



Ministry of Agriculture & Land Reclamation
US Agency For Intl. Development
Agriculture Policy Reform Program
Reform Design and Implementation

وزارة للزراعة واستصلاح الأراضي
للكالة الأمريكية للتنمية الدولية
مشروع إصلاح السياسات الزراعية
وحدة تصميم وتنفيذ السياسات

Ministry of Agriculture and Land Reclamation

AGRICULTURE POLICY REFORM PROGRAM

Reform Design and Implementation Unit (RDI)

USAID CONTRACT NO. 263-C-00-97-00005-00

Report No. 70



APRP

Reform Design and Implementation Unit

*Development Alternatives Inc. Group: Office for Studies & Finance, National Consulting
Firm Development Associates, Cargill Technical Services, The Services Group, Training
Resources Group, Purdue Universities, University of Maryland*

RDI REPORTS

Ministry of Agriculture and Land Reclamation
Ministry of Public Works and Water Resources

*Analytical Review of
Pesticide Laws And
Regulations In Egypt*

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JUNE 1999

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EXECUTIVE SUMMARY

Decree No. 663/1998 concerns the registration, handling, trading, and monitoring of regulations for chemical pesticides in Egypt. Decree No. 215/1985 is the backbone of this decree, with modifications based on the Code of Conduct issued by FAO.

The most notable changes in Decree No. 663/1998 and its draft explanatory manual in comparison to Decree No. 215/1985 are summarized as follows:

1. The pesticide definition of FAO is adopted, and any future changes by FAO are automatically accepted as part of the decree.
2. The articles of Decree No. 663/1998 are classified into groups which systematically deal with each objective.
3. The registration period for pesticides should not exceed three years. Efficacy of the product is tested during that period. Validation of the analytical methods of the end product and the residues should also be established during this period. The applicant will submit the toxicology file along with other necessary information to the appropriate authorities who scrutinize the information and make decisions regarding registration at the end of the three-year period.
4. End-product samples submitted by the applicant for experimental efficacy tests should be analyzed. The pattern of the product analysis (i.e. GC/MS spectrum) should be used as a reference for quality control analysis of the product following registration, and before its release for use.
5. Impurities in the formulation (i.e. end product) which do not state accepted ratios in the product specification should not exceed 1 mg/kg.
6. The information on the pesticide label should conform to the guidelines suggested by the FAO. Pre-harvest intervals (i.e. safety periods) are emphasized, and the Central Agriculture Pesticide Laboratory (CAPL) is assigned to issue such periods.
7. The trade name of an end-product pesticide should not be given to other pesticides.
8. Canceling or restricting the use of a registered pesticide should be based only on the following factors:
 - Unexpected hazards resulting from the pesticide's recommended use.

- Information on restriction received from international organizations; i.e. Prior Informed Consent (PIC) of the FAO/UNEP
 - Hazards of the pesticide's residues on public health or the environment. The Central Laboratory of Residue Analysis of Pesticides and Heavy Metals in Food is assigned to assess the risks. This laboratory handles the monitoring program of pesticide residues in Egyptian food in local markets. Data accumulated in the laboratory should be used in assessing consumers' exposure to pesticide residues through dietary intake. It is then compared to the Acceptable Daily Intake of the Joint Meeting on Pesticide Residues (JMPR) of the FAO/WHO. Additionally, decisions on objections to cancellation or restrictions on pesticides are regulated by Article 5 of Decree No. 663/1998.
9. Although transporting pesticides between governorates was prohibited in Decree No. 215/1985, Decree No. 663/1998 does not prohibit free movement of pesticides between governorates.
 10. An addition to Article 9 of Decree No. 663/1998 is very significant for developing countries. A special license is required for traders selling pesticides classified within WHO categories as grade 1a (extremely hazardous) and grade 1b (highly hazardous). The special license is obtained after completing a training course and passing a test. Training courses will be held periodically in the MOA-Central Agriculture Pesticide Laboratory.
 11. Pesticides classified under WHO categories as grade 1a (extremely hazardous) and grade 1b (highly hazardous) should be clearly identified by special marks on their labels.
 12. Full specifications for pesticide stores are set according to the FAO guidelines.
 13. Specifications have been defined for pesticide packages.
 14. Decree No. 215/1985 indicated that the time limit for analyzing the formulated end product for quality control purposes should not exceed one month. If the results of the analysis did not reach the applicant within one month, the product would be released from Customs into the country. Decree No. 663/1998 does not specify a time period. Thus, the analysis certificate verifying pesticide quality is required before the release of the pesticide into the country, regardless of the time taken for verification.
 15. Regarding objections to analysis results and re-analyzing the end product, Decree No. 663/1998 implies that the analyst involved in the re-examination shall not have participated in the first analysis.

16. Article 14 of Decree No. 663/1998 clarifies the purposes of pesticide sampling for analysis as follows:

- release from Customs for imported pesticides
- release of locally produced, formulated, or repackaged pesticides.
- monitoring of pesticide quality in the local market.

FUTURE PROSPECTS AND REQUIREMENTS

1. The explanatory manual of Decree No. 663/1998 is still in draft form. The manual should be disseminated and openly discussed among the various relevant parties (i.e. MOH, MOE, MOA, pesticide and food industries and most importantly, consumers).
2. Media communications with the public are needed to improve the public's understanding and to encourage them to participate in discussions on pesticide issues. Consumers also need to digest and respond to the information on monitoring pesticide residues in local food. These data are available for publishing so that the public will gain an understanding of this complicated subject matter.
3. There is an urgent need for a decree regulating registration of bio-pesticides which include microbes, fungi, viruses, natural products, etc.
4. Registration of pesticide application instruments is an important issue which needs to be addressed.
5. The licensing of applicators should be performed based on their education, training, and monitoring of their health status.
6. Encourage the pesticide industry to advocate and assist the government in education and training for applicators, traders, analysts, consumers, etc. This could begin by building trust within the pesticide industry.
7. The extension offices, agricultural cooperatives, and pesticide industry should coordinate and collaborate so that the government's role is limited to pesticide licensing and monitoring. The extension offices (including private offices) and cooperatives supported by the industry would then be responsible for implementing the application and the integrated pest management (IPM) programs.

GLOSSARY

DEFINITION OF TERMS

The definition of terms given below are intended for the purposes of the Codex Alimentarius and other Codex publications. Governments may wish to use different definitions. The definitions which have been reviewed by the Codex Committee on Pesticide Residues have been adopted by the 16th Session of the Codex Alimentarius Commission.

Animal feed: harvested fodder crops, by-products of agricultural crops and other products of plant or animal origin which are used for animal feeding and which are not intended for human consumption.

Pesticide: any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution, and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant-growth regulator, defoliant, dessicant, fruit-thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term normally excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.

Explanatory Note: "Agricultural commodities" refer to commodities such as raw cereals, sugar beet, and cottonseed which might not, in the general sense, be considered food.

Pesticide Residue: any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.

Explanatory Note: The term "pesticide residue" includes residues from unknown or unavoidable sources (e.g. environmental), as well as known uses of the chemical.

Good Agricultural Practice in the Use of Pesticides (GAP): the officially recommended or authorized usage of pesticides under practical conditions at any stage of production, storage, transport, distribution and processing of food, agricultural commodities, and animal feed, bearing in mind the variations in requirements within and between regions, which takes into account the minimum quantities necessary to achieve adequate control, applied in a manner so as to leave a residue which is the smallest amount practicable and which is toxicologically acceptable.

Explanatory Note: The “officially recommended or authorized usage of pesticides” is that which complies with the procedures, including formulation, dosage rates, frequency of application and pre-harvest intervals, approved by the national authorities.

Acceptable Daily Intake (ADI): the daily intake of a chemical which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical by the Joint FAO/WHO Meeting on Pesticide Residues. It is expressed in milligrams of the chemical per kilogram of body weight.

Explanatory Note: For additional information on ADIs relative to pesticide residues, refer to the Report of the 1975 Joint FAO/WHO Meeting on Pesticide Residues, FAO Plant Production and Protection Series No. 1, or WHO Technical Report Series No. 592.

Temporary Acceptable Daily Intake (TADI): an acceptable daily intake established for a specific, limited period to enable additional biochemical, toxicological, or other data to be obtained as may be required for estimating an acceptable daily intake.

Explanatory Note: A TADI estimated by the Joint FAO/WHO Meeting on Pesticide Residues normally involves the application of a safety factor larger than that used in estimating an ADI.

Maximum Residue Limit (MRL): the maximum concentration for a pesticide residue resulting from the use of a pesticide according to good agricultural practice that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity, or animal feed. The concentration is expressed in milligrams of pesticide residue per kilogram of the commodity.

Explanatory Note: The “recognized as acceptable” is intended to accommodate Member Countries which, under national legislation, do not use MRLs as legal limits. An MRL is principally based on supervised trials carried out under varying conditions of climate and pest control needs.

Extraneous Residue Limit (ERL): a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of a pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue or contaminant that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity, or animal feed. The concentration is expressed in milligrams of pesticide residue or contaminant per kilogram of the commodity.

Explanatory Note: The term “practical residue limit” had been used for residues in food from unavoidable sources and in food of animal origin arising from residues in animal feed. This term, which had led to much confusion, was abandoned. Residues in food of animal origin that are controllable by farming practices are now covered by MRLs.

Residues from unavoidable sources are covered by ERLs which are usually based on residue data from food monitoring programs.

Temporary MRL (TMRL) or Temporary ERL (TERL): an MRL or ERL established for a specified, limited period and is recommended under either of the following conditions:

1. where a temporary acceptable daily intake has been estimated by the Joint FAO/WHO Meeting on Pesticide Residues for the pesticide or contaminant of concern; or
2. where, although an acceptable daily intake has been estimated, the good agricultural practice is not sufficiently known or residue data are inadequate for proposing an MRL or ERL by the Joint FAO/WHO Meeting on Pesticide Residues.

Explanatory Note: TMRLs and TERLs are not to be advanced further than Step 7 of the Codex Procedure.

Guideline Level: used to assist authorities in determining the maximum concentration of a pesticide residue resulting from a use reflecting good agricultural practice but where an acceptable daily intake or temporary acceptable daily intake for the pesticide has not been estimated or has been withdrawn by the Joint FAO/WHO Meeting on Pesticide Residues. The concentration is expressed in milligrams of pesticide residue per kilogram of the commodity.

Explanatory Note: Guideline Levels are not to be advanced further than Step 4 in the Codex Procedure and are to be listed separately from MRLs and TMRLs in Codex documents.

