

BEFORE THE NATIONAL GREEN TRIBUNAL (SZ) AT CHENNAI

MEMORANDUM OF APPLICATION

Application No. 155 of 2017 (SZ)

Between

M. Gobineelan

.....

Appellant

and

The Secretary to Government, Department
of Environment and Forest, Chennai and others

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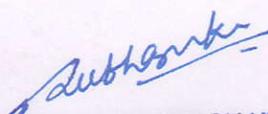
Respondents

Further reply on behalf of Respondent No. 5 (The Chairman, Central Insecticides Board and Registration Committee, Ministry of Agriculture and Farmers Welfare) :-

In continuation with the earlier reply submitted and the status report placed on record before this Hon'ble Tribunal and further with highest regards to observations of this Hon'ble Tribunal in its order dated 23.11.2021. It is submitted as under:-

Regulatory regime of the Insecticides Act, 1968

1. It is humbly submitted that the Insecticides are inherently toxic substances, therefore, they are required to be regulated. Most countries in the world have systems for regulation of pesticides. In India, import, manufacture, transport,


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distribution, sale and use of insecticides are regulated under a comprehensive legislation, namely, the Insecticides Act, 1968 (Act) with a view to prevent risk to human beings, animals and matters connected therewith. In order to facilitate implementation of provisions of the Act, a set of rules has been framed, known as the Insecticides Rules, 1971 (the Rules). In this context it is necessary to apprise the Hon'ble Court about the regulatory regime of Insecticides Act, 1968 and Rules, 1971 (the Act).

2. The Ministry of Agriculture and Farmer's Welfare, Department of Agriculture and Cooperation, administers, the Insecticide Act 1968 and Rules framed there under (the Act):

The Act extends to the whole of India. As per the provisions of section 3 (e) the term "insecticide" has been defined as under:

Section 3 (e) - "Insecticide" means

- i. *Any substance specified in the Schedule; or*
- ii. *Such other substance (including fungicides and weedicides) as the Central Government may, after consultation with the Board, by notification in the Official gazette, include in the Schedule from time to time; or*
- iii. *Any preparation containing any one or more of such substance*

Accordingly, pesticides/insecticides are the substances which are either specified in the schedule to the act or may be included by the applicant.

3. It is submitted that as per provisions enshrined under section 9 of the Act, any person desirous of importing or manufacturing an insecticide has to mandatorily obtain a registration from the Registration Committee (RC), constituted under Section 5 of the Act at Centre Government Level. The RC is responsible for satisfying itself with the safety and efficacy of the insecticide before granting registration. As per Section 5(5) of the Act, RC is also empowered to regulate its own procedure and conduct of the business to be transacted by it. It is also empowered to verify the claims made by the applicants.

4. It is submitted that under the provisions of the Act, a constitution of Central Insecticide Board has been made u/s 4 which reads as under:

The Central Insecticides Board (CIB) (Section 4)

1. The Central Government shall, as soon as may be, constitute a Board to be called the Central Insecticides Board to advise the Central Government and State Governments on technical matters arising out of administration of this Act and to carry out the other function assigned to the board by or under this Act.
2. The matters on which Board may advise under sub-section (1) shall include matters relating to:
 - a. the risk to human beings or animals involved in the use of insecticides and the safety measures necessary to prevent such risk;
 - b. the manufacture, sale, storage, transport and distribution of insecticides with a view to ensure safety to human beings or animals.
3. The board shall consist to the following members, namely:
 - i. the Director-General of Health Service, ex officio, who shall be the Chairman;
 - ii. the Drugs Controller, India, ex officio;
 - iii. the Plant Protection Adviser to the Government of India, ex officio;
 - iv. the Director of storage and inspection, ministry of food, Agriculture, Community Development and Co-operation (Department of Food) ex officio ;
 - v. the Chief Advisor of Factories, ex officio;
 - vi. The Director, National Institute of Communicable Diseases, ex officio;
 - vii. the Director-General, Indian Council of Agricultural Research, ex officio;
 - viii. the Director-General, Indian Council of Medical Research, ex officio;
 - ix. the Director, Zoological Survey of India, ex officio;
 - x. the Director-General, Indian Standards Institution, ex officio;

