

DRAFT

- MOSQUITO COILS ■ VAPORISING MATS ■
- LIQUID VAPORISERS ■ AEROSOLS ■

Report of the WHO Informal Consultation
3-6 February 1998
WHO, Geneva



World Health Organization
WHO Pesticide Evaluation Scheme
Division of Control of Tropical Diseases



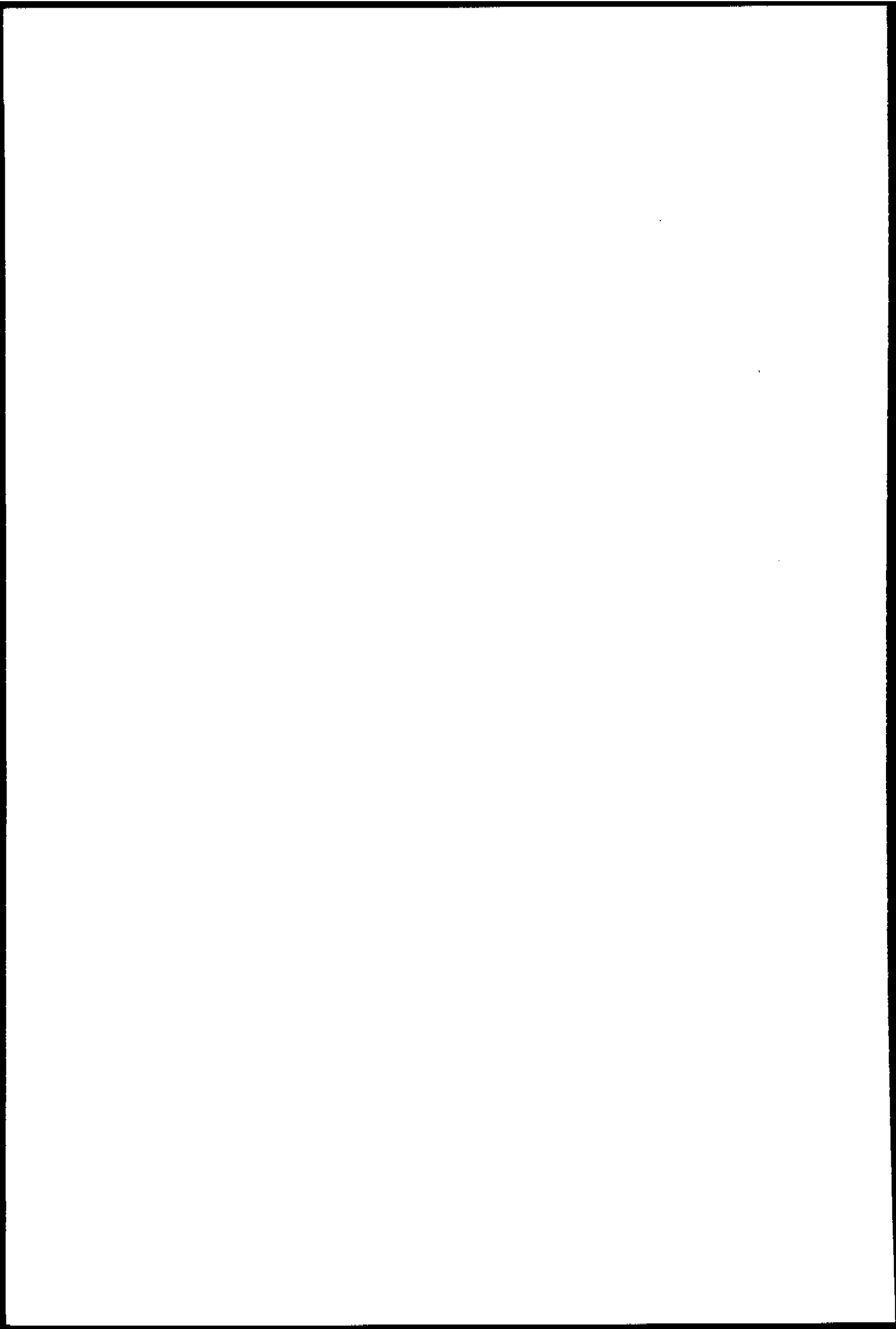
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1. Introduction

The consultation was opened by Dr R.H. Henderson, the Assistant Director-General of the WHO on behalf of the Director-General.

He noted that the demand for household insecticide products is on the increase particularly in many tropical developing countries and the yearly world-wide market for these pesticides is estimated to be more than two billion US Dollars.

He reiterated the need and importance for internationally agreed specifications which would assure the production of efficient and safe household insecticide products and protect both consumers and manufacturers. In addition, these specifications would promote the harmonisation of relevant national standards and thus, world trade in such pesticides. To address this need, this consultation has been convened to prepare draft guideline specifications for mosquito coils, vaporising mats, liquid vaporisers and aerosols for space and residual spraying, for consideration by the forthcoming WHO Expert Committee on Vector Biology and Control "Chemistry and Specifications of Pesticides", planned for autumn 1999.

Dr K. Behbehani, the Director of the Division of Control of Tropical Diseases, in his opening remarks expressed confidence that the objectives of the meeting would be achieved, and that the outcome of this meeting would expand the activities of WHOPES in providing more technical assistance to Member Countries. This would also result in the identification and designation of Collaborating Centres to assist WHO in the testing, evaluation and quality control of such products.

Dr Zaim presented an overview of the WHO Pesticide Evaluation Scheme (WHOPES). He highlighted the recent efforts of the WHO in strengthening WHOPES activities through the establishment of a Global Collaboration for Development of Pesticides for Public Health (GCDPP), which has a general objective to facilitate the search for alternative pesticides and application methodologies that are safe and more cost-effective.

The meeting was attended by seven representatives of national registration authorities, three scientists, eleven representatives of the pesticide industry as well as members of the Secretariat (see list of participants in Annex 1). The meeting reviewed and updated the "Guideline Specification for Household Pesticides", the report of an informal consultation held in Geneva from 18-22 June 1990. The meeting was only concerned with mosquito coils, vaporising mats, liquid vaporisers and aerosols. It did not consider other household insecticide products.

2. Present situation of the household insecticide product market and of specifications

2.1 Use of household insecticide products

Household insects which cause nuisance and contribute to sanitary and health problems are ubiquitous throughout the world. However, the household insect problems appear to be more serious in many tropical developing countries due to inherent favourable environmental conditions for the development of such pests in the tropics. In addition, the rapid uncoordinated urbanisation in many tropical areas have also aggravated the problems. The increasing awareness and the worsening situation of the household pest problems as well as the improved socio-economic conditions in many tropical developing countries have resulted in the increased demand and use of household insecticide products.

The present status concerning the worldwide usage of household insecticide products was reviewed. The annual worldwide consumption of the four major types of household insecticide products, namely aerosols, mosquito coils, liquid vaporisers, and vaporising mats, were estimated by the industrial sources to be around 0.986, 28.75, 0.070, and 6.21 billion units (cans/pieces), respectively. Regional distribution of usage is shown in Table 1.

Table 1

Estimated consumption of household insecticide products in 1996 (All values in billion units)

Region	Type and Consumption			
	Aerosol	Coil	Liquid Vaporisers	Vaporising Mats
Asia	0.298	26.81	0.048	4.54
America	0.378	1.60	0.006	0.71
Europe	0.132	0.08	0.015	9.55
Middle East & Africa	0.178	0.26	0.001	9.32
Total	0.986	28.75	0.070	6.12

It was noted that the usage of aerosols and mats was distributed widely throughout the world. However, the use of coils was predominantly in East Asia. Synthetic pyrethroids appear to be the choice active ingredients for household insecticide products, especially in the production of coils and mats. Consumption of synthetic pyrethroids as a group was estimated to be more than 1000 tons, in the world.

The worldwide market of household insecticide products was estimated to be around 1 billion \$US at the manufacturer level, with the retail value estimated to be around 2 billion \$US. Furthermore, the value of the household insecticide market was estimated to be around 5 to 10% of the total world insecticide market. On a regional basis, the trend for household insecticide product consumption appears to be stabilised for the developed countries (e.g., North America and western Europe). In contrast, the usage of household insecticide products in the tropical developing countries is on the increase. Generally on a worldwide scale, there appears to be a more rapid increase in the use of coils and vaporising mats in comparison with aerosols.

With regard to the efficacy of household insecticide products, comparative laboratory efficacy tests of pyrethroid-based coil and mat products against common vector mosquitoes in the genera of *Aedes*, *Anopheles* and *Mansonia* indicated that they are susceptible to such products. In contrast, the *Culex* species, especially *Culex quinquefasciatus*, indicated a high degree of tolerance.

Moreover, small-scale field efficacy trials indicated that coil and mat products provided overall protection of 70% and 50%, respectively, against indoor biting mosquitoes.

2.2 Existing specifications

The existing specifications for certain household insecticides are based on standards set/initiated by national or international organisations such as: Chemical Specialities Manufacturing Association (CSMA) in the United States of America, the British Aerosol Manufacturing Association/British Standards Institute (BAMA/BSI) in the United Kingdom, the Committee for European Normalisation (CEN) and the European Aerosol Federation (FEA, 49 Square Marie-Louise, 1000 Brussels, Belgium) in Europe, the South African Bureau of Standards (SABS) in South Africa, the National Registration Authority (NRA) in Australia, and the Standards and Industrial Research Institute of Malaysia/Malaysian Standard (SIRIM/MS) in Malaysia, and Tanzania Bureau of Standards.

3. Proposed guideline specifications for household insecticide products

3.1 Purpose

The purpose of proposing a guideline for specifications of household insecticide products is to initiate and facilitate the development of internationally agreed specifications for these products. Such specifications could promote: (1) the harmonisation of relevant national standards; (2) world trade; (3) an international basis to assist in the registration of household insecticide products; and (4) consumer protection and safety.

3.2 Scope

It is important that a specification be as concise as possible, unambiguous and be supported by appropriate test methods which are practical, to determine whether the material conforms to the criteria and standards established. Non-quantifiable parameters may also be included as information but not as part of the specifications. These proposed guidelines are intended for household insecticide products which are generally marketed in convenient ready-to-use formulations. The main common formulations are: (1) mosquito coils; (2) vaporising mats; (3) liquid vaporisers; (4) aerosols (space sprays and residual sprays); (5) non-pressurised dispensers; (6) baits; and (7) dustable powders.

However, the meeting considered only the first four formulations. Future meetings/discussions may cover other formulations.

3.3 General requirements

Household insecticide products, as mentioned above, are generally marketed in ready-to-use packages and labels containing the requirements for compliance with specifications of the product should also include clauses on its safe and efficient use. Listed below are some of the general requirements and the objectives of their inclusion in the guidelines for the preparation of specifications for these products. Confidentiality of information provided by the industry should be observed by WHO and/or registration authority when requested.

3.3.1 Description

The ISO¹ common name of the active ingredient(s) should be used, or if it does not exist, the common name or the chemical name according to IUPAC² or CA³ convention should be used.

The description of the product should include the physical state, formulation adjuvants (e.g., binders, fillers, solvents, propellants, etc.), colour and odour (if any). Each specification guideline should include a standard clause on description of formulations. The description must refer to the requirements of existing WHO specifications on technical materials.

3.3.2 Sampling

The required degree of assurance to ensure that the product purchased complies with the specification determines the sampling procedure.