Limit of Determination: the lowest concentration of a pesticide residue or contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity, or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

Regulatory Method of Analysis: a method that has been validated and can be applied using normal laboratory equipment and instrumentation to detect and determine the concentration of a pesticide residue or contaminant in a food, agricultural commodity, or animal feed for purposes of determining compliance with a maximum residue limit or extraneous residue limit.

Explanatory Note: For more information on regulatory methods of analysis and their application, refer to Recommendations for Methods of Analysis for Pesticide Residues and Codex Guidelines on Good Analytical Practice (Parts 7 and 8 of the Guide to Codex Recommendations concerning Pesticide Residues).

Intake Study: a study designed to measure or estimate actual dietary exposures of consumers to pesticide residues or contaminants in order to compare such exposures to the acceptable daily intakes for pesticides or contaminants.

Explanatory Note: For more information on intake studies, refer to Guidelines for the Study of Dietary Intakes of Chemical Contaminants prepared by the Joint FAO/WHO Food Contamination Monitoring Programme (WHO-EFP/83.53, FAO-ESN/MISC/83/2).

LIST OF ACRONYMS

APRP:	Agricultural Policy Reform Project
CAAE:	Central Administration for Agricultural Economics
CAPL:	Central Agricultural Pesticides Laboratory
CAPQ:	Central Administration for Plant Quarantine
CSSP:	Cotton Sector Support Program
EPA:	U.S. Environmental Protection Agency
FAO:	Food and Agriculture Organization
MALR:	Ministry of Agriculture and Land Reclamation
MOA:	Ministry of Agriculture
MOE:	Ministry of Environment
MOH:	Ministry of Health
MOI:	Ministry of Industry
MOT:	Ministry of Supply and Trading
WHO:	World Health Organization

I. Laws and Regulations Governing the Registration and Application of Pesticides by the Ministry of Agriculture (MOA)

1. Introduction

Laws and regulations governing the use of pesticides in Egypt issue from the Ministries of Agriculture, Public Health, Industry, and Environment. Other ministries are also involved in commercialization of pesticides (i.e. Ministry of Commerce, Ministry of Economics, etc.). Pesticide laws and regulations are necessary for the following reasons:

1. to provide for the proper, safe, and efficient use of essential pesticides for the production of food and fiber and for the protection of public health and safety.
2. to protect the environment from harmful pesticides by prohibiting, regulating, or controlling pesticide use.
3. to ensure safe working conditions for agricultural and pest control workers where pesticides are present.
4. to permit agricultural pest control via pesticide use by competent and responsible licensees under strict control of the appropriate local authorities who are authorized by the ministries involved.
5. to assure pesticide users that poisons are properly labeled and are appropriate for the use designated on the label.
6. to encourage the development and implementation of pest management systems, stressing application of biological and agricultural pest control techniques with the appropriate pesticides when necessary to achieve acceptable levels of control with the least possible harm to non-target organisms and the environment.

Failure to comply with established pesticide laws and regulations will subject a violator to fines and/or imprisonment, as well as to the possible loss or suspension of the violator's applicator license or certificate. Laws and regulations change periodically when new situations arise that are not addressed by existing laws and regulations. For example, pesticides and pesticide application equipment are constantly being improved and changed. Pest problems and pest management techniques may also differ from year to year. As new health and environmental problems are identified, regulations must be created or modified to accommodate them.

The purpose of recent changes in pesticide laws and regulations in Egypt is to achieve the following goals:

1. to further develop crop/pest management policy and strategy,
2. to maximize the benefits of pesticide use,
3. to minimize environmental impact and risks from pesticides,
4. to protect Egypt's citizens and its environment from hazards that might be caused by pesticide use;
5. to achieve proper, safe, and efficient use of pesticides under privatization;
6. to establish harmonization among the various ministries involved in pesticide monitoring;
7. to regulate trade and use of pesticides;
8. to protect and promote Egypt's agricultural exports to other countries.

2. Justification

The MALR has made notable progress in privatizing pest management services in Egypt. In the past few months the MALR/CAPQ, with the help of GTZ/CSSP and APRP, has embarked on handing over all pest management services to the private sector, including cooperatives, in two governorates. MALR/CAPQ/CAAE and GTZ/CSSP have provided extensive training to farmers in the pilot areas, and have set up a monitoring program to evaluate the results of the pilot program and prepare for its extension in the coming years.

In addition to practical implementation of this privatization program, the MALR, once again in cooperation with GTZ/CSSP and APRP, has made progress to alter existing laws and regulations on pesticide registration and licensing of applicators to correspond to the needs of the private sector. The MALR issued Ministerial Decree 663/1998 which provided a summary of all existing laws pertaining to pesticides in the MALR, and established some new procedures for registration. In addition, the MALR has in draft form, new protocols for pesticide registration. This draft document has been circulated unofficially to the private and public sectors for comment. It is expected to be formulated into a decree in the near future.

The progress made recently has stressed the need for final privatization of the industry while maintaining high safety standards for people and the environment. In this last regard, the MALR, CSSP, and APRP have recently come to know that a multiplicity of regulations exists in Egypt regarding the use and registration of pesticides. In addition to the Ministry of Agriculture, the Ministries of Health, Environment, Industry, and Trade all have their own sets of registration procedures, and most of these procedures are

less stringent than those in agriculture. This provides dealers of agricultural pesticides with the opportunity to register pesticides in other ministries without undergoing the same level of scrutiny required by the MALR. In some cases, this could mean that human and environmental safety are compromised.

The purpose of these terms of reference is to conduct a comparative analysis of current pesticide laws and regulations in the five ministries mentioned above. The analysis will, in particular, determine the areas where existing laws in one ministry may compromise the safety standards promoted in the regulations of a second ministry. This work will contribute directly to the achievement of Tranche III Benchmark D7, which requires a review of existing pesticide law. It will also lay the foundation for a proposed Tranche IV benchmark which proposes the harmonization of pesticide registration protocols between the Ministries of Agriculture and Health.

3. Background and Historical Review

The backbone of pesticide law and regulation in agriculture is the Agricultural Law promulgated by Law No. 53 in 1966. Consequently, many Ministerial decrees were issued to accommodate new policies and other concerns in pest control approaches. For example, Ministerial Decree No. 663/1998 provides for agricultural pesticides. Accordingly, the laws and decrees which were established and issued by other ministries in direct or indirect relation to pesticides were also considered in establishing this decree. Rules and regulations for pesticide use are primarily formulated by the Ministry of Agriculture (MOA), with the Ministry of Public Health (MOH) also issuing some laws and decrees. Through the implementation of integrated crop management (ICM) and integrated pest management (IPM) approaches, policy and strategy, the Ministry of Agriculture has achieved great success in minimizing the quantities of pesticides used in agriculture from 30,000 tons in 1980 to 3,000 tons currently.

Following are summaries of decrees affecting pesticide use which were issued from the 1950s to the present:

1. Law No. 453/1954 provides for regulation of industrial and commercial firms and other shops dealing with dangerous substances.
2. Law No. 2/1957 provides for the organization and encouragement of industry;
3. The Agricultural Law promulgated by Law No. 53/1966;
4. The Environmental Law promulgated by Law No. 4/1994 and its executive regulations;
5. Ministry of Industry and Mineral Wealth Decree No. 180/1996 provides for production compliance in conformance with Egyptian standards;

6. The recommendations of the Pesticides and Hazardous Chemicals Executive Committee formed by Ministerial Decree No. 1303/1995 and reorganized by Ministerial Decree No. 1006/1997;

7. Many issues and submissions by the legal consellor, etc.

4. Categorization of Ministerial Decree No. 663/1998 Providing for Agricultural Pesticides

Articles Grouping

The Ministerial Decree No. 663/1998 consists of 24 articles which can be classified into the following seven groups:

- Group 1 includes Articles 1-5 regarding the necessity, application, conditions, ad hoc registration and certification of pesticides, and cancellation of pesticide registration.
- Group 2 includes Article No. 6 regarding conditions and requirements for importing pesticides: whether pesticides were registered (or unregistered if samples are for trial purposes).
- Group 3 includes Article No. 7 concerning the manufacturing, formulating, or re-packaging of registered pesticides.
- Group 4 includes Articles 8-11 and 22 regarding agricultural pesticide trading (i.e. warehouse conditions and license, restrictions on highly hazardous pesticides, permissible trading of pesticides and application equipment, serial record-keeping on trading and movement of pesticides, and license validation for manufacturing and trading of pesticides).
- Group 5 includes Articles 12-13 concerning inspection of shops and warehouses trading in pesticides, license annulation in trading of hazardous pesticides, and specifications for containers in accordance with Egyptian standards.
- Group 6 includes Articles 14-20 regarding samples for quality assurance prior to release from Customs or prior to local manufacture/formulation; label conditions of flasks prepared for sampling and method of sampling in relation to package numbers; sample minutes; sample analysis (i.e. for registration, release from Customs, and authorization for circulation); objection to analysis results; and conditions and responsibilities for re-analysis.
- Group 7 includes Article 21 regarding granting the capacity of law officers to the pesticide control delegates.

5. Analysis and Review of Ministerial Decrees Prior to Decree No. 663/1998

5.1 Pesticides and the Agricultural Law Promulgated by Law No. 53 of 1966

The Law of Agriculture No. 53/1966 contains six sections (Nos. 78-83) regulating the use of pesticides. Section 78 gives the definition of pesticides. Section 79 grants the Minister of Agriculture authority to convene a committee to determine which pesticides are allowed and their specifications, steps for registration, and provisions for their handling. Section 80 details the decisions the Minister of Agriculture must make regarding the types of pesticides allowed for importing, provisions for importing and handling, registration steps, and the methods for sample analysis. Section 81 prohibits the manufacturing, preparing, selling, and importing of pesticides without a permit from the Minister of Agriculture. Section 82 regulates the declaration of pesticide specifications in accordance with MOA registration. Section 83 regulates methods of taking samples for analysis.

Various ministerial decrees were issued by the Minister of Agriculture providing the details required by the Law of Agriculture (i.e. Decree No. 50/1967, No. 125/1967, No. 45/1977; No. 215/1985, No. 1381/1989; No. 1303/1995; No. 1006/1997; No. 663/1998). Laws and decrees were also issued by other ministries (e.g. Law No. 453/1954 providing for industrial and commercial firms and other shops dealing with dangerous substances; Law No. 2/1957 for the organization and encouragement of industry; the Environment Law No. 4/1994; Law No. 180/1996 on production in conformance with Egyptian standards; etc.)