- xi.** the Director-General of shipping or, in his absence, the deputy Director-General of shipping, Ministry of Transport and Shipping, ex officio;
- xii.** the Joint-Director, Traffic (General), Ministry of Railways (Railway Board), ex officio;
- xiii.** the Secretary, Central Committee for Food Standards, ex officio;
- xiii.a.** the Animal Husbandry Commissioner, Department of Agriculture, ex-officio;
- xiii.b.** the Joint Commissioner (Fisheries), Department of Agriculture, ex officio;
- xiii.c.** the Deputy Inspector-General of Forests (Wild life), Department of Agriculture, ex officio;
- xiii.d.** the Industrial Adviser (Chemicals), Directorate-General of Technical Development, ex officio;
- xiv.** one person to represent the Ministry of Petroleum and Chemicals, to be nominated by the Central Government;
- xv.** one Pharmacologist to be nominated by the Central Government;
- xvi.** one Medical Toxicologist to be nominated by Central Government;
- xvii.** one person who shall be in charge of the department dealing with public health in a state, to be nominated by the Central Government;
- xviii.** two person who shall be Directors of Agriculture in States, to be nominated by the Central Government;
- xix.** four persons, one of whom shall be expert in industrial health and occupational hazards, to be nominated by the Central Government;
- xx.** one person to represent the Council of Scientific and Industrial Research, to be nominated by the Central Government;
- xxi.** One ecologist to be nominated by the Central Government.

4. The person nominated under clauses (xiv) to (xxi) inclusive, of sub-section (3) shall, unless their seats become vacant earlier by resignation, death or otherwise, hold office for three years from the date of their nominations but shall be eligible for re-nominations:

Provided that the person nominated under clauses (xvii) and (xviii) shall hold office only for so long as they hold the appointments by virtue of which their nominations were made.

5. No act or proceeding of the Board, the Registration Committee or any Committee appointed under section 6; shall be called in question on the ground merely of the existence any vacancy in, or any defect in the constitution of, the Board, the Registration Committee or such committee, as the case may be.

Functions of Board as under (Rule 3) are as under :-

The Board shall, in addition to the functions assigned to it by the Act, carry out the following functions, namely:

- a. advise the Central Government on the manufacture of insecticides under the Industries (Development and Regulation) Act, 1951 (65 of 1951);
- b. specify the uses of the classification of insecticides on the basis of their toxicity as well as their being suitable for aerial application;
- c. advise tolerance limits for insecticides, residues and an establishment of minimum intervals between the application of insecticides and harvest in respect of various commodities;
- d. specify the shelf-life of insecticides;
- e. suggest colourisation, including colouring matter which may be mixed with concentrates of insecticides, particularly those of highly toxic nature;
- f. carry out such other functions as are supplemental, incidental or consequential to any of the functions conferred by the Act or these rules.

THE RELEVANT TECHNICAL ISSUES ON WHICH ADVISE OF CIB IS SOUGHT:

As submitted herein above the Central Insecticides Board is to advise the Central Government and State Governments on technical matters arising out of administration of this Act and to carry out the other function assigned to the board by or under this Act. The meetings of CIB are being held regularly with in a interval of six months. The minutes of the meetings are being regularly uploaded and are available in the public domain on the official website of the respondents <http://ppqs.gov.in>. The minutes of the 57th, 58th, 59th, 60th & 61st meetings of CIB are enclosed at **Annexure-I-Colly**.

It is humbly submitted and emphasized that the issues on which CIB advices during its meeting for deliberations and appropriate suggestive measures to achieve the above objectives of the statute are as under:-

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- i. Progress report of the Registration Committee, Central Insecticides Laboratory and Regional Pesticides Testing Laboratories. The Board take the progress of the Registration Committee on monitoring to ensure compliance conditions of Registration.
- ii. The Board also suggest that infrastructural facilities with respect to manpower and machinery may be created.
- iii. Disposal facilities for pesticides complying with emission standards fixed by the Ministry of Environment & Forests by the registrants may be made mandatory.
- iv. Methodology for export registration to ensure safety of factory workers, as well as environment and toxicity data.
- v. Central Insecticides Laboratory: The Board also take care of progress of the CIL and suggested creation of more resources as well as facilities for testing of more number of samples in Chemistry, Bio efficacy and Toxicology.
- vi. The Board also take care of the progress of the RPTLs including testing facilities for bio-pesticides.
- vii. The Board also emphasizes that more and more number of samples should be drawn to ensure supply of quality pesticides to the farmers and defaulters be prosecuted.
- viii. The meetings of Central Insecticides Board are held under the chairmanship of Director General of Health Services, Ministry of Health & Family Welfare.
- ix. In Board meetings as mandated in the statute the applications for inclusion of new pesticides in the Schedule to the Insecticides Act, 1968 are considered.
- x. In Board meetings as mandated in the statute the applications for waiting period/pre-harvested interval between application and harvest are considered.
- xi. The board also advises on Assignment of color of identification bad (Tox Triangle) on label and classification of pesticides as per Toxicity.
- xii. The board also carry out as mandated in the statute the various type of notifications, inclusion in schedule and amendments of rules. The Revised Scheme for carrying out and submission of Storage Stability