In general, the lower the active ingredient content and/or the larger the size of the container, the larger must be the sample. A proposed sampling procedure for each formulation is described in the proposed guidelines but this does not preclude the purchaser from sampling in any way considered desirable that is acceptable.

¹ International Organization for Standardization

² International Union of Pure and Applied Chemistry

³ Chemical Abstracts

3.3.3 Expression of active ingredient content

The active ingredient(s) content shall be declared in terms of g/kg or % w/w, except for vaporising mats for which the active ingredient(s) content is declared on the basis of ...mg of active ingredient(s) per mat.

3.3.3.1 *Methods of analysis*

Methods of analysis for the active ingredient(s) or for determining physical properties should be based, as far as practicable, on CIPAC¹, AOAC² or other collaboratively tested methods. If the methods have not been collaboratively tested, then a copy of the full method of analysis intended for use with the specification shall be supplied. In this case, the method should include a statement of application and validation.

3.3.3.2 *Tolerance on content*

Tolerance³ on content is influenced by: (1) reproducibility of the method of analysis; (2) sampling error; (3) manufacturing variance; and (4) chemical nature of the active ingredient.

In the case of household insecticide products, the following figures are given as a guideline. However, these could be different depending on individual pesticides.

Declared content (g/kg)	Tolerance permitted
up to 25	± 15% of the declared content
above 25 up to 100	± 10% of the declared content
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
above 500	± 25 g/kg

Impurities in some technical materials are specified in the WHO specifications and where appropriate for formulations. WHO specification should always be used⁴.

3.3.4 Storage stability

Over a period of time, insecticide products may undergo chemical and/or physical changes. The rate at which they do so depends on the nature of the technical material(s), the formulation, the packaging and, in particular, the storage conditions.

¹ Collaborative International Pesticides Analytical Council

² Association of Official Analytical Chemists.

³ A tolerance is the acceptable variation on the concentration of the active ingredient.

⁴ Specifications for pesticides used in Public Health, 7th edition, WHO/Geneva, WHO/CTD/WHOPES/97.1; and Interim specifications for pesticides used in public health, WHO/CTD/WHOPES/97.7

From the practical point of view, it may be reasonable to expect the products to continue to be satisfactory in use after storage for at least two years in the unopened original containers, provided that these have been stored according to the instructions which should be precisely stated on the label.

Since storage stability tests under ambient conditions take considerable time to give significant results, they are not practical for quality control purposes. Accelerated storage stability tests have, however, proved most useful in rejecting many products that do not meet acceptable levels of storage stability. The meeting was concerned with the absence of standardised method and suggested that WHO in collaboration with the industry are requested to produce such a method. In the absence of this standardisation test, a temperature of $54 \pm 2^\circ\text{C}$ for 14 days should be used.

3.3.5 Packaging

Packaging of the material depends on the type of formulation. Specific requirements are therefore given in each of the guideline specifications.

3.3.6 Labelling

All packages shall be, durably and legibly, marked with at least the following:

- Trade Name,
- Name, Address, Phone # of responsible party in the country in which the product is sold (Manufacturers, retailers, and/or registrants)
- Type of Product to specification WHO/SIF/ ...
- Active ingredient(s) name and content to specification WHO/SIT/... (according to item 3.3.1)
- Synergist(s) name and content
- Net weight of contents
- Batch or reference number
- Date of manufacture and shelf life (.... years)
- Appropriate safety statement(s) including WHO hazard classifications and warning not to reuse container.
- Instructions for use (includes disposal statements)
- Use only as instructed
- First Aid Requirements

3.3.7 Determination of bio-efficacy

While specifications of a household insecticide product based on chemical and physical properties are essential to ensure quality, the biological efficacy of the product needs to be confirmed. Although several national efficacy test protocols are available, WHOPES has been asked to prepare internationally agreed test protocols for household insecticide products that could be widely recognised and used. In view of this, a test protocol was established at the WHO Informal Consultation on the evaluation and testing of insecticides, held in Geneva, 7-11 October 1996¹.

¹ Report of the WHO Informal Consultation on the evaluation and testing of insecticides, WHO/Geneva, CTD/WHOPES/IC/96.1

This protocol was discussed, reviewed and expanded to include other pests. Specific protocols for the four types of household insecticides were discussed in this meeting and outlines were produced. (Annex 6)

3.4 Specific requirements for different types of formulations

3.4.1 Mosquito coils

The meeting discussed the specific requirements for mosquito coils and decided that the following should be incorporated in the guideline specifications.

3.4.1.1 *Average weight of the coil*

This clause is to confirm that the coils meet the declared weight.

3.4.1.2 *Burning time*

This is a measurement of the time it takes for the whole coil to burn. This requirement is to ensure that the coil burns for a length of time, as stated on the label. (See Annex 2, Section 1.2.3)

3.4.1.3 *Water content*

This requirement is to limit the water content which might affect storage stability of the product as well as the ability of the coil to burn completely (see Annex 2, Section 1.2.4).

3.4.1.4 *Strength of coil*

This requirement is to ensure that mosquito coils do not break easily while in transit, during storage or usage.

3.4.1.5 *Separation of twin coils*

This requirement is to ensure that twin coils do not break easily when they are separated.

3.4.2 Vaporising mats

3.4.2.1 *Size of mat*

This requirement is to ensure that the mat fits into an appropriate heater¹, and that an adequate evaporation rate of active ingredient from the mat is obtained (see Annex 3, Section 1.2.2).

¹ The appropriate heater should accommodate the mat securely and give the correct temperature profile.

3.4.2.2 *Evaporation rate*

This requirement is to ensure adequate evaporation rate of the active ingredient so as to maintain the biological efficacy of the product for the length of time declared on the label.

3.4.3 **Liquid vaporisers (liquid emitter device, LED)**

3.4.3.1 *Minimum effective period*

This requirement is to ensure that the liquid vaporiser is effective for a minimum specified period (see annex 4).

3.4.4 **Aerosols**

3.4.4.1 *Solvents*

Household insecticide products generally have relatively low active ingredient concentrations. Nevertheless, as they are used in very close proximity to the general public, specifications should include clauses primarily to protect users and others who may be exposed to them. In addition to the active ingredient, additives, synergists and solvents which constitute a major portion of household insecticide formulations must also be taken into consideration. The meeting decided that solvents as listed in Table 2, which have been found to be of toxicological concern, should not be permitted and a statement to this effect should be included in the specification. It was also noted that this list should be reviewed from time to time.

Table 2
Solvents of toxicological concern

2-ethoxyethanol (ethylene glycol monoethyl ether)
2-ethoxyethylacetate (ethylene glycol monoethyl ether acetate)
2-methoxyethanol (ethylene glycol monomethyl ether)
2-methoxyethylacetate (ethylene glycol monomethyl ether acetate)
2-butoxyethanol (ethylene glycol monobutyl ether)
2-butoxyethylacetate (ethylene glycol monobutyl ether acetate)
chloroform
carbon tetrachloride
1,2-dichloroethane (ethylene dichloride)
benzene
chlorobenzene
n-hexane
2-hexanone (methyl n-butyl ketone)
trichloroethylene
tetrachloroethylene

It was agreed that methylene chloride, a very widely used solvent which is presently under review, should for the time being not be included in the list.

3.4.4.2 *Propellants*

The Montreal Protocol and EU¹ directive on the withdrawal of chlorofluorocarbons (CFCs) from aerosols were noted. Hydrocarbon propellants are recommended for insecticide aerosols, provided international safety standards are met by the aerosol producer. Industry should be encouraged to develop alternative and safer propellants and delivery systems.

3.4.4.3 *Droplet size*

It was recognised that droplet size is important in determining the performance of both pressurised aerosol space sprays and residual sprays. Indeed, it is one of the basis of distinction between these two types of aerosols. Further, it is appreciated that droplet size may influence the extent of inhalation exposure. The methods for droplet size determination currently available were reviewed and it was noted that further collaborative work is required before a clause on aerosol droplet size can be included in the specification.

3.4.4.4 *Internal pressure*

This measurement is to ensure that the droplet size and discharge rate are controlled and to check that the internal pressure of the filled dispenser is consistent with the anticipated internal pressure of the pack and does not exceed the design of the container.

3.4.4.5 *Discharge rate*

This measurement of discharge rate assists in checking valve performance of the dispenser.

3.4.4.6 *Flammability*

This clause aims at comparing and classifying the relative flammability hazards of aerosol products.

3.4.4.7 *pH (water-based aerosols only)*

To check on possible decomposition of the active ingredient and deterioration of the physical properties of the formulation and the container, the pH shall be measured.

3.4.4.8 *Ignition distance*

To assess the risk associated with the use by the customer.

3.4.4.9. *Clogging of valve/button*

No clogging or interruption to the spray shall be observed when a sample of aerosols is discharged until empty.

¹ European Union

3.4.4.10 *Packaging*

A clause on packaging is necessary to ensure that the container and valve/actuator combination provides soundness of the dispenser and physical and chemical stability of the formulation throughout the defined shelf life. Containers shall be suitable for their purpose and fully compatible with their contents.

3.4.4.11 *Maximum safe fill*

To ensure safety in use, the total liquid content shall not be more than 90% of the internal volume.

4. Safety

4.1 Overview

Household insecticide products raise several important considerations concerning safety. These are related to the use of insecticide by untrained individuals, the inability to control or ensure the safe use of these products once purchased by the consumer, the potential exposure of the very old and very young and the relatively limited regulatory and toxicological requirements in many countries concerning these insecticides.

Such factors increase the need for clear and well structured specifications, widely accepted by manufacturers and regulatory authorities, to ensure that products introduced to the consumer minimise potential hazards and misuse. "Coils, mats, and liquid vaporisers, being slow release systems, have particular potential for long-term exposure".

While regulators and manufacturers can minimise potential hazards, there remains a major responsibility on the part of the consumer to read, prior to use, the use and safety recommendations on the product label and to ensure that all insecticides are safely stored away from children and animals. As a major requirement for product safety all household insecticides should only contain well defined active ingredients (WHO Specifications)¹.

These should be non-genotoxic, non irritant, non-lung-damaging and non-accumulating in neither lung tissues or other body tissues. Active ingredients, which do not have this toxicological profile should be banned from this particular use, since alternatives are readily available.

As household insecticides are generally sold in ready-to-use formulations for use in and around dwellings, it is imperative that the safety of the product as a whole be taken into consideration. Manufacturers of household insecticides should be encouraged to incorporate child-proof packaging, along with other safety features in their product.

¹ Specifications for pesticides used in public health, 7th edition, WHO/Geneva, WHO/CTD/WHOPE/97.1; and Interim specifications for pesticides used in public health, WHO/CTD/WHOPE/97.7

Concern was expressed for the safe use and handling of household insecticide products, including mosquito coils, mats, aerosols and other household insecticide products.

4.2 Mosquito coils

While toxicological data of the insecticide content of mosquito coils are available, concern was expressed by the participants regarding the lack of published toxicological information on the pyrolysis products of organic fillers in mosquito coils.

Traditionally, coils were made from a mixture of ground pyrethrum flowers and filler from coconut-shell flour which were bound with an agent called "Tabu". The latter consisted of ground-up leaves and bark of *Machilis thunberii*, containing a complex polysaccharide, which formed a gum when wetted. Today, a number of other types of wood fillers are available which are used in greater proportion to the active ingredient than formerly and the number of available binding agents have also increased.

