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DEPARTMENT OF AGRICULTURE
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2.1.3 OFFICE OF THE REGISTRAR OF PESTICIDES (ROP) - PERADENIYA

Registrar of Pesticides (ROP) is the legal authority empowered and entrusted on the functions related to the registration and regulation of pesticides in Sri Lanka (appointed under the Control of Pesticides Act No. 33 of 1980, as amended by the Act No. 06 of 1994 & the Act No. 31 of 2011). According to the Act, it is the duty of the ROP (who is responsible to the Director General of Agriculture, DGA) to regulate pesticides imported to and produced in Sri Lanka, and to assure their quality and safe use, and to assess and to declare Maximum Residue Limits (MRLs) in agricultural produce.

The overall workload of the Office of the Registrar of Pesticides has been gradually strengthened to represent registration of pesticides imported to Sri Lanka and giving import permits, regulating labels and advertisements, registering pesticide importers, pest control services and pesticide traders, random quality checking of imported pesticides and testing pesticide residues in agricultural produce. The pesticide regulatory activities that have been managed by the ROP can be divided into two main categories as regulation of pesticides by registration and post-registration activities. However, for effective and total regulation of pesticides in the country, it is paramount that post-regulation activities are managed equally or much more intensively than in-house registration activities. The post-registration activities include (among others): monitoring of pesticide formulation and re-packing

factories, storage sites and outlets, detection of unauthorized activities and taking legal actions, analysis for pesticide quality, analysis of pesticide residues in/on agricultural products and setting legally allowed MRLs in food, monitoring of pesticide poisonings, etc.

In addition, many new challenging developments are continuously arising and sparingly managed with the current facilities available at the Office of the Registrar of Pesticides. Some of such challenges includes, disposal of pesticide containers, determination of heavy metals in pesticides, conducting regular programs on MRL testing, regulating pesticides sales and use in the field through Authorized Officers, and taking legal actions against offenders of the Act.

The society has voiced its concern of the fact that Office of the Registrar of Pesticides does not test, on its own, the quality and presence of impurities in pesticides that are harmful to human health and other organisms in the environment. Unless remedial actions are taken within a short period of time, the reliability of the whole process of pesticide regulation will be in jeopardy. Proposals have been submitted to the government for keeping positivity on such aspects & for strengthening the existing system to manage with utmost efficiency and to keep up mandates for the sake of the public and the environment.

As highlighted in subsequent sections, the Office of the Registrar of Pesticides has been able to create momentum for setting up of several environmental safety advocacy

programs such as empty pesticide container management and the management & disposal of obsolete pesticides. Examples of other significant initiatives and accomplishments include: plans for divisional arrangements in the office setup; development of registration procedures for indigenous biological pesticides; regulation of high-risk pesticides; upliftment of laboratory analytical calibre by

participating in international assessment for ISO/IEC 17025: 2005 accreditation & laboratory procurements; applicator safety initiatives; continuous improvement in training & awareness raising on pesticides and participating at local & international auditing on pesticide and residue management systems in Sri Lanka.

BUDGET

The annual allocation and expenditure under different votes are given in the following table.

Table 2.1.3.1: Annual budget – 2016

Vote	Allocation (Rs.)	Expenditure (Rs.)	Expenditure (%)	Income (Rs.)
Recurrent	4,313,799	4,023,875	93	
Capital	2,405,000	1,772,698	74	
Minimize potential adverse effects of pesticides in Sri Lanka (Special grant)	5,000,000	4,994,790	100	
1. Registration fee				7,542,500
2. Re-registration fee				416,000
3. Pesticide dealer license fee				803,550
4. Pest control service registration fee				100,000
5. Pest control service license renewal fee				205,000
6. Import lisencc fee				684,000
7. Company registration fee				600,000
8. Agrochemical sales & Technical Assistant application fee				46,600
9. Miscellaneous				3,300
Total	11,718,700	10,791,362	92	10,400,950

PROGRESS

No.	Item/Activity	Total Annual Physical Target	Achievement up to End of 2016	%
01. Program for registration of pesticides				
1	Acceptance of applications for registration	30	20	67
2	Acceptance of applications for re-registration	150	67	45
3	Evaluation of registration packages for registrations	30	56	183
4	Evaluation of re-registration applications	140	74	53
5	Evaluation of secondary registration applications	140	59	42
6	Preparation of original registration certificates for approval	280	191	68
7	Pesticide Technical & Advisory Committee meetings	6	5	83
8	ROP company dialog to inform the PeTAC decisions	6	1	17
9	Pesticides sub-committee meetings	18	8	44
10	Co-ordination of pesticides testing with the DOA (for bio-efficacy)	30	25	83
11	Evaluation & preparation of data for sub-committees	30	147	490
02. Program for awareness on all relevant target groups assurance of safe use and judicious marketing of pesticides & collection & compilation of pesticides related data				
1	Media Programs:			
	a) TV Programs	2	3	150
	b) Radio Programs	6	7	117
	c) Print Media Programs	4	2	50
2	Training / Certification of Agrochemical Sales and Technical Assistants (ASTA)	500	340	68
3	Awareness/ Exhibition	3	3	100
4	Awareness program for the Authorized Officers/ Enforcement Officers	10	7	70
5	Dealer training classes	15	16	107
6	Publishing revised guidelines for registration of pesticides / biocides and guidelines for new comers for the pesticide industry who needs to import pesticides	2	2	100
7	Participation as resource personal for invitations from the DOA/ other institutes	10	51	510
8	Collection, compilation & dissemination of import statistics (Central Bank, Universities, Researches, Govt. Institutes etc.)	10	18	180

No.	Item/ Activity	Total Annual Physical Target	Achievement up to End of 2016	%
03. Program for compliance monitoring (Product quality and residues in environmental compartments & action against violation of the Control of Pesticides Act, No. 33 of 1980)				
1	Issue of import approvals	1000	731	73
2	Issue of sample import approvals	100	78	78
3	Evaluation of quality certificates	350	282	81
4	Screening of labels for approval	500	1750	350
5	Screening of advertising materials for approval	150	143	95
6	Inspection of factories	12	4	33
7	Inspection of approved repacking facilities & stores	12	5	42
8	Inspection of premises for fumigation & house-hold pest control operators	30	7	23
9	Registration of pest control services	10	10	100
10	Development and implementation of programs for empty container disposal	2	9	450
11	Inspection of sales outlets	20	29	145
12	Field complaints	6	12	200
13	Legal prosecution	4	10	250
14	Approval of obtaining CH ₃ Br for quarantine & reshipment treatments on accountable basis	150	109	73
15	Dispatch of samples to the MRI & other institutes for obtaining test reports on suitability for acceptance of applications	25	15	60
16	Issue of dealer training certificates	450	656	146
17	Issue of dealer certificates	2000	1461	73
18	Issue of packing clearance as per the quality analysis of samples on consignment basis	150	209	139
19	Formulation analysis	400	475	119
20	Number of residue analysis*	200	348	174
21	Number of heavy metal analysis**	400	515	129
22	Random checking of pesticide impurities	12	2	17
23	Restricted pesticides issuing letters for pest control services	700	819	117
24	Evaluation notifications send by the European Union (EU) (on pesticides residue)	7	3	43

No.	Item/ Activity	Total Annual Physical Target	Achievement up to End of 2016	%
25	The EU audit to Sri Lanka to evaluate control of pesticides in food of plant origin intended for export to the EU			
25.1	Field inspection	30	39	130
25.2	Sample collection/sample analysis	50	93	186
26	Other activities (such as field surveys)	4	56	1400
Number of residue analysis*, Number of heavy metal analysis**= Number of injections				
04. Program for participation as technical experts/members/resource personal in intra & inter departmental organization meetings				
1	Ozone Unit of the Ministry of Mahaweli Development & Environmental	4	2	50
2	Basal / Montreal /Stockholm /Rotterdam Conventions	2	9	450
3	Department of Customs	2	2	100
4	Ministry of Health	4	11	275
5	Ministry of Agriculture	4	15	375
6	National Library Services Council	3	5	167
7	Sri Lanka Tea Board	2	2	100
8	Ministry of Mahaweli Development & Environmental/ CEA	4	12	300
9	Sri Lanka Standard Institute	2	7	350
10	Other	6	28	467
05. Program for income generation				
1	Fee for Agrochemical Sales & Technical Assistants (ASTA)	750 cheques of Rs. 100.00	(466) 46,600.00	62
2	Fee for dealer certification (Pesticide sales outlets)	2,000 Money Order/ Cheques of Rs. 550.00	(1461) 803,550.00	73
3	Permit fee for import approval	1,000 Money Order/Cheques of Rs. 1,000.00	(684) 684,000.00	68
4	Filing fee for restricted pesticides	10 Money Order/ Cheques of Rs. 6,500.00	(4) 26,000.00	40
5	Registration fee for restricted pesticides	60 Money Order/Cheques of Rs. 4,000.00	(6) 24,000.00	10
6	Re-registration fee for restricted pesticides	10 Money Order/Cheques of Rs. 4,000.00	(14) 56,000.00	140

