This is an unofficial translation. The binding version is the official Hebrew text.

Readers are consequently advised to consult qualified professional counsel before making any decision in connection with the enactment, which is here presented in translation for their general information only.

Hazardous Substances Regulations (Registration of Preparations for the Control of Pests Harmful to Humans), 5754 – 1994

By the power vested in me under Sections 10(3), 12 and 17 of the Hazardous Substances Law, 5753-1993 (hereinafter – "the Law"), and following consultation with the Minister of Health, I hereby make the following Regulations:

Definitions

1. In these Regulations –

Amendment 5763-2002 "Package" – a receptacle containing a preparation;

"Quality check" – a test that verifies the compliance of the preparation's composition with the specifications on the registration application;

"Supervisor" – The person authorized by the Minister of Environmental Protection for the matter of these regulations;

Amendment 5763-2002 "The register" –the register for the registrations of preparations stated in regulation 2A (b);

"Hazardous substance" – as defined in the Law;

Amendment 5763-2002 "Applicant" – A person that applies for the production, or import, of a preparation for domestic sale;

Amendment 5763-2002 "Container" – (omitted);

"Sale" – including giving, supplying and any other form of transferring ownership or right of possession to another;

"Laboratory" – a laboratory approved by the Supervisor for the purpose of conducting quality check of a preparation;

Amendment 5763-2002 "Label" – The label of the preparation, attached or printed on the package.

Amendment 5763-2002 "Preparation" – A material which is hazardous in any state of aggregation, or mixtures thereof, used or intended to be used for extermination or repulsion of insects and other types of arthropods, as well as rodents and other types of vertebrates that are a nuisance, inflict damage or might inflict damage to humans or their property; with the exception of any item or substance intended to be used on the human body.

Prohibitions
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2.

a) A person shall not sell, hold for the purpose of selling, or use a preparation, unless it is a registered preparation, and in accordance with the preparation's registration conditions.
b) A person shall not manufacture or import a preparation, with the intention of selling it in Israel, unless it is registered in the register, and in accordance with the preparation's registration conditions.
c) A person shall not sell, hold, use, manufacture or import a preparation, by any provisions other than those indicated in these regulations, and in accordance with the preparation's registration conditions.
d) A person shall not use a preparation unless it is a registered preparation, and it is used in accordance with the instructions of use that are specified on its label, and in accordance with its purpose of use.
e) A preparation should be stored in a closed place, and in a manner that prevents contact with food or access of children and pets.
f) For the purpose of these regulations – holding, manufacturing or importing for the purpose of sale are considered:
    1) Holding a preparation in a quantity that exceeding what is reasonably required for private use;

2) Any manufacture or import of a preparation in a quantity exceeding what is reasonably required for conducting quality checks or efficiency experiments with the preparation.

Application for Registration
In the Register
Amendment 5763-2002

2A.

a) An applicant shall submit an application for registration of a preparation in the register to the Supervisor, in accordance with the form provided in the Schedule, and accompanied by the required documentation, as specified in regulation 3 (hereinafter – "the application").
b) The register shall be administered by the Supervisor and he shall decide about its format and registration particulars contained in it.

Transfer of registration
Amendment 5763-2002

2B.

a) Where a preparation is registered in the name of a person, and another wants to register the preparation under his name - he shall submit an application for registration to the Supervisor, in accordance with the form in the Schedule, and he shall attach to the application:
    1) A copy of the original registration certificate;
    2) Written consent of the registration certificate holder to transfer the registration from his name to the applicant, and to allow the applicant to rely on his original application;
    3) In case of an imported preparation- approval of the preparation's manufacturer regarding his consent to transfer the registration of the preparation from the holder of the registration certificate to the applicant;
    4) A quality check certificate from the laboratory;
    5) A copy of the label that was approved in the registration certificate and of the proposed label referred to in regulation 5.
    6) If required by the Supervisor, additional data about the preparation and the transfer of registration.

b) Where the Supervisor approves the requested transfer of registration, he shall provide the applicant with a registration certificate under his name, whose expiration date shall be the same as that of the original registration certificate.