A better understanding is needed on what effect, if any, smoke generated from mosquito coils has on humans in view of the long exposure time to which people may be subjected. This is equally important if mosquito coils are used in poorly ventilated rooms where levels of carbon monoxide and other noxious gases/fumes increase and thereby potentially affect the occupants.

As an exposed "smouldering" point is typical of mosquito coils, special reference should be made on the label to the risk of flammability.

4.3 Mat heaters and liquid vaporisers

Acceptable safety standards are necessary in industry regarding the design, construction, materials, equipment and workmanship of vaporising mat heaters. The consumer must be protected against mechanical and electrical failures. The electrical component in such devices must be sound to guard against the risk of shock, and to provide protection from excess heat and the danger of fires since the operating temperature can be as high as 160°C. Therefore, an appropriate protective grid must be present to guard the heating surface.

The heaters must conform to the electrical safety standards as applicable in the country for which their use is intended. In addition, correct labelling information must be provided along with safety instructions with each unit which should be individually packaged.

4.4 Aerosols

For reasons of efficacy and safety, aerosols should be designed and labelled for use to control either flying or crawling insects, not both.

In general, less hazardous products should be used for space sprays. Formulation of aerosols should minimise hazards from droplet inhalation. Solvents may also have a potential for a toxic effect when inhaled.

The product should be designed and labelled in such a way so as to minimise the risk of accidentally discharging the aerosol towards the user.

There is increasing awareness of the potential hazards posed by "inert" additives in insecticide formulations. Table 2 shows a list of solvents that are of toxicological concern and should therefore not be used.

4.5 Assessment of inhalation toxicity

Because of their indoor usage, inhalation exposure presents a particular concern for household insecticides. The hazard from aerosol, mat and liquid formulations can be adequately assessed by consideration of the active ingredients or by appropriate sub-acute test methods. However, this is not likely to be the case for mosquito coils which are a special case since a complex mixture of combustion products may be expected. This mixture may vary depending on the type and/or amount of wood, coconut shells, binders, or colorants present in the coil.

For coils, safety testing should be based on the finished product, and involve an evaluation of upper and lower respiratory tract irritant potential, pulmonary toxicity, or impairment of pulmonary function. Appropriate tests are sub-acute/sub-chronic (repeated exposure 28 to 90 days) testing, the results of which may indicate a need for longer duration tests under some circumstances.

No coil ingredient should produce pneumotoxicity, adversely affect the capability of the lung to cope with the daily load of air borne pollutants, or increase the given irritant potential of the coil matrix.

Recommendations

1. WHOPES should devise an accelerated programme for implementation of the guidelines in this report to household insecticide products in current use, and prepare and publish specifications on such products.
2. WHO should further promote the consistent use of WHO specifications for pesticides used in public health at the national and international level so as to benefit public health and safety.
3. In view of the expanding usage of household insecticide products worldwide, WHO should collate information on current national regulatory requirements. WHO should

4. encourage and coordinate efforts in the international harmonisation of registration requirements for household and public health pesticides.
5. WHO should regularly prepare updated information/lists of the toxicological and ecotoxicological properties of solvents and other materials used in household insecticides.
6. Industry is encouraged to compile and to make available to WHO existing information on safety aspects of household insecticide products. Harmonisation of test procedures to evaluate inhalation toxicity should be led by WHO with participation of industry, national registration authorities, and research institutes.
7. WHO should assist Member Countries in creating awareness of effective and safe use of household pesticide products and in developing the capacity to build national registration authorities and laboratories for quality control. WHOPES, IPCS and WHO Regional Offices should conduct workshops to develop strategies and guidelines to be used by Member Countries. Industry collaboration should be encouraged.
8. The present WHO hazard classification of pesticides (based on the acute oral and dermal LD₅₀ values of a solid or liquid formulation) needs to be revised because it is not appropriate to household insecticides. A specific classification is therefore needed for household pesticide use where inhalation exposure can be important.
9. Guideline specifications for other classes of household insecticide products, not covered by this meeting should be prepared by WHOPES in collaboration with industry, national regulatory authorities and research institutes.
10. WHOPES, in collaboration with industry, national authorities, and research institutes, should prepare educational and training material on safe and effective use of household insecticides. This should be directed towards specific user groups.
11. To assist WHOPES and Member States, WHO should designate Collaborating Centres for testing of household insecticides for efficacy and product quality control.
12. The meeting identified the need for an industry group to be established which will provide WHO and national registration authorities with an effective contact to discuss and agree on technical issues in relation to household (and public health) pesticides. It was suggested that GCPF¹, in collaboration with the relevant national and international industry associations establish such a group.
13. WHO, in collaboration with national and international authorities shall draw up guidelines for the labelling household insecticide products.
14. The proposed WHO Global Collaboration for Development of Pesticides for Public Health (GCDPP) was noted, and its membership should be encouraged by industry.

¹ Global Crop Protection Federation

Annex 1

Participants

1. Temporary Advisors

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Annex 2

Guideline specifications for mosquito coils

1. Specification

1.1 Description

The product shall consist of an insecticide/repellent, organic fillers capable of smouldering well, binder and additives such as synergists, dye and fungicide, formulated in the form of a coil. The technical material (ISO common name) used in the manufacture of the coil shall comply with the requirements of specification WHO/SIT/...

The coil must burn without producing any flame except at the beginning, and should be readily extinguished after ignition of the coil.

1.2 Chemical and Physical requirements

The material, sampled from any part of the consignment in accordance with the procedure described in Appendix A or any other acceptable procedure, shall comply with the requirements of section 1.1 and with the following requirements.

1.2.1 Active ingredients (ISO common names)

The contents of the active ingredients (ISO common names) shall be declared (g/kg) and, when determined, the content obtained shall not differ from that declared by more than $\pm 15\%$, for active ingredient concentration up to 25 g/kg, and $\pm 10\%$ for active ingredient concentration above 25 g/kg.

Collaboratively tested CIPAC, AOAC or other methods of analysis shall be described. If the methods have not been collaboratively tested, then a copy of the full method of analysis intended for use with the specification shall be supplied. In this case, the method shall include a statement of application and validation.

1.2.2 Average weight of the coil

The average weight of the coil shall be declared (in g) and when determined on 20 single coils, the average weight shall not differ from that declared by more than $\pm 1\%$ (Typical average weight per coil is 12 g).

1.2.3 Burning time

The burning time of each of five single coils which must burn continuously in a draught-free atmosphere shall be declared. (A typical burning time should be 7.5 hours in order to ensure that the coil burns for a length of time approximately equivalent to the normal duration of sleep. However, in special circumstances to be stated on the label, the burning time may be increased or reduced accordingly).

1.2.4 Water Content

Maximum water content (g/kg) when tested in accordance with the method WHO/M/8.R1¹ or any other acceptable method shall be declared. (Normally, the water content should not exceed 120g/kg).

1.2.5 Strength of coil

Every coil of 20 single coils tested in accordance with the method described in Appendix B or any other acceptable method shall be able to withstand a minimum load of 120 g.

1.2.6 Separation of 'twin' coils

The mosquito coil, if in 'twin' form, shall be properly made so as to facilitate easy separation. When 50 twin coils are separated by the method described in Appendix C. The number of twin coils that break on separation shall not be more than 3.

1.2.7 Storage stability

After storage at $54 \pm 2^{\circ}\text{C}$ for 14 days, unless another temperature and/or time are specified, the product shall continue to comply with 1.2.1, 1.2.2, 1.2.3, 1.2.5 and 1.2.6.

2. Packaging and labelling

2.1 Packaging

Mosquito coils shall be packed in a container where the package offers sufficient protection from breakage and contamination of the coils. Each unit container shall contain at least one mosquito coil stand/holder. A typical unit container contains 5 double coils.

¹ Specifications for Pesticides used in public health, 7th edition, WHO/Geneva, WHO/CTD/WHOPES/97.1.

2.2 Mosquito coil stand/holder

The mosquito coil stand/holder must be made of suitable non-flammable materials which can hold the burning coil.

2.3 Labelling

All packages shall be, durably and legibly, marked with at least the following:

- Trade Name;
- Name, Address, Phone # of responsible party in the country in which the product is sold (Manufacturers, retailers, and/or registrants);
- Mosquito Coil to specification WHO/SIF/ ... ;
- Active ingredient(s) name and content to specification WHO/SIT/.. ;
- Synergist(s) name and content;
- Net weight of contents;
- Batch or reference number;
- Date of manufacture and shelf life (... years);
- Appropriate safety statement(s) including WHO hazard classification;
- Instructions for use (includes disposal statements);
- Use only as instructed;
- First Aid Requirements;
- Average burning time; and
- Number of coils.

Appendix A

Sampling

A1. General requirements

- A1.1 Samples shall be stored in such a manner that there is no deterioration of the material.
- A1.2 The sampling instrument shall be clean and dry.
- A1.3 Samples shall be protected against adventitious contamination.

A2. Sampling, testing and acceptance

- A2.1 In any consignment, all the master cartons containing containers of the same type shall constitute a lot.
- A2.2 Samples shall be drawn from each lot and individually tested to ascertain whether the material complies with the specified requirements.
- A2.3 Any sample failing to comply with the specified requirements shall be termed as defective. The acceptance number shall be the maximum number of defective samples permissible for a lot to be accepted.
- A2.4 The number of containers to be drawn from the lot and the acceptance number shall be as shown in the following Table.
- A2.5 Each of the containers to be tested shall be drawn from a different master carton which shall be selected at random. In order to ensure randomness of selection, random number tables shall be used. If such tables are not available, the following procedure may be adopted:

Starting from any master carton, count the master cartons as 1, 2, 3..... r in a systematic manner. Every rth carton shall be drawn, r being the integral part of N/n , where N is the total number of master cartons in the lot and n the number of master cartons to be selected.

Table
Scale of sampling

Total number of containers in lot	Number of containers to be tested	Acceptance number
300 or less	3	0
301 - 1 200	6	1
1 201 - 2 000	13	2
2 001 - 7 000	21	3
7 001 - 15 000	29	4
15 001 - 24 000	48	6
24 001 - 41 000	84	9
over 41 000	126	13

A3. Preparation of test samples

A sufficient quantity of samples is selected by taking at random a twin-form coil from each individual box of the reduced sample. From the total number of selected coils, sufficient coil samples are reserved for examination for compliance with the requirements of physical characteristics in 1.2.2, 1.2.3, and 1.2.5.

The remainder of the coils are ground in a hammer-mill to pass a 1-mm mesh-screen and reserved for test for compliance with 1.2.1 and 1.2.4. These groups of samples constitute the test samples. Each set of test samples shall be packed and marked according to the general precautions outlined in clause A1.

Appendix B

Method for determination of the breaking load/tensile strength of mosquito coil (Figures 1 and 2)

B1 Apparatus

- a) Plastic device
- b) Scale register of range of 0 to 500 ± 5 g accurately calibrated.

B2 Sampling

Select 20 boxes of mosquito coils randomly, pick one single coil from each box. Discard single coils that are broken or cracked due to careless separation in the selection process. Subject all the 20 single coils of the breaking load test.