No.	Item/ Activity	Total Annual Physical Target	Achievement up to End of 2016	%
7	Filing fee for general/domestic pesticides	60 Money Order/ Cheques of Rs. 68,500.00 (5) + Rs. 75,000.00 (68)	(73) 342,500.00 + 5,100,000 = 5,442,500.00	122
8	Registration fee for general/domestic pesticides	60 Money Order/ Cheques of Rs. 25,000.00	(82) 2,050,000.00	137
9	Re-registration fee for general/domestic pesticides	60 Money Order/ Cheques of Rs. 4,000.00	(90) 360,000.00	150
10	Registration fee for pest control services	20 Money Order/ Cheques of Rs. 20,000.00	(5) 100,000.00	25
11	Re-registration fee for pest control services	20 Money Order/ Cheques of Rs. 5,000.00	(41) 205,000.00	205
12	Filling fee for company registration	10 Money Order/ Cheques of Rs. 50,000.00	(3) 150,000.00	30
13	Registration fee for company registration	10 Money Order/ Cheques of Rs. 50,000.00	(9) 450,000.00	90
14	Miscellaneous		3,300.00	
Total			10,400,950.00	

REGISTRATION OF PESTICIDES

Pesticide registration is a scientifically-based, legal, and also administrative process, where a wide variety of effects associated with the use of a pesticide product and its potential effect on human health and the environment is assessed. The registration is an important step in the management of pesticides as it enables authority primarily to determine which pesticide products are permitted to be used and for what purposes, and also to exercise control over quality, usage rates, claims, labeling, packaging and advertising of pesticides, thus ensuring that the best interest of end-users as well as the environment are well protected.

Compulsory registration & re-registration on a regular schedule (3-year term) are considerable undertakings for pesticide management in the country. In addition, the registration process is restricted on the assumption that pesticides are only used for their intended function and envisages proving that such use does not promote unreasonable effects either on human health or the environment.

Before any pesticide can be used commercially, several tests and/or verification assessments are conducted including bio-efficacy (or based on scientifically-accepted data assessment submitted by the registrant from most authoritative sources) that

determine whether a pesticide has any potential to cause adverse effects on recommended crops, humans and wildlife, including non-target organisms, or potential to contaminate surface waters and groundwater from leaching, runoff, and spray drift.

Sri Lanka is one of the lowest pesticide using countries in the world. According to the general use statistics of pesticides, 0.308 g of active ingredients per hectare of arable lands are being used whereas 1.056 g of active ingredients are being used per hectare of actively cultivated lands. For comparison purposes, 0.998 g of active ingredients per hectare of arable lands are being used in the USA, while 4.676 g and 5.947 g of active ingredients per hectare of arable lands are being used in China & Japan, respectively (www.wikipedia.org pesticides). As per the use statistics of commodity pesticides, 59%

decline of imports were recorded viz., 6,843 metric tons in 2013 vs. 2,825 metric tons in 2015. The abrupt reduction of imports was due to stringent control over high volume pesticides such as Chlorpyrifos, Carbaryl, Carbofuran, Propanil & Glyphosate.

Status of registration of pesticides

There are approximately 190 active substances representing 647 registered pesticides in commercial use in Sri Lanka. Out of all active substances, 107 active substances are used in agriculture and the corresponding number of registered products is 459 as of December 2016. Statistical data of import of formulated pesticides shows that 1759.06 metric tons of insecticides, 2862.74 of metric tons of herbicides and 1233.8 metric tons of fungicides have been imported to Sri Lanka during the year of 2015. (Table 2.1.3.2)

Table 2.1.3.2: Import of formulated and technical grade pesticides to Sri Lanka during 2010-2015 (mt)

Type of Pesticide	2010	2011	2012	2013	2014	2015
Technical Material						
Insecticides	144.38	90.5	63.32	88.22	34.48	115.84
Herbicides	1,605.58	1,184.94	377.8	197.06	705.4	751.7
Fungicides	2	0.4	0.75	0	0	0
Formulations						
Insecticides	1,843.95	1,712.58	959.37	1,243.46	702.91	1,759.06
Herbicides	5,366.63	5,031.05	4,753.01	5,958.32	4,081.83	2,862.74
Fungicides	1,048.02	949.40	776.44	987.15	935.92	1,233.8

As pursuant to the requirements under the Section 9 of the Control of Pesticides Act No. 33 of 1980, a complete list of registered pesticides was compiled and published in the Government Gazette Extraordinary No. 1994/71 dated 24.11.2016. This document, which was last published in 2002, provides

legal endorsement for products as per the first tiered risk management, viz., general pesticides (459 products representing 107 active ingredients), domestic pesticides (66 products representing 27 active ingredients) and restricted pesticides (122 products representing

56 active ingredients), depending on the risk involved.

During the year 2016, 56 registration applications were screened (Table 2.1.3.3). In this process, relevant information and documents were evaluated upon submission by the registrant.

During the year 2016, the total revenue collected in this activity was Rs. 7,542,500.00.

Product assessment and registration of new molecules

Safer and environmental friendly pesticides were identified and promoted during the pre-evaluation of products for local trials, which facilitate the phase-out of hazardous products available in the market. Seven (7) pesticide formulations were evaluated during the year and three (3) products complied for stringent evaluation criteria for registration (Table 2.1.3.3).

Table 2.1.3.3: The overall status of the evaluation of pesticides for registration during the year 2016

Category	Status of registration	Number
New pesticides	Evaluations completed	07
	Registration granted	03
Conventional pesticides	Evaluations completed	49
	Registration granted	49

The following new molecules of pesticides were assessed for registration for agricultural applications: Imazethapyr 10% SC,

Triafamone 20% SC, Nicosulfuron 4% SC, Fenpyroximate 5% EC & Bistrifluron 10% EC. Four of the above molecules were low-risk pesticides belonging to the World Health Organization (WHO) Hazard Class III or below. However, Fenpyroximate 5% EC required a special justification for registration since it belongs to the WHO Hazard Class II. Based on the justification given by the Coordinator/ Entomology Working Group, the registration was granted for Fenpyroximate 5% EC for use on mites in rice; the justification was based on the control of panicle (sheath) mites in rice and it was reported that at present Profenophos (belongs to organophosphate group, WHO Hazard Class II) is being tentatively recommended for mites in rice while the other miticides available in the market are Sulphur 80 WP and Abamectin 1.8 EC; by comparing all four pesticides in consideration of the Environmental Impact Quotient (EIQ) values, Fenpyroximate 5% EC was recommended as the safest pesticide for the control of panicle (sheath) mites in rice cultivation.

Coordination with other institutions in registration matters

Pre-evaluation of pesticides is a critical step towards sustenance of pesticide management in Sri Lanka. The technical sub-committees on different product categories viz. agricultural, public health and industrial pesticides serve as the preliminary screening and approval mechanism for candidate pesticides. The sub-committees are established under the authority provided by section 5(1) b of the Control of Pesticides Act No. 33 of 1980 (as amended by the Acts of No. 06 of 1994 & No. 31 of 2011). In order to streamline smooth functioning of

the activities in the sub-committee, the clear mandates on Terms of Reference (TOR) & General Rules of the Meetings were prepared & re-adopted at meetings held in November 2016. The sub-committees are mandated to hold three to four meetings per year. However, depending on the periodic requests & issues, the Agricultural Pesticides Sub-committee (APeSC) held its 20th to 23rd meetings, while the Public Health Pesticides Sub-committee (PHPeSC) held its 11th – 12th meetings and the Industrial Pesticides Sub-committee (IPeSC) held its 7th meeting during the year 2016.

During the year, relevant technical sub-committees were directed to screen 147 candidate pesticide applications. Thirty nine (39) applications were rejected at the preliminary screening stage by technical sub-committees: three on unacceptable health hazards (e.g. high bee toxicity; twenty one on less priority grounds due to availability of adequate alternatives etc.; three on unacceptable health risks (e.g. high acute hazard in Class II etc.); and twelve on lack of complete data for review.