Application appendices

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3.

a) The applicant shall attach the following appendices to his application:

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1) Results of experiments with the preparation and literature regarding its mode of use, which testify to the preparation's efficiency in the fulfillment of its intended goals;

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2) (Omitted);

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3) In case of an imported preparation, documents testifying about the preparation's registration and sales in other countries, including the labels in these countries;

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4) If required by the Supervisor, sample of the preparation's packaging;

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5) Detailed summary of the toxicological file and Safety Data Sheets of the preparation, its active substance and each of its components;

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6) If required by the Supervisor, a complete toxicological file, including acute and chronic toxicity data in respect of the preparation's impact on humans, the environment, animals and plants;

7) Information on the preparation's shelf life;

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8) (Omitted);

9) A quality check certificate from the laboratory;

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10) A copy of the proposed label said in regulation 5;

11) If required by the Supervisor, additional data about the preparation.

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b) The appendices specified in subsection (a), with the exclusion of paragraph (6), shall be submitted in 12 copies; all appendices should be accompanied with translation into Hebrew, unless it they are written in English.

Completion of particulars

4. The Supervisor shall not submit for deliberation in the professional committee any application that does not comply with the provisions of regulation 3, and he shall return it to the applicant for completion of particulars and documentation.

Label of preparation

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5.

a) The preparation's package shall bear a label that shall be attached or printed on it, in a manner that prevents its removal, unless the Supervisor decides, with the consent of the professional committee said in regulation 9(a), to attach the label to the preparation in a different method.

b) The following particulars should be printed on the label, in clearly visible letters, in both Hebrew and Arabic:

1) Manufacturer's name and address;
2) Importer's name and address;
3) Preparation's commercial name;

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4) Preparation's formulation;
5) Common names of all active and synergistic substances;
6) Concentrations of the preparation's active and synergistic substances;
7) Preparation's purposes of use;

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8) Net weight or volume of the preparation in its package using the metric system;

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9) Preparation's production batch number and expiry date, or preparation's manufacture date and expiration period;

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10) If required by the Supervisor, preparation's classification;
11) Preparation's mode of use;
12) Detailed precautions in respect of the preparation's storage and use;

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13) Registration number of the Ministry of Environmental Protection and its year of expiration;
14) Instruction to see a doctor in case of poisoning suspicion;
15) Poison and flammability signs, as specified in regulation 8;

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16) The words "The Ministry of Environmental Protection has determined that use of this preparation contrary to the label instructions, might endanger the health of the public, the user and the quality of the environment".

c) The Supervisor may require the applicant, with the consent of the professional committee, to add more particulars to the preparation's label.

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d) The preparation's label and the particulars indicated in it shall be included in the preparation's registration conditions.

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e) A person shall not modify the label's phrasing without prior written permission of the Supervisor.

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6. (Repealed).

Publication and Display

7.

a) A person shall not advertise a preparation or display it for sale unless it is a registered preparation, and providing that the advertisement or display were carried out while the preparation's registration was valid, and subject to that stated on the label, the other registration conditions and the provisions of these regulations.
b) Any advertising of the preparation shall include the words "The Ministry of Environmental Protection has determined that use of this preparation contrary to the label instructions, may endanger your health and the quality of your environment".

Preparation's package
Amendment 5763-2002

7A. A person shall not manufacture, import or sell any preparation unless its package is -

1) Tightened, closed and sealed in a manner that prevents uncontrolled spillage, leakage, dispersion or evaporation of its contents.
2) Made of chemically stable substances that do not react with the contents.

Poison
and Flammability Signs
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8.

a) A poison sign shall be printed on the diamond shaped label, in the color black on a white background, including an image of a skull with crossed bones and the word "Poison" in large printed letters, in Hebrew, Arabic and English; the length of the diamond's side shall be no less than 15 millimeters; the marking should be clear, easily readable and permanent.
b) The poison sign shall appear on every preparation label, with the exception of special cases in which the Supervisor approves otherwise, with the consent of the professional committee.

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c) If required by the Supervisor, the label shall also include a flammability sign or any other sign.

