

THE COUNCIL,

Having regard to Article 5(b) of the Convention on the Organisation for Economic Co-operation and Development of 14th December 1960;

Having regard to the Report by the Committee on Consumer Policy of 12th February 1974 on Consumer Protection Against Toxicity of Cosmetics and Household Products [Doc. No. CCP(73)2(1st Revision)];

Having regard to the Report by the Committee on Consumer Policy of 8th February 1974 on Compulsory Labelling of Prepackaged Consumer Products [Doc. No. CCP(73)1(1st Revision)];

Having regard to the Report by the Committee on Consumer Policy of 5th August 1976 on Safety Controls Over Cosmetics and Household Products [Doc. No. C(76)144];

Considering that international harmonization of controls over cosmetics and household products and of the test methods which permit the determination of their safety is necessary in order to avoid non-tariff barriers to international trade;

On the proposal of the Committee on Consumer Policy;

I. RECOMMENDS that the Governments of Member Countries should implement the Guidelines concerning safety controls over cosmetics

* Adopted under the written procedure (Doc. Nos. C(74)133(1st Revision); C/M(74)24 Part I (Final), Item 259; C(76)166 and Corrigendum).

and household products respectively, as set forth in the Annex to this Recommendation, which forms an integral part of it.

II. INSTRUCTS the Committee on Consumer Policy to keep under review the application of the present Recommendation and to report to the Council when appropriate on measures taken by the Governments of Member countries to give effect thereto.

Annex

I. GUIDELINES FOR SAFETY CONTROLS OVER COSMETICS

1. Since all cosmetics and toilet preparations are designed to be applied to the body, the competent authorities in Member countries should take great care to ensure that such products do not endanger health when properly used for their intended purposes, and that their labeling warns the consumer of the potential hazards of misuse.

Ingredients

2. The use of toxic substances at levels which might be harmful to man in their intended use should be prohibited. The poison lists which most Member countries have established provides a useful reference point in this respect.

3. The use of other substances (save those proven to be harmless) should be permitted only when an assessment of the clinical and the toxicological data on them has shown that they are not likely to present a hazard, or do not do so within specified limits and when reasonable precautions are taken. Before any substance is considered acceptable for use in cosmetic products, information derived from biological studies relevant to the mode of use of the cosmetic products should be considered; such studies could include for example an evaluation of the irritant and sensitising effects of the product as well as the degree of its toxicity.

4. Substances which are responsible for severe allergy reactions or irritations or for a large number of cases of allergy or irritation when used under conditions of prescribed, intended or common use should not be permitted.

5. Ingredients which have a sensitising or irritant effect but which are nevertheless permitted should be named on the product label.

6. No colouring matter should be permitted unless it is generally accepted as not being likely to present a toxicological hazard.

7. In the case of products contained in aerosols, toxic propellants such as vinyl chloride monomer (VCM) should not be used.

8. Controls based on positive list of permitted substances (together with qualified lists of substances which are permitted within specified limits for particular uses and possibly also subject to precise labelling requirements) should be preferred to controls based on negative lists, that is to say lists of prohibited substances. Control might alternatively apply to the final product rather than to its ingredients.

Marketed products

9. As the mix of different substances in a product may alter the toxicity of individual ingredients, manufacturers should be required to conduct appropriate tests or evaluation to demonstrate that there is no hazard to the user. As products vary widely in their nature and mode of use, it is not possible to prescribe a single system of testing which will apply to all products. The testing or evaluation procedures adopted by manufacturers and enforcement authorities should relate not only to the normal use of the product but should also take into consideration the possibility that the product may be misused or come into contact with other parts of the body under normal conditions of use (for example, hair preparations may enter the eyes).

Labelling of prepackaged cosmetics

10. Cosmetic products and toilet preparations which may constitute a hazard from the point of view of toxicity or other risks should carry appropriate warning labels (see paragraph 19 below).

11. Aerosol containers should carry a special warning to the effect that they must not be exposed to heat or sunshine, punctured or incinerated, even when empty and that their content should not be inhaled.

