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OCCUPATIONAL CANCER - PREVENTION AND CONTROL

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FOREWORD

The question of the prevention of occupational cancer and the protection of workers against this risk has been under active consideration by the ILO during the past decade, in particular following the adoption of a resolution on this subject by the 1967 session of the International Labour Conference. It became a priority subject when the ILO Governing Body decided to convene a meeting of experts to examine possible ILO action with a view to submitting to the International Labour Conference proposals for international standards on this question. The Conference discussed at two successive sessions, in 1973 and 1974, the principles for the organisation of technical and medical prevention, and finally adopted two international instruments, a Convention (No. 139) and a Recommendation (No. 147) concerning the prevention and control of occupational hazards caused by carcinogenic substances and agents. The Convention states the most essential principles: replacement of carcinogenic substances by less dangerous ones; establishment of a list of carcinogens to be prohibited, or made subject to authorisation or to control; recording of data concerning exposure and exposed workers; medical surveillance; information and education. In the Recommendation, these principles are expanded and member States are invited, when implementing the provisions of the instruments, to take into account guides and other technical publications prepared by the ILO. The intention of the Conference was therefore to lay down general principles for implementation at the national level of the specific and detailed measures required and for the development of adequate control programmes.

Recognising the difficulties of action in this field, the 1975 session of the International Labour Conference also adopted two resolutions related to the problems of occupational cancer. The first refers to the adverse social and economic consequences, both for the workers and for the industry which may follow the implementation of strict preventive and protective measures prescribed by national legislation, and methods of meeting the hardships involved; the second asks for the establishment of an appropriate consultation mechanism to be used by the ILO in order to provide up-to-date information on the results of research and on the most effective methods of preventing occupational cancer. One important task specified in this connection is to provide guidance for the implementation of the principles set forth in the ILO Convention and Recommendation (see Appendix 2).

This publication represents a first step in this direction. It was originally drawn up with the valuable help of a group of consultants[1] and reviewed by the ILO Panel of Consultants on

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[1] Participated in this consultation (10-12 November 1975): Dr. E. Bolinder, Chief, Medical Department, Swedish Trade Union Confederation, Stockholm (Sweden); Dr. B. Holmberg, Associate Professor of Toxicology, National Board of Occupational Safety and Health, Stockholm (Sweden); Dr. A. Munn, Division Medical Officer, Imperial Chemical Industries Ltd., Manchester (United Kingdom); Dr. V.E. Rose, Department of Health, Education and Welfare, Houston (USA); Dr. G. Smagghe, Chef des Services de médecine et de toxicologie, Société de produits chimiques Ugine-Kuhlmann, Paris (France); Prof. R. Truhaut, Directeur du Centre de recherches toxicologiques, Faculté des sciences pharmaceutiques et biologiques, Paris (France).

Occupational Cancer.[1] The ILO expresses its thanks to these persons for their valuable collaboration. It is hoped that this publication will serve as a useful aid to all those having responsibilities in the planning and implementation of measures for the prevention of occupational cancer.

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[1] Panel of consultants on occupational cancer (1976-1981). Titular members: Dr. E. Bolinder, Chief, Medical Department, Swedish Trade Union Confederation, Stockholm (Sweden); Dr. A. Eiras de Araujo, Director, Instituto Nacional de Cancer, Rio de Janeiro (Brazil); Dr. C. Eskandari, Chief, Industrial Medical Services, National Iranian Oil Company, Abadan (Iran); Dr. A. Munn, Medical Director, Monsanto Europe S.A., Bruxelles (Belgium); Prof. N.P. Napalkov, Director, Petrov Research Institute of Oncology, Leningrad (USSR); Dr. J. Paris, Confédération générale du Travail, Paris (France); Dr. H. Sakabe, Chief, Department of Industrial Physiology, National Institute of Industrial Health, Kawasaki (Japan); Prof. T. Schramm, Head, Department of Chemical Cancerogenesis, Central Institute for Cancer Research, Academy of Sciences of GDR, Berlin - Buch (DDR); Dr. G. Smagghe, Chef des Services de médecine et de toxicologie, Societé de Produits chimiques Ugine-Kuhlmann, Paris (France); Prof. R. Truhaut, Directeur du Centre de recherches toxicologiques, Faculté des sciences pharmaceutiques et biologiques, Paris (France); Dr. J.K. Wagoner, National Institute for Occupational Safety and Health, Cincinnati (USA). Substitute members: Dr. J.W. Charters, Corporate Medical Director, The Steel Company of Canada Ltd., Hamilton (Canada); Prof. D. Henschler, Director, Institut für Toxicologie, Wurzburg (Fed. Rep. of Germany); Dr. S. Holmes, Chief Health Physicist, T.B.A. Industrial Products Ltd., Rochdale (United Kingdom); Dr. J. Lepoutre, Médecin-chef, Services médicaux, S.A. Eternit, Kapelle-op-den-Bos (Belgium); Prof. P. Purriel, Subdirector del Instituto de Tisiologia, Montevideo (Uruguay); Dr. P.V. Thacker, Chief, Department of Industrial Health, TATA Services Ltd., Bombay (India); Monsieur U. Viviani, Montedison, S.p.A., Milan (Italy).