B3 Procedure

A piece of mosquito coil is placed within the plastic device supported by opposite grooves so that on one side the groove only supports 2 cm of the coil from the tip. The coil and plastic device is then placed on the flat platform of the 500 g scale register. The pointed end of the screw is lowered and adjusted to fit into the head/eye of the coil. The screw is then turned gently and gradually in a clockwise direction depressing the mosquito coil downwards until it breaks. The register on the scale is recorded at the breaking point. The minimum specification for the standard coil is 120 g. Repeat the above procedure for the remaining 19 single coils.

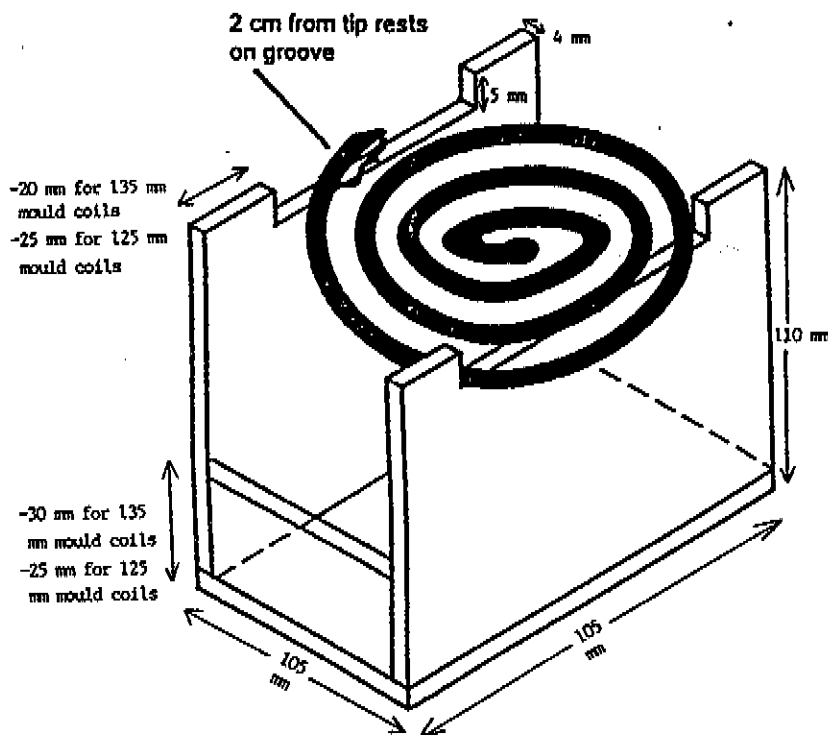


Figure 1. A single mosquito coil supported by plastic device in position

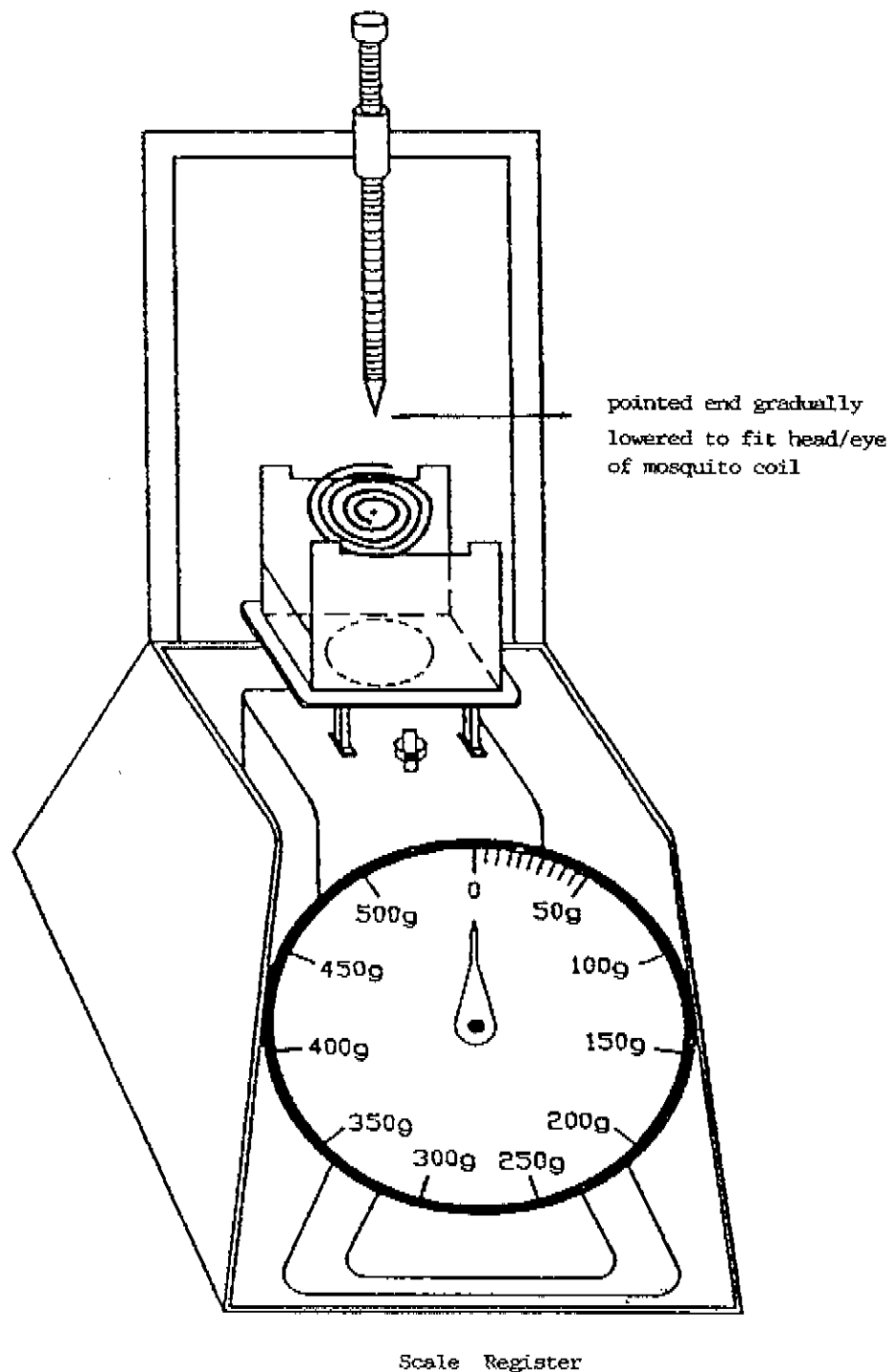


Figure 2. Method for determination of the breaking load/tensile strength of mosquito coil

Appendix C

Method for separation of twin mosquito coils

C1. Procedure

C1.1 Hold both heads/eyes of the double coils with thumbs and forefingers.

C1.2 Gently push the heads or eyes in the opposite direction and pull them apart to displace into single coils. Gentle twisting could be done if necessary.

C2. Results

Separation of twin coils is considered achieved if no breakage occurs.

Annex 3

Guideline specifications for vaporising mats

1. Specification

1.1 Description

The vaporising mat shall consist of a pulp-made mat or a mat made of other suitable inert materials impregnated with an insecticide. Stabilisers, synergists, slow-release agents, perfumes and colouring agents may be added. The technical material (ISO name) used in the manufacture of the mat shall comply with the requirements of specification WHO/SIT/...

1.2 Chemical and Physical requirements

The material, sampled from any part of the consignment in accordance with the procedure described in Appendix A or any other acceptable procedure, shall comply with the requirements of section 1.1 and with the following requirements.

1.2.1 Active ingredients (ISO common names)

The contents of the active ingredient (ISO common names) shall be declared (mg/mat) and when determined, the content obtained, shall not differ from that declared by more than $\pm 10\%$.

Collaboratively tested CIPAC, AOAC or other methods of analysis shall be described.

If the methods have not been collaboratively tested, then a copy of the full method of analysis intended for use with the specification shall be supplied. In this case, the method should include a statement of application and validation.

1.2.2 Size of mat

The size of the mat should be compatible with the associated heater for easy insertion or removal of mat (Typical size of mat is 35 mm by 22 mm, 2.6 mm thick).

1.2.3 Evaporation rate

An indication of the suitable evaporation rate may be determined by the active ingredient analysis of the mat after four hours. Then heating the mat on the appropriate heater, a minimum of 20 percent of the initial claimed action ingredient content should remain.

1.2.4 Storage stability

After storage at $54 \pm 2^{\circ}\text{C}$ for 14 days, unless another temperature and/or time are specified, the product shall continue to comply with 1.2.1, 1.2.2., and 1.2.3.

1.2.5 Heater

The heating unit should comply with any relevant national safety standards.

2. Packaging and labelling

2.1 Packaging

Vaporiser mats shall be packed in suitable materials which are impermeable to air and light. At the same time, the outer package shall offer sufficient protection from breakage and contamination of the mats.

2.2 Labelling

All boxes containing the mats shall bear, durably and legibly marked, at least the following:

- Trade Name;
- Name, Address, Phone # of responsible party in the country in which the product is sold (Manufacturers, retailers, and/or registrants);
- Vaporiser mat to specification WHO/SIF/ ... ;
- Active ingredient(s) name and content to specification WHO/SIT/... ;
- Synergist(s) name and content;
- Net weight of contents;
- Batch or reference number;
- Date of manufacture and shelf life (... years);
- Appropriate safety statement(s) including WHO hazard classification;
- Instructions for use (includes disposal statements);
- Use only as instructed;
- First Aid Requirements;
- Use appropriate heating apparatus and voltage; and
- Duration of Action.

Appendix A

Sampling

A1. General requirements

- A1.1 Samples shall be stored in such a manner that there is no deterioration of the material.
- A1.2 The sampling instrument shall be clean and dry.
- A1.3 Samples shall be protected against adventitious contamination.

A2. Sampling, testing and acceptance

- A2.1 In any consignment, all the master cartons containing containers of the same type shall constitute a lot.
- A2.2 Samples shall be drawn from each lot and individually tested to ascertain whether the material complies with the specified requirements.
- A2.3 Any sample failing to comply with the specified requirements shall be termed as defective. The acceptance number shall be the maximum number of defective samples permissible for a lot to be accepted.
- A2.4 The number of containers to be drawn from the lot and the acceptance number shall be as shown in the following Table.
- A2.5 Each of the containers to be tested shall be drawn from a different master carton which shall be selected at random. In order to ensure randomness of selection, random number tables shall be used. If such tables are not available, the following procedure may be adopted:

Starting from any master carton, count the master cartons as 1, 2, 3..... r in a systematic manner. Every rth carton shall be drawn, r being the integral part of N/n , where N is the total number of master cartons in the lot and n the number of master cartons to be selected.

Table
Scale of sampling

Total number of containers in lot	Number of containers to be tested	Acceptance number
300 or less	3	0
301 - 1 200	6	1
1 201 - 2 000	13	2
2 001 - 7 000	21	3
7 001 - 15 000	29	4
15 001 - 24 000	48	6
24 001 - 41 000	84	9
over 41 000	126	13

Annex 4

Guideline specifications for liquid vaporiser (liquid emitter device, LED)

1. Specification

1.1 Description

The product shall consist of a liquid insecticidal formulation in a cartridge/bottle and the formulation shall be effective as it passes up the heated wick and evaporates at a suitable rate cover the period claimed by the manufacturer (Figure 1). The product should be designed in such a way so as to minimise the risk of accidental ingestion of the contents. The technical material (ISO common name) used in the manufacture of the liquid vaporiser shall comply with the requirements of specification WHO/SIT/...

