Pesticides and Toxic Chemicals Control Board

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PESTICIDES AND TOXIC CHEMICALS CONTROL BOARD

THE PESTICIDE REGISTRATION PROCESS

Pesticide registration often involves a process with many steps and actions, both by the applicant for registration as by the registration authority. They go from the initial submission of the application by the applicant to the final registration decision by the Registrar and subsequent follow-up activities by both entities. The registration process may therefore be lengthy and cumbersome.

However, a minimum number of steps will generally have to be followed to ensure that the application for registration is handled effectively and correctly, the evaluation conducted in a standard manner and decisions taken in a transparent way.

The pesticide registration process consists of a number of steps that generally are done in four phases: pre-registration, registration, post-registration and review of existing registrations.

The information provided below outlines the requirements for pesticides registration.

Pesticides Registration

New product registration:	18. A new product registration is the registration of a product containing an active ingredient that has not been previously registered by - (i) the Board; or (ii) the applicant.
New use registration:	19. A new use registration is the registration of a product that contains an active ingredient that is already registered by the Board, but has not previously been used in the manner proposed and include, any use affecting foods that would require establishment, or increase, of a product residue Maximum Residual Limits, any new aquatic, terrestrial, outdoor or forestry pattern or any other use pattern that would increase potential exposure to the product.

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Similar product registration:	20. A similar product registration is the registration of a product that is identical to, or substantially similar to, and contains the same active ingredient and similar inert ingredient in approximately the same percentage and have the same or similar use as a product that is already registered by the Board;
Amended registration:	21. An amended registration is the registration of a change in the active ingredient concentration, substitution of an inert ingredient or an additional use for any product already registered by the Board.

Subpart E - Registration Procedures

Applicant for registration:	22. (1) A person may apply for new registration of a product. (2) A registrant may apply for new use, similar product or amendment of the registration of that product.
Application for registration of a pesticide or toxic chemical.	23. An application for registration of a pesticide or toxic chemical shall be addressed to the Registrar and submitted in duplicate by the applicant containing the information specified in regulation 24.
Content of application	24. Each application for new registration or application for amended registration must include the following information - **(i)** name and address of the applicant. An applicant not resident in Guyana must also designate an agent to act on behalf of the applicant in all registration matters; **(ii)** list of the data submitted in the application with a brief description of the results of the study; **(iii)** product identified by - (a) product name, (b) trade name; and (c) Pesticide Registration Number when filing an Application for Amended Registration;

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(iv) a draft label for the pesticide product including a statement of all claims made for it, directions for use, ingredients, applicator warnings and precautions and procedures for its safe transportation, storage and disposal;

(v) the complete formula of the pesticide and a full description of the tests made and the results thereof upon which the claims for the pesticide are made.

Data for the following are required -

(a) physical characteristics:

(1) colour;
(2) physical state;
(3) odour;
(4) melting point;
(5)boiling point;
(6)density, bulk density or specific gravity;
(7)solubility;
(8)vapour pressure;
(9)dissociation constant;
(10)octanol-water partition coefficient;
(11)Ph;
(12)stability;
(13)oxidizer or reducing action;
(14)flammability;
(15)explodability;
(16)storage stability;
(17)viscosity;
(18)miscibility;
(19)corrosion characteristics;
(20)dielectric breakdown voltage;

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	(b) chemical composition of the pesticide product as sold to the end-user with directions for use must be supplied. Data for the following are needed - **(1)** active ingredients - for each active ingredient in the pesticide the following information must be reported - **(a)** chemical and common name of the active ingredient; **(b)** molecular, structural and empirical formula (e) and the molecular weight or weight range; **(c)** the chemical name according to Chemical Abstract Society (CAS) nomenclature, the CAS Registry Number and any common names; **(d)** nominal concentrations of the active ingredient in the pesticide; **(e)** upper and lower certified limits of the active ingredient **(f)** purpose of the active ingredient in the formulation.
	(2) inert ingredients - for each inert ingredient, if any, in the pesticide the following information must be reported - **(a)** chemical name of the ingredient according to CAS nomenclature, the CAS Registry Number and any common names; **(b)** nominal concentration in the pesticide; **(c)** upper and lower certified limits in accordance with (c); **(d)** purpose of the inert ingredient in the formulation.

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	(3) impurities of toxicological significance - for each impurity associated with the active ingredient that is determined to be of toxicological significance, the following information is required - **(a)** identity of the ingredient as a impurity; **(b)** chemical name of the impurity; **(C)** nominal concentration of the impurity in the product; **(d)** a certified upper limit.
	(4) other impurities - for each other impurity associated with the active ingredient that is present at ≥0.1 percent by weight, the following information is required: **(a)** identity of the ingredient as an impurity; **(b)** chemical name of the impurity; **(c)** nominal concentration of the impurity in the product; **(d)** a certified upper limit.
	(c) certified limits - the applicant must propose certified limits for the ingredients in the pesticide product Certified limits, which become legally binding upon registration of the pesticide, will apply for the date of production to the date of use, unless the product label bears a statement prohibiting the use after a certain date, in which case the certified limits will apply only until that date. The Board may collect commercial samples of the registered pesticide and analyze them for the active ingredient(s), inert ingredients or impurities determined by the Board to be toxicologically significant.