Studies (Data) for registration of insecticides including packaging changes.

Registration Committee (RC) (Section 5)

- (1) The Central Government shall constitute a Registration Committee consisting of a Chairman, and not more than five persons who shall be member of the Board (including the Drugs Controller, India and the Plant Protection Advisor to the Government of India)
 - i. to register insecticide after scrutinizing their formulae and verifying claims made by the importer or the manufacturer , as the case may be, as regards their efficacy and safety to human beings and animals; and
 - ii. to perform such other functions as are assigned to it by or under this Act.
- (2) Where the Chairman is not a member of the Board, his term of office and other conditions of service shall be such as may be determined by the Central Government.
- (3) Subject to the provisions of sub-section (2), a member of the Registration Committee shall hold office for so long as he is a member of the Board.
- (4) The committee may also co-opt such number of experts and for such purpose of period as it may deem fit, but any expert so co-opted shall have no right to vote.
- (5) Registration committee shall regulate its own procedure and the conduct of the business to be transacted by it.

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Functions of the Registration Committee (Rule 4) are as under:-

The Registration Committee shall, in addition to the functions assigned to it by the Act, perform the following functions namely:

- a. Specify the precautions to be taken against poisoning through the use or handling of insecticides;
- b. Carry out such other incidental or consequential matters necessary for carrying out the functions assigned to it under the Act or these rules.

It is humbly submitted that the meetings of RC are being held regularly and so far 434 meetings have been held. The minutes of the meetings are being regularly uploaded and are available in the public domain on the official website of the respondents <http://ppqs.gov.in>. The progress made by the RC is regularly appraised to the Board.

Scientific Guidelines for registration of insecticides to achieve legislative Intent:

It is humbly submitted that the Act is basically safety oriented and the object is primarily safety to human beings, animal life and environment at large that is matters connected there with. To achieve the very objective of the Act, besides Board (CIB), The Registration Committee (RC) also evolved guidelines on scientific parameters viz. chemistry, bio-efficacy, toxicity, packaging and legal disciplines with the following objectives:-

- a. The Registration Committee (RC) constituted u/s 5 of the Act, a statutory highly technical body comprising of highly technical eminent scientists from different fields grants registration. The RC registers insecticides after scrutinizing formulae, verifying claims of efficacy and safety to human beings and animals, specifying the precautions against poisoning and any other function incidental to these matters. To assess efficacy of the insecticides and their safety to human beings and animals, the RC has evolved exhaustive guidelines / data requirements which *inter-alia* includes data on acute and long term effect of pesticides, its reproductive toxicity, genotoxicity, neurotoxicity, teratogenic (effect on developing foetus or embryo)and carcinogenic potential, its effects on environment which also include toxicity to birds, fish, honey bees, its residues in air, water, soil,

residue in crops and their edible produce on which the insecticides are intended to be used etc., besides the efficacy trials for its applicability in the country. The onus lies with the importers / manufacturers to generate data relating to the insecticides for which registration is sought. The data thus submitted to the RC is evaluated and registrations are granted only when RC is satisfied about the efficacy and safety of the product under the conditions of use in the country. Whenever the RC is not satisfied about the safety and efficacy of the products, the registrations are refused for such insecticides.

- b. The RC grants registration to an insecticide for use in the country only after complete satisfaction w.r.t. data submitted before it on scientific parameters as stated above. Accordingly, RC prescribed conditions, use pattern, instructions etc. on the certificate/label/leaflets accompanying the package of the insecticide product. If a pesticide is used in accordance with directions as prescribed on the label and leaflet, it does not cause any risk.