1. PROBLEMS RELATING TO THE ESTABLISHMENT OF OCCUPATIONAL STANDARDS FOR CARCINOGENS

For the purpose of this document, occupational carcinogens are chemical substances, physical agents or work processes which may cause cancer in man due to conditions of exposure in the workplace. Occupationally induced tumours are no different in type and nature from those arising from non-occupational factors. Indeed, they may cause a significant increase of a particular type of cancer in the exposed working population.

These considerations extend to the so-called "benign" tumours. Many benign spontaneous human neoplasms and induced animal neoplasms may become frankly malignant, so that for the purpose of prevention, no differentiation is made between "tumourigens" and "carcinogens".

1.1 Animal experimentation

Current approaches to the control of occupational cancer now rely heavily on animal experimentation usually involving the rat or mouse. More and more the approach from the regulatory point of view is to consider experimental carcinogens as potential human carcinogens when a significant human exposure exists. In following this line of reasoning, however, the magnitude of the potential problem becomes considerable. For example, the National Institute for Occupational Safety and Health (NIOSH) of the United States has identified some 1,500 substances which have produced some tumourogenic or carcinogenic effect in animals.[1] However, a number of these cases need further confirmation because they are inferred from published studies for which there are insufficient data with regard to the design of the research or the criteria for evaluation.

The actual extent of occupational exposure to many of these chemicals may be minimal. Nevertheless, there can be no doubt that some, if not many, of these substances are capable of producing cancer in humans. In addition, the number of chemicals to which workers are exposed and which lack adequate evaluation is unknown.

In evaluating experimental animal data, it must be recognised that this is not a perfect tool. There are substances, such as the inorganic compounds of arsenic, which are highly suspected of producing an increased incidence of cancer in workers, but for which animal experimentation has to date been unsuccessful.[2] Just as "false negative" results exist, so do "false positives". There is some evidence to indicate that while certain substances, such as o-toluidine and diethyleneglycol, are carcinogenic in test animals, their hazard potential in the workplace is not significant.

Another factor of concern involves the evaluation of trace impurities especially as more sophisticated analytical techniques

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[1] National Institute for Occupational Safety and Health (1975) Suspected carcinogens. A subfile of the NIOSH Toxic Substances List, NIOSH, Rockville (Maryland), p. 342.

[2] International Agency for Research on Cancer (1973) IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man, 2.

become available. Serious concerns exist as to whether the basic chemical or the impurity is the aetiological agent. The best example of this probably involves 1- and 2-naphthylamines. Here the 2-isomer is without doubt a carcinogen. Some researchers have attributed the increased incidence of bladder cancer among workers involved in the manufacture of 1-naphthylamine to the 2-impurities. However, lacking definitive data, certain countries which regulate carcinogens have chosen to include I-naphthylamine as a carcinogenic substance.