Scope of controls required

12. For the reasons given in paragraph 9 above, any system of control which is limited to checking, by means of positive or negative lists, whether the ingredients contained in a cosmetic are acceptable or not, is not adequate to ensure the safety of the final product. Both under a system of statutory or of voluntary controls:

- (i) manufacturers should be under a general obligation to take all necessary measures to ensure that for each of the products they market there is no hazard to health in normal use;
- (ii) manufacturers and importers should be required to submit to a central body concerned with enforcement of the regulations - either as a matter of routine or at the specific request of that body - full information with respect to all active ingredients of each product and the toxicological data obtained by tests carried out on ingredients and on the end product.

13. Provision should also be made for a system of information on adverse physiological reactions that may occur after a product has been marketed.

General

14. These Guidelines are not concerned with the nature of the tests to be applied to determine the safety of cosmetics and toilet preparations, nor with the methods which should be used to interpret the results of such tests. It would however be desirable that common standards be adopted by the competent authorities of Member countries in these fields. In the absence of legal provisions or regulations the choice of tests and their interpretation should be made by each manufacturer and his experts, in co-operation with the competent official bodies, if necessary in confidence.

II. GUIDELINES FOR SAFETY CONTROLS OVER HOUSEHOLD PRODUCTS

15. The following Guidelines apply in particular to the fourteen classes of household products shown in the attached illustrative list.

Controls over composition of household products

16. In general, the competent authorities in Member countries should bear in mind the following considerations:

- (i) manufacturers should be encouraged or, if necessary, required to use safer products whenever possible in place of a hazardous substance;
- (ii) manufacturers should be encouraged to keep the quantity of hazardous substance contained in a household product to the minimum necessary to ensure the product's effectiveness.

17. As the more hazardous poisons are already subject to statutory controls in most, if not all, Member countries the relevant basic laws should be sufficient to prohibit the use of highly toxic substances in ordinary household products, or permit it only under carefully controlled conditions. If however, such basic laws do not have this effect or have not been enacted, then controls over household products covering the following matters should be introduced:

- (i) strict limitation of the amount of a toxic substance allowed to be present in a product;
- (ii) maximum concentration permitted for the intended use;
- (iii) special labelling and packaging requirements.

18. Similar controls should be applied to other hazardous substances in household products, for example those which are highly flammable, explosive or corrosive.

Controls over labelling

19. Household products which may constitute a hazard from the point of view of toxicity or other risks should be covered by a system of compulsory warning labels involving some or all of the following features, the first two of which should be harmonized as far as possible and wherever appropriate with those used for other categories of hazardous substances and preparations:

- (i) warning symbols indicating nature and degree of hazards involved;
- (ii) use of colour to underline the danger;
- (iii) names of active hazardous ingredients;
- (iv) cautionary wording;
- (v) action to be taken in case of accident;*
- (vi) instructions for storage and use.

When a product has an outer and an inner package the warning label should appear on both.

20. Additional special labelling should be provided for in the following cases:

Classes 6, 9, 11 and 12 of the attached list

Users should be warned not to smoke while using the product, not to use it in a confined space without adequate ventilation, and not to inhale the fumes from the product.

Class 7 (and other classes as appropriate) of the attached list

Where a product contains a substance on the poisons list this should be indicated in writing or by a symbol or by a combination of both, in a way that cannot be misunderstood.

Classes 12 and 13 of the attached list

The label should indicate that the product must be stored outside the house and in such a way that it is out of the reach of children.

Class 14 of the attached list

Users should be warned not to mix bleaches with other cleaning products. The same warning may be need for other products, e.g. some products in class 8.

21. Where warning symbols are used they should conform to a recognised and appropriate international system where it exists.

* An emergency treatment should only be indicated if it is easy to apply and highly effective. Otherwise it should suffice to indicate that a physician or a poison treatment centre, for instance, should be consulted.

The protection of children

22. The protection of children, who are most frequently the victims of accidents in the home involving not only household products but also cosmetics, calls for special measures by competent authorities which should include the following:

(a) Special packaging

23. Special packaging should be designed as a means to discourage children from tasting or ingesting household products. For example, liquids may be sold in opaque containers and these should have a distinctive shape so that they are not confused with soft drinks containers. Built-in dispensers (which allow only a small quantity of the contents to be poured out or shaken out at any one time) and closures which children, especially young children, will find it difficult to open, should be provided where the possible hazards justify it.

(b) Labelling

24. The instructions for storage and use should specify that the product must be kept out of reach of children, particularly young children.

(c) Retail sales

25. The sale of household products in containers which were originally used for foodstuffs, beverages or medical products should be discouraged.