Central Insecticides Laboratory (Section -16)

1. It is submitted that under the provisions of the Act, a constitution of Central Insecticide Lab has been made u/s 16 which reads as under:

The Central Government may, by notification in the Official Gazette, establish a Central Insecticides Laboratory under the control of Director to be appointed by the Central Government to carry out the functions entrusted to it by or under this Act;

2. Provided that if the Central Government so directs by a notification in the Official Gazette, the functions of the Central Insecticides Laboratory shall, to such extent as may be specified in the notification, be carried out at any such institution as may be specified therein and thereupon the functions of the Director of the Central Insecticides Laboratory shall to the extent so specified, be exercised by the head of the institution.

Functions of the CIL (Rule 5) are as under:-

- a. to analyse such samples of insecticides sent to it under the Act by any officer or authority authorized by the Central or State Governments and submission of certificates of analysis to the concerned authority;

- b. to analyse samples of materials for insecticide residues under the provisions of the Act;
- c. to carry out such investigations as may be necessary for the purpose of ensuring the conditions of registration of insecticides;
- d. to determine the efficacy and toxicity of insecticides;
- e. to carry out such other functions as may be interested to it by the Central Government or by a State Government with the permission of the Central Government and after consultation with the Board.

Insecticide Analysts (Section 19)

1. The Central Government or a State Government may, by notification in the Official Gazette, appoint persons in such number as it thinks fit and possessing such technical and other qualifications as may be prescribed to be Insecticide Analysts for such areas and in respect of such insecticides or class of insecticides as may be specified in this notification:
2. Provided that no person who has any financial interest in the manufacture, import or sale of any insecticide, shall be so appointed.

Insecticide Inspectors(Section 20)

1. The Central Government or a State Government may, by notification in the Official Gazette, appoint persons in such number as it thinks fit and possessing such technical and other qualifications as may be prescribed to be Insecticides Inspectors for such area as may be specified in the notification:

Provided that any person who does not possess the required qualifications may be so appointed only for the purposes of clauses (a) and (d) of sub section (1) of section 21: Provided further that no person who has any financial interest in the manufacture, import or sale of any insecticide shall be so appointed.

2. Every Insecticide Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal code (45 of 1860), and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

5. It is submitted that as already stated herein above the Registration Committee (RC) constituted u/s 5 of the Act, a statutory highly technical body comprising of highly technical eminent scientists from different fields grants registration. The RC registers insecticides after scrutinizing formulae, verifying claims of efficacy and safety to human beings and animals, specifying the precautions against poisoning and any other function incidental to these matters. To assess efficacy of the insecticides and their safety to human beings and animals, the RC has evolved exhaustive guidelines / data requirements which *inter-alia* includes data on acute and long term effect of pesticides, its reproductive toxicity, genotoxicity, neurotoxicity, teratogenic (effect on developing foetus or embryo)and carcinogenic potential, its effects on environment which also include toxicity to birds, fish, honey bees, its residues in air, water, soil, residue in crops and their edible produce on which the insecticides are intended to be used etc., besides the efficacy trials for its applicability in the country. The onus lies with the importers / manufacturers to generate data relating to the insecticides for which registration is sought. The data thus submitted to the RC is evaluated and registrations are granted only when RC is satisfied about the efficacy and safety of the product under the conditions of use in the country. Whenever the RC is not satisfied about the safety and efficacy of the products, the registrations are refused / banned / withdrawn for such insecticides. Accordingly, 63 insecticides have been banned / refused / withdrawn registration. Further, 18 pesticides have been refused for the grant of registration, besides 09 pesticides are restricted for use in the country (**Annexure – II –Colly.**). Presently, 299 insecticides are registered for use in the country (**Annexure – III**).
6. It is further apprised, that as drugs are used for human diseases and saving precious human lives, similarly, pesticides are used for saving the crops /plants from disease/insect/pest and weed etc. thereby ensuring the food security for the ever growing population of the country and protecting the public from vector borne diseases like Malaria, Filariasis, Dengue, Chicken guinea, Kala-azar , Viral encephalitis etc . “Green Revolution” during the 1970s and 1980s, has considerably increased the crop production and made India self-sufficient in food. It is mentioned that apart from high yielding seeds, chemical fertilizers, irrigation; pesticides played a very important role in enabling the Green Revolution. However, it is difficult to segregate the contribution, exclusively made by pesticides.