1.2 Chemical and physical requirements

The material, sampled from any part of the consignment, in accordance with the procedure described in Appendix A, shall comply with requirements of section 1.1 and with the following requirements:

1.2.1 Active Ingredients (ISO common names)

The contents of the active ingredient (ISO common name) shall be declared and when determined, the content obtained shall not differ from that declared by more than $\pm 10\%$.

1.2.2. Cartridge/bottle

The cartridge/bottle shall be as follows:

- It shall be made of a suitable heat resistant material.
- It shall be of a suitable shape and size to fit the heater unit for which it was designed.
- It shall hold a suitable quantity of liquid to enable the product to function for a minimum of the period claimed by the manufacturer (Appendix B).
- It shall hold the wick firmly with a stopper preventing spillage should the bottle be inverted with the covering cap.

1.2.3. Wick

- It shall be made of a suitable porous heat resistant material.
- It shall draw up sufficient insecticide formulation, when heated at one end, for vaporisation to provide a suitable level of protection against mosquitoes.
- Its material and design shall be such that it can vaporise the total content of the insecticide formulation in the bottle/cartridge to which it is attached.
- It shall also be such that the insecticide formulation vaporises from its heated end at a constant or close to constant rate to enable continuous emission throughout the claimed effective period of the product.

1.2.4 Heater

The heating unit should comply with any relevant national safety standards.

1.2.5 Minimum Effective Period

The minimum effective period shall be declared. (Appendix B)

2. Packaging and labelling

2.1 Packaging

The bottle/cartridge should be packed in such a manner so as to prevent leakage.

2.2 Labelling

All liquid vaporisers shall bear, durably and legibly marked at least the following:

- Trade Name;
- Name, Address, Phone # of responsible party in the country in which the product is sold (Manufacturers, retailers, and/or registrants);
- Liquid vaporiser to specification WHO/SIF/ ... ;
- Active ingredient(s) name and content to specification WHO/SIT/... ;
- Synergist(s) name and content;
- Net weight of contents;
- Batch or reference number;
- Date of manufacture and shelf life (... years);
- Appropriate safety statement(s) including WHO hazard classification;
- Instructions for use (includes disposal statements);
- Use only as instructed;
- First Aid Requirements;
- Use appropriate heating apparatus and voltage; and
- Minimum effective period.

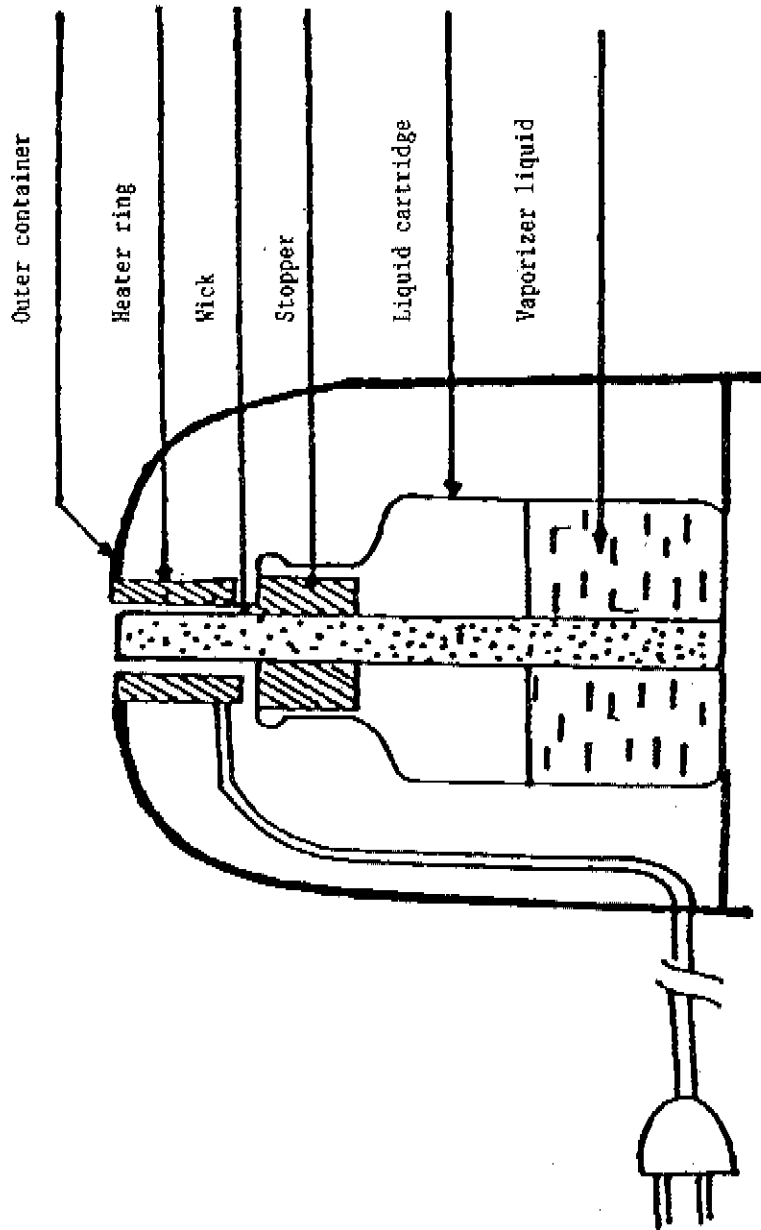


Figure 1. Diagram of the structure of mosquito electric liquid vaporizer
(refill bottle and its heating device)

Appendix A

Sampling

A1. General requirements

- A1.1 Samples shall be stored in such a manner that there is no deterioration of the material.
- A1.2 The sampling instrument shall be clean and dry.
- A1.3 Samples shall be protected against adventitious contamination.

A2. Sampling testing and acceptance

- A2.1 In any consignment, all the master-cartons containing electric liquid vaporiser refill bottles of the same type, shall constitute a lot.
- A2.2 Samples shall be drawn from each lot and individually tested to ascertain whether the material complies with the specified requirements.
- A2.3 Any samples failing to comply with the specified requirements shall be termed as defective. The acceptance number shall be the maximum number of defective permissible for a lot to be accepted.
- A2.4 The number of refill bottles to be drawn from the lot and the acceptance number shall be as shown in the Table.

Table
Scale of sampling

Total number of containers in lot	Number of containers to be tested	Acceptance number
300 or less	3	0
301 - 1 200	6	1
1 201 - 2 000	13	2
2 001 - 7 000	21	3
7 001 - 15 000	29	4
15 001 - 24 000	48	6
24 001 - 41 000	84	9
over 41 000	126	13

- A2.5 Each of the refill bottles to be tested shall be drawn from a different master-carton which shall be selected at random. In order to ensure randomness of selection, random number tables shall be used. If such tables are not available, the following procedure may be adopted: Starting from any master-carton, count the master-cartons as 1,2,3,.....r in a systematic manner. Every rth. carton shall be drawn, r being the integral part of N/n , where N is the total number of master-cartons in the lot and n the number of master-cartons to be selected.

Appendix B

Determination of minimum effective period of a refill bottle of a liquid vaporiser

B1 General requirements

A refill bottle of a liquid vaporiser shall provide continuous protection against mosquito throughout the claimed effective period.

B2 Procedure

B2.1 The minimum effective period shall be determined under the following conditions:

- | | |
|------------------------|---|
| i. Room size: | Approximately 30 m ³ |
| ii. Ventilation: | Normal ventilation as in common households without air conditioner. |
| iii. Temperature: | 30± 3°C |
| iv. Relative humidity: | 80± 10% |

B2.2 The heating unit of the liquid vaporiser shall be switched on for 8 to 10 hours per day (24 hours) until all the insecticide formulation from the refill bottle is discharged or the minimum emission of 300 hours is attained.

B2.3 The weight of the refill bottle shall be determined by using an analytical electric balance (accuracy 0.001 g) at the following check points:

- i. Before the initiation of the heating mode to measure the total weight with or without insecticide formulation.
- ii. At the end of heating regime to determine the total consumption of the insecticide formulation.

Annex 5

Guideline specifications for household insecticidal aerosols (space and residual sprays)

1. Specification

1.1 Description

The product shall consist of a liquid insecticidal formulation in a pressurised, non-refillable aerosol dispenser. When released into the air in the form of an aerosol, it should be effective as claimed. The technical (ISO common name(s)) used in the manufacture of the formulation shall comply with the requirements of specification(s) WHO/SIT/...

1.2 Chemical and physical requirements

The product, sampled from any part of the consignment, in accordance with the procedure described in Appendix A or any other acceptable procedure, shall comply with requirements of section 1.1 and with the following requirements.

1.2.1 Ingredients

1.2.1.1 Solvent

The formulation shall not include any solvent listed in Appendix B. The solvent used should ensure complete solubility of the active ingredient(s).

1.2.1.2 Active ingredient(s) and synergist(s) (ISO common names)

The content of the active ingredient(s) and synergists (ISO common name(s)) shall be declared (g/kg) and, when determined, the content obtained shall not differ from the permissible tolerance, as follows:

Declared content (g/kg)	Tolerance permitted
up to 25	± 15% of the declared content
above 25 up to 100	± 10% of the declared content
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
above 500	± 25 g/kg

Collaboratively tested CIPAC, AOAC or other methods of analysis shall be described. If the methods have not been collaboratively tested, then a copy of the full method of analysis intended for use with the specification shall be supplied. In this case, the method should include a statement of application and validation.

1.2.1.3 Net content

The net content of the formulation shall be declared in g.

1.2.2 Internal pressure

The internal pressure of the filled dispenser, determined in accordance with the method described in Appendix C or any other acceptable method, shall not exceed ... kPa at $54 \pm 2^{\circ}\text{C}$.

1.2.3 Discharge rate

Determined in accordance with the method described in Appendix D or any other acceptable method, the discharge rate of the filled dispenser shall be g/second.

1.2.4 Flammability

The filled dispenser shall be tested in accordance with the method described in Appendix E and labelled accordingly:

- (i) "non-flammable", if the spray does not ignite,
- (ii) "flammable", if the flame projection is 250-450 mm, and
- (iii) "highly flammable", if the flame projection exceeds 450 mm.

1.2.5 Ignition Distance

The ignition distance shall be determined and declared in...cm (Appendix F)

1.2.6 pH range (applicable to water-based formulations only)

The pH range shall be declared and determined by any acceptable method.

1.2.7 Clogging of aerosol dispenser valves

No clogging shall occur when aerosol dispenser valves are tested in accordance with the procedure as described in Appendix G or any other acceptable method.

1.2.8 Storage stability

1.2.8.1 Pressure loss

Test of long term preservation and measurement of the loss of weight of aerosol containers. (Appendix H)

1.2.8.2 Corrosivity

Under normal storage conditions, the aerosol container should be able to hold the contents for two years.

2. Packaging and labelling

2.1 Packaging

The ingredients shall be packed in a clean and leak-proof container and sealed with a suitably protected aerosol valve. If the container is metallic, it may be suitably lacquered for internal protection. The maximum fill shall not be more than 90% of the volume of the container.