The intensive use of sulfonyl urea herbicides has shown some indication on possible resistance emergence among some of the weed spectra in rice fields. Based on farmer complaints on sulfonyl urea herbicides, for inefficient weed control in rice fields, which led the Office of the Registrar of Pesticides to request from the Research & Extension divisions of the Department of Agriculture (DOA) and from the pesticide industry to look for reforms for resistance management, including actions such as use restrictions and regional recommendations. Since the initial trials were not accepted by the APeSC due to procedural lapses, further collaborative

assessment covering the whole spectrum of sulfonyl urea herbicides were proposed for the 2016/2017 Maha season though the Research & Extension divisions of the DOA, in order to resolve weed management issues on sulfonyl urea herbicides.

Another salient feature in the management of pesticides is the denial of overdosed pesticide-treated articles for household use; for example, proposals for introducing Insecticide-treated Long Lasting Mosquito Nets (LLMN) containing higher concentrations of synthetic pyrethroids than the WHO recommended doses would create unnecessary public exposure and emergence of resistant mosquito populations. Therefore, the PHPeSC denied two applications on the above technical grounds.

Preliminary review of indigenous bio-pesticides for registration in Sri Lanka

Along with the government policy to promote safe initiatives in agricultural production, there are entrepreneurial motives to introduce biological pesticides in the country. In this effect, draft proposals were developed by a team of experts on the requirement for registration of biological pesticides on different origins. The draft proposals were further discussed at the Consultative Workshop on Registration of Bio-pesticides in Sri Lanka and Review of Relevant Guidelines held on 28th October, 2016 at the Ministry of Agriculture (MOA). Accordingly, on the advice and on behalf of the Director General of Agriculture, a committee was set up to review of preliminary data submitted for local/indigenous bio-pesticides with the

intention that “upon bio-efficacy evaluations are conducted at a government research institution satisfactorily and in parallel, the chemical composition is analysed, known & justifiable, a provisional registration can be granted pending submission specifically mentioned other data requirements for registration under the Control of Pesticides Act No. 33 of 1980”. The preliminary data packages consisting of botanicals (plant extracts) & bio-control organisms were screened and prioritized the products for local testing and further chemical verifications being high priority areas under the present circumstances.

Removal of high risk pesticides

As per the decision taken at the 81st Pesticides Technical & Advisory Committee (PeTAC) meeting held on 28th September, 2016, the ROP was authorized to implement import restrictions on Diazinon, with an annual quota of 25% depreciation from January 2017 through December 2019. Accordingly, the maximum annual quotas of technical and formulated Diazinon (50%) were decided for individual registrants based on average volumes imported to Sri Lanka during the 2014-2016 by respective registrants. The decision was based on the listing of Diazinon under the International Agency for Research on Cancer (IARC) 2A category (Probably carcinogenic to humans on mechanistic evidence) and in tandem with the pesticide safety initiatives to the general public. The PeTAC considered that there are sufficient numbers of insecticide alternatives on key pests in recommendation and any loss of opportunity can be supplanted by

recommending reduced-risk pesticides on any key/minor pests during the phase-out period.

In addition, the PeTAC granted approval in October 2016 for banning of Chlorpyrifos, Carbofuran and Carbaryl in a form of formal declaration in the government Gazette Extraordinary, as they are highly toxic and high volumes had been used in the past. The regulation was published in the Government Gazette Extraordinary No. 1999/33 dated 28.12.2016.

Management of high risk pesticides

Restricted use of Krismat 75% WG (a product containing 73.1% of Ametryn + 1.8% of Trifloxysulfuron Sodium Reg. No. M710000)

In August 2016, actions were taken to introduce unprecedented proposal to initiate a new culture of use of high risk pesticides in Sri Lanka by introducing a “prescription-based” sale and distribution based on Krismat 75% WG . In order to qualify for this initiative, the Office of the Registrar of Pesticides proposed some preparatory tools as follows:

1. List of potential users (Name, Complete Address and ID Number) certified by the certifying crop research institution.
2. An ID format (to be issued for purchasing of the product from certified sales outlets, which will be signed by the Registrar of Pesticides)
3. List of dealers and distribution points (Name, Complete Address, Contact Number etc.)
4. Record format for the dealer for record keeping while on sale/issue

This initiative was taken in support of registration of Krismat 75% WG by considering its WHO Hazard Class II for

exclusive use in sugarcane cultivations in Sri Lanka.

Freeze of Marshall 20 SC (Carbosulfan 20% SC) Imports at 155 Kiloliters per Annum

In order to complement with safe use initiatives on pesticides in the country, the Office of the Registrar of Pesticides declared its interim decision for maximum volume of imports at 155 kiloliters per annum (from January 01st to December 31st) for Carbosulfan 20% SC. The decision to freeze at the above level was based on the average volumes imported to the country within past two years (2014 - 2015), without taking into consideration the withdrawal of whitefly from existing recommendations since March 2016.

Suspension of Glufosinate Ammonium

Glufosinate Ammonium 150 g/L SL (Basta®) has been recommended in tea & sugarcane as a non-selective, contact, post-emergent herbicide since 1994. Basta® has been classified under the WHO Hazard Class II (which is the highest hazardous classification amongst existing over-the-counter pesticides), and shown to be having significant dermal/ eye irritation potential for the applicator. Due to its inherent toxicity potential and extensive use in the field has led to trending misuse such as intentional suicides. As an institution entrusted with far-sighted responsibility on averting any overly misuse potential by the community in this country, the use of Basta® were proposed to be restricted for tea and sugarcane sector, where there are control over safe and effective use by necessary supervision. The PeTAC at its 76th meeting had formerly accepted the policy against liberal use over Basta®.

However, by July 2016 two Glufosinate Ammonium products including hitherto registered Glufosinate Ammonium 280 g/L SL (Lifeline® Glufosinate Ammonium) were cancelled on specific directives given by the President Secretariat, pending a justification for declaring Glufosinate Ammonium in a Government Gazette Extraordinary as a banned pesticide.

Prohibition of Propanil-based Pesticides in Restricted Areas as per the Government Gazette Extraordinary No. 1894/4 dated 22.12.2014

In consequent to the regulations made by the Government Gazette Extraordinary No. 1894/4 dated 22.12.2014 to prohibit the use, offer for sale or sale of Propanil within the districts of Anuradhapura, Polonnaruwa, Kurunegala, Moneragala and within the Divisional Secretariat Divisions of Mahiyanganaya, Rideemaliyadde, Kandeketiya in the Badulla district, the pesticide industry was instructed to take strategic actions to maintain the above restrictions in the declared regions of the country. In consequent to this regulation, the PeTAC at its 77th meeting held on 02.10.2015 decided to liberalize Propanil-based mixture herbicides to be imported & used in the country, as there were no effective alternatives in rice weed control and some of the herbicides (e.g., sulfonyl ureas) were suspended very recently due to poor efficacy reasons. Therefore, the above decision did not revoke the above regulation with respect to Propanil (as an active ingredient). Therefore, strict distribution advisories were issued to the pesticide industry to instruct their direct and indirect dealership to refrain from issuing unjustifiable quantities of Propanil-based

mixtures to clientele within the free-sale areas of the country, and maintain records of bulk sale (e.g. >2 hectare requirements) at the dealer/sub-dealer with details of the purchaser.

However, PeTAC emphasized the practical difficulty of implementing the prohibition of Propanil mixtures in the restricted areas as there are few other herbicides available as alternatives. On the advice of the PeTAC, the ROP declared applicable quotas for Propanil-based herbicides among three registrants, based on the total rice extent in the non-restricted regions of the country.

Amendments to the Labels- Diuron

80% (w/w) WP & Diuron 50% (w/v) SC

Consequent to the banning of some of the total herbicides (viz., Glyphosate and Glufosinate Ammonium), there is tendency for using Diuron products in sensitive cultivations such as rice fields, and the situation could be aggravated further if Diuron product were used on lands just before intercropping. Misuse of existing herbicides in Sri Lanka could lead to adverse effects in future. Therefore, in order to overcome this issue, Advisory Circulars were issued in August 2016 to all field Authorized Officers and the Pesticide Industry. In addition, necessary awareness materials in all 3 languages were approved for distribution through respective registrants to accompany Diuron products (Diuron 80% (w/w) WP & Diuron 50% (w/v) SC) until new label amendments are done.

Phasing out strategy on Technical Malathion in Public Health Sector

The 81st meeting of the PeTAC held on 28th September, 2016 proposed to review of the use of Malathion in consultation with the Ministry

of Health. During the review it is expected to consider available alternatives and the cost factor as “good” aspects against the risk of impurities (e.g. *iso*-malathion), the by-product of Malathion, which is more toxic than the mother molecule, as “bad” aspects. Further, the decision on this review was based on the listing of Malathion under IARC 2A category (Probably carcinogenic to humans on mechanistic evidence) and in tandem with the pesticide safety initiatives to the general public.

