කෘෂිකර්ම දෙපාර්තමේන්තුව
விவசாயத் திணைக்களம்
DEPARTMENT OF AGRICULTURE

පළිබෝධනාශක රෙජිස්ට්‍රාර් කාර්යාලය
பீடைகொல்லி பதிவு அலுவலகம்
Office of the Registrar of Pesticides

අංක 1056, ගැටඹේ, තැ.පෙ. 49, පේරාදෙණිය 20400, ශ්‍රී ලංකාව
இல 1056, கெடம்பே, த.பெ.இல 49, பேராதனை 20400, இலங்கை
No. 1056, Getambe, P.O. Box 49, Peradeniya 20400, Sri Lanka

දුරකථන/தொலைபேசி/Telephone : (94)812388076/388135
ෆැක්ස්/தொலைநகல்/Fax : (94)812388135
ඊ මේල්/மின்னஞ்சல்/E-mail : pest@slt.lk
වෙබ්/மின்னஞ்சல்/Web : www.doa.gov.lk

මගේ අංකය / எனது எண் / My No	RP/IV/C4	ඔබේ අංකය / உமது எண் / Your No		දිනය / திகதி / Date	26.06.2019

CIRCULAR NO. RP/2019/GL

Dear Sir/Madam,

Subject: Consideration of Applications for Re-registration of Pesticides under the Control of Pesticides Act No. 33 of 1980 as Amended by the Acts No. 06 of 1994 & No. 31 of 2011

Under the Control of Pesticides Act No. 33 of 1980 (as Amended by the Acts No. 06 of 1994 & No. 31 of 2011), Registrar of Pesticides registers pesticides imported, manufactured, distributed, sold or offered for sale & use in Sri Lanka, prescribing labeling & other regulatory requirements for safe & effective use. On receipt of an application, submitted along with necessary pre-requisites [Section 6(1)], relevant to *product's identity, quality, efficacy, safety, regulatory standards & Laws of the country of origin*, Registrar of Pesticides reviews the information, in the forefront, registering the pesticide [Section 7(1) (a)], registering pesticide provisionally, notifying the registrant minor deficiencies in the data or the need for additional information [Section 7(1) (b)], or reject the application [Section 7(1) (c)]. The relevant regulatory clauses are as follows:

> "7 (1) The Registrar shall, on receipt of an application under subsection (1) of section 6-
>
> (a) register the pesticides and issue a licence valid for a period not exceeding three years; or
> (b) register the pesticides provisionally, and pending the issue of licence or *in lieu* of a licence issue a provisional permit valid for period not exceeding twelve months for restricted marketing and use of the pesticide in accordance with the conditions stipulated in such permit;.
> (c) reject the application and state the reasons for such rejection.
>
> (2) The issue of a licence or a permit shall be effective for the period stated in the licence or permit, and shall be renewable on application made in that behalf. Such renewal shall be conditional upon a review by the Registrar of the data on the pesticide in question" [8,6 of 1994].

Once a regulatory decision has been made to accept a pesticide provisionally, Registrar of Pesticides, on the advice of the Pesticide Technical & Advisory Committee (PeTAC), typically grants a period of one (1) year for the registrant to

provide the required data or additional information. Specifically, re-registration of pesticides hitherto, in most situations, has been limited to the receipt of application made on that behalf along with necessary fees on the presumption that pesticide products of re-registration are identical to already declared standards & sources under Section 7(1) (a) *as meeting the same identity, quality, efficacy, safety, regulatory standards & Laws of the country of origin*. Therefore, according to regulatory belief, continually marketed pesticides are in consistent with data ownership & integrity of data and do not pose unreasonable adverse effects on human health or the environment.

Accurate & reliable data are essential requirements for efficient & effective regulation of pesticides. The following requirements should be regarded as specific considerations to assess whether the older registrations continue to meet the *identity, quality, efficacy, safety, regulatory standards & Laws of the country of origin* and to review applications submitted after re-registration cycle from 01st July, 2019.