Another area of current controversy involves the concept of dose-effect relationship and the existence of a "no effect" dose level. The problem of "no effect" levels of exposure to carcinogens has been much debated over many years. Our knowledge about dose-effect relationships and cancer is mainly based on animal experimental work. The dose-frequency curve obtained with, for instance, methylcholanthrene after a single subcutaneous injection has the S shape known from classical toxicology.[1] The shape of the curve implies the existence of a zero-effect level of the carcinogen. In a probit diagram the S shape curve can be transformed to a linean curve.[1] It should be remembered, however, that an increase in the number of experimental animals per dose group increases the probability of obtaining an animal with a tumour at a low dose level. The zero-effect dose seems thus to be a phenomenon closely related to the number of animals, the species and the route and type of administration, which cannot be extrapolated to other population sizes, nor to other species, absorption routes or exposure times.

The fractioning of a single dose of a potent carcinogen into small doses administered over a long period seems to increase the response.[2] Thus, twelve subcutaneous injections of 0.042 mg each of benzo(a)pyrene in mice induce tumours in 70 per cent of the animals. The same total dose (0.5 mg) administered at one single injection induces tumours in about 20 per cent of the animals. If any generalisation can be made from one experiment with one substance, then it would appear to be more dangerous to be exposed to small amounts of a carcinogen repeatedly and for a long time than to have one single peak exposure.

Dose-latency studies seem to indicate that low single doses induce tumours with long latent periods, while high single doses induce tumours with short latent periods.[1] It should therefore be theoretically possible to derive a dose for a given animal species, number of animals, route and type of administration, which does not induce a tumour within the life expectancy of that particular species. However, even if this were possible for one substance and one test species, it is not possible to extrapolate such a zero-effect dose level to any other species.

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[1] Bryan, W.R. and Shimkin, M.B. (1943) Journal of the National Cancer Institute, 3, 503.

[2] Payne, W.W. and Heuper, W.C. (1960) American Industrial Hygiene Association Journal, 21, 350.

1.2 Extrapolation from animal to man

The same problems arise in the extrapolation of laboratory tests to industrial exposures because of variations in response in different animal species and in man, in respect of both tumour induction and target organ. The problem is enhanced in so far as in most experiments it has not been possible to reproduce industrial exposure in respect of either dose level or route of entry into the body.

The following arguments are adduced against an extrapolation of dose-response data from laboratory animals in an attempt to establish limits of occupational exposure:

- Man is genetically more heterogeneous than test animal strains. It is thus more likely that a highly sensitive or highly resistant individual will be found in any human population than that such an individual will be detected among a limited number of animals.

- There are reasons to believe that a number of endogenous and/or exogenous factors interfere with the response towards a carcinogen, either strengthening or antagonising the carcinogenic action of a substance. Some of these factors, such as nutrition or physical stress are standardised for laboratory animals, but not for man.

- The age of the individual at the start of the exposure may be an important parameter in determining the response. Young animals are more sensitive than old animals. Laboratory animals are selected according to age, weight or both at the start of the experiment and are thus more biologically homogeneous. Human populations are not standardised in any respect when occupational exposure starts.

- Fractioned exposure, i.e. low doses over a long time, is a common feature in human populations which may increase the risk of cancer.

- Human populations are likely to be exposed to more than one potential carcinogen at one time during life. Synergistic effects may therefore be expected. Moreover, carcinogens are metabolised by different species in a different manner and at different rates into biologically active or inactive metabolites. There are differences in the metabolic mechanisms of man and animals. Extrapolation of "safe" doses from animal experiments to man is therefore at present still not possible, and in any case it would not ensure safety when the total exposure panorama is considered.

- The size of an animal test population as compared to man is a considerable problem when discussing zero-effect levels of carcinogens. Table 1, taken from Zbinden, illustrates the relation between test group sizes and the predictability of animal tests in quantitative terms for human populations. Within 59 animals in each dose group one can, for instance, detect at least one animal responding to a carcinogen which will lead to 5 per cent tumour-bearing individuals in an exposed human population, if one accepts a confidence level of 0.95. In order to detect a low potent carcinogen, causing say one tumour per thousand workmen, it is necessary to use at

least 2,995 test animals in each dose group. Such a comparison is based upon the assumption that human populations and test animal populations respond identically, an assumption which may well be false.