On September 5, 2016, Sri Lanka was declared malaria-free at the 69th Session of the WHO Regional Committee for South-East Asia held in Colombo. This is another milestone in Sri Lanka’s outstanding achievements in public health safety, and partly corroborated to the actions on insecticide regulations in Sri Lanka under the Control of Pesticides Act No. 33 of 1980 by facilitating variety of control measures such as insecticide-impregnated bed nets, mosquito adulticides, larvaecides & repellents in a multi-pronged attack on malaria vectors.

Re-registration of pesticides

The registration of a product is valid only for 3 years after which the product status is reassessed for new scientific and regulatory standards. During the year, 74 applications were processed under this category. Under this scheme, product safety, quality and the performance will be assessed from freshly generated toxicity and product quality tests from most authoritative sources (e.g. Good Laboratory Practices complied & accredited laboratories). Currently, there are over 647 pesticide products handled in general (mostly agricultural pesticides), domestic and restricted categories, and the overall chronology of

regulatory actions were supplemental to become pesticide use increasingly safer each year. Total revenue realized under this category was Rs. 416,000.00.

Registration of pesticide establishments

All pesticide companies are required to be registered with the ROP with the intention that all functions associated with pesticide business are critically evaluated in a competent manner to safeguard human health, environment and wildlife resources as pursuant to the Sections 5 (a) and 5 (b) of the Government Gazette Extraordinary No.1870/63 dated 10.07.2014.

The aforementioned regulation directly affect 76 major pesticide importers (including indenting businesses), who have divergent interests such as importation, formulation, packing, re-packing, labeling, distribution, storage & transport. Accordingly, the regulation required to evaluate all prospective trade links and partnerships of pesticide life-cycle activities in the country including the store up & use of pesticides (in bulk) for necessary compliance with any applicable national law(s) of the country with respect to the environment, public and worker health safety, and the requirements of local government authorities and others. During the year 2016, all establishment profiles were thoroughly reviewed for competency certification. The major outcome of this exercise was that the entire Pesticide Industry is shown mandatory accomplishments in ISO 9001 (quality), 14001 (environment) & 18001 (health), and other accomplishments for environmental protection goals as set out under the National Environment Act No. 47 of 1980, depending on the nature of business.

During the year, the revenue realized under this category was Rs. 600,000.00.

Pesticide dealer empowerment

As an ongoing program, the Office of the Registrar of Pesticides continued to co-ordinate with the Provincial, Inter-provincial and Mahaweli Authority staff to implement the pesticide dealer certification & licensing scheme. During the year, 16 pesticide dealer training programs were conducted for 656 participants as a bridging program before hand to train pesticide dealers up to the National Vocational Qualification (NVQ) level IV competency certifications as per the regulations imposed under the Control of Pesticides (Sales and Supply) No. 01 of 1999 (Government Gazette Extraordinary 1716/23 of 27.07.2011).

Pesticide dealer licenses are valid for one year unless cancelled for specific reasons. A fee of Rs. 550.00 is charged as a part of the regulatory requirements for issuing a license. Total revenue realized under this category was Rs. 803,550.00. The number of dealer shops licensed was 1,461.

Import approvals

Importation of pesticides in the country is subjected to regulation by the Section 17 of the Control of Pesticides Act No. 33 of 1980. The ROP issues import approvals for pesticides upon receipt of requests from the companies on consignment basis, and the period of validity would be limited to 3 months from the date of its issue. A considerable effort and time is required to undertake such requests. This process ensures that products are imported from the correct source of supply conforming to the required quality standards and prevents

importing excess volumes. During the year, 282 quality certificates submitted by the importers were assessed for this purpose prior to issue of import approvals. Meanwhile, 475 samples were cross-screened as a mean of compliance verification for the FAO quality standards before issuing of packing clearance on consignment basis.

Screening of labels and advertising materials

Label approval procedure enabling dissemination of proper information to the end user has been a recurrent activity. Approximately 1,750 labels and over 143 advertising materials (leaflets, posters, banners and danglers, etc.) were screened during the year 2016. There were complaints promoting considerable outdated material and/or information on pesticides in the field, which prompted to introduce and maintain a special coding system on every printed advertising material in order to verify the status of contemporary approval by the ROP.

Actions against unethical pesticide promotions

Although a significant compliance over unethical and unapproved advertising on pesticides were maintained by pesticide companies including the house-hold sector during the year, in few instances, there were abrupt occurrences of marketing of multiple packs composited in a single-labeled pack (e.g., 5 x 100 g in 500 g packs of powder formulations of Diuron) by a leading company and in another instance, there were promotions on in-tank mixtures of two herbicides (as pre-land preparation total herbicides), which are

strictly prohibited. The complaints were immediately addressed and errors were rectified. Since label recommendations and licensing conditions are specifically stated during the pesticide registration process, any impending violations will be rectified & necessary corrective actions will be taken for consumer protection.

Training and awareness programs

For the year 2016, Rs. 2.0 million was granted through the National Food Production (NFP) Program (2016-2018) of the MOA for the continuation of training of Agrochemical Sales and Technical Assistants (ASTA) in collaboration with the National Apprentice and Industrial Training Authority (NAITA). 466 new applicants were selected for continuation trainings by the regional officials of the DOA & NAITA covering the districts of Anuradhapura, Nuwara Eliya, Hambanthota, Polonnaruwa, Kalutara, Kurunegala & Matale during the year 2016. As of October, 2016 new training programs were started in Kandy & Ampara districts while several other districts viz., Colombo, Batticaloa, Trincomalee, Puttalam, Moneragala and Badulla were instrumental in selection of candidates. It is evident from the past that the success of the training was some of the districts were at its 3rd round (e.g., Anuradhapura & Polonnaruwa) while the districts of Badulla, Hambanthota, & Matale were at its 2nd round.

The necessary pre-requisites including the preparation of national competency standards (Code: D24S001) and competency-based assessment resources (Code: A01S001) were validated by NAITA and endorsed by the Tertiary & Vocational Education Commission (TVEC). It is expected that all the certified

ASTA personnel will be eligible for the NVQ Level IV competency certificates upon completion of the formal competency requirements including curriculum development by University of Vocational Technology (UniVOTEC) and accredited by the TVEC within 2 years. This is a recurrent program.

Quality control of pesticides

Quality control of pesticides is one of the major undertakings at the analytical laboratory of the Office of the Registrar of Pesticides. It has been functioning for compliance monitoring purposes with the existing capacity, which is being upgraded for service-oriented activities upon receiving the status of laboratory accreditation ISO/IEC 17025: 2005, hopefully within the first quarter of 2017 (see actions under Special Activities). The analytical laboratory of the Office of the Registrar of Pesticides is in the possession of most sophisticated equipment in analytical caliber such as Gas Chromatograph-Mass Spectrometry (GC-MS), Inductively-Coupled Plasma Spectrophotometer (ICP-MS), Gas Chromatograph (GC) & High Performance Liquid Chromatography (HPLC) for qualitative and quantitative testing of pesticides, food & environmental samples.

Due to the overwhelming cost incurred on analytical work, the sustainability of the functions are always hampered by limited budgetary allocations to the Office of the Registrar of Pesticides, and therefore, imposing a levy on services given to the industry on item wise would be the best solution. As per the provisions under the Section 23 (2) of the Control of Pesticides Act No. 33 of 1980, a levy on the importer,

manufacturer, formulator or packer of a pesticide can be imposed for the general purpose of making proper financial provision for the effective implementation of this Act and of the regulations made there under. As per the above initiative and with the available provisions of the Act, the ROP requested services for assessing the cost of analysis for the entire spectrum of services currently undertaken at the analytical laboratory, in July 2016. Through open bidding procedures, M/s SGS Laboratory Services (Pvt.) Limited was selected for providing services. They undertook preliminary auditing for estimating the cost of analysis for the entire scope, in December 2016.

During the year 2016, 475 pesticide formulations (i.e. production batches) were analyzed for quality and performance parameters and 397 production batches were confirmed valid on quality grounds (based on physico-chemical parameters in the FAO specifications and own quality certificates) & approved for marketing. Meanwhile, one (1) pesticide consignment was re-shipped to the manufacturer on the failure of quality standards.

