ANIMAL DISEASES REGULATIONS (CHEMICAL PREPARATIONS), 1982

By the authority vested in me by Section 20 of *Animal Diseases Ordinance*, 1945 and with the approval of the Finance Committee of the Knesset according to Section 1(b) of the *Basic Law, State Economy*, I hereby authorise the following Regulations:

1. Definitions:

"Sale" - including display, advertising, holding and distributing even without payment.

"Pest" - insect, tick, mite, or micro-organism which causes damage to an animal in any manner whatsoever.

"Preparation" - a chemical or mixture of chemicals, or micro-organisms used to destroy pests or micro-organisms, sterilise them, prevent them from multiplying, change their development, repel or attract them.

"Active Substance" - a chemical or biological substance found in a preparation and whose presence causes the activities for which the preparation is used.

"Manufacturer" - including importers of preparations.

"Certificate of Registration" - a certificate from the Director, including temporary certificates, which certifies that the preparation has been registered in accordance with these regulations.

"Director" - Director of the Veterinary Services in the Ministry of Agriculture.

"Micro-organism" - bacterium, virus, or parasite which may cause disease in an animal.

"Animal Holding Facilities" - cattle farm, chicken farm, sheep farm, stable normally used to hold or transport animals including any parts thereof and including service installations for animals.

"Service Installations for Animal" - installations for feeding and watering animals, installations for transporting animal fodder, installations for producing animal products such as milking parlours, facilities for egg collecting or slaughter, as well as herd installations and the like.

2. Prohibition of the Sale of Preparations without a Registration Certificate:

No person shall sell any preparation unless the preparation has a Registration Certificate according to these Regulations.

3. Request for Registering a Preparation:

A person requesting a Registration Certificate for a preparation, which he or she manufactures or imports, will submit to the Director a request on the form which will be determined and attach samples of the preparation according to the demand of the Director.

4. Details of the Request for Registering a Preparation:

The request for a Registration Certificate will include the following details:

(1) Name and address of the manufacturer;

(2) Name and address of the plant that manufactured the preparation;

(3) Commercial name of the preparation;

(4) Formulation;

(5) Purpose of its use;

(6) Name and percentage of the active substance in solid preparations per weight and in liquid preparations per volume;

(7) If the preparations contains a synergist its name, chemical formula and concentration in the preparations shall be stated;

(8) Corrosivity of the preparation for its package and for its applicator;

(9) Flammability of the preparation;

(10) Stability of the preparation during storage and details of storage conditions;

(11) Detailed toxicological date;

(12) Effect of the environment on the effectiveness of the preparation;

(13) Possibilities of combining the preparation with other preparations;

(14) Detailed methods of testing for residues of the preparation in animal products;

(15) Details regarding the active substance;

(16) Chemical formula;

(17) Name and address of the manufacturer of the active substance and the name of the plant where it was manufactured;

(18) Boiling point or freezing point;

(19) Specific weight;

(20) Degree of purity;

(21) Detailed method for chemical analysis;

(22) Samples of the active substance and of its breakdown products as required by the Director.

5. Attachments to the Request for a Registration Certificate (Amendment 1985):

The manufacturer will attach to the request for certificate of registration:

(1) Samples of the packaging;

(2) Sample of the proposed packing label mentioning the following:

(a) The details mentioned in Sections (1) to (7);

(b) Net weight or volume of the preparation;

(c) Manufacture number, as requested by the Director;

(d) Number and date of valid Registration Certificate issued according to these regulations, if the request is for renewal of the registration;

(e) Details of the purpose of the preparation and of the manner in which it is to be used including -

(1) Pests against which the preparation is to be used;

(2) Animal for which the preparation is intended;

(3) Dosages for use of the preparation according to the type of pests and animal species or the type of animal holding installations;

(4) Method of preparing the preparation and how to use it in each animal species;

(5) Harmful side effects in animals and humans;

(6) Precautionary measures during storage, preparation and use of the preparation;

(7) Antidote and first aid treatment in case of poisoning of humans and animals by species;

(8) Toxicity making of the preparation as detailed in the addendum;

(9) Special instructions and limitations;

(f) Limitations of "Veterinary Use Only" in large bold letters;

(3) Professional literature regarding the use and efficacy of the preparation;

(4) Toxicological certification for the preparation from the Ministry of Health.

6. Testing the Preparation:

(a) A request having been submitted the Director is entitled, at his or her discretion, to send samples of the preparation for laboratory testing or field trials;

(b) The manufacturer will pay for the laboratory test or field trials the sum determined by the Directory depending on the scope of the laboratory testing or field trials;

7. Decision Date for the Director:

(a) The manufacturer having submitted a request to register the preparation, the Director will inform him or her in writing within two years whether the preparation will be registered whether the request has been refused.

(b) Despite what is stated in Subregulation (a) the Director will inform the applicant of his decision -

(1) If the preparation does not require field trials - within four months;

(2) If the request is for renewal of registration or if the Director has exempted the preparation from laboratory test and field trials within one month.