Professional Committee for
Registration of Preparations

9.

a) The Minister of Environmental Protection shall appoint a professional committee for the registration of preparations composed of six members, three representatives of the Minister of Environmental Protection, one of whom shall serve as committee chairman, and three representatives of the Minister of Health, one of whom shall serve as vice chairman.

b) The roles of the professional committee are to advise the Supervisor on any professional matter under these regulations and to discuss any application submitted to the Supervisor, as provided in regulation 2B.

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c) Any decision of the Supervisor under these regulations, including a decision on registration, renewal or cancellation of a preparation and setting of the registration conditions is subject to approval by the professional committee.

d) The professional committee may determine for itself the procedures of its work and deliberations.

Classification of Preparation

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9A. The Supervisor may determine, in consultation with the professional committee, a classification for types of preparations, including according to their degree of toxicity, degree of risk in usage, type of users and degree of impact on the environment; if the Supervisor determines a classification as said, the preparation's registration certificate shall include its classification.

Registration of preparation

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10.

a) The Supervisor may register preparations and grant a registration certificates, stipulate registration conditions, add to them and modify them, all with the approval of the professional committee. The application form and its accompanying documentation, as approved by the Supervisor, shall be part of the preparation's registration conditions.

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b) The registration shall be valid for a period of three years or six years from the date of its issuance, or for a period shorter than three years, as determined by the Supervisor with the consent of the professional committee.

Refusal to register a preparation

11. The Supervisor, with the consent of the professional committee, may refuse to register a preparation in any of the following cases:

1) The preparation might, in his opinion, endanger humans, the environment, animals or plants;
2) The applicant did not provide proof, to the satisfaction of the professional committee, that the preparation is effective for the purposes declared in the application;
3) The results of the chemical test show that the preparation does not contain the declared amount of active substances.
4) There is a registered preparation, designated for the same purposes, which is less harmful to humans, the environment, animals and plants;

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5) The package or label does not comply with the requirements of these regulations.

Renewal of registration
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12.

a) An application for registration renewal shall be submitted to the Supervisor at least six months before its expiry, in accordance with the form in the Schedule. If the registration of the preparation was valid for less than three years, the renewal application shall be submitted on the date specified in the preparation's registration conditions; the application shall be accompanied by -

    1) A declaration affirming the particulars of the preparation's registration application, or updated material on particulars that were changed compared to the registration application;
    2) Documents testifying the preparation's registration and sale in other countries, including the labels in these countries;
    3) Certificate of a quality check in the laboratory;
    4) A copy of the approved label and the proposed label;
    5) If required by the Supervisor, additional data about the preparation.

b) The application and its appendices shall be submitted in twelve copies.

Cancellation of registration

13. The Supervisor may, with the approval of the professional committee, cancel a registration he granted or make it conditional, if one or more of the following is found :

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1) The package does not protect the preparation from spoilage or from risk to humans, the environment, animals or plants;
2) The preparation is harmful and presents risk to humans, the environment, animals or plants;
3) The preparation is not efficient in fulfilling its purpose;
4) The preparation's composition is not identical to the composition of the sample approved in the quality check; where such is suspected, the Supervisor may require a repeat test in the laboratory;
5) The label is not identical to the label approved during registration;
6) The manufacturer or importer violated one of the conditions stipulated in the registration;
7) New information was received, different from that submitted during registration;

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8) The manufacturer or importer violated one of the provisions of these regulations, or the provisions of any other law, in regard to his dealing with the preparation.

Date of decision

14. The Supervisor shall notify the applicant about his decision regarding the registration within six months of the day in which the submission of the application was completed, including the submission of its accompanying appendices according to these regulations; where the Supervisor refuses to register the preparation - he shall justify his decision in writing.

Sale

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15. A person shall not sell a preparation, or hold it with the intention of selling it, except in its original label bearing package.