The analytical laboratory of the Office of the Registrar of Pesticides undertook testing for toxic heavy metal contamination levels in some popular & generic synthetic pesticides in comparison with herbicides of plant extracts by using the ICP-MS. Although the results cannot be generalized, the data showed some of the popular misconceptions that “organic” pesticides are benign and synthetic pesticides are “harmful” in terms of hazardous impurities (Table 2.1.3.3). The following Limits of Detection (LOD) values were valid for the most recent assessment of heavy metals in the

laboratory of the Office of the Registrar of Pesticides: As, 0.003 ppm; Se, 0.076 ppm; Cd,

0.002 ppm; Hg, 0.004 ppm; Pb, 0.001 ppm.

Table 2.1.3.3: Toxic heavy metal contaminants in selected pesticides (ppm)

Product	Arsenic (As)	Selenium (Se)	Cadmium (Cd)	Mercury (Hg)	Lead (Pb)
Q-Star [®]	0.019	<0.076	0.0985	0.0965	<0.0823
Beloukha WH [®]	0.0165	0.080	0.085	0.037	0.196
Nominee [®]	0.043	0.0827	0.0095	0.0212	<0.0823
BPMC	0.0675	<0.076	0.0097	<0.0133	0.194
Profenophos	0.0326	<0.076	0.0097	0.048	0.2047
Quinalphos	0.135	0.1105	0.0052	0.017	0.092

Establishment of four Technical Management Divisions

As a part of efficient management of regulatory activities, and in parallel to the preparation of a project proposal to restructure the present system of pesticides regulation in the country to cater to the global developments and to address human and environmental health issues as a one-stop-shop for pesticide-related matters, the following management divisions were established in the Office of the Registrar of Pesticides. Below is a summary of divisions & their responsibilities.

(a) *Pesticide Registration & Import Control Division I*: Product registrations, re-registrations, import & experimental use permits, of agricultural pesticides.

(b) *Pesticide Registration & Import Control Division II*: Product registrations, re-registrations, import & experimental use permits, of domestic & industrial pesticides.

(c) *Field Monitoring & Legal Support Division*: Training & awareness activities, field complaint handling & legal support, Pesticide dealer training & certification, pest control service certification & monitoring.

(d) *Compliance Monitoring and Safety Division*: Pesticide product quality testing, residue analysis and laboratory training etc.

In order to be excellent in services for local and international standards, a proposal for 424 million was presented to the Government in November 2016 with a view to construct a new building/office complex for the Office of the Registrar of Pesticides & to establish a pesticide analytical laboratory at the entry point, at Colombo harbor premises. Supply of necessary equipment & human resource developments are further activities proposed under the above proposal. It is absolutely essential that the Office of the Registrar of Pesticides be restructured and provided with improved physical and human resources to tackle pesticide-related issues in the country, holistically.

SPECIAL ACTIVITIES

Upliftment of laboratory proficiency up to the international standards

Assisted with the technical & instrumental capacity development under the special project on technical collaborative grant aid under the

TCP/SRL/3402 by Food and Agriculture Organization, FAO (through Asia-Pacific Regional Center in Bangkok) to improve “Management of Risks Associated with Pesticides Used in Agriculture in Sri Lanka” through the MOA (Ref. Performance Report 2015), the analytical laboratory of the Office of the Registrar of Pesticides has gained its proficiency caliber for (a) pesticide residue analysis in water, (b) heavy metal analysis in pesticides/ food items and (c) physical and chemical testing of pesticide formulations for common parameters as set out in the FAO specifications on plant protection products with a limited stipulated parameters and/or scope.

As a candidate client in international accreditation ISO/IEC 17025: 2005, the maintenance of track records in proficiency in testing has always been a high priority. The FAPAS® Proficiency Test is such a program to measure the ability to report results in the specified units and within the given time scale are part of the proficiency test. The inter-laboratory analysis under the FAPAS® Proficiency Test 07251 on vegetable puree sample was in compliance with Cadmium (Cd) while FAPAS® Proficiency Test 07248 on soya flour was in compliance with Arsenic (As) and Mercury (Hg) elements. The analytical laboratory of the Office of the Registrar of Pesticides also participated in the FAPAS® Proficiency Test 19205b pea pod sample pesticides residue analysis & shown its international competency.

Training workshop for fellow investigators on other Acts & other officers

During the year 2016, there were 6 training classes held for 210 participants of Public Health Inspectors (PHI) from the Department of Health. It is hoped that they will be functioning as facilitators for prosecution for illegal activities under the Control of Pesticides Act No. 33 of 1980 as “Enforcement Officers” (i.e., persons empowered to institute proceedings and conduct prosecutions). The Section 24(A) of the Control of Pesticides (Amendment) Act No. 06 of 1994 has been crafted in such a manner to exploit external resources for legal actions, nominated as persons empowered to institute proceedings and conduct prosecutions. The Office of the Registrar of Pesticides will embark on recruiting external Officers for field monitoring of pesticides during the year 2017.

Implementation of Empty Pesticide Container Management in Sri Lanka

The Office of the Registrar of Pesticides in collaboration with the Ministry of Mahaweli Development & Environment (MMDE) has initiated a program to develop strategies to manage empty pesticide containers in the country. There are two pertinent sources of containers viz. by company disposals of large drums and smaller containers disposed at farmer fields. It is estimated that yearly turnover of empty glass containers only is nearly 1,000 tons at a worth of Rs. 38 million. It has been estimated that 14.6 million pesticide containers (which includes all types of containers as of 2011) are disposed of

haphazardly every year into the environment without a proper management option.

In the light of the above, it was proposed that the problem of empty pesticide containers would need a proper solution through a well supervised recycling mechanism under controlled conditions in line with the waste management hierarchy. After successful discussions during stakeholder meetings on strategies to implement the program, all agreed on (a) the necessity of a solution for container disposal, (b) social responsibility of all parties concerned and (c) to explore technical feasibilities for recycling of glass and plastic containers in the country. This is a part of the theme under the Basel Convention to implement strategies to minimize health and environmental implications from empty pesticide containers at the field level.

The recycling of glass and plastic containers is a well established private enterprise in the country, which is regulated by the Central Environment Authority (CEA). Currently, there are several projects executed by the CEA to strengthen waste management systems within the industry under the premise of “public-private partnership” programs. By considering the unique & hazardous nature of wastes, it was proposed to develop an exclusive mechanism for private organizations including the Crop Life, Sri Lanka (which is the pesticide industry coalition in Sri Lanka) for collection, processing and manufacturing of non-consumable items.

The proposed empty pesticide container management program was expected to obtain the fullest implementation support of the CEA. On 22nd August 2016, the above initiative was officially launched with the participation of

Secretaries/ representatives of Secretaries to the MOA & the MMDE, Director General of Agriculture and other stakeholders & signed a memorandum of understanding (MOU) among key stakeholders. In order to mark the shared responsibility, the Office of the Registrar of Pesticides distributed two plastic waste crusher machines to deploy at pilot projects on waste recycling through the CEA. Also, four regional container collection centers were built and declared open during the ‘Govi sathiya’ from 8-15 October, 2016. These centers will be functioning as the link between the farmer (at the field level) and the recycler. Field collection mechanism will be implemented by the Crop Life, Sri Lanka (company association with the membership of 29 pesticide companies in Sri Lanka, as of December 2016). The regional container collection centers are located at (i) Seetha Eliya Government Seed Farm, (ii) Polonnaruwa Government Seed Farm, (iii) Pelwehera Government Seed Farm, and (iv) Regional Agricultural Research & Development Institute, Makandura (NW).

The following recyclers are enrolled in the approved mechanism to accept “triple-rinsed” glass and plastic (HDPE) empty pesticide containers: (1) M/s Polykar PVC (Pvt.) Ltd., & (2) M/s Piramal Glass Company (Pvt.) Ltd.

The Office of the Registrar of Pesticides facilitated this program through financial provisions by purchasing 2 crusher machines (Rs. 1.43 Mn.), construction of 4 regional container collection centers (Rs. 3.7 Mn.), printing of stickers for field collection bins (Rs. 0.49 Mn.) & poster/ leaflets for farmer awareness (Rs. 0.43 Mn.), at a total cost of nearly Rs. 5.7 million.

The Office of the Registrar of Pesticides has also taken initiatives to popularize the concept of “bio-beds” among farming communities to avert injudicious disposal of pesticide wastes and empty containers in to the environment. The “bio-bed” concept which has been implemented by many European farms uses microorganisms naturally present in organic media to detoxify pesticide wastes. It is expected to collect old soiled-containers unattended in the field and in house-holds and to direct them to the regional field collection and recycling, after thorough cleaning on “bio-beds”.

The segregation and collection of pesticide containers at the field level were facilitated by raising farmer awareness through field extension staff. For this purpose, the Office of the Registrar of Pesticides created and funded for distribution of 400,000 posters on 4 thematic designs both Sinhala & Tamil languages; 300,000 technical advisory leaflets on 3 thematic designs in both Sinhala & Tamil languages, among farmers & extension officers.