2.2 Labelling

All containers shall be, durably and legibly, marked with at least the following:

- Trade Name;
- Name, Address, Phone # of responsible party in the country in which the product is sold (Manufacturers, retailers, and/or registrants;)
- Type of Product to specification WHO/SIF/ ... ;
- Active ingredient(s) name and content to specification WHO/SIT/... ;
- Synergist(s) name and content;
- Net weight of contents;
- Batch or reference number;
- Date of manufacture and shelf life (.... years);
- Flammability;
- Appropriate safety statement(s) (including WHO hazard classification);
- Instructions for use (includes disposal statements);
- Use only as instructed;
- First Aid Requirements;
- Shake well before use, for water-based aerosols only; and
- Pictogram to indicate that the product is used either as a space spray or a residual spray against specific target insects.

Appendix A

Sampling

A1. General requirements

- A1.1 Samples shall be stored in such a manner that there is no deterioration of the material.
- A1.2 The sampling instrument shall be clean and dry.
- A1.3 Samples shall be protected against adventitious contamination.

A2. Sampling, testing and acceptance

- A2.1 In any consignment, all the master cartons containing containers of the same type shall constitute a lot.
- A2.2 Samples shall be drawn from each lot and individually tested to ascertain whether the material complies with the specified requirements.
- A2.3 Any sample failing to comply with the specified requirements shall be termed as defective. The acceptance number shall be the maximum number of defective samples permissible for a lot to be accepted.
- A2.4 The number of containers to be drawn from the lot and the acceptance number shall be as shown in the following Table.
- A2.5 Each of the containers to be tested shall be drawn from a different master carton which shall be selected at random. In order to ensure randomness of selection, random number tables shall be used. If such tables are not available, the following procedure may be adopted:

Starting from any master carton, count the master cartons as 1, 2, 3..... r in a systematic manner. Every rth carton shall be drawn, r being the integral part of N/n , where N is the total number of master cartons in the lot and n the number of master cartons to be selected.

Table
Scale of sampling

Total number of containers in lot	Number of containers to be tested	Acceptance number
300 or less	3	0
301 - 1 200	6	1
1 201 - 2 000	13	2
2 001 - 7 000	21	3
7 001 - 15 000	29	4
15 001 - 24 000	48	6
24 001 - 41 000	84	9
over 41 000	126	13

Appendix B

Solvents not permitted for use in aerosols

2-ethoxyethanol (ethylene glycol monoethyl ether)
2-ethoxyethylacetate (ethylene glycol monoethyl ether acetate)
2-methoxyethanol (ethylene glycol monomethyl ether)
2-methoxyethylacetate (ethylene glycol monomethyl ether acetate)
2-butoxyethanol (ethylene glycol monobutyl ether)
2-butoxyethylacetate (ethylene glycol monobutyl ether acetate)
chloroform
carbon tetrachloride
1,2-dichloroethane (ethylene dichloride)
benzene
chlorobenzene
n-hexane
2-hexanone (methyl n-butyl ketone)
trichloroethylene
tetrachloroethylene

Propellants

The Montreal Protocol and EU¹ directive on the withdrawal of chlorofluorocarbons (CFCs) from aerosols were noted. Hydrocarbon propellants are recommended for insecticide aerosols, provided international safety standards are met by the aerosol producer. Industry should be encouraged to develop alternative and safer propellants and delivery systems.

¹ European Union

Appendix C

Determination of pressure in finished aerosol packs¹

C1. Introduction

The determination of the pressure existing in the finished aerosol packs is necessary to verify that the true pressure is compatible with the pressure limitations of the pack, and in accordance with the regulations in force.

True pressure is the relative pressure given by a manometer of precision at a given temperature.

C2. Objective

The objective of this standard is to describe the method and apparatus used for the determination of the true pressure in the finished aerosol pack:

1. in such a way that the measure affects as little as possible the value of the real pressure.
2. in such a way that the manometer will not be polluted by the product under pressure present in the pack.

C3. Scope

This method is recommended for the determination of the true pressure of all the filled aerosol packs.

C4. Apparatus

The following appliances are used:

1. A source of reference gas (nitrogen for instance) where the pressure can be regulated by means of a control valve.
2. A manometer of high precision, if possible cushioned by an oilbath and adapted in an adequate way to fit the aerosol container on which the measurement will be effected.

The apparatus must be assembled in such a way so that, in the state of rest, the manometer is connected to the reference gas (the pressure of this gas being slightly higher than the actual pressure in the pack) and, for taking the measurement, the manometer is connected to the interior of the pack to show the actual pressure.

¹ European Aerosol Federation (49 Square Marie-Louise, 1000 Brussels, Belgium)

C5. Working operation

1. To make sure that the finished pack to control is in equilibrium with the temperature chosen for the measure.
2. The measuring apparatus must be fitted with an appropriate adaptor for the valve employed.
3. The pressure of the reference gas must be regulated to a value slightly higher than the anticipated pressure.
4. Apply the measuring apparatus to the valve and press lightly in order to open the valve and the slide of the apparatus.
5. Read on the manometer the true pressure when the needle has stabilized.

C6. Precision of the Measure

The measurement of the true pressure will be the more precise:

1. as the aerosol pack increased the size.
2. as the excess pressure of the reference gas diminishes with respect to the true pressure; if necessary, when there are several finished packs available, additional measurements can be made after adjusting the reference gas pressure to a value very close to the true pressure.
3. as the dead volume of the manometer of precision decreases (lower than 2 ml)

C7. Test Report

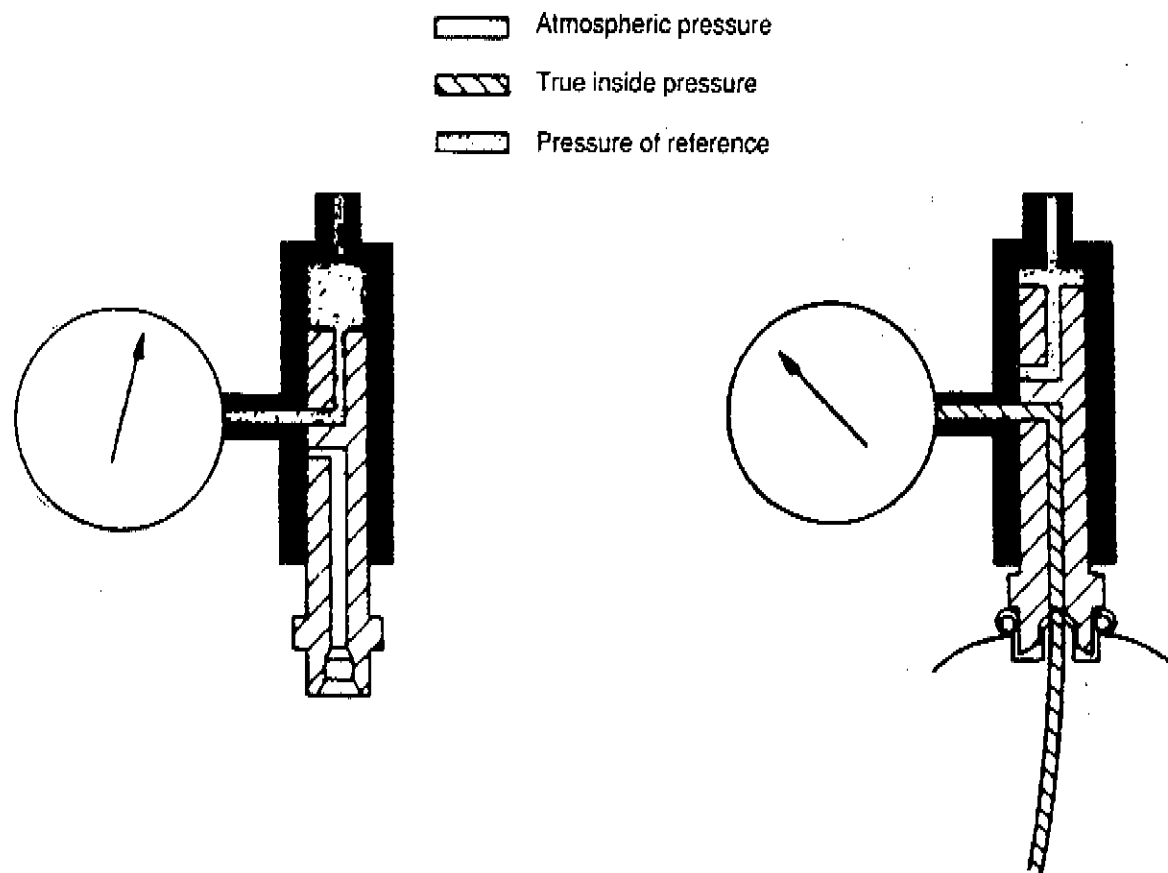
The test report must indicate, in addition to the results and the test conditions, the working details not provided for in this standard including any incidents suspected of having influenced the results.

Note

- It is necessary to calibrate frequently the manometer, for example with the aid of a manometric balance.
- A non-return valve can eventually be placed in the apparatus to avoid the rising of the aerosol product in the apparatus in case that the pressure of the reference gas being lower than the true pressure in the pack.
- For the uniform control of packs on the production line it is possible to eliminate mechanically the over pressurised packs by an appropriate electro-manometric appliance.
- The uniform control of the packs on the production line can be combined with an operation of automatic purge of the dip tubes with the gas of reference. For this, it is sufficient to increase the overpressure of the reference gas or to enlarge the dead volume of the manometer.

Example

Diagram showing principle of the apparatus presented by the Society L' AIR LIQUIDE.



Determination of pressure in finished aerosol packs

Appendix D

Evaluation of discharge rate of filled aerosol packs¹

D1. Scope

This method is applicable to the majority of aerosols marketed at the present time. It may be used with discretion for packs fitted with vapour phase taps where there will be a continually changing composition as the contents are discharged. It is not suitable for use in the inverted position for packs with vapour phase taps as there will be an erratic discharge dependant upon the liquid content of the dip tube. It is important that discharge tests shall follow the instructions for use appearing on the can. Where cans are intended to be used in an inverted position, it is vital that the test shall be done in that way. The method is not intended for use with metering valves.

D2. Principle

The discharge rate of an aerosol dispenser is determined by measuring the quantity of material expelled through the valve in the given time. The exact duration of discharge, normally 10 seconds, and the temperature of the dispenser must be carefully controlled for good reproducibility. Normally the test is repeated three times to give three determinations but in the case of products filled with vapour phase tap valves it is preferable to reduce the time interval to 5 seconds and the number of determinations to two. This change is to minimise the variation in composition that will occur as the contents are sprayed off. Obviously, there must be some loss of accuracy using the shorter duration.

An alternative procedure is also given whereby the discharge rate is determined at different stages in the life of the can (e.g. 90%, 70%, 50%, 30% and 10% fill) which then allows the value to be plotted graphically. Where the composition is changing with the emptying of the packs, this offers a particularly convenient way of showing the effect of this change. In the case of storage test samples, a single test is normally performed at each examination to conserve the contents.

D3. Apparatus

A water bath held at $25^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$, a stop watch accurate to 0.2 second, a balance weighing to 0.1 g. and a pressure gauge accurate to 2 p.s.i.g. are required.

D4. Procedure

- a) Aerosol samples shall be randomly selected from production after hot water testing or from carefully prepared experimental batches. In the case of the latter, filling of each component should be better than $\pm 1/2\%$ of the specification. They may be single samples.

