



**PESTICIDES (FEES) REGULATIONS 1997**

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MICHAEL HARDIE BOYS, Governor-General

ORDER IN COUNCIL

At Wellington this 15th day of December 1997

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to section 76 of the Pesticides Act 1979, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, makes the following regulations.

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REGULATIONS

**1. Title and commencement**—(1) These regulations may be cited as the Pesticides (Fees) Regulations 1997.

(2) These regulations come into force on 15 January 1998.

**2. Fees**—(1) The fees set out in the Schedule are payable in respect of the matters to which they relate.

(2) The fees prescribed by these regulations are inclusive of goods and services tax.

**3. Revocations**—The Pesticides (Fees) Regulations 1993\* and the Pesticides (Fees) Regulations 1993, Amendment No. 1† are consequentially revoked.

\*S.R. 1993/172  
†S.R. 1993/102

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## SCHEDULE

Reg. 2

## FEES PAYABLE UNDER PESTICIDES ACT 1979

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1. On application under section 21 for authority to import pesticides for use by their proprietors, for each importation of each pesticide—	
(a) Where the application is made by a single proprietor ... ..	55.00
(b) Where the application is made by 2 or more proprietors (payable in such proportions as the proprietors decide)	60.00
2. On application under section 22 for registration of a pesticide (other than an application in respect of a pesticide for which an experimental use permit referred to in clause 5 (b) is in force)—	
Pre-screening cost ... ..	364.50
Plus administration cost ... ..	1,685.81
Plus manufacturing assessment ... ..	136.69
Plus toxicology evaluation—	
(a) For an application for a pesticide with an active ingredient that is new to pesticides or to pesticides of that type	3,280.50
(b) For an application for a pesticide with no active ingredient that is new to pesticides or to pesticides of that type, but which requires more than the basic evaluation referred to in paragraph (c)	911.25
(c) For an application which involves only minimal public or environmental exposure, which requires no assessment of data, and which requires only a basic toxicology evaluation ... ..	546.75
Plus, in the case of pesticides that are to be used in respect of a food crop and that require a residues/metabolism evaluation,—	
(a) For the first named food crop to which the pesticide is to be applicable ...	956.81
(b) For each additional named food crop to which the pesticide is to be applicable	455.63
Plus environmental fate and toxicity assessment—	
(a) For an application for a pesticide with an active ingredient that is new to pesticides or to pesticides of that type	1,959.19
(b) For an application for a pesticide with no active ingredient that is new to pesticides or to pesticides of that type, but which requires more than the basic assessment referred to in paragraph (c)	911.25

SCHEDULE—*continued*FEES PAYABLE UNDER PESTICIDES ACT 1979—*continued*

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(c) For an application which involves only minimal public or environmental exposure, which requires no assessment of data, and which requires only a basic environmental fate and toxicity assessment ... ..	546.75
Plus efficacy/phytotoxicity review—	
(a) For the first named pest and crop to which the pesticide is to be applicable	1,184.63
(b) For each additional named pest or crop to which the pesticide is to be applicable	546.75
3. On application under section 22 for registration of a pesticide in respect of which an experimental use permit referred to in clause 5 (b) is in force—	
Pre-screening cost ... ..	364.50
Plus, in respect of each of the following modules that would be required if the application had been made under clause 2, and that have not been successfully completed and passed during the processing of the application for the experimental use permit: manufacturing assessment, toxicology evaluation, residues/metabolism evaluation, environmental fate and toxicity assessment, and efficacy/phytotoxicity review ...	The fee, or part of the fee, that would have been payable if the application had been made under clause 2
4. On application to vary any registration or experimental use permit, or to revoke or vary any term, condition, or requirement imposed by the Board,—	
(a) For minor changes (including change of proprietor's name and address, change of trade name, transfer of registration or experimental use permit, and administrative change to a label) ...	364.50
(b) For substantive changes (including change in sourcing of active ingredients, change of manufacturer or method of manufacture, and change in the shelf-life)	The fee, or part of the fee, that would have been payable if the application had been made under clause 2
5. On application under section 25 for an experimental use permit—	
(a) Where the product is not for sale ...	364.50

SCHEDULE—*continued*FEES PAYABLE UNDER PESTICIDES ACT 1979—*continued*

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(b) In the case of any other application	The fee, or part of the fee, that would have been payable if the application had been made under clause 2
6. Annual registration fee payable in respect of any pesticide, payable on 1 July in each year	562.50
7. On application for transfer of rights of proprietor under section 32(2) or for reinstatement of any registration that has been cancelled or revoked at the request of the proprietor or revoked for failure to pay the annual fee,—	
(a) In the case of an application made within 24 months of the cancellation or revocation of the registration	A fee equivalent to the annual fees that would have been payable under clause 6 between the date of cancellation or revocation and the date of application, if the registration had not been cancelled or revoked
(b) In the case of any other application	The fee, or part of the fee, that would have been payable if the application had been made under clause 2

MARIE SHROFF,  
Clerk of the Executive Council.