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	If, upon analysis, the composition of such a sample is found to differ from that certified, the results may be used by the Board in regulatory enforcement actions. Certified limits are required for the following ingredients of a pesticide product - **(1)** an upper and lower limit for each active ingredient; **(2)** an upper and lower limit for each inert ingredient; **(3)** an upper limit for each impurity of toxicological significance.
	(d) environmental fate - **(1)** degradation - hydrolysis, photodegradation in water, soil and air; **(2)** metabolism – anaerobic aquatic , aerobic aquatic, aerobic soil; **(3)** mobility - leaching, absorption / desorption, volatility; **(4)** dissipation field studies - soil, aquatic sediment, forestry, long-term soil; **(5)** accumulation: rotational field crops, irrigated crops, fish, aquatic non-target.
	(e) based on the anticipated use pattern(s) for a pesticide, the following data on toxicity must be provided - **(a)** acute testing : acute oral toxicity – rat, acute dermal toxicity, acute inhalation toxicity – rat, primary eye irritation – rabbit, primary dermal irritation, dermal sensitization, acute delayed neurotoxicity – chicken;

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	(b) sub-chronic testing: 90-day feeding studies – rodent and non-rodent, 21-day dermal, 90-day dermal, 90-day inhalation – rat, 90-day neural-toxicity – chicken and mammal; **(c)** chronic testing: chronic feeding – rodent and non-rodent, oncogenicity – rat, mouse, teratogenicity, reproduction – 2 generations; **(d)** mutagenicity testing: gene mutation, structural chromosonal aberration, other genotoxic effects; **(e)** metabolism: general, dermal penetration, domestic animal safety
	(f) based on the anticipated use pattern(s) for a pesticide, the following data are required to establish restricted entry intervals - **(a)** foliar dissipation; **(b)** soil dissipation; **(c)** dermal exposure; **(d)** inhalation exposure.
	(g) based on the anticipated use pattern(s) for a pesticide, the following data are required to assess a pesticide's spray drift character - **(a)** droplet size spectrum; **(b)** drift field evaluation.
	(h) based upon the anticipated use pattern(s) for a pesticide the following data are required to assess its toxicity to non-target organisms - **(1)** wildlife and aquatic organisms - **(i)** avian and mammalian testing - (a) avian oral LD_{50} ; (b)avian dietary LC_{50} ;

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	(c)wild mammal toxicity; (d)avian reproduction; (e)simulated and actual field testing of mammals and birds;
	(ii) aquatic organism testing - (a) freshwater fish LC_{50} ; (b) acute LC_{50} in freshwater invertebrates; (c) acute LC_{50} estuarine and marine organisms; (d) fish early life stage and aquifer invertebrate life-cycle, fish life-cycle; (e) aquatic organism accumulation, (f) simulated and actual field testing of aquatic organisms; **(2)** plant protection data - **(i)** non-target area phytotoxicity: **(a) Tier I:** seed germination; seedling emergence; vegetative vigour; aquatic plant growth. **(b) Tier II:** seed germination; seedling emergence; vegetative vigour; aquatic plant growth. **(c) Tier III:** terrestrial field tests; aquatic field tests.

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	(3) non-target insect toxicity - **(i)** non-target insect testing: pollinators (honey bee acute contact LD50, honey bee - toxicity of residues on foliage, field testing for pollinators); **(ii)** non-target insect testing - aquatic insects (aquatic insect acute toxicity, life-cycle study and simulated and actual field testing, non-target insect testing – predators and parasites).
	(i) based on the anticipated use patterns for a pesticide the following data are required to asses its performance efficacy - (a) efficacy of antimicrobial agents (product to treat water systems); (b) efficacy of fungicides and nematicides (control organisms producing mycotoxins); (C) efficacy of vertebrate control agents (avian toxicants, avian repellants, avian frightening agents commensal rodenticides, rodenticides on farms and rangelands, rodent fumigants, rodent reproductive inhibitors, mammalian pesticides). **(vi)** an applicant shall furnish with his application any factual information of which he is aware regarding significant adverse effects of the pesticide on man or the environment. **(v)** when the pesticide is proposed for use on food or feed crops, the applicant must determine whether pesticide residues including residues of any active ingredient, inert ingredient, metabolic or degradation product, are authorized by a Maximum Residual Limits under the Food and Drugs Act (1977), as amended, or the Plant Protection Act (1942), as amended and where such residues have not been authorized,

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	the application must be accompanied by a petition for establishment of appropriate Maximum Residual Limits or a request for exemption from the requirement of setting a Maximum Residual Limits.
Format of data submission:	25. All data submitted in support of a single administrative action must be accompanied by a single transmittal document which shall include the - (i) identity of the applicant or agent of the applicant; (ii) date of the submission; (iii) identity of the requested Board action; (iv) bibliography of all specified documents included with the submission.
Individual scientific or field studies:	26. **(1)** All data must be submitted in the form of individual studies. Each study shall address a single data requirement and be listed separately in the transmittal document bibliography in accordance with 25(iv). **(2)** Each study must include the following elements in addition to the study itself - **(a)** title page including the title of the study, identity of the substances tested, the test name, author(s) of the study, date of study completion, laboratory in which the study was undertaken, references to any published data; **(b)** statement of data confidentiality, if requested; **(c)** certification that the study was conducted following good laboratory procedures. **(3)** If the original study is not in the English language, a complete and accurate English translation.