(c) The period stated in Subregulations (a) and (b) will start on the day on which all the details of the request have been submitted.

8. Refusal to Register (Amendment 1985):

The Director may refuse to register a preparation in any of the following cases:

(1) The data attached to the request and other information or the testing of the preparation have shown that the preparation is not effective for its stated purpose;

(2) The packaging does not protect the preparation against spoiling;

(3) The packing label does not include the required details according to Regulation 5 (2) and (3) or the details are incorrect;

(4) The name of the preparation is misleading;

(5) The preparation presents a danger to humans or animals;

(6) The manufacturer did not comply with the instructions of this Regulation;

(7) The preparation was found to be ineffective according to the instructions by the manufacturer;

(8) The material was found to be contaminated.

9. Appeals Against the Refusal to Register:

In case of refusal of the Director to register the preparation as stated in Regulation 8, the applicant may appeal, within thirty days from receipt of the refusal notice, before an appeal board of three people appointed by the Minister of Agriculture for this purpose.

10. Temporary Registration of the Preparation:

(a) If the Director finds, after the tests of the preparation have been completed and all the documents submitted to him or her were examined, that the preparation is suitable to its purpose but its use has not yet been tested on a sufficient number of animals, he or she may temporarily register the

preparation for one year; at the end of which the Director may extend the period for an additional period which will not exceed one year.

(b) The Director may cancel the temporary registration at any time by a detailed logical explanation.

11. Registration of the Preparation:

If the Director finds, after the tests of the preparation have been completed and all the documents submitted to him or her were examined, that the preparation is suitable to its purpose, he or she will register the preparation in the register and include in the registration all the details of the preparation regarding its composition, description, packing and packing label.

12. Registration Certificate:

After the preparation has been registered, the manufacturer will receive a permanent or temporary Registration Certificate, as may be required. The certificate will include all the details stated in Regulation 4.

13. Registration Register:

The Director will keep a register of all the registrations, which will include copies of the Registration Certificates.

14. Validity of the Registration Certificate and its Renewal:

(a) The validity of the Registration Certificate will be for three years from date of issue.

(b) If the manufacturer desires to renew the Registration Certificate of the preparation he or she will submit to the Director a new request according to Regulations 3, 4, and 5 not later than thirty days prior to expiration of Registration Certificate now held by him or her.

15. Cancellation of the Certificate of Registration:

(a) The Director may, in a written notice sent to the manufacturer by recorded mail, stipulate conditions, change or add conditions or cancel the certificate if one of the following become evident:

(1) The preparation is not effective for its purpose, according to the instructions of the manufacturer, may be harmful to humans, animals or to adverse by effect upon the environment;

(2) The label attached to the preparation is not identical to the label which was authorised when the Registration Certificate was issued;

(3) The composition of the preparation is not identical to that of the sample submitted for testing when submitting the request for registration;

(4) The manufacturer has not met the conditions of the Registration Certificate;

(5) New information was received which is different from that on which the Registration Certificate was issued.

(b) The applicant is entitled to appeal the decision of the Director according to Subregulation (a) before an appeal board, as stated in Regulation 9, within thirty days after receiving the decision of the Director.

16. Additional Packing Label or Changes in Packing Label:

(a) The Director may demand that the packing label have a specific colour for purpose of identification.

(b) In cases of double packing the Director may demand that each packing be labelled.

(c) The manufacturer is entitled, at all times, to request the Director authorisation for additional packing of the preparation or to change any item on the packing label.

(d) If a request has been submitted to change an item on the packing label as stated in Regulations 5(2) (a) or 5(2) (e), items 1 to 3, the Director is empowered to send a sample of the preparation for a field trial; the cost of the field trial will be paid by the manufacturer according to the requirements of Regulation 6.

(e) If the Director refuses to authorise an additional package or changes in the packing label, Regulation 9 becomes effective as though there is a refusal to register the preparation.

17. Changing the Package Label According to the Demand by the Director:

(a) The Director may instruct the manufacturer to correct or change the packing label, if such a change is required by his or her opinion.

(b) If the Director has ordered a change, according to Subregulation (a), the manufacturer has to carry out the change within 90 days and not distribute the preparation unless accompanied by a corrected label.

(c) If the manufacturer has not changed the packing label as stated above, the Director may cancel the Registration Certificate.

ADDENDUM

Regulation 5(2) (e) (8)

1. A preparation whose killing rate, when taken orally, whose LD50 is 50 mg/kg for solid preparations and up to 200 mg/kg for liquid solutions, will be marked with a skull and crossbones label and the word "POISON" printed on it in large letters in Hebrew, Arabic and English;
2. The label of a preparation with toxicity less than that in Paragraph 1 will be marked "POISON" printed in letters Hebrew, Arabic and English;

27 April 1982

Simcha Ehrlich
Minster of Agriculture