Return and disposal
of preparation
Amendment 5763-2002

15A.

a) Any holder of an unregistered preparation or of a preparation which does not comply with the provisions of these regulations or with any of the registration conditions, shall return it to the owner of the registration certificate or dispose it to a plant for the neutralization and treatment of industrial wastes and hazardous substances wastes in Ramat Hovav, or any other location approved by the Supervisor, and he shall undertake the required means for preventing adverse impact on the quality of the environment.

b) Where an unregistered preparation, or a preparation which does not comply with the provisions of these regulations or with the registration conditions, is sold, the Supervisor may instruct the owner of the registration certificate to retrieve the preparation that was sold, or any other instruction that is needed, in his opinion, to ensure the fulfillment of the provisions of the law and of these regulations.

c) An owner of a registration certificate shall not refuse to accept a preparation registered under his name, whose registration has expired or whose expiration period has ended, from its holder who wants to return it, but the owner of the registration certificate may charge the holder the cost of treatment or disposal of the preparation.

Saving of laws

16. These regulations do not derogate from the provisions of any other law.

Penalties
Amendment 5758-1998

17.

a) A person who does one of the following is liable to six months imprisonment or a fine, as said in Section 61(a)(1) of the Penal Law, 5737-1977:

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1) Violates the provisions of regulation 2, 5(e) or 15;

2) Produces, markets, imports or holds a preparation, whose attached label does not comply with the provisions of regulations 5 and 8;
3) Advertises or displays for sale an unregistered preparation, or advertises or displays a preparation in a manner which does not comply with the preparation's label, contrary to the provisions of regulation 7;

b) An offense, under this Section, is a strict liability offense.

Commencement

18. These regulations shall enter into force three months from their date of publication.

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Schedule

(Regulations 2A (a), 2B (a) and 12))

Application for registration / registration renewal / transfer of registration of a preparation for the control of pests harmful to humans

In accordance with the Hazardous Substances Regulations (Registration of Preparations for the Control of Pests Harmful to Humans), 5754-1994 (hereinafter – "the Regulations")

To: the Supervisor, Ministry of Environmental Protection, P.O.B 34033, Jerusalem

We hereby apply for registration of a preparation

1. Manufacturer - _____, _____, _____, _____, _____
   Name Street and no. Locality Zip code P.O.B

   Importer - _____, _____, _____, _____, _____
   Name Street and no. Locality Zip code P.O.B

2. Preparation's commercial name:
   _____, _____
   in Hebrew In Latin

3.
   A. The active substances of the preparation:

   _____

The substance	Scientific name and formula	Concentration in preparation (%)	L.D 50 in oral intake in rats (mg / kg)

   B. The non-active substances of the preparation:

   _____

The substance	Concentration in Preparation (%)	Remarks

   C. L.D 50 of preparation in oral intake for rats (mg / Kg): _____
   D. The preparation contains a substance which is controlled under the provisions of the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer

(available for review by the public in the Ministry of Environmental Protection):
Yes, specify: _____
No

E. Formulation Type: _____

4. Stability: After manufacture, the preparation is fit for use for a period of _____

5. The packages:
   A. Package description Packaging material weight/volume Method of closure

   B. The method of closure was checked and found to prevent uncontrolled spillage, leakage, dispersion or evaporation of content:
   Yes
   No

   C. The package was checked and was found to be made of chemically stable materials, which do not react with the preparation's content:
   Yes
   No

6. Purpose of use:
   The preparation is used for pest extermination: _____
   The preparation is used for pest repulsion: _____

7.
   A. Mode of use:
   The preparation is ready for use
   The preparation needs to be diluted or mixed

   B. For preparations that need to be diluted or mixed before use:
   Solvent and dilution ratio Solid material and mixing ratio

   C. The preparation is intended for the use of:
   The general public
   Pest control operators
   D. Mode of implementation (e.g.: dusting, spraying, warm misting):
   _____

E. Places in which the preparation should be uses:
   Inside the house – specify: _____
   Outside the house – specify: _____

8. This application is accompanied by the appendices referred to in regulation 3(a) / regulation 12(a) (erase the irrelevant option) of the regulations.

9. Declaration:
   I, the undersigned _____, I.D. no. _____, authorized signator of the business/corporation _____, hereby declare that the information I submitted above is accurate, complete and correct, and that the registered preparation shall be sold in compliance with the particulars of its application file, and that no modification shall be performed in the preparation without the Supervisor's written consent.

   Date _____ Signature: _____
   Business / Corporation stamp: _____