(d) Advertising

26. Advertising which is likely to mislead children or others concerning the real nature of the product in such a way as possibly to present a hazard should be discouraged.

(e) Information and education

27. Publicity arranged by government information services, consumers' organisations, safety organisations and so on should remind the public of the need to keep household products out of the reach of children. Safety courses given to children of school age should include advice on the correct and safe use of household products and a discussion of the items listed in paragraph 19.

Other methods of control

28. The sale of hazardous products which constitute a hazard to such a degree or of such a nature that cautionary labelling or controls over composition would be inadequate should be prohibited.

Aerosols

29. Certain supplementary precautions are necessary for a product contained in aerosols. Aerosols must comply with national standards and carry special warnings against exposure to heat or sunshine, or

use in the proximity of an open fire and against puncturing or incinerating, even when empty. Toxic propellants such as vinyl chloride monomer (VCM) should not be used. Flammable propellants should be avoided where practicable if, in association with certain other substances, they produce an excessively flammable spray as determined by flame-extension tests.

Paints

30. Although paint is not mentioned in the attached list, it is a common household substance. The basic principle is that any paint intended for indoor use, in particular for toys or children's bedroom furniture, or for any other article accessible to children, should be free of lead or other heavy metals or highly toxic substances as far as possible and necessary. Containers used for paint which is intended for exterior use and might thus contain a proportion of lead and other toxic substances should carry a clear warning that the product must not be used indoors or for children's toys, etc. and their sale in small containers should be discouraged. Every encouragement should be given to manufacturers to develop lead-free dryers and pigments and to discontinue the production and sale of lead-based primer for use on wood. The same principles should apply for paint sold in aerosols.

National poison information centres

31. In Member countries where poison information centres do not yet exist, consideration should be given to the practicability, having regard to existing practices in those countries, of setting up such centres. These serve to provide doctors and hospitals rapidly and at all times with complete information on the health hazards of household or other common products, including cosmetics, together with advice on treatment in cases of poisoning. The necessary information should be transmitted to these centres on a confidential basis by manufacturers and importers and the centres should ensure that information is always kept up to date. Information on the possible effects of certain household products and cosmetics based on the experience of the poison centres, would be particularly useful for setting the levels of certain ingredients at which warning labels are needed.

ILLUSTRATIVE LIST OF THE MAIN HOUSEHOLD PRODUCTS TO WHICH THE RECOMMENDATION SHOULD APPLY

1. Soaps (other than toilet soaps), detergents and other dish and clothes-washing products, automatic dishwashing compounds.

2. Rug shampoos, floor cleaners, wall cleaners, window cleaners in whatever form they are used (including products in aerosols).

3. Floor waxes, furniture waxes, furniture polishes in whatever form they are used (including products in aerosols).

4. Scouring cleansers, oven sprays and cleaners in whatever form they are used (including products in aerosols).

5. Bathroom and kitchen disinfectants, room deodorisers in whatever form they are used (including products in aerosols).

6. Paint and varnish removers, adhesives, cleaning solvents (including methyl alcohol, isopropyl alcohol), thinning agents (containing toluene, acetone, benzene, methylethylketone, etc.).

7. Metal polishes, cleaning and plating agents (containing hydrocyanic acid or its salts, etc.).

8. Corrosive chemicals (e.g. hydrochloric acid, sulphuric acid, nitric acid, phosphoric acid, acetic acid, formic acid, sodium hydroxide, potassium hydroxide, ammonia, ammonium hydroxide, phenol, o-cresol, m-cresol, p-cresol, silver nitrate, zinc chloride, iodine, oxalic acid and its salts, etc.).

9. Polishes and cleaning agents containing chloroform or other chlorinated hydrocarbons, etc., shoes polishes and creams.

10. Turpentine - irrespective of the method by which is produced; spot removers.

11. Halogenated aliphatic compounds (carbon tetrachloride, 1, 1, 2, 2 tetrachloroethane - fire extinguishing fluids).

12. Petroleum distillates - naphtha, kerosene, gasoline, mineral spirits, petroleum ether.

13. Ethylene glycol, diethylene glycol (anti-freeze compounds).

14. Bleaches.

In adopting this Recommendation, the Council:

1. NOTED the Report by the Committee on Consumer Policy of 5th August 1976, referred to above;

2. DECIDED to derestrict the Recommendation.