1. Original certificate of Confidential Product Formula (*technical material or technical concentrate*) with specific impurities;
2. Original certificate of Confidential Product Formula (*formulation*) with specific adjuvants or mixture of adjuvants with specific CAS Number/s;
3. Manufacturer declaration(s)/trade agreement(s) & corresponding Material Safety Data Sheet(s) (MSDS) for proprietary/non-proprietary adjutants including surfactants/solvents in composition more than 20% in the formulation;
4. Separate declarations (*in original, signed by regulatory manager or product stewardship manager or an officer with equivalent capacity*) by the manufacturer of the technical material or the technical concentrate[1]/formulator of the finished product[2]/supplier of the formulation and/or technical material or the technical concentrate[3] (*as the case may be*);
5. Valid registration certificate (*original, certified duplicate or certified copy of the original by the regulatory body/agency*) of the technical material or the technical concentrate in the country of origin[4];
6. Valid registration certificate (*original, certified duplicate or certified copy of the original by the regulatory body/agency*) of the formulation in the country of origin;
7. Valid proof/s of document/s (*in original*) by the manufacture of the technical material or the technical concentrate/formulator of the finished product for supplying of the technical material or the technical concentrate and/or the formulation from a country/entity other than the country of origin (*e.g. billing/invoicing/trading purposes*);
8. Valid factory/manufacturing license/s (*original, certified duplicate or certified copy of the original by the licensing body/agency)* for the technical material or

[1] Where technical materials/technical concentrates or formulations are produced in different plants this information must be provided for each of the plant/country, separately.

[2] Ibis.

[3] Ibis.

[4] All technical materials/technical concentrates on which formulations are based, this information must be provided for each of the plant/country, separately.

the technical concentrate and the formulation issued by the licensing authority/certification body in the country of origin;

9. Five batch analysis for the material base/offered product (*the technical material or the technical concentrate and/or the formulation*) from an accredited laboratory;
10. As per the *Gazette Extraordinary* No. 1870/63 dated 10.07.2014, every registrant should furnish a local bio-efficacy trial report conducted by a government institute/crop research institute once in every 6 years (i.e. every 2 re-registration cycles) for the continuation of re-registration;
11. Duly filled re-registration application along with a bank slip of Rs. 4,000.00 credited to the Account of Director General of Agriculture, BOC-Peradeniya 588/7042565, People's Bank- Peradeniya-057-1-001-3-9027201 or Cheque drawn in favour of Director General of Agriculture & draft labels (*for the all requested pack sizes, in duplicate*).

Office of the Registrar of Pesticides note that the conditions for most of the re-registration requirements have likely been satisfied during original data submissions for registrations [Section 7(1) (a)]. However, as a result of routine regulatory assessments [Section 7(2)], the current initiative will constitute a "*quality assurance check*" on registered pesticides. Since, current regulations do not declare specific interventions for periodic re-evaluation of registered pesticides other than the provisions for re-evaluation under the Section 7(2), ensuring each registration continues to satisfy *identity, quality, efficacy, safety, regulatory standards & Laws of the country of origin.*

Office of the Registrar of Pesticides does not foresee any burden on registrants submitting/declaring their true identity of pesticide products. The current re-evaluation will be continuing for one (1) full registration cycle of 3 years. All registrants are typically have maximum one (1) year to provide above regulatory considerations required by a provisional permit/registration with effect from 01st of July, 2019. Please be informed that review of requested information and/or data may lead to request additional verifications and/or clarifications, as may be required. Depending on the merits of submissions & acceptability of data, provisional status will be converted from the provisional status (*1-year permit*) to the licence status (*3-year licence*). If any registrant fails to submit information requested by this Circular, Registrar of Pesticides, on the advice of the Pesticide Technical & Advisory Committee (PeTAC), may be obliged to withdraw, suspend, or modify pesticide registration under the authority of Section 11 (1) of the Control of Pesticides Act No. 33 of 1980.

Should you require any clarification in this regard please do not hesitate to contact me. Thanking you.

Dr. J.A. Sumith
Registrar of Pesticides

SRI LANKA Department Of Agriculture LICENSING AUTHORITY FOR PESTICIDES

i.c. 1. Director General of Agriculture- FYI, please.
2. Chairman, Crop Life Sri Lanka – FYI&NA, please.