5.2 Law No. 453/1954 on Work Places Handling Pesticides

In addition to the above-mentioned MOA laws, Law No. 453/1954 concerns industrial, commercial and other work places and regulates, among other things, the conditions for those places handling pesticides. The Ministry of Housing issues the decrees necessary for carrying out the rules of this law. Law No. 127/1955 concerns the pharmacy profession and regulates the handling of domestic pesticides. Those working in Public Health and in Environment consider this legislation inadequate for protecting human health. What makes the situation worse is that the rules for implementing these regulations, although deficient, are not followed due to lack of supervision and information.

5.3 Agricultural Use of Pesticides and Ministerial Decrees

Decree No. 50/1967

In accordance with MOA Decree No. 50/1967, pesticides are imported only through state companies. These pesticides should be among those recommended

by the MOA for use in Egypt. The same decree confines marketing of bulk pesticides to the cooperative bank. State companies, through licensed shops, are allowed to sell certain pesticides (e.g. sulfur, mineral oils, certain non-hormonic herbicides, copper- and zinc-containing products, and other relatively safe pesticides).

According to this decree, pesticides should be packed in their original sealed packages and properly labeled. The degree of product toxicity must be clearly stated on the label.

The Ministry of Agriculture issues the regulations for protection from hazards of toxicity. These regulations are published annually within the official book of recommendations for control of agricultural pests, diseases and weeds. The book is disseminated to all concerned organizations and persons, including farmers, local agricultural officers, pest control workers, extension services, and many others.

Decree No. 48/1977

This decree was issued by the Ministry of Agriculture in cooperation with the Ministry of Public Health, and regulates security measures for the handling and application of agricultural pesticides. In accordance with this decree, a committee comprised of representatives from the Ministry of Agriculture (including specialists in agriculture and veterinary medicine) and the Ministry of Public Health is established in each governorate. The committee is responsible for coordinating the work of both ministries to secure all protective measures against toxicity and to supervise the implementation of the decree's regulations. Responsible personnel from the three groups (i.e. agricultural, veterinary, and medical) are to be appointed at different levels of the governorate on down to the village level. Further, they are responsible for informing the appropriate medical and veterinary officials prior to spraying about place and time of application, type of pesticides used, and if an emergency arises, about any cases of poisoning among man and animals. They are to take all appropriate measures to limit harmful effects.

The following provisions are also covered in the decree:

- i) Regulations jointly designed by the Ministries of Agriculture and Health for the safe use of pesticides are to be implemented by the spray workers and their supervisors. These regulations include type of clothing worn by the workers; methods for handling pesticide concentrates, containers, and spray equipment; recommended behavior during and after spraying (e.g. prohibitions against eating and drinking; and the washing or changing clothes); labeling of treated areas; proper pesticide storage; and proper disposal of left-over pesticides.
- ii) The Ministry of Health has an important role in the following areas:

- 1) Analyzing and determining the toxicity rate for all tested pesticides prior to forwarding the results to the MOA.
- 2) Determining the rate of toxicity affecting workers in field application tests or affecting farm animals.
- 3) Determining toxicity in commercial amounts of imported pesticides to ensure its similarity to the initial samples.
- 4) Supervising the operations, periodically inspecting workers, and removing and treating any cases occurring during field application of pesticides.
- 5) Analyzing fruit and vegetable samples from markets to ensure that toxic residues do not exceed permissible levels.

iii) Each spraying group must have a first aid kit containing all recommended materials and medicines.

Decree No. 215/1985

This decree is the backbone of the present Decree No. 663/1998. The decree concerns the registration of agricultural pesticides and prohibits the application of any pesticides in Egypt unless they are officially registered with the Ministry of Agriculture, who ascertains that samples and all required information have been submitted. These samples and information should then be forwarded for testing to the following institutes:

- Plant protection institutes within the Agricultural Research Centre of the Ministry of Agriculture and other institutes as recommended by the Ministry.
- Ministry of Health
- Institute of Animal Health, Ministry of Agriculture
- Central Laboratory for Pesticides, Ministry of Agriculture
- Administration of Pest Control, Ministry of Agriculture.

Reports from these institutes are submitted to the Committee for Recommendations of Pest Control and then to the Committee of Agricultural Pesticides, both within the Ministry of Agriculture. If these committees are satisfied, the pesticide is officially registered and the Minister of Agriculture decrees that it can be applied in the country for three years, after which time the pesticide must be re-

evaluated for its efficacy and then re-registered. However, registration of the pesticide may be cancelled before that time if a reasonable need to do so arises.

This decree emphasizes the role of the Pesticides Committee in approving the importing and handling of pesticides. The decree prohibits registration of agro-pesticides unless they are subjected to experiments by MOA and their chemical and physical properties are assured. Prior to registration and recommendation, evaluation trials should be performed for three successive years. Registration documents, including labeling information, should be completed by the applicant. Pesticides should be imported through public sector companies, but the door is open to private sectors for importing some registered pesticides for vegetables, fruits, ornamentals, medicinal plants and herbicides. Manufacturing and formulating pesticides should be licensed through MOA. Trading of agricultural pesticides was allowed for those companies or traders specified and nominated by MOA. The license for pesticide trading should be renewed every three years. Shops for pesticide trading should be selling pesticides and equipment for their application only; the same rule applies for fumigation facilities. Pesticide trading license conditions and information should continue to be obtained from MOA with no changes. The recording of pesticide movement is necessary. The decree details specifications for pesticide containers. Transporting pesticides between governorates should accord with MOA regulations. Handling pesticides or clearing them from Customs is prohibited unless analysis results prove that all specifications have been met. Sampling for analysis is specified for solid and liquid forms of pesticides. Labeling conditions of sample containers are also specified. Analysis should be conducted at the Department of Pesticides Analysis Research.

Ministerial Decree No. 1381/1989

This decree concerns the amendment of Article (8) of Ministerial Decree No. 215/1985 on agricultural pesticides. The decree added a new condition for trading pesticides: shops selling pesticides should be under the supervision of a manager (Agricultural Engineer) qualified by the Faculty of Agriculture and registered in the Agricultural Syndicate.

6. Environment Law No. 4/1994

Because of rising environmental concerns not only in Egypt but also on a global level, the Government of Egypt established the Environmental Affairs Agency in response to those concerns. This law was issued in 1994, and governmental agencies as well as non-governmental organizations concerned about the environment showed great support for it. The law contains 104 articles categorized into four sections in addition to the final provisions and index. Specifically, the Agency referred to Law No. 48/1982 regarding protecting the Nile River and waterways, where pesticides are directly involved, from pollution.

Article (1) of the law concentrates on defining environmental concerns, particularly environmental pollution, deterioration and protection (Nos. 7, 8, 9); air pollution (No. 10); polluting substances and factors (No. 13); water-polluting substances (No. 14); hazardous materials and wastes (Nos. 18, 19); material handling (No. 20); waste management, disposal and recycling (Nos. 21, 22, 23); liquid substances harmful to the water environment (No. 24); discharge and dumping (Nos. 26, 27); and establishments (No. 34). Unfortunately, the definitions of this article are not specific for hazardous materials (including pesticides), nor were public health concerns specified. The article considers environmental monitoring networks, which is a timely issue, on a national and international scale. The most impressive and notable item in the Article is No. 36: "Environmental Impact Assessment." Under its aegis, risk/benefit assessment of pesticides and other pollutants will be carried out in harmony with the national and international organizations involved in environmental safety and preservation.

Article (5) in Chapter (2) outlines the tasks and responsibilities of the Environmental Affairs Agency. The Agency shall formulate the general policy and prepare the necessary plans for the protection and promotion of the environment. The Agency shall also follow up on the implementation of these plans through coordinating with administrative authorities. The Agency shall coordinate with other authorities for organizing and securing the safe handling of dangerous materials. The Article does not refer to specific pesticides or to those used in agriculture.

Chapter (4), Section (1) outlines the protection of land environment from pollution. Article (19) considers assessing the environmental impact of new establishments (including pesticide formulating factories). Article (24) concerns the environmental monitoring networks on pollution in the environment. Article (26) describes the obligations of public and private authorities and private individuals to provide prompt assistance and support, if required, to confront an environmental disaster.

Chapter (2) refers to hazardous materials and waste. Article (29) states that handling hazardous substances and wastes is forbidden without a permit from the appropriate authority. Article (30) refers to management of dangerous wastes through procedures and regulations listed in the executive regulations of the law. Articles (31) and (32) concern importing hazardous materials as well as constructing an establishment for housing them. Article (33) is significant for the agricultural sector, as it deals with regulating the production or handling of dangerous materials and the procedures necessary to ensure that no harm shall be done to the environment.

Section (2) regards protecting the air from pollution (Articles 34-47), while Section (3) involves the water environment and pollution (Articles 48-59). There is also a separate division on pollution from harmful substances, including pesticides (Articles 60-65). Section (4) outlines the penalties for violating the provisions of any article of this law. Such penalties need to be added to Agriculture Law No. 53/1966 as well as the Ministerial Decree No. 663/1998 and in other decrees concerning the use of pesticides and hazardous substances.

7. Rationale for Issuing Ministerial Decree No. 663/1998

As previously noted, laws and regulations governing the safe use of pesticides should be changed periodically to contend with policy and strategy changes in plant protection. However, Decree No. 663/1998 was set mainly following the Guidelines for Registration and the Code of Conduct issued by the Food and Agriculture Organization of the United Nations. Decree No. 215/1985 was amended to adapt to the new policy established by MOA for pesticides (e.g. registration, experimentation, importation, safe handling, storage, disposal, etc.), in harmony with corresponding decrees by the Ministry of Health (MOH), Ministry of Environment (MOE), Ministry of Trading (MOT), etc. The decree considers the challenges confronting trading of pesticides; establishments that are environmentally friendly; and avoiding high levels of pesticide residues in export crops, water, air, etc. The decree also considers hazards to health of consumers or laborers. Additionally, the decree deals with avoiding pesticide counterfeiting (i.e. through importation, local formulation, trading, storage, transportation, application, etc.). It also considers the shape of trading under privatization and liberalization of pest management services.

Decree No. 663/1998 is classified into seven groups covering all of the above articles. The decree is well written and its articles are clear. From a practical viewpoint, the approved ministerial decree should be accompanied by guidelines detailing each topic and outlining the necessary steps to fulfill all requirements for achieving safe pesticide treatment from the beginning of the process until its conclusion. Because of the continuing demand for pesticide use in pest control, and the difficulty or perhaps impossibility of prohibiting use of these dangerous materials as the MOA policy proposes, guidelines should be attached to the Decree to fill in gaps and cover any points which may have been omitted. This decree was subjected to long and serious discussion; the proposed guidelines should be subject to the same scrutiny.