7. The use of pesticides is of paramount importance for food security of our ever growing population and combating the vector borne diseases prevalent in the country. However, Government of India was aware of that chemical pesticides are inherently toxic in nature and hence for their safe use need to be regulated, hence, enacted the Insecticides Act 1968 and rules were framed in 1971.

Integrated Pest Management (IPM)

8. The Central Government was aware about Indiscriminate and injudicious use of chemical pesticides in agriculture has resulted in several associated adverse effects such as environmental pollution, ecological imbalances, pesticides residues in food, fruits and vegetables, fodder, soil and water, pest resurgence, human and animal health hazards, destruction of bio-control agents, development of resistance in pests etc. Therefore, Govt. of India has adopted Integrated Pest Management (IPM) as cardinal principle and main plank of plant protection in the overall Crop Production Programme since 1985. IPM is an eco-friendly approach which encompasses cultural, mechanical, biological and need based chemical control measures. The IPM approach is being disseminated through various schemes/ projects at national and state level with the main objectives to Minimize the crop losses caused by pests and diseases, Encourage farmers to use various ecologically sustainable pest management approaches rather than relying only on chemical pesticides, Promote use of bio-pesticides & bio-control agents in plant pest management, To promote Indigenous Technology Knowledge (ITKs), Conserve the diverse Agro- ecosystem for build-up of various natural enemies for plant pests, Create awareness amongst farmers on Safe and judicious use of chemical pesticides and To follow the label claims and instructions on dose and use as approved by CIB&RC, Carryout survey and surveillance for pest and diseases with main emphasis to forewarn the farmers on the potential epidemics of plant pests, Popularizing IPM in farming community by imparting training to Agriculture / Horticulture Extension Functionaries and Farmers at Grass Root Level by organizing Farmers Field Schools / 2 days / Five days HRD programmes and Season Long Training Programmes of 30 days. In these programmes, they are being trained on latest IPM technology and to adopt organic farming and bio-fertilizers as well, Liaison with Pesticide industry associations, ATMAs, State Agriculture Department, KVKs, Farmers Clubs, SAUs, NGOs, etc. The activities carried out by the IPM are as under:

- a. Popularizing IPM approach among farming community.
- b. Conducting regular pest surveillance & monitoring to assess pest/disease situation.
- c. Rearing biological control agents for their field use and conservation of naturally occurring bio-agents.
- d. Promotion of bio-pesticides and neem based pesticides as alternative to chemical pesticides.
- e. To play a catalytic role in spread of innovative IPM skills to extension workers, land farmers equally to resource-poor and resource-rich states.
- f. Human Resources Development (HRD) in IPM by imparting training to master trainers, extension workers and farmers through Farmers' Field Schools (FFSs).
- g. HRD programme (short duration) courses of two days and five days for pesticides dealers/NGOs/Graduates/Post-graduates/Pvt. Entrepreneurs and progressive farmers.
- h. Season Long Training (SLT) programme on major agricultural/horticultural crops.

Department of Agriculture & Farmers Welfare (DA&FW) in the Union Ministry of Agriculture & Farmers Welfare promotes the Integrated Pest Management (IPM) approach under the scheme "Strengthening & Modernization of Pest Management" through 35 Central Integrated Pest Management Centres (CIPMCs) located in 28 States and 2 Union Territories.

The mandate of these Centres is pest/disease monitoring, production and release of bio-control agents, conservation of bio-control agents and Human Resource Development in IPM by imparting training to Agricultural Extension Officers and farmers at the grassroots levels by organizing Farmers' Field Schools (FFSs) in the farmers' fields. They are taught to use chemical pesticides judiciously and as a last resort. They are advised to follow strictly the directions mentioned on label and leaflets of Registration Certificates and essentially available with each pesticide packs. On label and leaflets the dose, method and time of application/s of the pesticides and waiting period after application of a pesticide, safety related issues and precautions to be followed during the application of pesticides and safe disposal of pesticide containers are incorporated. The Central and State Governments organize training to farmers on safe and

judicious use of pesticides including disposal of pesticides and used containers etc. The information on harmful effects of pesticides and observance of safety in their use is also provided to the farmers during Krishi Melas and other interactive meetings with farmers including the trainings organized by the 35 Central Integrated Pest Management Centers across the country and also 680 Krishi Vigyan Kendra (KVK) of ICAR, State Agriculture Universities and State Government wherein specialized scientists impart training to the farmers. In addition 591 districts have Agricultural Technology Management Agency (ATMA) centers which are instrumental in convergence of various activities at the district level to the farmers. The copy of Physical achievements of the Schemes (last 5 years) is at Annexure- IV.