Table 1: Number of animals in toxicity experiments

Probability of toxic effects in man (%)	Animals in experiments* Probability 0.95	Probability 0.99
100	1	1
80	2	3
60	4	6
50	5	7
40	6	10
20	14	21
10	29	44
5	59	90
2	149	228
1	299	459
0.1	2 995	4 603
0.01	29 956	46 050

Source: Zbinden G. (1973) Progress in Toxicology, 1, Springer, New York.

*Number of animals to be included in an experiment in order to find at least one subject with the toxic effect (assuming identical incidence of toxic effect in animals and man). (Calculated by T. Marthaler, Biostatistics Centre, University of Zurich.)

It is clear from the above points that the study of the response to low doses of carcinogens is extremely difficult. Extrapolation from high dose levels down to low dose levels might be regarded as a possibility. Such an extrapolation can be done from a linear dose-response curve in a probit diagram. Our knowledge about the shape of dose-response curves at low dose levels is, however, limited. A study on chemical carcinogenesis referred to above, indicates that the dose latency curve has a flatter slope at low dose levels than at high levels, though a linear curve at all dose levels studied is suggested for tobacco carcinogenesis and for radiation-induced cancer in human populations. A simple extrapolation of a linear part of a dose curve obtained by epidemiological studies may thus be hazardous even when a safety factor is introduced.

The conclusion is, in summary, that experimental studies on chemical carcinogenesis, although providing very useful information, are insufficient for establishing a risk estimate for human exposure in the work environment. The best way to establish a true risk estimate for human exposure is by means of an integrated evaluation

of epidemiological studies and proper animal experiments. In the absence of an adequate dose-response curve for a human population as obtained by epidemiological studies, animal data should essentially be used to establish carcinogenicity as such, and possibly for comparing the risk potential from one substance to another. Experimental animal testing remains indeed necessary in the case of new substances for which epidemiological studies are obviously not applicable. From a practical point of view, exposure to an experimental carcinogen should be kept as close to zero as possible in the occupational environment, irrespective of dose level in the test system, animal species, tumour site, type or frequency.

1.3 Epidemiological studies

The most effective contribution to the establishment of a reliable risk estimate for human exposure in the working environment is by means of epidemiological studies. An epidemiological study is a statistical means of comparing the frequency of a particular effect in one group of people with that of another group or with the population as a whole. Ideally, it should be possible in such a study to measure the level of exposure and the incidence of effects so as to establish a dose-response relationship. This is however, seldom possible in studying the incidence of occupational cancer because of the small populations at various risk levels and of inadequate or even complete absence of relevant analytical data on the contaminants. When these data are available, then valid information is obtained. Some recent studies have confirmed the validity of this method for assessing the relationship between the incidence of certain types of cancer and an occupational exposure. This was the case, for example, for pleural mesothelioma in asbestos workers and for hemoangioma of the liver in vinyl chloride workers.

Many uncontrolled factors can contribute to making an epidemiological study on occupational cancer less informative or even to making it non-valid. Thus, the size of exposed populations may be small or the exposure time shorter than the time period necessary for tumour induction; information on past exposure levels may be semi-quantitative or even absent, the technological process may have changed quantitatively or qualitatively during the actual induction period, etc., all factors negatively influencing the risk assessment. In some occupations a multiplicity of chemical products is used making it impossible to correlate exposure to a given agent with an increased risk of cancer.

The problems of establishing a dose-response relationship at low dose levels are of the same magnitude in human populations as in test animal populations. This means, among other things, that for practical purposes the concept of a safe level of exposure for human populations is closely connected to the size of the exposed population and any increase in population size may increase the probability of observing a cancer due to occupational exposure. Moreover, epidemiological studies are naturally based upon comparisons with control populations which are themselves changing. The cancer incidence in the population of industrial societies is increasing even over a relatively short-time perspective. For certain cancer sites, for instance lung cancer, the incidence in some countries has increased considerably over a ten-year period. Any risk estimate obtained in an occupationally-exposed population is thus based on a comparison with a population having a continuously increasing "background noise", and it might be argued that

this mere fact involves an acceptance that an increase in cancer incidence is reasonable. The conclusion is that a risk estimate based on an epidemiological study should be corrected by a "safety factor", the size of which could be 2 or higher. Even if an occupational standard could tentatively be established according to such estimations, the exposure should be kept as close to zero as possible because a zero-effect level might not exist or at least would be most difficult to validate.