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- b) Defective samples such as packs failing hot water bath testing or packs having incorrectly aligned or blocked valves shall be rejected.
- c) The valve of the aerosols shall be handled according to label instructions and the valve shall be operated for five seconds to remove material in the dip tube which may not be homogenous with the bulk of the filling.
- d) The aerosols shall be immersed in a water bath maintaining at $25^{\circ} \text{C} \pm 0.5^{\circ} \text{C}$ for half an hour or for sufficiently long for the contents to attain the temperature of the water bath.
- e) The aerosol shall be removed from the water bath wiped completely dry, the valve operated for one second to remove any water in the valve, the internal pressures of the packs shall be measured and then the packs shall be weighed to within 0.1g.
- f) The aerosols shall then be shaken for 3 seconds by hand or other suitable means and the valve shall be fully operated for ten seconds timed by the stop watch. During the discharge, the aerosols shall be positioned as indicated in the instructions for use.
- g) The aerosols shall be wiped clean of any liquid and reweighed to within 0.1 g.

Procedures (d) to (f) shall be repeated twice or more and the internal pressure of the packs shall be measured again.

D5. Calculation

The difference in weights derived from procedure (g) and procedure (e) shall be divided by 10 (seconds). Results should not differ by more than 0.1 g from the mean of the three results. If a greater difference is found at least two more readings should be taken.

D6. Reporting

Report valve discharge rates as grams per second at the mean pressure of the pack obtained. The method eg. 3 x 10 secs., 2 x 5 secs. or 1 x 5 secs. (90%....50%....10%) spray etc. shall be quoted together with references to the formula code, container specification, full valve specification, and initial level of fill.

Notes

Where discharge rates are to be determined at various stages of pack life it is advisable to allow the pack to reach equilibrium at 25°C in the water bath, shake and spray for 5 seconds, reshake vigorously and respray of another 5 seconds and replace in water bath. This procedure may then be repeated until the correct pack content is reached. This rather tedious procedure avoids errors arising from the fall in temperature of the contents of the pack during prolonged spraying.

Results may show variations from sample to sample that are greater than might be expected from normal manufacturing tolerances. This may be due to the additional variable of orifice diameter.

The discharge rate of freshly prepared aerosols will not normally be the same as for samples allowed to mature due to the effect of solvents on the gasket.

Appendix E

Determination of the flammability of the spray-jet on discharging a filled aerosol can¹

E1. Introduction

This method is designed to evaluate the risk caused by the possible flammability of an aerosol formulation.

E2. Aim

This standard concerns the flammability of the gaseous and /or liquid mixtures contained in a filled aerosol can when the latter are "projected" onto the flame. The range of the spray (or the jet) shall be at least equal to 15 cm.

E3. Method

Since the actuator of the aerosol can is operated opposite a burner, the test permits measurement of the length of the flame which forms when the spray jet is projected onto the flame of the burner.

E4. Apparatus

- Graduated rule, 1 m long (graduations in centimetres)
- 2 stands adjustable in height
- 1 gas burner (for example, bunsen burner)
- 1 gas generator (propane, butane)
- 1 chronometer (graduation in seconds)

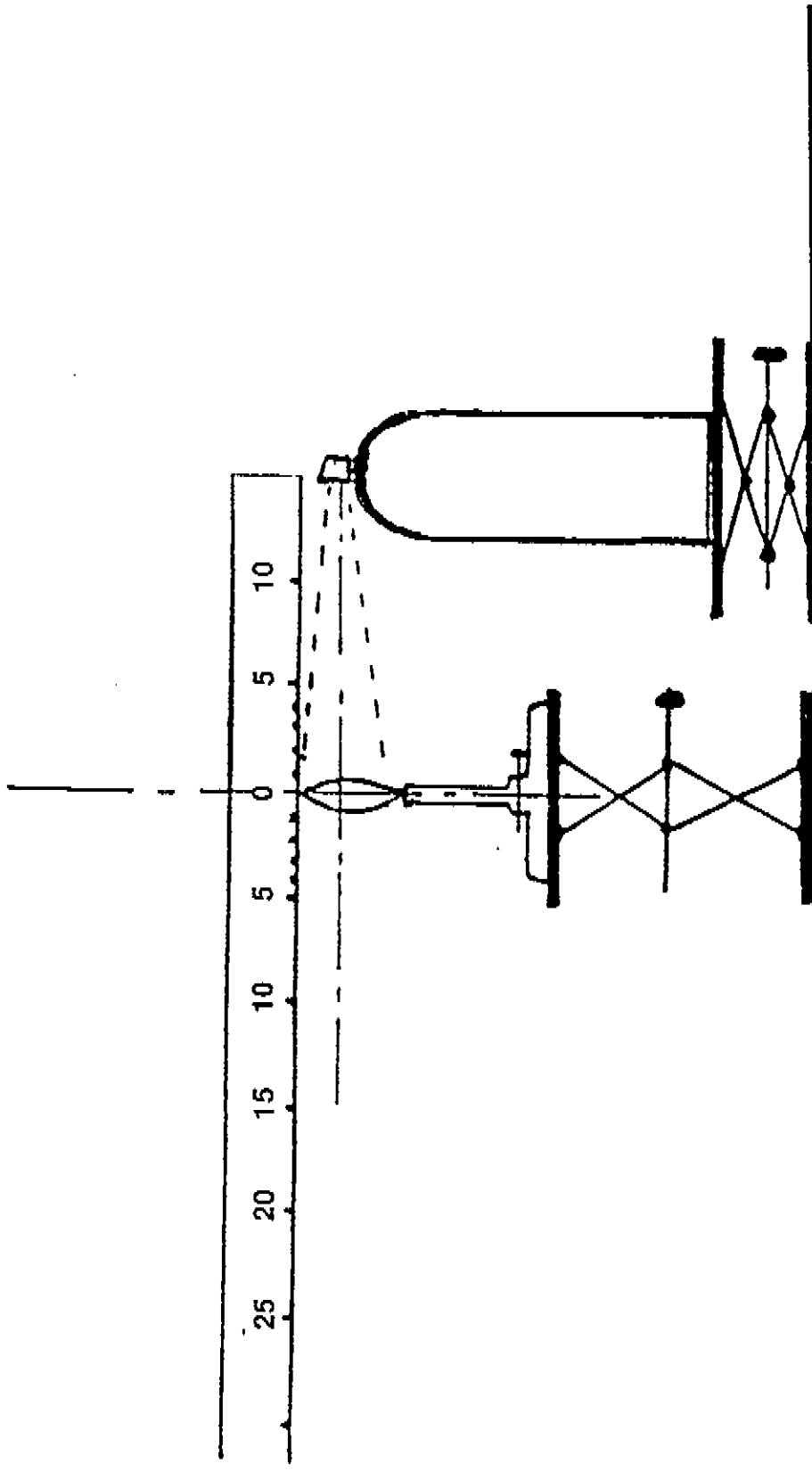
E5. Operating conditions

- The graduated rule shall be perfectly legible and placed behind the can and the gas burner
- The non-luminous flame of the gas burner shall have a height of 5 cm.
- The upper extremity of the flame shall be situated at the lower level of the reference graduation.
- The aerosol can shall be placed so that the distance between its actuator and the axis of the gas burner is 15 cm. The height of the actuator shall be level with the median horizontal line of the flame.
- The axis of the product dispensed and the axis of the flame shall intersect at 90°.

E6. Mode of operation

The test shall be conducted in an adequately ventilated and draught-free area. the temperature of the area shall lie between 18 and 25° C and it will be necessary to note the relative humidity at the moment of the test.

¹ European Aerosol Federation (49 Square Marie-Louise, 1000 Brussels, Belgium)



Determination of the flammability of the spray-jet
on discharging a filled aerosol can

Appendix F

Determination of the ignition distance of the spray jet ¹

F1. Objective

This Test Standard describes the method to determine the ignition distance of an aerosol spray, and spray or jet intended to foam on contact with a surface, in order to assess the flame risk associated with its use by the consumer.

F2. Principle

An aerosol is sprayed in the direction of a flame at intervals of 15 cm distance, to observe ignition and sustained combustion of the spray.

Ignition is defined as a stable flame maintained for at least 5 seconds.

F3. Scope

This test is applicable to aerosol products with a spray distance of 10 cm or more. Aerosol cans dispensing foams, mousses and gels or fitted with a metering valve are excluded from this test.

F4. General Requirements

Before conditioning, prime each aerosol dispenser by discharging for approximately 1 second. The purpose of this action is to remove non-homogeneous material from the diptube.

A minimum of 3 samples per product shall be conditioned to $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$ before each test, for at least 30 minutes. The cans should be fully immersed in a waterbath, or if not possible for at least 95%.

The tests must be carried out in a draught-free environment capable of ventilation, with the temperature controlled at $20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ and relative humidity in the range 30 - 80%.

Liquid phase products

Follow strictly the instructions of use, in particular when shaking is required. Shake Immediately before spraying.

Each aerosol dispenser is to be tested:

- when completely full
- when 10% full (by weight)

Each product will also be required to be tested on discharge rate and fill pressure according to the test methods of Appendices C and D, respectively.

¹ European Aerosol Federation (49 Square Marie-Louise, 1000 Brussels, Belgium)

F5 Equipment and apparatus

- a water-bath with a temperature setting of $20^{\circ} \pm 1^{\circ}\text{C}$
- a laboratory balance for weighing the aerosol can (accuracy ± 0.1 g)
- a stopwatch
- a graduated scale (graduations in cm), support and clamp
- a gas burner with support and clamp
- a thermometer
- a hygrometer

F6 Test procedure

- I. Comply with the General Requirements. Record the temperature and relative humidity close to the test set-up.
- II. Determine the empty (tare) weight of the aerosol product.
- III. Weigh an aerosol dispenser and note its weight.
- IV. Calculate the mass of contents of the aerosol dispenser.
- V. Determine the fill pressure according to the Test Methods of Appendix C at $20^{\circ} \pm 1^{\circ}\text{C}$.
- VI. Support the gas burner on a flat horizontal surface or fix the burner to a support by means of a clamp.
- VII. Ignite the burner; the flame shall be non-luminous and approximately 5 cm high.
- VIII. Place the actuator's exit orifice at 90 cm from the flame
- IX. Level the actuator's orifice and burner flame, ensuring that the orifice is properly directed towards and aligned with the flame (Figure 1). The spray shall be expelled through the middle of the flame.
- X. Actuate the valve of the aerosol dispenser, to discharge its contents for 5 to 10 seconds. If the criteria of ignition is met (see *PRINCIPLE*), the discharge may be discontinued before 10 seconds have elapsed.
- XI. If ignition occurred:
 - A. note the distance between the gas burner and the aerosol dispenser, this is the ignition distance of a full aerosol can
 - B. weigh the aerosol can and calculate the actual fill level
 - C. repeat step 11.1 and 11.2 for another two times for the same can at the distance between gas-burner and aerosol actuator
 - D. discharge the aerosol can to a 10% fill level (by weight) in bursts of 30 seconds maximum, re-conditioning to approximately 20°C between bursts for approximately 30 minutes
 - E. note the weight of the aerosol can at 10% fill level (by weight)
 - F. place the actuator's exit orifice at the last tested distance from the flame, and level with it, ensuring that the orifice is properly directed towards and aligned with the flame (Figure 1). The spray shall be expelled through the middle of the flame.