8. As stated herein above the RC grants registration to an insecticide for use in the country only after complete satisfaction w.r.t. data submitted before it on scientific parameters as stated above. Accordingly, RC prescribed conditions, use pattern, instructions etc. on the certificate/label/leaflets accompanying the package of the insecticide product. If a pesticide is used in accordance with directions as prescribed on the label and leaflet, it does not cause any risk.
9. It is humbly apprised to this Hon'ble Tribunal that besides active ingredient the effect of inert ingredients, metabolites, contaminants, transformation by-products and synergistic effect are also examined while evaluating safety of an insecticides.
10. It is humbly submitted that the statute provides for the grant of registration u/s 9 of the Insecticides Act for various categories at the centre level by the Registration Committee which is a statutory body comprising of highly technical scientific experts from various fields. The Committee grants registration only after satisfying itself to the safety of an insecticide under the prescribed conditions of use in the country and assessing the efficacy of the pesticide based on multi location data for its use across the country. Further, it is to apprise that the statute provides for the grant of licenses to manufacture, sell, stock or distribute etc of an insecticides u/s 13 of the Act by the respective State Government after due assessment of the infrastructure facilities etc. of the registrant. It is again reiterated that the RC is sensitive of its mandate to assess the safety and efficacy of the product before the grant of registration.

11. It is humbly submitted that the Insecticides Act, 1968 also provide for penal action under section 29 of the Act besides the cancellation of the registration on safety issues under section 27 of the Act. Therefore, any person who uses an insecticide in contravention with the label claim is liable to be punished under the Act. Further, it is submitted that the Statute provides for various Authorities/Functionaries at the State level, besides Central Insecticides Board and Registration Committee at central level. The State functionaries like Insecticides Analysts, Insecticides Inspector, Functionaries to notify pesticide poisoning, Licensing Officer etc. They all function to achieve the very objective of the Act. It is submitted that there is an exhaustive mechanism w.r.t. safe use of pesticide, as label and leaflet are the integral part of the Certificate of Registration which provide for details about crop on which it is to be used, target organism, method of application, doses, precautions, directions, warnings, first aid, antidote etc. so as to ensure safe use of any insecticide.
12. It is humbly submitted that the Insecticides Act, 1968 in its present format is the two tier system wherein the grant of registration rests with the Central Govt. and look after by the Registration Committee further Central Insecticides Board at Central Govt. level is to advice the Central Government and State Governments both on insecticides related issues as stated above, whereas the manufacture, sale, distribution, stock etc is in the purview of the State Department of Agriculture. For this purpose, there is provision of licensing authority at state level, responsible for each and every aspects relating to manufacture, stock, distribution and sale etc. It is submitted that there is an adequate co-ordination between Central and State functionaries. There is sufficient interface exist between the two functionaries and even the state representatives are also invited in CIB meetings and regular Zonal Conferences and also National Conference once in a year are being hold by the Union Department of Agriculture and Farmers Welfare with the State Department Agriculture prior to the Rabi and Kharif seasons. Furthermore, there is active co-ordination between the notified insecticide inspector and officer of State and Central Governments. Similarly, the statute provides for the establishment an apex laboratory, called as CIL constituted under section 16 of the Act, besides two Regional Pesticides Testing Laboratories (RPTLs) and State Pesticide Testing Laboratories (SPTLs) for ensuring the quality standards of insecticides.