## EXPLANATORY NOTE

*This note is not part of the regulations, but is intended to indicate their general effect.*

These regulations, which come into force on 15 January 1998, prescribe the fees payable in respect of matters under the Pesticides Act 1979.

The regulations provide, among other things, for—

- (a) Fees payable in respect of an application for registration of a pesticide:
- (b) Fees payable in respect of amendments to the register:
- (c) Fees payable in respect of an application for an experimental use permit:
- (d) Fees payable in respect of reinstatement of registration:
- (e) The annual fee for a registered pesticide, payable on 1 July in each year. The Board has power to revoke the registration of a pesticide if the annual fee remains unpaid for more than 6 months (s. 27A (2)).

The regulations replace the Pesticides (Fees) Regulations 1993 (as amended in 1995).

The regulations introduce differential fees for applications for registration of a pesticide. The current fee for these applications is a flat fee of \$3,150. The new fee is broken down to reflect the number of stages through which an application may need to be processed. These consist of a pre-screening stage, followed by the full processing of the application. The various stages are as follows:

#### *Pre-screening Module*

This consists of the administrative pre-screen, followed by the technical pre-screen. All applications received will be progressed through these 2 sub-modules. If there is a deficiency in the application, at the conclusion of this pre-screening section the application will be referred to the Board or its sub-delegated decision-making authority with a recommendation that the application be declined. The total amount payable at this point is \$364.50.

#### *Administrative Cost*

All applications that are not declined at the end of the pre-screening module will attract a charge of \$1,685.81 to cover all administration in respect of the processing of the application. This charge will make up part of the final application fee.

#### *Manufacturing Assessment*

Every application will be evaluated under this module. The cost to the applicant per application is \$136.69 for costs incurred in respect of an assessment of the chemical identity, properties, formulation details and manufacturing processes, including specifications and analytical methods for all formulation ingredients, and impurities in the final product. An assessment of the stability of the final manufactured product may be included.

#### *Toxicology Module*

Every application will be processed and evaluated in respect of toxicology. There are 3 different toxicology sub-modules. Every product which has a new active ingredient will be required to undergo an assessment of the full range of acute studies, short-term repeat dose studies, sub-chronic toxicity studies, long-term toxicity studies, reproduction studies, developmental studies, genotoxicity studies, metabolism and toxicokinetic studies, human toxicological data, special toxicity data (eg neurotoxicity), first aid and safety directions assessment and any other additional data which may be required to make a full assessment of the hazard or risk of the active ingredient and the product. The fee for the module is \$3,280.50.

An alternative module will be applied where the active ingredient is known. The fee for this module is \$911.25. Another alternative is the basic toxicological assessment module. The cost of the module will be \$546.75.

#### *Residues/Metabolism Module*

Every product that is going to be used in respect of a food crop will be subject to an assessment in this module. The assessment will cover the data showing the nature and level of residues and significant metabolites resulting from the proposed use-pattern in the target crop, and the establishment of withholding periods. It reviews the analytical methods used to determine the residues. It also includes an assessment of the effect of any major variables needed to determine the need for, and if necessary, the establishment of residue limits. For the first food crop the product is claimed to treat pests, the cost under this module is \$956.81. For every other food crop the product is claimed to treat pests, the cost will be an additional \$455.63.

*Environmental Fate and Toxicity Assessment*

Every application will be required to be assessed in this area. There are 3 levels of assessment. Where the active ingredient is new, the assessment will be thorough and involves an assessment on environmental chemistry, fate, and toxicology. This will include full studies on degradation, mobility, accumulation and metabolism in the environment. The studies will include toxicity studies in birds, mammals, and other vertebrates, aquatic organisms, non-target invertebrates, and non-target plants. The cost of the assessment will be \$1,959.19.

Where the active ingredient is a known active ingredient, the assessment will not be as thorough and will rely to some extent on established data. The cost of this will be \$911.25.

A basic assessment will be made in other circumstances. The cost where a basic assessment is all that is required will be \$546.75.

*Efficacy/Phytotoxicity Module*

This module covers a review of the data provided in respect of efficacy against the pest and phytotoxicity in the host species. This will involve field trials and any other trials or studies to justify claims made in respect of the target pest. The cost under this module will be \$1,184.63 for the first claim in respect of the target pest and \$546.75 for each additional claim.

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These regulations are administered in the Ministry of Agriculture and Forestry.