8. Background and Regulations on Rules for Controlling, Importing and Handling of Pesticides in Egypt Based on Agricultural Law No. 53/1966 and Prior to Current Decree No. 663/1998

Before Decree No. 663/1998 on pesticides and its detailed guidelines were issued, the Central Agricultural Pesticides Laboratory, in harmony with the Pesticides and Recommendation Committees, outlined the rules of pesticide control, recommendation, registration, importation, and handling in Egypt based on the principles of Agricultural Law No. 53/1966. The issues include the following:

(I) Rules and Laws Governing Registration and Handling of Pesticides in Egypt

This section defines the pesticides based on FAO's issuance in this respect in 1991. The guidelines for Decree No. 663/1998 add that any change in definition issued by FAO in the future will be automatically considered as part of the current decree.

(B) Ministerial Law No. 215/1985 on Agricultural Pesticides

This law covers the following:

(1) Importing or handling of any pesticides is prohibited until the Pesticides Committee approves the pesticide and the applicant obtains registration.

(2) Steps for registration of pesticides in Egypt are as follows:

(a) The Pesticide Committee should receive all required documents (e.g. data sheet including all information on pesticide chemistry and properties; formulation nature and properties; biological characteristics and application, effects on the environment; conditions for safe use; and storage and disposal of empty containers).

(b) The applicant will provide an adequate number of samples for chemical and physical tests on active ingredients and formulation.

(c) The applicant will submit a Registration Certificate from the country of origin.

(d) Studies carried out in the country of origin on the effects of the pesticide on the environment will be supplied by the applicant for review.

(e) Toxicological studies on the pesticide and decisions taken by EPA and WHO will be supplied by the applicant for review.

(f) Classification of pesticides according to FAO will be submitted by the applicant.

(C) Protocols for Registration of Pesticides by Pesticides Committee

The Pesticides Committee should study the applicant's submitted documents to judge their accordance with the following established protocols, principles, and rules:

- ❖ First Protocol: Classification of pesticides according to acute toxicity and effects on the environment
 - Group (1A): Extremely hazardous: handling allowed only with nematicides and anticoagulants.
 - Group (1B): Highly hazardous: With the exception of pesticide use on cotton crops, this group is prohibited.
 - Group (2): Moderately hazardous: Allowed for use on vegetables and fruits.

- Group (3): Slightly hazardous: Allowed for use on vegetables and fruits.
- ❖ Second Protocol: EPA classification of pesticides in relation to tumors and cancer in humans. Treatment with or registering of any pesticides is prohibited, with the exception of groups classified as “D” (not classified as carcinogenic) and “E” (not carcinogenic).
- ❖ Third Protocol: Based on studies carried out by the Agricultural Research Center, the product may be accepted for trials and registration if test battery studies prove that no mutagenicity exists.
- ❖ Fourth Protocol: The Committee agreed on the classification and maximum residue limits in agricultural products as well as the safe level of residues for each pesticide, based on those established by Codex of FAO and the World Health Organization (WHO).
- ❖ Fifth Protocol: Studies on delayed neurotoxicity should be carried out on products with some indication of this phenomenon in the Agricultural Research Center and faculties of agriculture.

(D) Recommendation of Pesticide by Recommendation Committee

After all the steps for registration established by the Pesticides Committee are completed, the pesticide will be accepted for testing. Thereafter, the formulation should be transferred to the Recommendation Committee to arrange official trials at agrochemical research stations (under the MOA) and at universities for three successive seasons. The tests and specified laboratories performing them are as follows:

- Chemical, physical and biological testing on the active ingredient and formulation at the Central Agricultural Pesticides Laboratory (CAPL).
- Toxicological and mutagenicity studies at CAPL.
- Biological effectiveness and deleterious side effects on treated plants at ARC research stations and universities.
- Acute and chronic toxicity as well as acquired immunity at CAPL.
- Residues of pesticide in the environment at MOA institutes and faculties of agriculture.

After evaluating test results, the Recommendation Committee may recommend use of the pesticide on the targeted pest.

9. Registration with Local Registration Number for Pesticide

After the Recommendation Committee approves the pesticide, the Pesticides Committee will review the product, noting whether registration is continued in FAO, WHO and EPA. If the product passes all of the requirements, it should be registered and assigned a local registration number valid for three years. The local registration number continues, but the Registration Certificate is renewable every three years. The label should be approved concurrently, ensuring that it contains both common and trade names, chemical structure, application, safety precautions, production date, expiration date, and local registration number.

10. Rules for Pesticide Importing and Customs Clearance

- Article (16) of Ministerial Decree No. 215/1985

Handling of end products or locally-repacked formulation of products or clearance from Customs is disallowed until physical and chemical specifications are met on the product and an Analysis Certificate is issued by the Department of Pesticides Analysis at CAPL. The product should also pass all biological efficacy tests established by the Recommendation Committee.

- Rules Regarding Objection to Analysis Results

The applicant will submit a letter objecting to analysis results to CAPL. The letter should be accompanied by the following:

1. copy of the analysis results (certificate)
2. one of the two samples retained by the Pesticide Control Department
3. the receipt establishing settlement of the re-analysis costs, which shall be returned to the complainant if entitlement to object is established. The results of the re-analysis should be issued within 30 days from the laboratory's receipt of the sample.

- Article (8), Decree No. 215/1985

Trading or selling of pesticides without a license from MOA is prohibited. If an owner has more than one shop, he must obtain a separate license for each. Trading without a license will expose the trader to penalties of jail (for not less than one month and up to one year) in addition to a fine of LE 100.

- Ministerial Decree No. 1381/1989

A shop dealing with pesticides should be managed by an agriculture engineer who is registered in the Agriculture Syndicate.

- Article (12) of Ministerial Decree No. 258/1990

Private sector traders with licenses are prohibited from selling pesticides to farmers without official agreement from the area Supervisory Engineer, based on examination of the fields considered for pest control. The approval sheet should contain the following information: pest name; pesticide name, quantity; area; rate of application; and any remarks.

Pesticide traders should deliver invoices to customers, indicating the pesticide name, quantity, and percentages of contents. The trader should retain a copy of the invoice to be produced upon request.

The above laws and ministerial decrees confirm the rules and role of the MOA in ensuring proper registration, importation, local formulation, safe use, handling, transportation, storage, disposal, trading, quality control, implementation of IPM, etc., of pesticides through well considered regulations in harmony with other ministries, especially the Ministries of Industry and Environment.

11. Guidelines for Registering, Handling, and Controlling Chemical Pesticides in Egypt in Accordance with Ministerial Decree No.663/1998

After the issuance of the accepted Ministerial Decree No. 663/1998 providing for agricultural pesticides the MOA, along with highly qualified experts in pesticide regulations, conducted a thorough study to review all articles in this decree. They concluded that detailed guidelines should be issued to clarify any questionable points and/or articles. The following is an analytical review of the guideline issued by MOA. This study's authors are careful in our approach, indicating similarities and/or differences in explanation, literal wording, purpose, necessity, certainty, liability, etc., among MOA concerns and the other three Ministries involved: Public Health, Environment, and Industry. The aim of the four ministries regarding pesticides is the same: to achieve safe use of these toxicants and hazardous materials in order to minimize harmful effects to humans and to the environment.

11.1 Definition of Pesticide

The Ministries of Agriculture, Public Health, and Supply and Trading define pesticide in the same manner, while the Ministry of Environment refers to it as hazardous material. The definition used by MOA, MOH, and MOT is derived from the Food and Agriculture Organization (FAO). The present decree automatically accepts any future change in the definition by FAO as part of this decree.

11.2 Pesticide Registration

Registration of pesticides is carried out in the Ministries of Agriculture and Health only, with the Ministries of Supply and Trading (MOT) and Environment (MOE)

accepting the decisions made by MOA and MOH. Registration of pesticides is less stringent in MOH as compared to MOA. Accordingly, MOH registration should be intensified to harmonize with MOA's system and regulations. Because of the importance of pesticide registration, Decree No. 663/1998 devotes five articles to addressing this critical step before handling and trading.

11.3 Guidelines' Models for Pesticide Registration

The guidelines create models to be completed by the registration applicant and submitted to the Secretary of the Pesticides Committee. The required information is listed in the models as follows:

Pesticide Information

Common name (ISO, BSI, IUPAC)

Trade name

Chemical name (IUPAC)

Chemical formula (structure)

Empirical formula

Code No.

Synonyms (Local) (Others)

Chemical class

Molecular weight

Applicant Information

Applicant Name

Address

Phone Number, Fax No.

Nationality

Letter of Authorization to approach supplier

Plant details (if manufacturing, formulating, or repackaging)

Name

Address

Phone No., Fax No.

End-Use Product

Identification

- distinguishing name
- formulation type
- active constituent(s) and concentration

Chemical and physical properties

- color

- odor
- bulk density (solids)
- density/specific gravity (liquids)
- viscosity (liquids)
- vapor pressure
- volatility
- flash point
- corrosive hazard

Formulation stability

- containers
- formulation
- storage conditions
- shelf life
- analytical method and data

Chemical and Physical Properties of Pure Active Constituents, Technical Grade Active Constituents (TGAC), and Manufacturing Concentrates

Property	Pure Active Constituent	TGAC/ Manufacturing Concentrate
Purity	-	-
Color	+	-
Odor	+	-
Physical State	+	-
Melting point/range(solids)	+	-
Melting/crystallization point (liquids)	-	-
Condensation point (gases)	+	-
Boiling point (liquids)	+	-
Octanol/water partition coefficient	+	-
Vapor pressure	+	-
Refractive index (liquids)	+	-
X-ray diffraction spectrum (inorganics)	+	-
UV/visible spectrum	+	-
IR spectrum	+	-
Mass spectrum	+	-
NMR spectrum	+	-
Solubility in water	+	+
Solubility in organic solvents	+	+
Density/specific gravity	+	+
Hydrolysis	+	-
Photolysis	+	-
Viscosity (liquids)	+	+
Oxidation stability (air)	+	-
Thermal stability	+	+
Dissociation constants	+	+

Formulation

Type of formulation
 Content
 Concentration(s)

Packaging of End-Use Products

Details of the size, shape, construction and lining of suitable containers which might be used for end-use products should be supplied. The integrity of the container should not be impaired by the end-use product (i.e. the absence of corrosive action should be shown).

Use

- Target pest(s)
- Crop
- Rate of application
- Number of applications
- Season of application

Methods of Analysis (in detail)

To determine the amount of active constituents and impurities whose concentrations exceed 1 g/kg in the technical material (provide references to published methodology).