13. It is submitted that the Food Safety and Standards Authority of India (FSSAI) has been entrusted with function of fixation of Maximum residue limit under Ministry of Health & Family Welfare.
14. The Scientific Panel on Pesticide Residue and Antibiotics under FSS Act, 2006 has devised a Proforma for submission of data/information about the particular pesticide/pesticide formulation for which MRL has to be fixed. The applicant who desires to register a pesticide product submits the data/information in the said Proforma. Secretariat of CIB&RC, Directorate of Plant Protection Quarantine Storage, Ministry of Agriculture and Farmers Welfare, after verification forwards this Proforma containing information data to FSSAI for fixation of MRL. Further, it is reiterated that labels and leaflets which are integral part of certificate of registration and pesticide packages provide details about the direction of use, precautions, cautionary statements etc. to guide the farmers about its safe use.
15. It is humbly submitted that the Government is concerned about the public safety and no pesticides (which require for fixation of MRL) are registered for use in the country, without fixation of MRL by the scientific panel under FSSA Act, 2006 administered by Ministry of Health and Family Welfare. It is submitted that Government is propagating Integrated Pest Management strategy, a Central Sector Scheme for minimizing the excessive use of pesticide by utilizing other methods of pest control viz cultural, mechanical, biological and only need based judicious use of pesticides. Furthermore, Government is also promoting use of safer pesticides like bio-pesticides, plant based pesticides. It is also further apprised that 680 Krishi Vigyan Kendra (KVK) of ICAR having subject matter specialist on Plant Protection, State Agriculture Universities and State Government wherein specialized scientists impart training to the farmers.
16. It is relevant to mention that the Department of Agriculture, Cooperation & Farmers Welfare, Ministry of Agriculture & Farmers Welfare had started a Central Sector Scheme, "Monitoring of Pesticide Residues at National Level" in food commodities and environmental samples during 2005-06 with the participation of various laboratories representing Ministry of Agriculture, Indian Council of Agriculture Research, Ministry of Health and Family Welfare, Ministry of Environment and Forest, Council of Scientific and Industrial Research, Ministry of Chemical and Fertilizer, Ministry of Commerce and State Agricultural Universities

across the country. Under the central sector scheme, "Monitoring of Pesticide Residues at National Level" (MPRNL) sponsored by Department of Agriculture, Cooperation & Farmers Welfare, Ministry of Agriculture & Farmers Welfare, the samples were collected and analysed by 25 NABL accredited participating laboratories for the possible presence of groups of pesticide residues such as organo-chlorine, organo-phosphorous, synthetic pyrethroids, carbamates, herbicides. The samples of vegetables, fruits, spices, red chilli powder, curry leaves, rice, wheat, pulses, fish/marine, meat and egg, tea and milk were collected from the retail outlets, mother dairy and agricultural produce marketing committee (APMC) markets, farm gate, organic outlets and surface water from water resources such as ponds, reservoirs, lakes, river, etc. located at different parts of the country.

National Institute of Plant Health Management (NIPHM): Objectives and Vision towards Agriculture.

17. The National Institute of Plant Health Management (NIPHM) earlier known as The National Plant Protection Training Institute (NPPTI) is a premier autonomous Institution under the Department of Agriculture and Farmers Welfare, Ministry of Agriculture and Farmers Welfare, Government of India. The Institute is a centre of excellence for promoting environmentally sustainable Plant Health Management practices in diverse and changing agro-climatic conditions and to provide policy support with focus on Sanitary and Phytosanitary (SPS) issues and emerging Biosecurity Challenges. The objectives of the Institute are:
- i. To promote; environmentally sustainable Plant Health Management practices in diverse and changing agro-climatic conditions;
 - ii. Pesticide Management and Biosecurity & Incursion Management through capacity building programmes;
 - iii. To extend policy support to Central and State Governments.
 - iv. The main focus of Plant Health Management programmes of the NIPHM is to promote agro-ecosystem analysis (AESA) based Plant Health Management in conjunction with Ecological Engineering (EE) through Farmer Field Schools (FFS), which takes into account the intricate interdependence among various components of an ecosystem, to promote biointensive approaches.

- v. NIPHM offers training programmes in Biosecurity Management, Plant Quarantine, Sanitary and Phytosanitary issues to effectively tackle the challenges arising out of the globalization of trade in Agriculture;
- vi. The Institute offer specialized programmes in Pesticide Management, Rodent/Vertebrate Pest Management, Production of Biocontrol Agents and Integrated Nutrient and Weed Management.
- vii. In order to promote safe and judicious use of pesticides, special programmes are offered in Pesticide Application Technology.
- viii. To play a crucial role in enhancing agricultural production addressing the emerging challenges in the field of Plant Health Management by assisting the Government of India, States, and other stakeholders.
- ix. To achieve the above said goal / objective through the core role of Teaching, Training, Research, Certification & Accreditation and Policy Support on SPS issues and Bio-security challenges within national and international contexts.
- x. NIPHM also plays an important role in capacity building of agricultural extension officers in South Asia, Africa & other developing countries.
- xi. NIPHM in collaboration with USDA organized international programmes at NIPHM and building capacity of NIPHM faculty through USA based programmes and other international collaborations in the field of agriculture.