National Food Production (NFP) Program 2016-2018: Food Safety Assurance

As public and international demand for safe food free from harmful levels of pesticide residues has been heightened, though quite belatedly, work continues to secure national and international commitments to manage pesticide residues to acceptable levels. Currently, pesticide residues on fruits and vegetables is a major concern due to not following Good Agricultural Practices (GAP) in agricultural production. Higher pesticide

residue levels have been detected in exported consignments of vegetables and fruits to the European Union (EU), not complying with their standards. Hence, EU is in the process of continuous auditing of the existing implementation strategies in Sri Lanka on the same. However, information on pesticide residue analysis and detection in fresh food products in the country was limited. Therefore, there was an urgent need to establish a reliable database for pesticide residues on various agricultural products in local production channels.

A national residue data base

The NFP Program (2016-2018) implemented by the MOA gives priority & financial support to quality control of agricultural produce and implementation in terms of monitoring of pesticide residues according to local and international standards. In order to mark the commitment, the MOA has initially allocated Rs. 12.25 million for developing a National Pesticide Residue Database by targeting analysis of 500 food samples during 2016 (Rs. 7.25 million) & 2017 (Rs. 5 million) for major pesticides used in agriculture. The pesticide residue monitoring program will be operating from September 2016 through September 2017.

Agricultural product contamination with pesticides

The results of monitoring for major pesticides in 145 vegetable samples from the local market revealed that 63 samples had been tainted with pesticides but only one sample exceeded the proposed regulatory limits adopted from the CODEX Alimentarius Commission, CODEX (i.e., Crop: Bean, Violation: Tebuconazole

0.37 vs. 0.30 ppm). The results of a collaborative study (Senthuran et al., 2016. Assessment of pesticide residues in vegetables of selected domestic markets in Sri Lanka) on pesticide residue in 45 market-basket vegetable samples from Nuwara Eliya, Puttalam & Matale districts revealed detectable residue levels but none of the samples were exceeding regulatory limits of CODEX. Meanwhile, 28 vegetable samples taken from exporter pack houses were tested (during 07/2016) for major pesticides and 12 samples were found to be tainted (43%), and except 8 samples (28%), all the other sample contamination levels were below the EU MRLs of respective pesticides. Profenophos, Thiamethoxam, and Tebuconazole were among the detected out of 52 pesticide active ingredients including commonly used contemporary pesticides and several banned pesticides (Method Detection Limit, MDL =0.01 ppm), according to the scope of analysis at the Industrial Technology Institute; there were more frequent violations in leafy vegetables. However, the quite narrow scope of analysis hinders a meaningful decision on food safety with respect to pesticide residues. The EU MRLs are much more stringent, and it is only about 40% of the local MRLs adopted from the CODEX.

Meanwhile, 41 commercial rice samples (local, imported & some traditional varieties) were analysed in a collaborative study (Panapitiya et al., 2016, Levels of selected heavy metals in rice in Kandy district) and it was found that none of the rice samples were contaminated with toxic heavy metals (assessment included Pb, Cd, As, Hg & Se) exceeding the FAO/WHO Tolerable Daily Intake Levels.

Scope of analysis

The laboratory of the Office of the Registrar of Pesticides is geared towards strengthening of laboratory standards to the international level, ISO/IEC 17025: 2005 accreditation with the focus on pesticide quality and residue assessments. The initial assessment has shown compliance on residue assessment on 5 active ingredients (i.e., Fipronil, Tebuconazole, Chlorpyrifos, Prothiophos and Diazinon) in water and agricultural produce but the laboratory is competent in analysis of 10 active ingredients. It is continuously being upgraded its testing requirements and analytical capabilities, with a practical target to increase the analytical scope up to 30 during the year 2017. For comprehensive assessment of agricultural products for pesticide residues, the whole analytical infrastructure in the country must meet to analyse over 107 active ingredients (used in agriculture as of December 2016) within the next couple of years.

Setting maximum residue limits

The Control of Pesticides Act No. 33 of 1980 (Section 26- Manner of the sale and use of pesticides) has set out ample provisions to declare safe limits for pesticide residues in local consumptions of fresh fruits and vegetables. In order to complement national food safety assurance, 221 pesticide tolerance limits (maximum residue limits, MRLs) on 39 crop/food categories for 65 active ingredients were finalized for the Government Gazette Extraordinary notification. The Law requires the Office of the Registrar of Pesticides to set MRLs for over 100 active ingredients to ensure food safety in the country. This assessment may require another step forward in preparation for analyzing foreign active

ingredients in order to complement total food safety by focusing imported agricultural products as well, within the next couple of years.

Acquisition of high-tech instruments for pesticide quality assurance

The policy of the formulation & residue laboratories is to maintain good professional practices meeting international standards of testing of pesticides with highest achievable accuracy and to provide traceable high quality services in conformity with the applicable requirements of ISO/IEC 17025: 2005 international standards. Therefore, the infrastructure development at the analytical laboratory of the Office of the Registrar of Pesticides was further upgraded by spending nearly Rs. 20 million through the NFP Program for acquiring ancillary equipment and laboratory chemicals. Out of which nearly Rs. 5 million was spent on acquiring a Fourier Transform Infrared (FTIR) Spectroscopy machine for solving analytical challenges with easy to achieve qualitative and quantitative analysis of a wide range of pesticide and non-pesticide (organic and inorganic) samples needing special identifications, such as adulteration during manufacturing and field activities.

Management plans for obsolete pesticides

As of December 2016, 26 metric tons of obsolete pesticides were accumulated in government farms and research institutions of the DOA, over the period of last 2–3 decades. The preliminary discussions prompted the Office of the Registrar of Pesticides to maintain a secure storage facility at the DOA,

which was considered as the only feasible interim solution for the management of obsolete pesticides.

With the financial allocations through the Office of the Registrar of Pesticides, an existing building from the Field Crop Research and Development Institute (FCRDI), Mahailuppallama was completely renovated by June 2016, by taking into account the commonly acceptable standards of secure storage facilities for hazardous substances. During the initial trial storage, approximately 0.4 metric tons of obsolete pesticides were stored in a secure manner at the above facility and another 24 metric tons of obsolete stock at regional locations were inspected for verification purposes. Some of the stocks at regional centers (e.g. Deputy Director's Office at Ampara) were voluminous and badly decayed requiring great caution in handling. The Office of the Registrar of Pesticides noted that a separate secure storage facility is needed in order to manage some of the regional stocks of obsolete pesticides in possession with the DOA.

Legal prosecutions and ongoing proceedings against illegal pesticides

The Office of the Registrar of Pesticides has made some significant progress during the year 2016 on revealing illegal attempts to sell Glyphosate containing products after the cancellation of registration & stop-sale regulations (Government Gazette Extraordinary No. 1937/35 dated 23.10.2015) have been issued. In January 2016, a pesticide trader in Naula area was prosecuted for selling and/or offering for sale of Weedol® Glyphosate and a stock of illegal Malathion. In another incident, a pesticide seller in Siripura

area was found to sell Knockout® Glyphosate. In another attempt, an unscrupulous trader was caught while smuggling of D-Era® (containing 71% ammonium salt of Glyphosate) at the airport Customs. Necessary legal steps are being taken against the above violators.

Examples of significant enforcement actions on illegal pesticides over the past year include:

- In January 2016, a seller of illegal Glyphosate was confiscated at Naula area & summoned at the Naula Magistrate Court. The court proceedings are on-going.
- In December 2015, a main pesticide dealer at Wanathavilluwa, Puttalam area was found storing a large stock of counterfeit illegal pesticide of Finchem® Carbofuran. The same dealer was also found storing illegal Counter® Glyphosate. After several hearings at the Puttalam Magistrate Court, the case was disqualified due to procedural lapses, but as a result of appeal by the ROP in October 2016, and on the advice of the Attorney General's Department, the case is being processed at the Puttalam High Court. The court proceedings are on-going.

Audit on laboratory compliance

During November 14-15, 2016, the analytical laboratory of Office of the Registrar of Pesticides had successfully undergone a 2-day peer evaluation by the joint peer evaluation team of Sri Lanka Accreditation Board (SLAB). The peer evaluation team consisted of 5 peer evaluators. They conducted a thorough, deep, detailed and strict assessment on SLAB accreditation programs for conformity

assessment under ISO/IEC 17025: 2005, 41-5.10 quality management systems. During the evaluation, more than 25 accreditation files were checked by the peer evaluators. They had also checked corrective actions over pre-assessment requirements proposed on 14.03.2016. In addition, the peer evaluation team had witnessed 4 on-site assessments performed on heavy metal & residue analysis, wettability tests conducted by the laboratory staff. They concluded that the laboratory performance is satisfactory with little non-compliance for corrective actions before granting recommendations for international accreditation.

