1.** | **Information on the active ingredient(s)**<br>- Chemical name<br>- Common name<br>- Other name (if any)<br>- Empirical and structural formula<br>- Molecular weight<br>- Physical properties<br>• melting point<br>• boiling point<br>• specific gravity<br>• refractive index<br>• vapour pressure (mmHg at 20 $^{o}$C)<br>• other volatility data<br>• solubility of active ingredient(s) and technical product in water<br>• solubility of active ingredient(s) and technical product in other solvents<br>• partition coefficient between water and an immiscible organic solvent<br>- Chemical properties<br>• stability (in air, in water, photo-stability, thermal degradation, stability in organic solvent used in the formulation) and the breakdown product<br>• corrosiveness<br>• flammability and flash point | * |
| **2.** | **Information on the technical grade active ingredient(s) (TGAI) added to product**<br>- Source; name and address of manufacturer<br>- Appearance (physical state, colour and odour)<br>- The minimum (and maximum) active ingredient content in g/kg<br>- Complete manufacturing process, including all raw materials, reagents and solvents<br>- Known contaminant(s) or impurity(ies) associated with the active ingredient(s) in the manufacturing process Identity and amount of isomers, impurities and other by-products, together with<br>- information on their possible range expressed as g/kg<br>- Maximum limits for impurities present in the technical material at 1g/kg or greater<br>- Up-to-date method of analysis of active ingredient(s)/ technical material<br>- A copy of analytical report showing the test results of at least two batches/lots of the technical product obtained by using the methods and procedures as described above<br>- | √ |
| **3.** | **Information on the formulated product**<br>- Manufacturer's name and address<br>- A copy of the manufacturing certificate<br>- Complete composition including chemical identities of inert ingredients<br>- Physical condition and nature of the formulation<br>- Stability and shelf life of the formulation<br>- Corrosiveness towards packing materials and application equipment<br>- Flammability under storage and application conditions<br>- Up-to-date method of analysis of the formulation<br>- A copy of analytical report showing the test results of at least two batches/lots of the formulated product obtained by using the methods and procedures as described above<br>- Incompatibility with other pesticides | √ |

[2] A biochemical pesticide is a pesticide that is a naturally-occurring substance or structurally-similar and functionally identical to a naturally-occurring substance. Examples include, but are not limited to: Semiochemicals (insect pheromones and kairomones), natural plant and insect regulators, naturally-occurring repellents and attractants and enzymes.

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| | - Decontamination/ neutralising agent; Disposal method for the formulation and its containers<br>- Known contaminant(s) or impurity(ies) associated with the active ingredient(s) in the formulation | |
| **4.** | **Information on the usage**<br>- The control efficacy of the pesticide, including its designated use against the target pest(s) and disease(s) in relation to crops<br>- Instruction for use, recommended dosage and application method<br>- Mode of action<br>- Phyto-toxicity on plants<br>- Compatibility with other pesticides<br>- Precautionary measures<br>- For pesticide used on food crops<br>• pre-harvest interval<br>• maximum residue level and acceptable daily intake in other countries where the same pesticide has been registered should be included | √ |
| **5.** | **Residue trial report** on agricultural produce and up-to-date method of analysis of residue in crops. | * |
| **6.** | **Information on the toxicity in mammals**<br>- Acute oral ($LD_{50}$) of the product<br>- Acute dermal ($LD_{50}$) of the product | √ |
| | - Inhalation toxicity ($LC_{50}$)<br>- Degree of irritation to eye<br>- Degree of skin irritation and sensitization<br>- Chronic toxicity of active ingredient<br>- No observable effect level of active ingredient<br>- Supplementary studies of toxicity (long/short term studies) of active ingredient(s)<br>• Carcinogenicity<br>• Reproductive toxicity including teratogenicity<br>• Mutagenicity<br>• Neurotoxicity<br>- Persistence and metabolic breakdown pathway of the active ingredient<br>- Endocrine disrupting properties that may be of toxicological significance in humans | * |
| **7.** | **Information on environmental effects and ecotoxicity**<br>- Toxicity to beneficial insects, non-target pests, avian and fish<br>- Endocrine disrupting properties that may be of toxicological significance on non-target organisms<br>- Impact on soil ecology; Residual effect in soil<br>- Leaching, degradation of product in the soil and possibility of accumulation | * |
| **8.** | **Information on measures to be taken in case of poisoning**<br>- Antidote(s) for the active ingredient/formulation; First aid treatment for active ingredient/formulation | √ |
| **9.** | Other technical literature, data, and supporting documents related to the pesticide product. | √ |
| **10.** | Registration status in other countries (Copies of registration documents should be attached) | √ |
| **11.** | Approval from relevant local and overseas authorities for manufacture, import, distribution, sale, supply, transport, storage and usage of the pesticide product (if any) | √ |