Metabolic and Toxicokinetic Studies

- Metabolism in target plants
- Metabolism and toxicokinetics in laboratory animals
- Metabolism database

Toxicology

Studies should be performed by certified or accredited laboratories. Studies should have been recently conducted.

Acute toxicity studies

- studies on the end product
- studies on the active ingredient

Short-term repeat dose studies

Sub-chronic toxicity studies

Long-term toxicity studies

- chronic toxicity studies
- oncogenicity studies
- chronic toxicity/oncogenicity studies

Reproduction Studies

Delayed Neurotoxicity Studies

Developmental Studies

- embryotoxicity and fetotoxicity
- development anomalies and abnormalities
- altered growth

Genotoxicity Studies

Additional Studies

- toxicity of metabolites and impurities
- other adverse effects
- toxicity of mixtures

Human Toxicological Data

No-Observable-Effect Level (NOEL)

Acceptable Daily Intake

First Aid and Safety Directions

Residues

Summary of Residue Studies

Residue Database Form

Crop Residues

- crops for human consumption
- crops used as livestock feed
- other crops

Livestock, Poultry, Egg and Milk Residues

- from direct application
- from feeding of treated crops (animal transfer data)

Analytical Residue Methods

Fate of Residues during Storage, Processing and Cooking

Maximum Residue Limits

- producing country
- other countries
- Codex
- applicant's proposed MRL

Applicant's Proposed Withholding Periods

Occupational Health and Safety

Occupational Exposure Data

- nature of work performed
- prevention of worker exposure

Health Conditions Contraindicating Use of Product

Occupational Health Monitoring

- atmospheric monitoring
- biological monitoring

Information Provision

- label information (if relevant)
- Material Safety Data Sheets
- education and training

Environmental Chemistry and Fate

Assessing Extent of, and Potential for, Environmental Exposure

- (i) amount of chemical to be used
- (ii) manufacturing plant (end-use product/active constituent)
- (iii) formulating plant (end-use product)
- (iv) product disposal
- (v) accidental release

Physiochemical Degradation

- (i) hydrolysis
- (ii) photodegradation (aqueous, soil)

Biodegradation

- (i) soils (aerobic, anaerobic)
- (ii) water

Mobility

- (i) potential for transport
- (ii) volatility
- (iii) adsorption/desorption
- (iv) leaching potential

Field Dissipation

- (i) soils
- (ii) water
- (iii) plants

Accumulation/Metabolism

- (i) bio-accumulation in fish/aquatic organisms
- (ii) accumulation potential in soils
- (iii) other (e.g. birds, earthworms)

Modeling Studies

Applicant's Proposed Directions for Storage and Disposal

Environmental Toxicology

Birds, Mammals and Other Vertebrates (Wild)

- (i) acute
- (ii) short-term
- (iii) special studies (e.g. chronic, reproduction, simulated or actual field testing, etc.)

Aquatic Organisms (Freshwater and Marine)

- (i) acute
- (ii) short-term
- (iii) special studies (e.g. chronic, early life-stage, simulated or actual field testing, etc.)

Non-Target Invertebrates (Terrestrial)

- (i) predators
- (ii) parasites
- (iii) bees
- (iv) earthworms
- (v) soil micro-organisms
- (vi) other

Non-Target Native Vegetation

- (i) results from laboratory tests
- (ii) observations from field trials/efficacy tests

Assessment of Environmental Hazard

Proposed Environmental Protection Statement

Efficacy in Pest Control and Safety of Target Plants

Efficacy Studies

Phytotoxicity Studies

- (i) target crops
- (ii) non-target crops
- (c) non-target animals

It is evident that the above registration requirements are reasonable, strict, serious and accountable. These requirements will ensure safety in all pesticide use and minimize the impact of their use on living creatures and on the environment.

11.4 Test Protocol for Efficacy/Suitability of Pesticide Container in Accordance with Standard Specifications

Previous decrees provide no details on specifications for pesticide containers, which play a critical role in the safe use and handling of pesticides. Containers should pass rigorous testing (e.g. dropping, leakage, moisture penetration, temperature tolerance to heating or cooling, resistance to diluted acids, resistance to diluted alkali, rust test, corrosion, and absorption tests). The guidelines should also identify the tests to be performed on the pesticide while in storage (e.g. emulsion stability, foaming, pH, acidity and alkalinity, and active ingredient content). These tests are similar to those requested by the Ministry of Industry and the Ministry of Public Health.

11.5 Methods of Analysis for Active Ingredient, Content, and Impurities Which Exceed 1 g/kg in Technical Grade Form

Published methods should be attached to the registration documents and sent to the appropriate department. Review of literature on the metabolism and toxicity in plants and animals should be prepared and submitted.

11.6 Pesticide Residues

Because of critical concerns about pesticide residues, the guidelines create a "Residue Database-Experiment Summary". This database will be helpful in registering pesticides at MOH and will strengthen enforcement of the environmental law concerning hazardous substances. The database summary, located in Appendix III of the guidelines, is well constructed.

For the first time in laws or decrees on pesticides, the guidelines define the criteria for maximum residue limits (MRLs). These values should be included with the registration documents and compared with the values recorded in the Codex (or with any other values used in developed countries). Agreement on the issued MRL values should take into consideration the nutrition habits in Egypt as well as the pre-harvest interval (PHI) (i.e. safety period). MRLs should be in accord with the nature, level and safety of residues of the parent compound and its metabolites. Data concerning pesticide residues should cover all environmental components (i.e. food, feed, animal tissues, milk, eggs, etc.). Dissipation pattern and rates should also be provided along with other criteria to correctly estimate the MRLs and PHI. Additionally, information should be reviewed on occupational hazards due to exposure to pesticide residues through harvesting and through processing contaminated plant and animal foods.

To facilitate the review process for the Registration Committee, residue data should be prepared according to the established model's "Residue Data Base". Metabolic studies should be carried out on animals and plants affected by pesticide application, as well as on animals feeding on contaminated plants, etc. The registration applicant should introduce any available data from other countries on pesticide residues. Also, simple trials should be performed on environmental conditions in Egypt to identify the pesticide level in treated and exposed targets. Researchers for these trials should refer to the "Codex Classification of Foods and Animal Feeds", which lists crops and agricultural commodities necessary for inclusion in experiments estimating MRLs. Comparison to data from other countries seems necessary.

The guidelines detail the requirements regarding analysis methods and their conditions. An acceptable method should have a limit of determination less than the MRL and should have certain specificity. Accordingly, an assay based on AchE inhibition is unacceptable for organophosphorous insecticides (general assay method).

Details on extraction, clean-up, standardization, and instrumentation should also be supplied by the applicant, as well as methods for analysis of formulation and residues. Sometimes the same method is used for both purposes.

Post-harvest treatments should be addressed to determine the fate of pesticide residues (i.e. degradation, dissipation, transformation, effect of processing and human consumption, etc.). In order to identify the residue level in food during consumption, not only for the parent compound, but also for metabolites, data should cover the fate of the pesticide during storage, processing, and cooking. The guidelines instruct that the pre-harvest interval (PHI) should be stated on the pesticide label. The guidelines also established a model for MRLs in accordance with application purposes. For products with no MRLs, the applicant should introduce evidence indicating that there is no need for these data. As for seed treatment, data for residues on plants grown from treated seeds should be prepared. Similar data should be included for residues in animals fed treated seeds or chicken feed made with treated seeds. Data indicating that the residues do not affect the flavor of the product during consumption or through food processing is also necessary.

11.7 Occupational Health and Safety

The current Ministerial Decree No. 663/1998 considers for the first time - not only in agricultural law but also in decrees governing pesticide registration and regulation - detailed information on occupational factors to be submitted by the applicant. This information will enable authorities to estimate the occupational health and safety of the workers. The applicant of a pesticide establishment in Egypt should indicate all types of possible occupational exposure by both technical grade and end product. This includes manufacturing, formulating, packing, transporting, handling, applying, and disposing of these products. The information prepared by the applicant should also indicate possible exposure to pesticide residues resulting from handling treated crops. If the product is manufactured abroad as technical grade or formulation, the required information should include occupational exposure in Egypt. The applicant should supply, as a supplement to the application, any additional information that is published after applying for registration. Documents should include registration requirements on new end-products containing a new active ingredient, or on new end-products containing a previously- accepted active ingredient.

These requirements and regulations regarding occupational exposure are in harmony with and supported by industrial and environmental laws and decrees for safety of establishments housing hazardous materials. In addition, laws and decrees regulate the avoidance of dangers in pesticide use (e.g. in construction, establishments, workers, inspectors, surrounding environment, etc.) Accordingly, safety inspections on occupational health and exposure should be carried out regularly by complementary teams from the ministries involved in pesticides (i.e. MOA, MOH, and MOE) in addition to non-governmental associations and societies.

The guidelines detail the requirements, steps and regulations necessary to ensure occupational safety in pesticide establishments and during handling of pesticides. These steps are listed below:

(i) Number and Categorization of Workers

The maximum number of workers and their categories based on the nature of the exposure and on job characteristics should be identified. Workers should be surveyed at the outset of the manufacturing or importing process. Along with employers, this category includes workers responsible for handling, transporting, disposing, packaging, and driving. Exposure to pesticides from crops previously treated with the end-product, as well as pesticide exposure during harvesting and crop processing, must also be considered.

(b) Job Nature

The nature of the job should be specified on a daily, seasonal and/or yearly basis in addition to specifying which jobs require protective clothing in relation to formulation nature (i.e. dust, liquid, gas, etc.).

(c) Avoidance/Prevention of Exposure to Pesticides

Standard measurements should be taken to prevent exposure to pesticides: isolation of spray operation, geometric control, safety of working system, and availability of precaution facilities. For workers subjected to pesticide exposure by handling harvest or entering treated fields or silos containing grains, they should be prevented from entering such areas until safety criteria is met. Precautions should be taken for routine handling, transporting, and storing of pesticides, as well as for pesticide services.

(d) Workers' Health Conditions Which Prevent Job Performance

Health conditions of workers connected with technical grades or end-products should be considered which would prevent workers from performing their jobs. Examples of these conditions are skin wounds, ingesting drugs or alcohol, and cigarette smoking.