Pre-audit mission to Sri Lanka by the EU

In preparation for the EU audit on pesticide management in support of assurance of pesticide residues in compliance to the EU MRLs in exported agricultural products to the EU member countries from Sri Lanka, the STDF project under the ITC financially supported the mobilization of two EU Experts on agronomy (Mr. Manel Orpella from Spain) and chemical testing (Mr. Benoit Glaud from Spain) aspects during 22-29 June, 2016. During the 8-day mission, the experts were instrumental in heightening awareness through training workshops on the EU food control systems and its challenges, pesticide control, procedures of the marketing and use of pesticides, the EU requirements for laboratory analysis and related control systems in tandem with field visits. Many diverse groups of trainees including policy makers from stakeholder organizations, agricultural product exporters, researchers, extension and

laboratory staff of the DOA participated at the workshops.

The Audit to Sri Lanka to evaluate control of pesticides in food of plant origin intended for Export to the EU

Since there were number of interceptions from the EU in the recent past on exceed of MRLs on farm produce exported to the EU member countries from Sri Lanka, a 3-member team from the European Commission, two auditors from the Directorate General for Health and Food Safety and one expert from a European Union (EU) member state, visited Sri Lanka from 14-22 September 2016, in order to evaluate country's preparedness for future improvements needed to prevent violations. The entire assessment composed of the assessment to control mechanisms of pesticides in food of plant origin intended for export to the European Union from Sri Lanka.

The Office of the Registrar of Pesticides prepared an action plan under the guidance of the Director General of Agriculture in preparation for the Audit and to make the activities sustainable as the competent authority. The response of the ROP (as the competent authority of Sri Lanka) to the recommendations in the Report Ref. DG (SANTE)/2016-8787-MR on the Audit was submitted on 18 October, 2016.

Recommending Suitable Reduced Risk Pesticides for Leafy Vegetables with Short Pre-Harvest Intervals

According to the recommendations given by the EU Audit Report, it has been persistently stressed recommending specific recommendations for leafy vegetables

including Pennywort (Gotukola - *Centella asiatica*). Most of the Pennywort cultivators are used to apply pesticides like Acephate, Carbosulfan, Profenofos, Tebuconazole, Thiamethoxam etc. As some of the pesticides (e.g. Profenofos) are banned in EU countries, the above Audit has raised negative impressions in this regard. It is imperative that export products to the EU market must comply with most stringent Maximum Residue Limits (MRLs), where in most cases the EU banned compounds are set at a default MRL at 0.01 ppm. Other than that, if in cases our farmers were used to apply the EU-authorized pesticides for leafy vegetables, we may need to pay special attention on application rates & frequency of application etc. to meet most stringent EU MRLs compared to CODEX MRLs. Discussions were had on 18 November 2016 at the APeSC to propose recommendations to meet the above task with utmost priority in order to protect the export market of the Fruits and Vegetables from Sri Lanka.

Implementation of Exporter Registration Scheme under EU Audit to Evaluate Control of Pesticides in Food of Plant Origin Intended for Export to the European Union

Registering of the exporters who send their Fresh Fruits and Vegetables (including leafy-vegetables) to the EU market is one of the main activities identified by the EU Audit team during 14-22 September, 2016 (Ref. DG (SANTE)/2016-8787-MR). The exporter registration process was proposed with the anticipation of full implementation by 15

September 2016. The Agri-Business Council of the Department of Agriculture (ABC-DOA) was proposed as the Registration Focal Point for EU Exporters & necessary applications were designed by the ROP. Accordingly, six potential exporters of Fresh Fruits and Vegetables (including leafy-vegetables) to the EU have been registered under the scheme through the Agri-Business Council, as of December 2016.

At this very critical stage of implementation of the EU Export Requirements for Pesticide Residues in Food of Plant Origin from Sri Lanka, and having close scrutiny of Production and Processing of Fresh Fruits and Vegetables (including leafy-vegetables) through Counselors of Agri-Business (CAB) of the DOA, necessary initiatives were taken by the Office of the Registrar of Pesticides through the Director General of Agriculture to restrict all exports of Fresh Fruits and Vegetables (including leafy-vegetables) to the EU member States through registered parties by November 2016. Accordingly, the current Directive will be serving as an immediate and short-term strategy in order to prevent tarnishing EU Export Hub of Fresh Produce (Fresh Fruits and Vegetables, including leafy-vegetables) from Sri Lanka with unauthorized pesticide residues. The Office of the Registrar of Pesticides is working with the CAB Officers of the DOA to establish a “direct farmer & exporter link” to ensure that pesticide residue limits are not violated at the EU entry point.

Implementation of the use of safety kits for pesticide application

The ROP sent a Circular No. PPE/Saf/04/2016 dated 25.04.2016 on popularizing of safety kits

among farmers and this novel initiative will be compulsorily implemented with effect from January 31st 2017. Under this initiative, the ROP requested that complete Personnel Protective Equipment (PPEs) are available at the market place at a reasonable price in compliance to the existing regulations made under the Control of Pesticides Act No. 33 of 1980.

It is acknowledged here that the “International Code of Conduct on the Distribution and use of Pesticides” under the Article 5 to state that for Reducing Health & Environmental Risks, Government & Pesticide Industry should cooperate in further reducing risks by promoting the use of proper & affordable PPEs. Alternatively, there are regulations published under the Control of Pesticides Act No. 33 of 1980 to promote farmer use of PPEs by the Government Gazette Extraordinary No.1113/5 dated 05.01.2000 *Vide* Regulation 6 (b) that “every person who sells or offer for sale any general or restricted pesticides shall sell or offer for sale all protective clothing which may become necessary in the application of pesticides in order to ensure the safe use of such general or restricted pesticides”.

The use of PPEs during application of plant protection products including pesticides by the local farmers are expressively meager resulting in danger to human lives. While chemical pesticides have contributed greatly to the increase of yields in agriculture by controlling pests and diseases, and towards the control of some vector-borne diseases in the human health sector, their continued & irresponsible use has surfaced many problems. According to a recent collaborative study (K.G.A.P.

Dulanjalee, Uva Wellassa University, Badulla. Impact of Pesticide Use Practices on Farmer's Health: A Case Study in Wijayagama and Eheranda in Matale District). conducted in rural farming villages in Matale district, it has been revealed that the type of pesticide, the dosage of pesticide, hours of exposure, number of bad practices and awareness on re-entry period were the significant factors affecting severity level of impact on farmers' health due to pesticide use practices. A majority of farmers (55%) used pesticides above the recommended doses. It was only 11% of the farmers qualified under "good" category in use of PPEs. Almost 75% of the farmers were used to throwing away empty pesticide containers as their preferred disposal option. Only 24% of farmers had a slight awareness on re-entry period and the rest of 76% was not aware about it. Only 16% of the total sample was not affected with discernible acute effects while 84% of the sample was reported to having one or more considered acute pesticide poisoning symptoms, after routine application of pesticides. The study documented a serious consequence of the indiscriminate use of pesticides for the farmers' health. This study gave indications that a majority of farm households do not take cognizance of the long-term and short-term health hazards of occupational exposure and acute pesticide poisoning symptoms are under-reported.

The Office of the Registrar of Pesticides envisaged that despite clear & concise recommendations and directives given in the past, there is a serious lacuna on implementation and compliance aspects, and availability of suitable PPEs in the market place is almost non-existent for decades. The standard PPEs include: protective eye wear,

nose guard, face mask, long sleeved vest + longs or overall, hand gloves, boots, etc. Therefore, it is high time to design effective and targeted outreach programs which deal specifically with pesticide risk, safe handling and averting behavior.

The matter has embarked needing expeditious attention of the pesticide industry on this requirement. The Office of the Registrar of Pesticides has determined to make it a deliberate responsibility of the pesticide industry to create the availability of suitable PPEs in the market place, especially in all pesticide dealer outlets island wide. Individual proposals were sought from individual pesticide industries on avenues for making availability of PPEs suitable & affordable to the farmer, and in the meantime, take appropriate actions to make the farmers aware about the importance of using PPEs, through their field staff (i.e. to conduct demonstrations as many as possible) by 01st August 2016. The pesticide industry is being attending for fulfilling the requirements under their stewardship initiatives.