This is the concept which led, for certain carcinogens, to the establishment of "technical reference concentrations". These were laid down for practical purposes in order to provide guidance for the planning and implementation of the technical control of the working environment. Where these concentration limits were established they have been primarily based, in a number of cases, on the concept of "least feasibly detectable" or attainable concentration using existing technology. However, the setting of occupational standards according to technological criteria must be made with an understanding of technology's potential for change when specifically directed towards improving work hygiene. The story of vinyl chloride exemplifies this situation. The Swedish occupational exposure limit of vinyl chloride was temporarily lowered in the spring of 1974 to 20 ppm time-weighted average. This level was merely an adjustment to the practical level already maintained in the polymerisation industry at that time. A limit below 10 ppm was considered technologically not possible by the industry. Animal data indicated, however, that 50 ppm, which was the lowest dose tested, induced tumours in mice and rats, a fact which strengthened the demand for a zero exposure. In the autumn of 1974, 1 ppm was adopted as the time-weighted standard. Today the Swedish companies are able to maintain that limit of exposure. The technologically impossible task of today might thus be feasible tomorrow.

1.4 New chemicals and chemicals in use

A prevention programme for new chemicals could include an obligatory adequate testing of chemicals for their possible carcinogenic potential.

For chemicals already in industrial use, testing for carcinogenicity and mutagenicity may be required by national authorities, especially for suspect substances where no epidemiological data exist or can be obtained.

Although testing would be desirable for all new chemicals and for a large proportion of chemicals already in use, this is obviously a most difficult task considering the number of new substances introduced each year onto the market as well as those already in use. Moreover, taking into account the relatively long duration and the complexity of animal experiments, it becomes necessary to evolve criteria for selecting substances to be submitted to further animal experiments. Promising avenues in this connection seem to be provided by testing substances for mutagenicity in bacteria or other inferior organisms, for malignant cell transformation in vitro or for unscheduled DNA synthesis. These methods are more rapid than experimental testing in laboratory animals and, although they still present considerable difficulties in their interpretation, substances found to be active in these tests may also be suspected for carcinogenicity. In spite of certain differences of opinion in the assessment of the screening

tests, the present approach is therefore to carry out tests in animal systems on chemicals which (a) are found to be active by screening tests for mutagenicity; and (b) are structurally related to known experimental or human carcinogens. Other important factors to be considered when establishing priorities are the physical, chemical and biochemical properties, especially as they relate to potential routes of exposure; the quantity of material produced or the anticipated potential; the number of workers exposed and the level of exposure; the ultimate community involvement, whether for instance exposure is limited to industrial settings or a wider contamination is possible. These problems have been actively studied in recent years.[1]

As a consequence it has been felt necessary to develop practical guidelines for the conduct of these experimental studies. At the international level such guidelines have been developed by the International Agency for Research on Cancer (IARC) and, in essence, these require: exposure to dose levels lending to measurable effects; appropriate length of testing; presentation of a satisfactory protocol involving appropriate exposure routes; use of an adequate control group; interpretation of results in relationship to a control group.

In addition to experimental studies and animal testing, epidemiological studies should be performed in order to establish a risk estimate for chemicals in use.

The final evaluation, especially as regards the establishment of preventive regulatory measures, should consider the carcinogenic hazard to working populations. Consequently, several factors should be taken into consideration, among which are: evaluation, both qualitative and quantitative, of experimental data; critical evaluation of epidemiological data when available; consideration of physical, chemical and bio-chemical factors; the nature of the technology where exposures may result; and other possible influencing factors, such as synergistic/antagonistic potential, the potential for personal factors such as diet and smoking to have a contributory effect and the possibility of mutagenic and/or teratogenic effects to be manifested, especially where exposure of females of childbearing age is possible.

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[1] See also:

World Health Organisation (1971) Principles for the testing and evaluation of drugs for carcinogenicity, Technical Report Series No. 482, WHO, Geneva.

World Health Organisation (1971) Evaluation and testing of drugs for mutagenicity: principles and problems, Technical Report Series No. 482, WHO, Geneva.