(e) Survey of Occupational Health

This survey addresses the surrounding conditions and the environment affecting workers in pesticide factories as well as end-users. The survey should include air, personnel and site pollution. A sampling system should be outlined on sites and workers. Biological surveys are needed to measure the amount of pesticide and its metabolites in body tissues, liquids, excretions, blood, or urine. Biological effects should be measured (i.e. depression in acetylcholine esterase in organophosphorous insecticides). The biological survey is a complementary

measure to the air survey in measuring the actual occupational exposure in cases of re-analysis of workers or the work environment. Factors to consider are significant exposure to pesticides, quality control, similarity of methodology and survey nature, equipment, standardization and tactics

(f) Availability of Information on Pesticide Safety

To ensure the safe use and handling of pesticides, information must be made available through education and training on the hazards caused by the pesticide and the measures necessary for its evaluation. Requirements include labeling contents for technical grade and end-products, information on handling, transporting, etc. On the application for registering the new end-product, product safety information for all end-products causing hazard should be included: technical grade; content (manufactured or imported); and cause hazard according to WHO. Product safety should involve all work groups who are potentially exposed to pesticides and their application. If product safety information is unavailable, the applicant should suggest the exposure level through instructions which prohibit entering the treated zone for a specified time period from the start of treatment and before harvest. These details should be submitted to the Pesticides Committee. Education and training programs should give details for manufacturing, formulating, and handling, and information should accord with existing regulations. Education and training programs should include the use and maintenance of precaution facilities; proper use of manufacturers' facilities; rules for emergencies; information on product safety; and the period and frequency of training.

(g) Guidelines' Requirements for Active Ingredients

The requirements for active ingredients are the same as for pesticide concentrates. Requirements include the new active ingredient list (AIL) or alternative to the AIL (i.e. locally manufactured or imported). Safety data on active ingredients and label information should be supplied by the applicant. For the first time, the guidelines require follow-up information after the applicant supplies the required documents. New information (i.e. on diseases or hazards which may result from pesticide exposure) in addition to other health conditions (positive or negative) should be evaluated and attached to the original application. The applicant will also file any new findings on the product as a supplement to previously submitted data. If the submitted data on occupational health later proves to be invalid or unreliable, new data should be introduced (i.e. local formulation instead of importation).

The safety requirements listed above for the pesticide process (e.g. registration, handling, etc.) indicate that the guidelines for Ministerial Decree No. 663/1998 carefully consider each factor which may affect the safety of workers due to pesticide exposure. These requirements are stronger and more stringent

than those that are briefly mentioned or not addressed by industrial and/or environmental laws and decrees.

11.8 Environmental Studies

Information is supplied by the applicant and other available data is obtained from various sources (e.g. review studies and reports from EPA, OECD, IPCS, and ECCP). These data are needed to estimate the degree of environmental exposure; product toxicity on aquatic and terrestrial organisms, birds and green lands; and general hazards to the environment based on the nature of the exposure and the toxicity level. Rules to minimize the hazard of pesticide exposure should also be specified. The guidelines outline the factors relating to environmental exposure throughout the manufacturing or formulating process. These factors are summarized as follows:

- quantity of applied product as end formulation (locally prepared or imported) through the first years of use and subsequent periods. The applicant must provide information on the release of the active ingredient into the environment (e.g. air, water, and soil) and methods for disposing the remaining amounts or leakage portion. Regarding formulation factories, information on release and disposal of the active ingredient or the end-products must be supplied by the applicant. The guidelines give considerable attention to product disposal as well as accidental release to the environment.
- physical and chemical degradation of the product should be introduced (i.e. hydrolysis in water, photolysis in water and soil).
- biodegradation in soil (aerobic and anaerobic) is requested.
- pesticide movement in the environment, including transportation, volatilization, adsorption, leaching, etc., should be introduced.
- pesticide dispersion in soil, water and plants is requested.
- accumulation and metabolism studies on the product should be prepared by the applicant. Studies would include the bio-accumulation in fish and aquatic organisms, accumulation in soil, and the accumulation and metabolism of the pesticide in birds and earthworms.
- The guidelines establish models for environmental data, especially the applicant's proposed approaches for storage and disposal of the product and its waste.

These requirements are necessary to achieve the safe use, handling, storage, disposal, etc., of the pesticide in harmony with industrial and environmental regulations.

11.9 Toxicological Studies

Estimating the effect of toxicity on the environment is essential. The applicant must measure these hazards and include a prediction on exposure and toxicity levels. This information should be in accord with the system used by the U.S. Environmental Protection Agency. Environmental toxicology should include the following:

- (1) Hazards to aqueous organisms and their ecosystem. The hazard estimate should employ the worst-case scenario for the estimated environmental concentration (EEC) where the pesticide is sprayed directly on water stream at the highest rate. The EEC should be divided based on the inherent toxicity of the product to obtain the factors (9) which indicate the hazard to the organism in question. These factors indicate the existence of hazard.
- (2) Hazards to soil. The guidelines explain how to estimate the comparative concentration of the product in soil at the highest applied level. Toxicity should be compared to the toxicity on invertebrates in soil.
- (3) Soil Organisms. This section concentrates primarily on birds. Some estimates are available based on the work of Urban and Cook, 1986, USEPA. Their study includes estimate of pesticide hazards by (1) granules or treated seeds or (2) by weeds or insects contaminated through spraying.

11.10 Models Proposed by MOA Guidelines for Pesticide Management in Egypt

The current guidelines for Ministerial Decree No. 663/1998 establish models addressing the entire pesticide process and are discussed below.

- (1) Model for Request to Test Product for Registration. The applicant should obtain the request and upon completion send it to the Pesticides Committee in accord with Articles (2) and (3). A copy of the request should be given to the Recommendation Committee. The proposed model is well constructed and covers all necessary criteria (e.g. applicant's name; physical, chemical, and biological properties of the product; rate and method of application, etc.). The guidelines establish the necessary coordination between the Pesticides Committee and the Recommendation Committee.
- (2) Recommendation Notification Model. This model issues from the Recommendation Committee to determine whether the product, after trials according to the established protocol, could be recommended for the first time or continue to be recommended. The model contains the necessary information on the pesticide (e.g. form, active ingredient content, crop, pest, date of Recommendation Committee meeting and approval).

(3) Label Model. This model contains every detail required for pesticide labels according to Article No. 3 of the Decree. It includes the required information on pesticide usage (e.g. crop, rate, pest, agricultural season) and method of application. Various other items are considered (e.g. product name, active ingredient content, formulation, structure, w/w, w/v, v/v, common name, adjuvant and solvent percentages). A safety precaution is required (i.e. rules for use, precaution facility, first aid, and antidotes). Also required is information on the safety period (i.e. pre-harvest period in days for each crop). The World Health Organization (WHO) product categorization is also necessary. Accordingly, the color of the label and warning signs should be determined by the pesticide's classification based on the toxicity parameter (LD50) on test animals. w i

This classification and label specifications are in accord with the requirements of the Ministries of Industry and Environment. Warnings on product hazards (e.g. on handling, storage, transportation, package treatment, and disposal of empty bottles and remaining quantities) are deemed necessary. Further, methods for disposal and return to the producer should be specified. The name and information on the producing company must be supplied, as well as the manufacturer's data and expiration date, batch number, and local registration number. The guidelines include a pictogram to illustrate product hazards. In case of a free trial sample a warning must be given, indicating that the sample is for experimentation only and is not approved for handling or selling, in accordance with Article No.(6) of the Decree.

(4) Model for Registration Certification. This is a well-done model and contains all requirements for the product (e.g. target crop, target pest, safety, producer, etc.). The Central Agricultural Pesticides Laboratory prepares and issues this certificate in accordance with Agriculture Law No. 53/1966 and Ministerial Decree No. 663/1998, Article No. 4. This certificate should be prepared by the Pesticides Committee. The current decree and its guidelines include conditions for cancellation or restriction of registration. Cancellation may be on a periodic or geographic basis and may result from the product's hazardous quality or its cancellation by an international organization or by its country of origin. Registration may also be cancelled because the level of pesticide residues in agricultural products exceeds the acceptable daily intake. Exposure assessment, risk analysis, risk management and risk communication are also considered in the guidelines. Cancellation of registration or restriction on its usage should be decided by the Pesticides Committee.

(5) Model for Requests to Import Agricultural Pesticides. The guidelines developed this model according to Article No. (6) of the Decree. The model contains the applicant's name, license number, product name and registration status, quantity required, package type, arrival port, etc. All of the requirements should be legally stamped and certified.

(6) Model for License to Import Pesticides. This license is issued by the Central Agricultural Pesticides Laboratory, MOA, after the applicant completes the model according to Article (6) of the Decree. The license includes pesticide names, number and date of registration, quantity, package type, country of origin, manufacturer, purpose of importation, importer, and arrival port.

(7) Model for Requesting License for Pesticide Manufacturing Factory. This model is obtained from the Central Agricultural Pesticides Laboratory according to Article (7) of the Decree and contains the following information on the applicant as well as the factory: location, nationality, and address of factory, trading record number, taxation license number, manager's name (i.e. agricultural engineer), approval of industry organization, approval of environmental issues, Ministry of Health approval, trading record, factory specifications, legal issues from the Pesticides Committee and Agricultural Syndicate, insurance certificate on the factory manager, all grantee conditions on recording, formulation locations, safety, handling, and quality control assurance. The analysis should be conducted based on Article (14) of the Decree. Inspection of the factory should be performed in accordance with Law No. 453/1954 concerning industrial and commercial establishments as well as factories dealing with hazardous substances and those causing noise.

(8) Model for License to Establish a Pesticide Factory. This model was set up to obtain approval to register a factory dealing with pesticide manufacturing and/or formulating. The model is efficient and in accord with Article (7) the Decree, although it requires the additional approval of the Ministry of Environment. The model is well prepared and in harmony with the laws and decrees of the Ministry of Industry.

(9) Model for Requesting Agricultural Pesticides Trading License. This license is obtained from the Department of Pesticides Control at the Central Agricultural Pesticides Laboratory. Based on the Decree, if an applicant proposes to establish more than one shop, he must request a separate license for each shop. The request should include all information on the applicant, shop location and specifications, trading conditions, management conditions, trading purposes, etc. The license is valid for three years.

(10) Model for Pesticides Trading License. This license is issued after approval of the Pesticides Committee according to Article (8) of the Decree. The license is issued from the Central Agricultural Pesticides Laboratory, MOA, and is valid for three years.

(11) Model for Extremely and Highly Hazardous Pesticides. The guidelines list the names, local registration number and WHO classification based on the acute toxicity of the listed products. This list is in harmony with Article (9), and includes rodenticides, pesticides for field crops, pesticides for vegetables and fruits, nematicides, etc. The guidelines indicate that MOA may permit trading of

hazardous pesticides which were cancelled two years ago. In order to avoid misuse of these pesticides, it is advisable to consider using these cancelled products only in emergency situations and/or under restrictions. This action will ensure the stability of the policy and strategy of pesticide regulations, laws and decrees. Based on Article (9) of the Decree, the guidelines propose to train and educate the agricultural engineer responsible for dealing with highly hazardous pesticides on their safe use. To avoid problems in health and the environment, the authors of this study do not advise importing, using or recommending these highly toxic products. Because of the high inherent risks associated with these products, either the restrictions should be very severe or Article (9) of the Decree should be cancelled entirely. This article did not exist in the previous laws and/or decrees.