Chemical Policy Coordination & International Participation

Sri Lanka is a party under the Basel, Rotterdam, Stockholm & Minamata Conventions. The ROP has been functioning as the Designated National Authority (DNA) on powers vested with regulation & control of pesticides. Therefore there are direct responsibilities under the Rotterdam & Stockholm Conventions while there are indirect responsibilities under the Basel & Minamata Conventions. Inter-agency responsibilities under the above four Conventions are fulfilled by official

representations at the National Coordinate Committee (NCC-BRSM) under the MMDE.

The Rotterdam Convention covers pesticides which are banned and severely restricted under the conditions of use in developing countries and countries of economies in transition. Under this Convention, banned and severely restricted pesticides are managed in a form of international information sharing during importation and exportation, which is called as “PIC”, Prior Informed Consent Procedure.

The Stockholm Convention covers Persistent Organic Pollutant (POP) pesticides which are highly toxic and persistent in the environment and they have global concerns due to their transboundary transport. The global elimination and safe disposal of these types of compounds are the ultimate objectives of this Convention. The National & International Obligations under this Convention has been fulfilled by the ROP by participating at the development of National Implementation Plan (NIP) through the compilation of “POPs Pesticide Inventory” by the year 2016. This document provides an overview of the current state of the situation of POP pesticides in Sri Lanka as it pertains to availability of POPs pesticides, levels of environmental contamination, estimation of obsolete stocks, and identification of data gaps and action plans to implement the objectives by the Stockholm Convention.

In this regard, Sri Lanka has been prodigious in making decisions well advance of the announcement of international actions on POPs pesticides, banned and severely restricted pesticides under the Stockholm & Rotterdam Conventions, respectively; the current status is spectacular as that almost all

POPs pesticides, banned and severely restricted pesticides have been de-registered and/or banned from major uses at least 15 years earlier. The inventory also revealed insignificant amounts of POPs pesticides (e.g. Aldrin, DDT, BHC & Endosulfan) waiting for disposal, which was estimated to be 71.53 kg (0.17%), available from few locations in government farms of the DOA. Thus, the use of the term “POPs pesticide stockpile” in terms of the Stockholm Convention would not be meaningful for Sri Lanka due to two reasons:

- (i). there were insignificant stocks of obsolete POPs pesticides in Sri Lanka; and
- (ii). there were no records of production and/or formulation of POPs pesticides in Sri Lanka and hence production discards were almost non-existent.

In the meantime, the ROP has been functioning in various capacities in the implementation of the above Conventions in the past within the scope & the mandate and in particular the representations at Chemical Review Committees (e.g. POPRC, CRC) & Conference of Parties (COPs), locally & internationally.

Change of Status of Sri Lanka's Position on Ethylene Oxide

Ethylene Oxide (EtO) had been declared as “No consent” under the Rotterdam Convention as per the previous decision by the PeTAC. According to the Ministry of Health sources, few hospitals are still using this chemical for medical instrument sterilization and are looking for alternatives of EtO. However, on the urgency of limited quantities for the medical sector, the ROP proposed a revocation to the earlier decision in October 2016, and

submitted a revised decision as “Consent with Restrictions” to the Rotterdam Convention Secretariat with the approval of the PeTAC. The interim response has been published in the PIC Circular Volume XLIV dated 12th December 2016.

PLAN FOR 2017

Pesticide Management in Sri Lanka

Program for registration of pesticides

- Acceptance of applications for new registration
- Acceptance of applications for re-registration
- Evaluation of technical dossier for registration for new registrations
- Evaluation of technical dossier for re-registration
- Preparation of new registration certificates
- Preparation of re-registration certificates
- Pesticides Technical & Advisory Committee (PeTAC) meetings
- Dialog with the pesticide industry & other stakeholders
- Pesticides sub-committee Meetings of Agricultural Pesticides Sub-committee
- Pesticides sub-committee meetings of Domestic & Public Health Pesticides Sub-committee
- Pesticides sub-committee meetings of Industrial Pesticides Sub-committee
- Evaluation & preparation of data for Agricultural Pesticides Sub-committee
- Evaluation & preparation of data for Domestic & Public Health Pesticides Sub-committee
- Evaluation & preparation of data for Industrial Pesticides Sub-committee

- Coordination of pesticides testing with the DOA (for its bio-efficacy)

Program for awareness on all relevant target groups assurance of safe use & judicious marketing of pesticides & collecting & compilation of pesticides related data

- Media programs:
 - TV
 - Radio
 - Print media
- Training / Certification of Agrochemical Sales and Technical Assistants (ASTA)
- Awareness exhibitions
- Awareness programs for AUOs & Enforcement Officers
- Dealer Training Classes*
- Publishing revised guidelines for registration of pesticides/guidelines for registration of pesticide companies
- Services for participation as technical experts/ members/ resource personnel on invitations by the DOA/other institutions
- Collection & compilation dissemination of import statistics (Central Bank, Universities, Researches, Govt. Institutes, etc.)*

Program for compliance monitoring (Product quality and residues in environmental compartments & action against violation of the Control of Pesticides Act, No. 33 of 1980)

- Issue of import permits**
- Issue of sample import approvals**
- Evaluation of quality certificates in consignment basis**
- Screening of labels for approval**

- Screening of advertising materials for approval**
- Inspection of formulation factories
- Inspection of pesticides impurities
- Inspection of approved repacking facilities & stores
- Inspection & certification of premises of fumigation & house-hold pest control service providers
- Development & implementation of programs for empty pesticide container disposal
- Registration of pest control services***
- Approval of CH₃Br for quarantine & pre-shipment treatment on accountable basis
- Issue of restricted pesticide use permits (excluding CH₃Br) for pest control services
- Inspection of sales outlets
- Field complaints****
- Action taken to legal prosecution
- Issue of dealer training certificates
- Issue of dealer certificates by the AUOs
- Dispatch of samples to the MRI & other institute for obtaining test reports on suitability for acceptance of applications
- Issue of packing clearance as per the quality analysis of samples on consignment basis
- Establish a compliance monitoring scheme to assure the levels of pesticide residues in vegetables/ fruits/water
- Number of heavy metal analysis for food/ water
- Formulation analysis
- Acceptance of test reports for suitability (Bio-efficacy & heavy metal reports)
- Evaluation notifications send by the European Union (EU) (on pesticides residue)*****
- Under the EU audit residue analysis data base *****
- Other activities (such as field surveys)

Program for participation as technical expertise/members/resource person for intra & inter

- Ozone Unit of the Ministry of Mahaweli Development & Environment
- Basal/ Montreal/ Stockholm/ Rotterdam Conventions
- Department of Custom
- Ministry of Health
- Ministry of Agriculture
- National Library Services Council
- Sri Lanka Tea Board
- Ministry of Mahaweli Development & Environmental / CEA
- Sri Lanka Standard Institute
- Other

Program for income generation

- Fee for Agrochemical Sales & Technical Assistant (ASTA) (Rs.100.00)
- Fee for dealer certification (pesticide sales outlet) (Valid only for 1 year) (Rs. 550.00)
- Permit fee for import approval (Rs.1,000.00)
- Filing fee for restricted pesticides (Rs. 6,500.00)
- Registration fee for restricted pesticides (Rs. 4,000.00)
- Re-registration fee for restricted pesticides (Rs. 4,000.00)
- Filing fee for general/domestic pesticides (Rs. 75,000.00)

- Registration fee for general/domestic pesticides (Rs. 25,000.00)
 - Re-registration fee for general/domestic pesticides (Rs. 4,000.00)
 - Registration fee for pest control services (Rs. 20,000.00)
 - Re-registration fee for pest control services (Rs. 5,000.00)
 - Filling fee for company registration (Rs. 50,000.00)
- Registration fee for company registration (Rs. 50,000.00)
 - * As per the request.
 - ** These targets will be decided depending on company requirements.
 - *** As per the request & fulfilling required qualifications.
 - **** As of number of received complaints
 - ***** As these are special activities, items could be changed at any time.

STAFF LIST

Designation	No. Approved	No. Existing
Registrar of Pesticides	01	-
Deputy Registrar of Pesticides	01	-
Assistant Director of Agriculture (Research)	08	05
Assistant Director of Agriculture (Development)	02	02
Research Assistant (Special Grade)	01	-
Agriculture Monitoring Officer	02	01
Program Assistant (Agriculture)	02	02
Development Officer	04	04
Agriculture Instructor	06	05
Research Assistant	07	07
Public Management Assistant.	05	05
Technological Assistant	03	01
Driver	03	03
Storeman	01	01
Research Sub Assistant	01	-
Office Employee	01	-
Watcher	02	02
Laborer	05	05
Laborer (Contract)	02	02
Total	57	45