Therefore, the Government of India is instrumental in taking all appropriate steps to prevent any risk to human being, animals & environmental at large. Thus the Government is popularizing the plant protection technology among the farming communities including extensions functionaries of central, states / UTs / Public / Private Sectors and other Non Governmental Organization. Hence, benefits accrue from the adoption of new technique in the field of agriculture inputs in terms of increased and qualitative produce with minimum residues and optimized use of agriculture inputs such as pesticides and its impact on human, animal life and environment with a goal to enhance the farmers income.

18. It is submitted that the total daily intake is the amount of substance that can be ingested daily over a life time without any significant health risk. Hence, total pesticide intake should not exceed this amount. It is further

clarified that the pesticides are inherently toxic and while granting registration the Registration Committee evaluates data on safety w.r.t. all aspects viz its short term, long term effects on health including effect on various organs , neurotoxicity, genotoxicity or mutagenicity, teratogenicity, effect on reproduction, carcinogenicity (which are the part of the guidelines of Registration Committee). The Registration Committee while registering the pesticides for use in the country evaluates safety and efficacy of pesticide based on established scientific guidelines where bio-accumulation in animal tissues and its degradability and persistence in soil and other environmental components are taken into consideration.

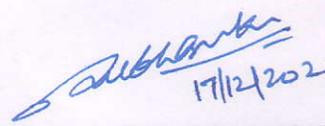
19. It is submitted that as stated herein above that non judicious and indiscriminate use may adversely affect human health and environment. The strategy of integrated pest management which envisages cultural, mechanical, biological and other method of pest control is being propagated besides promoting the use of safer alternative like bio-pesticides. Further, the Governments both Central and States/UTs impart training to the users regarding safe and judicious use of pesticides under various programs.
20. It is further submitted that while registering any pesticide for use in the country the Registration Committee not only evaluates the pesticides for its safety to human and animal health but also for its ecological impact by seeking data on various parameters like its effects on parasites and predators, translocation in plant, Metabolism in soil, Metabolism in water, Metabolism in plant, Persistence in soil, Persistence in water, Persistence in plant, Residue in plant, Residue in soil.
21. As submitted earlier the statute provide for the registration of pesticides at the central level through Registration Committee constituted under section 5 of the Insecticides Act, 1968 which has Plant Protection Adviser to Government of India and Drugs Controller General of India as Ex-officio members besides other experts from various Government Departments as members and co-opted members. It is a highly specialized technical body and while evaluating the efficacy of pesticides rely on the efficacy data generated by various State Agricultural Universities or ICAR Institutes. Hence, the committee ensures the suitability of pesticides for use under various agro climatic conditions in the country by different socio economic groups.

22. As submitted earlier the Registration Committee, a highly technical Committee under the Act evaluates the safety of the product based on the voluminous data submitted by the applicant as per the guidelines framed by the Registration Committee. The testing of any pesticide for its safety to human health and environment takes three to five years, sacrifice of many animals and several millions of rupees. Any pesticide once evaluated for its safety by this highly technical Committee does not require re-evaluation at State level. This will create confusing state of affairs at regional and national level and among consumers. Under the statute there are sufficient provisions to ensure making available safe and quality pesticides to the farmers/other users. The mandate of quality control of pesticides has been assigned to both Central and State Government under the statute.
23. As submitted earlier the regulatory mechanism already exists at the State level and the enforcement of various provision w.r.t. issue of licenses for manufacture, sale, distribution and quality control of pesticides is under the State control. However, some times the incidence of misuse of pesticides occur. The Central and State Government are imparting education and training to the farmers to curb such misuses. It is submitted that import, manufacture and use of unregistered pesticides is an offence of u/s 29 of the Act. As such the provisions are sufficient to look after the illegal activity in the pesticide trade.

PRAYER

In view of the position submitted herein above, the stand of the answering respondent No. 5 be taken on records and may pass appropriate directions as this Hon'ble Tribunal may deem fit and proper in the interest of justice.

Place - Faridabad


17/12/2021
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