(12) Rules and Conditions for Opening Pesticide Shops and Stores. Based on Law 453/1954 regarding the opening of shops for industrial and/or commercial purposes and Law (4)/1994 on the environment, the guidelines specify and outline the conditions necessary to open shops with safety facilities. The same rules apply to stores. These guidelines are in harmony with the regulations established by the Ministries of Industry and Environment.

(13) Model for Requesting Analysis of Imported or Locally Formulated Pesticides. The purpose of this model is to receive requests from applicants to carry out analysis for quality control checks to clear cargo from Customs or to allow for handling of locally-made pesticides. The request includes all necessary information on the applicant, product, purpose of analysis, arrival port, production, license, etc.

(14) Model for Certificate of Analysis. This certificate is issued by the Central Agricultural Pesticides Laboratory and contains all necessary information (e.g. laboratory number, pesticide name, formulation, receiving date, number and mark of sample, imported or locally formulated quantities, analysis results, active ingredient content, and name of chemist). If these requirements are followed and the analysis results are acceptable, the certificate will be issued. If the analysis shows the sample was out of specification, the sample will not be allowed to clear Customs, based on Articles (17), (19) and (20) of the Decree. Procedures for sampling should be in accord with Article Nos. (14), (15), (16), and (17) of the Decree. Analysis should be performed at the Central Agricultural Pesticides Laboratory in accordance with Article (18) of this decree.

For the first time, the guidelines consider samples for experimental trials. The samples should be analyzed by gas chromatograph-mass spectrometer (GC/MS) in order to identify all components of its makeup. Analysis results should be retained with the model and filed with the registration certificate at the Central Agricultural Pesticides Laboratory for comparison. This will aid in preventing product counterfeiting after registration and during trading.

(15) Approval for License to Clear Pesticides from Customs. Based on Article (6) of the Decree, the guidelines designed this model for clearance of pesticides through Customs. The application model includes copies of the registration certificate, import license, invoice, trading license, product label, importation model, and clearance model.

Another model was created to deal with pesticides under registration and for pesticides used in research. The guidelines set up the conditions necessary to clear samples from Customs. The applicant should obtain approval from the Pesticides Committee and the license is obtained from the Central Agricultural Pesticides Laboratory.

(16) Importing License for Agro-Pesticides: After approval from the Pesticides Committee, the applicant should obtain a license for importing agro-pesticides through the same committee. Based on the Agricultural Law No. 53/1966 (Article 80) and Ministerial Decree 663/1998 (Articles 2, 6, and 8), the license should include approval number, name and information on the importer, product name and quantity, package size, producing company, export country, and local registration number. Analysis should be performed at the Central Laboratory, MOA, to ensure that quality and specification of pesticides are in accord with Article No. (2) of the current Decree.

12. General Considerations

The guidelines also take into consideration certain rules regarding the importation and registration of specific materials as follows:

1. Technical grade needs approval only if the end product was registered. Analysis of imported to locally-made active ingredients for formulating the end product is conducted in accordance with the rules and conditions in Decree No. 663/1998.
2. Mineral pesticides (e.g. copper, sulfur, mineral oils, etc.) should be registered after experimentation for one year. Impurities should be analyzed based on Article (17), Section (a, b) of the decree.
3. Inspectors should have total rights to obtain samples for quality assurance from any site, shop, establishment, store, etc. Clearance of the sampled pesticide is not allowed until the analysis proves that acceptable specifications are met.
4. Ministerial Decree No. 215/1985 should be cancelled in addition to any of its rules.

In conclusion, it is evident from the present review that more detailed studies on the environmental and economic impacts of pesticides are necessary. Objective criteria for assessing the environmental risks and economic impacts associated with pesticide use at the level of individual users as well as on a national level should be established.

Pesticides are and will continue to be a valuable pest control tool. With more accurate, realistic cost/benefit analysis, Egypt can attain an approach which minimizes the risks while developing and increasing the use of non-chemical pest control in order to maximize the benefits of pest management strategies.

II. COMPARATIVE REVIEW ANALYSIS ON PESTICIDE LAWS AND MINISTERIAL DECREES AMONG THE FIVE CONCERNED MINISTRIES IN EGYPT

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
1. Issued laws and decrees by concerned ministries	Agriculture Law No. 53/1966 providing for all elements in agricultural production (i.e. conditions, organizations, inputs, outputs, job specifications and pesticides)	MOH observes pesticide regulations issued by MOA (i.e. Ministerial Decree No. 215/1985 and currently Ministerial Decree 663/1998 on pesticides)	Law No. 453/1954 providing for industrial and commercial firms and shops dealing with hazardous materials	Law No. 4/1994 and its executive regulations (Environment Law)	Law No. 95/1945 on food supply; amended by Law No. 109/1980
	Ministerial Decree No. 663/1998 providing for agricultural pesticides	Law No. 10/1966 regulating food handling and surveillance	Decree of Minister of Industry & Mineral Wealth No. 180/1996 providing for compliance with production in conformance with Egyptian standards	Articles 18 and 19 regarding hazardous materials and waste	Law No. 118/1975 on importation and exportation of food
	Decree No. 50/1967 on agricultural pesticides and food regulations Decree No. 125/1967 Decree No. 45/1977 Decree No. 215/1985 Decree No. 1381/1989 Decree No. 1303/1995	Decree No. 48/1977 issued by MOA in cooperation with MOH on regulating security measures in handling and application of agricultural pesticides	Law No. 2/1975 on standardization	Article 19 considers environmental impact assessment of new establishments, including pesticide formulation factories Article 33 considers the avoidance of any harm to the environment caused by the handling of hazardous materials.	

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	<p>Decree No. 1006/1997</p> <p>Decree No. 48/1977 in cooperation with MOH for regulating security measures in handling and application of agricultural pesticides</p>				
2. Definitions of pesticides	Guidelines on the registration, handling, and surveillance of pesticides in Egypt according to Ministerial Decree No. 663/1998	Same as MOA Law and Decree No. 663/1998	Pesticides are classified as industrial materials. MOI follows MOA and MOH definitions.	Hazardous materials including pesticides. MOE follows MOA and MOH definitions.	Pesticides as commodities. MOT follows definitions of MOA and MOH.
3. Protocols for registration of pesticides	<p>Articles 2, 3, 4 of Decree 663/1998 regulating registration requirements.</p> <p>Protocol #1 is based on acute toxicity and effects on the environment.</p> <p>Protocol #2 is based on EPA's classification on toxicity.</p> <p>Protocol #3 is based on studies at ARC of Egypt.</p> <p>Protocol #4 is based on FAO/WHO</p>	MOH follows registration requirements established by MOA, but their requirements are simpler with fewer documents requested. MOH follows EPA and WHO regulations and recommendations.	No registration required. MOI considers standard specifications of each compound.	No registration required. MOE refers to MOA and MOH registration and regulations.	No registration required. MOT follows MOA and MOH registration and regulations for importing and exporting pesticides.

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	classification of MRL (maximum residue levels). Protocol #5 is based on delayed neurotoxicity.				
4. Registration documents required	MOA Decree No. 663/1998 prepared models for applicants for registration, such as: pesticide information applicant information end-user product identification properties formulation stability packaging use methods of analysis metabolic and toxicokinetic studies toxicology residues occupational health and safety environmental	Same as is used in MOA, but simpler. MOH restricts WHO registration, certificate of origin, registration in the country of origin.	Not involved. MOI observes MOA and MOH regulations.	Not involved. MOE observes MOA and MOH regulations.	Not involved. MOT observes MOA and MOH regulations.

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA) chemistry and fate	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	<p>environmental toxicology</p> <p>efficacy in pest control and safety of target plants</p>				
5. Protocol for testing suitability of pesticide packages	Decree 663/1998 established tests to assure specifications of packages and containers for pesticides (i.e., dropping, leakage, moisture penetration, tolerance to high temperatures and cooling, acid and alkali resistance, rust test, and corrosion.	MOH follows MOA regulations, but no tests are required (only examining packages).	MOI follows the standardization requirements. Same specifications as MOA and MOH.	MOE is not involved, but Environment Law should be respected.	MOT is not involved.
6. Effect of storage conditions on pesticide specifications and properties	The guidelines for Decree 663/1998 request that pesticide quality be assured before and after storage. Tests needed are emulsion stability, foaming, pH, acidity, alkalinity, and active ingredient contents. Routine checks on these properties are done by	Same as MOA, but no routine checks and tests are performed.	Not involved.	Not involved.	Not involved

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA) Central Laboratory for Pesticides, MOA.	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
7. Analysis Methods	Decree 663/1998 regulates the analysis of active ingredient content and impurities in pesticide formulation. Publications are required.	Same as MOA for quality control assurance.	Not involved.	Not involved.	Not involved.
8. Toxicity data requirements	<p>The guidelines for Decree 663/1998 request the following data:</p> <ul style="list-style-type: none"> Acute toxicity studies studies on end product studies on active ingredient Short term repeat dose studies Sub-chronic toxicity studies Long-term toxicity studies chronic toxicity studies oncogenicity studies chronic toxicity/oncogenicity studies Reproduction Studies 	MOH requests a summary on the toxicity data, but does not require details.	MOI follows recommendation, registration, regulations and other considerations required by MOA, MOH and MOE	MOE is not involved in submitting toxicity data. MOE requirements are in harmony with MOA, MOH, and MOI regarding establishments.	MOT is not involved in toxicity data, but their work is based on approvals of MOA, MOH, MOE and MOI in addition to international and national regulations on safe trading of commodities.