Notes
[√] 1st tier: Required information
[*] 2nd tier: Required on a case-by-case basis

## Annex 2: Data Requirements for Microbial Pesticides

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| 1. | **Information on the active substances(s)**<br>- Common name<br>- Taxanomic name and strain<br>- Biological properties of the organism<br>• History of the organism and its uses<br>• Effects on target organism. Pathogenicity or kind of antagonism to the host. Details of host specificity range should be included<br>• Pathogenicity and infectivity for known parasites/predators of the target species<br>• Transmissibility, infective dose and mode of action including information on presence, absence or production of toxins with, if appropriate, information on their nature, identity, chemical structure and stability and potency |
| 2. | **Information on the technical grade active ingredient(s) added to product**<br>- Source, name and address of manufacturer<br>- Composition of the final active organism material i.e. nature, purity, identity, properties, content of any impurities and extraneous organisms<br>- Complete manufacturing process<br>- Methods, procedures and criteria used to establish the presence and identity of the organism (eg. morphology, biochemistry, serology, etc)<br>- A copy of analytical report showing the test results of at least two batches/lots of the technical product obtained by using the methods and procedures as described above<br>[Required on a case-by-case basis for biostimulant/fertilizer/soil conditioner that contains microbial pesticide.] |
| 3. | **Information on the formulated product**<br>- Manufacturer's name and address<br>- Detailed composition (active organism, inert ingredients, extraneous organisms, etc)<br>- Known contaminant(s) or impurity(ies) associated with the active ingredient(s)/organism in the formulation<br>- A copy of the manufacturing certificate<br>- Analytical methods and procedures for quantifying the amount of active ingredient(s), contaminant(s) and impurities present in the formulated product<br>- A copy of analytical report showing the test results of at least two batches/lots of the formulated product obtained by using the methods and procedures as described above<br>- Physical condition and nature of the formulation<br>- Stability and shelf life of the formulation<br>- Incompatibility with other pesticides<br>- Any circumstances or environmental conditions under which the active organism should not be used<br>- Disposal method for the formulation and its containers<br>- Possibility of destruction or decontamination following release in or into the following: air, water, soil, others if appropriate. |

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| 4. | **Information on the usage**<br>- The control efficacy of the pesticide, its designated use against the target pest(s) and disease(s) in relation to crops<br>- Instruction for use, recommended dosage and application method<br>- Compatibility with other pesticides<br>- Precautionary measures<br>- For pesticide used on food crops: pre-harvest interval |
| 5. | **Information on the toxicity in mammals**<br>- Acute oral ($LD_{50}$) of the product<br>- Acute dermal ($LD_{50}$) of the product<br>- Inhalation toxicity ($LC_{50}$)<br>- Degree of irritation to eye, skin and sensitization<br>- Any allergic reactions to human/mammals<br>- Any pathogenicity and infectivity to man and animals under conditions of immunosuppression<br>- Any genotoxic potential especially for fungi and actinomycetes |
| 6. | **Information on measures to be taken in case of poisoning**<br>- Antidote(s) for the active ingredient/formulation<br>- First aid treatment for active ingredient/formulation |
| 7. | Registration status in other countries (Copies of registration documents should be attached) |
| 8. | Other technical literature, data, and supporting documents related to the pesticide product |

**All information attached with the application will be treated in strictest confidence.**

[Updated in Oct 2020]