World Health Organisation (1974) Assessment of the carcinogenicity and mutagenicity of chemicals, Technical Report Series No. 546, WHO, Geneva.

2. CLASSIFICATION OF CARCINOGENS FOR THE PURPOSE OF LEGISLATION

In the field of occupational carcinogenesis, as in other scientific fields, very little is known in comparison with what is not known. The resources available to cope with the entire spectrum of occupational safety and health problems are finite, and occupational carcinogenesis is just one part of this spectrum. Hence the need to classify carcinogens by some rationale, in order that governmental authorities, employers and employees can put the problem into a proper perspective.

While every classification system is arbitrary, it is accepted that some form of classification is useful. For practical purposes a list of carcinogens can, for instance, be structured according to one or more of the following criteria:

(a) human carcinogens/animal carcinogens;

(b) highly/moderately/low potent carcinogens;

(c) prohibited/permitted carcinogens according either to "necessity" (cost-benefit assessment), or technological feasibility, or to potential hazard, i.e., degree of risk, as regards occupational exposures.

A listing according to principle (a) would for instance include 2-naphthylamine, bis-chloromethyl ether, benzene and vinyl chloride as human carcinogens. The most satisfactory criterion for listing a substance as a human carcinogen is an increased cancer risk (adjusted for age, sex and other compounding factors) in occupationally exposed groups (at best with different dose levels) compared to control groups. This is derived from epidemiological studies which are unfortunately only available in a minority of cases for the establishment of the carcinogenic activity of chemicals.

Further, the number of factors already mentioned which can influence negatively a correct risk assessment, and the multiplicity of exposure to chemicals inside and outside the work site, may invalidate the conclusions of such inquiries or call for caution in their interpretation. There is thus a tendency to underestimate the true number of human carcinogens. This means that a listing of human carcinogens apart from experimental carcinogens, in so far as the listing implies separate levels of restriction of the occupational exposure, does not necessarily reflect the true risk situation. A rather widely accepted pragmatic approach from the regulatory point of view is to consider experimental carcinogens as potential human carcinogens when a significant human exposure exists. This point is illustrated by the findings concerning, for instance, vinyl chloride, bis-chloromethyl ether, diethylstilboestrol, which, having shown carcinogenic action in animal experimentation, were subsequently found to be carcinogenic also for man.

A listing of carcinogens according to potency is the second possibility. This, however, is not accepted by a number of scientific workers, because of the difficulty of defining criteria of potency. Generally speaking, potency may be defined as being the amount of carcinogen required for the production of a given

proportion of malignancies and the steepness of the slope of the dose-response curve. However, the carcinogenic potency of a chemical is not a characteristic independent of the experimental condition nor of biological parameters. Animal species, strain of animals, sex, age at start of exposure, nutritional factors, enzymatic pattern, immunological factors, routes or types of administration are among those factors influencing the dose-response. Thus, 2-naphthylamine seems, for instance, to be a carcinogen of lower potency for rats and rabbits than for dogs and humans. Some experimental highly active carcinogens, like methylnitrosourea and diethylnitrosourea, occur in environments where the establishment of their risk in occupational handling is difficult. The listing of carcinogens as high potent/low potent carcinogens, implying different levels of legislative action according to potency, may thus lead either to workers being exposed to potential carcinogenic hazards or to unnecessary stringent legislation.

A listing of carcinogens occurring in the occupational environment could be structured according to technological criteria. This may refer either to the technical necessity of using a specific substance having a carcinogenic action for a given technological process, or to the degree of exposure to a carcinogen under normal operating conditions. Both approaches may result in a list of prohibited substances. There is no doubt that some potential carcinogens used by industry could be dispensed with, although the economic impact of the withdrawal of such potential carcinogens varies from country to country. There is also no doubt that many carcinogenic substances can be substituted by other non-carcinogenic compounds or by compounds known to present less risk in a carefully controlled work environment, as estimated in reliable epidemiological studies.