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	<p>Delayed Neurotoxicity Studies</p> <p>Developmental studies embryotoxicity and fetotoxicity development anomalies/abnormalities altered growth</p> <p>Genotoxicity studies</p> <p>Additional studies toxicity of metabolism and impurities other adverse effects toxicity of mixtures</p> <p>Human toxicological studies</p> <p>No-Observable-Effect Level (NOEL)</p> <p>Acceptable daily intake</p> <p>First aid and safety precautions</p>				
9. Residue data requirements	<p><u>Residues</u> Summary of residue studies</p>	<p>MOH is not directly involved with data, but they follow acceptable limits of residues</p>	<p>MOI follows MOA recommendations and regulations in addition to MOI standard</p>	<p>MOE follows MOA, MOH, MOT and MOI regulations.</p>	<p>MOT does not deal directly with residue pesticide data but follows regulations</p>

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	<p>Residue database form</p> <p>Crop residues crops for human consumption crops used as livestock feed other crops</p> <p>Livestock, poultry, egg and milk residues from direct application from feeding of treated crops (animal transfer data)</p> <p>Analytical residue methods</p> <p>Fate of residues during storage, processing and cooking</p> <p>Maximum residue limits producing country other countries Codex applicant's proposed MRL</p> <p>Applicant's proposed withholding periods</p>	<p>approved by MOA in food commodities and animal feed.</p>	<p>specifications for human and animal food and for other commodities, some of which have MOH rules.</p>		<p>established by the other ministries(i.e. MOA, MOH, MOE, and MOI) as well as other trade organizations (local and/or international).</p>
10. Occupational Health and Safety	The guidelines for Decree 663/1998	MOH requires summary but not details. They	MOI does not require data but follows MOA,	MOE is not directly involved but follows	MOT does not request such data but follows

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	<p>require the following data:</p> <p>Occupational exposure data nature of work done prevention of worker exposure</p> <p>Health conditions contraindicating use of product</p> <p>Occupational health monitoring atmospheric monitoring biological monitoring</p> <p>Information Provision label information Material Safety Data Sheets Education and Training</p>	<p>follow MOA, MOI, MOE, and MOT, as well as MOL regulations</p>	<p>MOI, MOE, MOT and MOI regulations and recommendations.</p>	<p>MOA, MOI, MOI, MOT and MOI regulations and recommendations.</p>	<p>recommendations of domestic ministries and organizations, as well as international trading laws.</p>
<p>11. Environmental chemistry and fate</p>	<p>Assessment of extent of, and potential for, environmental exposure</p> <p>(i) amount of chemical to be used</p> <p>(ii) manufacturing plant (end-use product/active constituent)</p> <p>(iii) formulating plant (end-use product)</p>	<p>MOH requires a summary in applicant's request for registration filing. MOH depends on MOA, MOI, and MOE recommendations for safety.</p>	<p>MOI follows the recommendations and regulations issued by MOA, MOI, and (in particular) MOE. No data is required unless the applicant is constructing an establishment.</p>	<p>This is an important issue for MOE, but they don't ask for data. MOE follows MOA, MOI, MOI, and MOI regulations. They also consider recommendations of governmental and non-governmental organizations.</p>	<p>MOT is not directly involved but follows the recommendations and regulations of the other ministries.</p>

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	(iv) product disposal (v) accidental release Physiochemical degradation (i) hydrolysis (ii) photodegradation (aqueous, soil) Biodegradation (i) soils (aerobic, anaerobic) (ii) water Mobility (i) potential for transport (ii) volatility (iii) adsorption/desorption (iv) leaching potential Field dissipation (i) soils (ii) water (iii) plants Accumulation/ Metabolism (i) bio-accumulation in fish/aquatic organisms (ii) accumulation potential in soils (iii) other (e.g. birds,				

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	earthworms) Modeling studies - Applicant's proposed directions for storage and disposal				
12. Environmental toxicology	Birds, mammals and other vertebrates (wild) (i) acute (ii) short-term (iii) special studies (e.g. chronic, reproduction, simulated or actual field testing, etc) Aquatic organisms (freshwater and marine) (i) acute (ii) short-term (iii) special studies (e.g. chronic, early life stage, simulated or actual field testing, etc.) Non-target invertebrate (terrestrial) (i) predators (ii) parasites	MOH requests summarized data and depends mainly on MOA recommendations.	MOI requests summarized data and follow the recommendations of MOA, MOI, MOE and others.	MOE follows the recommendations and regulations of MOA, MOH, MOI and non-governmental organizations	MOT is not involved and depends on the regulations and recommendations of MOA, MOH, MOE, and MOI.

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	(iii) bees (iv) earthworms (v) soil micro-organisms (vi) other Non-target native vegetation (i) results from laboratory tests (ii) observations from field trials/efficacy tests Assessment of environmental hazard Proposed environmental protection statement				
13. Efficacy of pest control and safety to target plants	Efficacy Studies Phytotoxicity studies target crops non-target crops non-target animals The guidelines also set up a Residue Database.	MOH is involved only in pest control, not in plant hazards.	MOI is not directly involved, but follows MOA regulations and recommendations on pesticide residues.	MOE is involved in plant hazards by the nature of their duties. However, they do not ask for data.	MOT is not involved but follows the regulations and recommendations of the other ministries.
14. Applicant's request for trials for registration of pesticide	MOA set up a model on this request, including data on the applicant, product, production, analysis, etc., for	MOH set up a special model for household and public use of pesticides. Their model contains the same	MOI is not directly involved in pesticides registration. They follow MOA and MOH regulations and	MOE is not involved but follow the recommendations of the other ministries.	MOT is not involved.

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA) agricultural pesticides.	Ministry of Public Health (MOH) information as MOA's model.	Ministry of Industry (MOI) recommendations.	Ministry of Environment (MOE)	Ministry of Trading (MOT)
15. Notification of Registration of Pesticide	Recommendation Committee issues this notification if the product passes all required tests and evaluations through biological assays.	MOH issues this notification by the Institute of Medical Entomology if the product passes all biological and chemical requirements.	MOI is not involved.	MOE is not involved.	MOT is not involved.
16. Label requirements for agricultural pesticides	MOA set up a model to assist applicants with labeling pesticides. The model contains 9 areas: application method, compound information, safety precautions, pre-harvest period, hazard classification, warnings on hazards, produce information, manufacturing date, and pictogram.	MOH set up a label model which is almost the same as MOA's model.	MOI is not directly involved but follows the rules and regulations of MOA and MOH regarding labels.	MOE is not directly involved but follows regulations of other ministries. They are planning to include a pictogram on environmentally friendly workplaces.	MOT is not directly involved but accepts other ministries (MOA, MOH, MOE and MOI) regulations on labels.
17. Registration certificate for pesticide	MOA set up a model for certificate of registration of agricultural pesticides which includes: number and date of registration; pesticide and pest information; use; warning; WHO classification; toxicity; storage period; pre-	MOH set up a model for registration certificate, in a much simpler form than MOA's model. The certificate is valid for 3 years.	MOI is not involved directly but accepts certificates issued by MOA and MOH.	MOE is not directly involved but accepts certificates issued by MOA and MOH.	MOT is not directly involved but accepts approvals issued by the concerned ministries.

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	harvest period; and importer. The certificate issues from Central Laboratory of Pesticides, MOA, and is valid for 3 years.				
18. Registration Cancellation	MOA set up rules and conditions for canceling pesticide registration. The rules also address restriction of use due to hazards and residues.	MOH set up the same rules as MOA. They follow MOA regulations and approvals.	MOI is not involved but accepts issuance from MOA, MOH and other concerned ministries.	MOE is not directly involved but accepts approvals and issues from MOA, MOH and other concerned ministries.	MOT is not directly involved. They follow the rules and issues from MOA, MOH, MOI, and MOE. They also consider international cancellations.
19. Request for importing of pesticides license	MOA set up a model for requests to obtain importation license. The model contains all necessary information (e.g. importer's name, purpose, trading license, pesticide information, amount, package type, country of origin, and arrival port). The license is issued through Central Laboratory of Pesticides, MOA.	MOH set up a model which is the same as MOA's. The Pharmaceutical Department, MOH, issues the license.	MOI is not directly involved but accepts regulations of MOA, MOH and other involved ministries.	MOE is not directly involved but accepts MOA and MOH licenses.	MOT is not involved directly but accepts MOA and MOH licenses.
20. Import License	MOA set up a model for importation of pesticides. License is issued from Central	Pharmaceutical Department of MOH issues the license to import pesticides to the	Not directly involved.	Not directly involved.	Not directly involved.

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
	Laboratory of Pesticides. (Requirements are the same as in #19).	applicant.			
21. License to establish pesticide factory	MOA set up models for request and license. They include information on the applicant, location, trading license, manager name and qualifications. Request letter should include agreement/approval from MOI, MOE, MOH and industrial organization. The license is issued from the Central Laboratory of Pesticides.	MOH is directly involved, and MOH approval is required.	MOI is directly involved, and MOI approval is required.	MOE is directly involved, and MOE approval is required.	Not directly involved.
22. License for trading in pesticides	MOA set up a model to request and obtain a trading license. The model contains information on the applicant, manager's qualifications, and location and specifications of the shop. The license is issued from Central Laboratory of Pesticides, MOA.	MOH accepts MOA license.	MOI accepts MOA license.	MOE is not directly involved but accepts MOA license.	MOT is not directly involved but accepts MOA license.

Items Involved in Pesticide Regulation	Ministry of Agriculture (MOA)	Ministry of Public Health (MOH)	Ministry of Industry (MOI)	Ministry of Environment (MOE)	Ministry of Trading (MOT)
23. List of pesticides classified as extremely hazardous and highly hazardous	MOA publishes the list and regulations on the safety and restricted use of these pesticides.	MOH follows the MOA list and regulations.	MOI follows and accepts the MOA list and regulations.	MOE follows the MOA list and regulations.	MOT follows the MOA list and regulations.
24. Request to obtain license for trading in pesticides classified as extremely hazardous and highly hazardous	MOA set up a request model and license model to be used under special conditions. The license is issued through Central Laboratory of Pesticides, MOA.	MOH follows MOA regulations.	MOI follows MOA regulations.	MOE follows MOA regulations.	MOT accepts MOA license.
25. Conditions for Pesticide Shop	MOA set up stringent conditions for establishing shops and stores dealing in pesticides.	MOH follows MOA regulations and accepts MOA license.	MOI is not involved directly but accepts MOA's license.	MOE is not involved directly but accepts MOA's license.	MOT is not involved directly but accepts MOA's license.
26. Quality control check on pesticides for clearance from Customs (Same information applies to local formulation of pesticides.)	MOA set up a model for request and issuance of this certificate. The model contains information on applicant, product, purpose of analysis, arrival port, country of origin, license number, etc.	MOH set up a model and certificate similar to MOA's model.	MOI is not directly involved but accepts MOA and MOH issues and regulations.	MOE is not directly involved but accepts MOA and MOH issues, licenses, and regulations.	MOT is not directly involved but accepts MOA and MOH licenses and approvals.
27. Clearing pesticides from Customs for commercial and trial purposes (free)	MOA issues license from Central Laboratory of Pesticides, MOA.	MOH issues license and approval from the Pharmaceutical Department, MOH.	MOI is not directly involved but accepts MOA license and regulations.	MOE is not directly involved but accepts MOA issues and regulations.	MOT is not directly involved but accepts MOA issues and regulations.