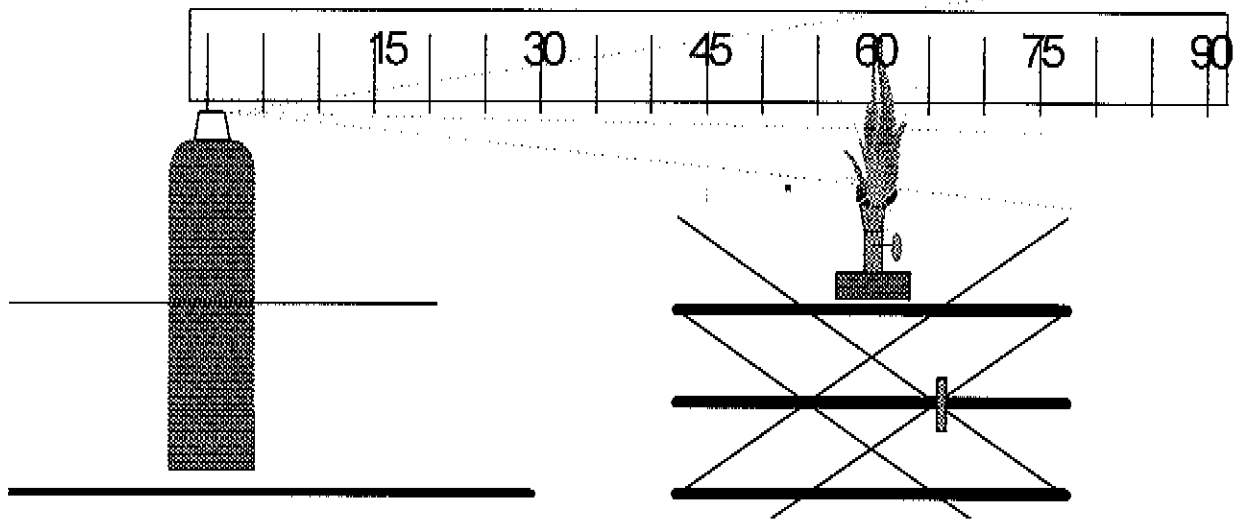


Figure 1 Determination of the ignition distance of the spray jet

Appendix G

Testing of valves of filled insecticidal low-pressurised dispensers for clogging

G1. Apparatus

G1.1 Fume hood

G1.2 Protective clothing and mask

G2. Procedure

Shake the aerosol dispensers thoroughly and, keeping them in an upright position, disperse the contents of each into the fume hood until empty. Examine the valves for clogging.

Appendix H

Test of long-term preservation and measurement of the loss of weight of filled aerosol packs¹

H1. Introduction

The integrity of the seal and the quality of contents during storage of filled aerosol products must be assured by rigorous controls during formulation and manufacture. This can be done by undertaking storage tests to check the effect of time on both formulation and packaging specification. In addition storage tests can be undertaken to monitor the performance of a product in manufacture.

In all cases the problem to be faced is the size of the test; the larger the size, in terms of sample number, conditions of storage and time of storage so the greater will be the accuracy of the results. However, compromise is necessary to meet the limited resources of time and space available. The scale of this test as laid out in the table under the section "Working Operations" is designed to meet most situations but should be regarded as the minimum size. Where the formulation or pack specification is known to be suspect or where the nature of the deterioration is known to be erratic, then it would be prudent to enlarge the size of the test.

H2. Objective

The objective of this method is to determine, on the one hand the loss of weight in storage at different temperatures and during a given time, on the other hand to determine under the same conditions, the stability of the contained product vis-à-vis the components of the aerosol container, valve and its components.

H3. Scope

This method is recommended for the long-term testing of the closure and of the storage of all aerosol products in metal, glass and plastic containers.

H4. Apparatus

1. Laboratory balance with a precision of 0.01 g or 0.05 g according to the need.
2. Gauge for the determination of the pressure as described in Appendix C.
3. Storage space at ambient temperature, at 37° C and at 50° C equipped with controls for the regulation of temperature to within $\pm 3^{\circ}\text{C}$.

H5. Working Operation

Test samples must be identical with the containers and valves envisaged for the proposed production. If several types of containers or valves are to be compared, they must be subjected to the same test, with the same conditions of preparation, and the same temperature and duration of storage.

¹ European Aerosol Federation (49 Square Marie-Louise, 1000 Brussels, Belgium)

All the samples destined to be tested must be prepared in a way as close as possible to the future industrial conditions.

Before the storage, and at least 24 hours after the filling, the following operations must be performed:

- i. All the samples shall be carefully numbered.
- ii. The noted pressure at ambient temperature shall be determined on all the samples according to Appendix C.
- iii. All the samples shall be weighed.

The storage temperature, the minimum storage time and the minimum quantity of samples for every variant of packs must be entered in the table below.

For each batch of samples, one adds to the test, for every storage temperature, two samples for comparison filled in coated aerosol glass bottles and two samples of the product alone filled in sealed bottles.

Number of samples	Storage temperature	Position of storage	Time of storage	Glass aerosols for comparison	Pure product for comparison
12 minimum	ambient t°	half ↑ half ↓	1 year minimum	2	2
12 minimum	ambient t°	half ↑ half ↓	6 mth minimum	2	2
12 minimum	37° C	half ↑ half ↓	4 mths minimum	2	2
12 minimum	50° C	half ↑ half ↓	2 mths minimum	2	2

H6. Test and results

Only the comparison of observation made from all the test at different temperatures defined above and at the end of the fixed minimum times will give maximum efficiency for this test method.

After the fixed duration of storage, it is necessary to proceed in the following way:

- Take the samples out of the storage rooms and store them for 24 hours at ambient temperature.
- Weigh the samples in order to determine the loss of weight during the time of storage.
- Determine the pressures in the samples according to the method in Appendix C, at the temperature noted on the occasion of the first measurement.

- Actuate the valves in order to verify their good functioning. In case of poor functioning, an examination will be made after observing the final result.
- Transfer two samples into coated glass aerosol bottles for visual examination (colour, precipitation, etc.) and compare with the glass aerosol controls.
- Pierce and empty samples to recover the product. Compare the condition of the residual product with control samples of the base.
- Examine the inner walls of the containers and of the mounting cups of the opened samples.
- Examine any valves which did not function correctly in order to determine the cause.

H7. Test report

The test report must indicate:

- The origin, description and the controlled characteristics of the samples.
- The number of samples submitted to the test.
- The test conditions
- The loss of weight ascertained on every sample.
- The original pressure and the final pressure of the samples.
- The changes found in the internal protection of the containers or of the valves, the mechanical resistance, the functioning of the valves.
- The changes found in the product, alone or in presence of the propellant.
- The time elapsed from the filling until the start of the test(*).
- The working details not provided for in this Standard as well as the eventual incidents suspected of having influenced the results.

(*) The time elapsed from the filling until the start of the test has an influence on the loss of weight of the aerosol because of the period of stabilization proper to every type of pack.

Annex 6

Outline for the determination of bio-efficacy of mosquito coils, vaporising mats, liquid vaporisers and aerosols

The basic principle of bio-efficacy tests is to compare the relative efficacy of a formulation versus a standard formulation in a designated and regulated laboratory environment. The performance of the test formulation should be equal or better than a designated standard formulation.

The group agreed that efficacy of coils, vaporising mats and liquid vaporisers shall be compared using knockdown as a criterion on *Aedes aegypti* as the test species. In the case of space spray aerosols, knockdown and kill shall be the criteria and tests shall be carried out on *Aedes aegypti*, housefly and/or other claimed target insects. For flying insect killer aerosols (FIK) knockdown/kill shall be the criteria. In the case of crawling insect killers (CIK) the two types of effects shall be tested: a) residual effect (kill on contact over the defined period of time), b) knockdown and kill following direct spraying. The main test insects shall be the German cockroach (*Blattella germanica*) and the American cockroach (*Periplaneta americana*) and/or other claimed target insects. It was recommended that susceptible local strain of insects, where possible, should be used for the test.

For the standard formulation, insecticides which are commonly used and are easily accessible should be chosen as active ingredients for formulating the products. Appropriate and well-known knockdown and residual/kill agents may be used as active ingredient for the respective products. The list of insecticides and the concentration range for household insecticide products are listed in the WHO publication (WHO/CTD/WHOPES/97.2)¹. The final formulation will be specified and the detailed test will be developed by WHOPES in collaboration with the industry and research institutes.

Coils, vaporising mats and liquid vaporisers

It is understood that mosquito coils, vaporising mats and liquid vaporisers typically work on the target insects at sub-lethal levels (e.g. repellency, bite inhibition and knockdown). Studies have indicated that an accurate indication of activity may be obtained by a laboratory test determination on the speed of knockdown.

Coils, vaporising mats and liquid vaporisers may be tested in a chamber made of non-absorbent material (e.g. glass) which can be thoroughly cleaned to remove residues of earlier treatments. The chambers size should be a minimum of 5.8 m³ (PeetGrady chamber, figure 1). The air in the chamber is circulated with a gentle fan action to assist active ingredient distribution in the test chamber.

¹ Chavasse DC, Yap HH. *Chemical methods for the control of vectors and pests of public health importance*. Geneva, World Health Organization, 1997, (WHO/CTD/WHOPES/97.2).

Rapid knockdown is desired by users of household insecticides, and emphasis is therefore given to the observed time of knockdown for sample of introduced mosquitoes. The KT_{50} and KD_{95} (time for 50% and 95% knockdown) is then calculated by probit analysis. After exposure period, a knockdown reading is taken and the mosquitoes are collected and safely disposed of. Emphasis is given to standard rearing conditions of the mosquitoes (preferably 2-5 day old sugar fed female mosquitoes are tested). A minimum of 4 replicates of tests must be performed for all tests. For coils, mats and liquid vaporiser, continuous emanation of the test samples is conducted throughout the period of the test.

For mosquito coils, the test samples should be burnt throughout the test period of 60 minutes whilst the mosquitoes are exposed. For vaporising mats, test may be carried out after 1, 2, 4, 6, and 8 hours of heating the mat in a ventilated chamber on its electric heater so as to test for decline in emission of insecticidal vapour. The mats and heater are brought into the test chamber after the above mentioned periods of heating. In the chamber, the mat is heated throughout a 60 minute exposure of mosquitoes.

The liquid vaporisers are tested in the same way as the mats but the periods of heating outside the chamber between tests are evaluated at the early, middle and towards the end of the declared period. A pre-heating time of 4 hours is done at the initial period.

Space aerosols (FIKs)

In testing the space aerosols (FIKs), insects are released into the chamber before emission of the insecticide. The amount of emitted insecticide is measured by weighing the container before and after emission. The chamber should be made of non-absorbent material (e.g. glass). The knockdown and mortalities shall be recorded over a fixed period of time (e.g. 20 minutes). The knock down times (KT_{50} and KT_{95}) are then calculated. The insects are collected after the trial and kept under standard conditions for 24 hours for recording of the final mortality. 2-5 day old female mosquitoes and/or flies should be used. A minimum of 4 replicates must be performed.

Residual aerosols (CIK)

For the study of the residual activity, a forced contact test on sprayed surface (e.g. glass, plain plywood or ceramic tile) for a fixed period should be used. Healthy, normal, undeformed last nymphal instars or young roaches should be used.