In the recommendations which follow, carcinogenic chemicals, physical agents and processes are classified on the basis of their estimated potential for inducing cancer in working populations. Therefore, a number of factors are combined in the assessment. It is not proposed that the listings as shown in Appendix 1 are all-inclusive, but they are rather an attempt to identify the risks for which, in the view of the ILO Panel of Consultants, sufficient information is available at the present time. It is anticipated that as more information becomes available on these and other problems, the listings will be modified and appropriate additions and/or deletions made.

Specific recommendations have not been made as to the appropriate course of action to be taken by governments or industries to arrive at the degree of control recommended for each category. Depending on a number of complex individual factors, these may include banning the use of certain chemicals, the need to obtain special authorisation for use and/or the establishment of levels of exposure based on current control technology.

In cases where the competent authority has power to deliver special authorisation for the production or use of specified carcinogenic substances, such authorisation should stipulate the obligation to apply strict preventive measures. These should include such appropriate technical, hygiene and personal protective measures that would ensure a satisfactory protection; the medical supervision, biological tests or other investigations to be carried out; the records to be maintained and the professional qualifications of those dealing with the supervision of exposure to the substances in question.

Due to the paucity of epidemiological data, uncertainties in extrapolating animal data to human exposures, and the conceptual difficulty in formulating acceptable degrees of risk, it would appear particularly difficult to recommend "safe" levels of exposure for carcinogenic substances at this time. There is, however, from a practical point of view, a clear need to provide guidance for cases in which the production or use of carcinogenic substances cannot be dispensed with, in particular where they also present other types of risks, such as intoxication, explosion, etc. One way to cope with this need at the present time is to prescribe for certain carcinogens the "technical reference concentrations" referred to above, whose role is to give guidance in the implementation of technical preventive measures designed to reduce to a minimum the exposure to these substances. This has been done in certain national lists, where provisional limit values have been assigned to less dangerous carcinogens.

3. PREVENTIVE MEASURES

3.1 General principles

Safety and health measures should be applied to ensure that work involving the use of one or more carcinogens does not endanger the health of workers or of persons living in the neighbourhood of the plant, by giving due consideration to all the various possible modes of contamination and to the circumstances under which this contamination might occur. Carcinogens may enter the body by: inhalation (vapours, mists, dusts), skin absorption (splashes, soiled work clothes) or ingestion (eating with soiled hands, smoking, etc.). The nature and scope of these measures may therefore vary depending on the situation; they may also vary depending on the evolution of scientific or technical knowledge.

The material set out in this section is intended to be used as a guide to enable each case to be studied individually and at the same time enable consideration to be given to the different points listed herein.

Each carcinogen encountered in a plant should be the subject of a document which indicates the practical measures to be taken in relation to the agent's characteristics and to the type of occupational exposure.

Where appropriate, workers or their representatives should be involved in the development of specific procedures and should have the reasons for these procedures explained to them.

The installations (areas, buildings) or workplaces for which special measures should be drawn up and applied should be designated. If necessary, "controlled areas" or "supervised zones" should be marked out.

These measures should be related to the health hazard as it may arise through inhalation, skin absorption, or ingestion, for:

(a) workers involved directly in the process in question or doing jobs close by; production workers and maintenance workers; direct employees and indirect employees (external contractors);

(b) persons living in the neighbourhood who may be exposed to: airborne effluents (gases, dusts, mists); liquid effluents; and solid wastes.

All aspects of the industrial process should be covered, including:

- sources of hazard (raw materials, intermediates, by-products, finished products, impurities);
- all stages of manufacture, packaging, transport and use;
- production;
- laboratory operations;
- normal operating conditions;

- repairs and preventive maintenance;

- incidents.

3.2 Technical measures

Basic principle

Technical preventive measures should form an integral part of all work in which carcinogens are encountered or might be encountered, and before commencing or continuing operations it should be ensured that these measures are effectively implemented. Their implementation should be such as to render other measures unnecessary and taken only on precautionary grounds.

Substitution

Wherever possible, products known to be carcinogenic in man or likely to be carcinogenic in man should be replaced by other products. Nevertheless, it must be proved that these substitution products constitute a significantly lower health hazard from all toxicological points of view.

Where information is lacking on the health hazards of a given product, for example with new products, literature studies and experimental research should be carried out at the appropriate time with particular reference to potential carcinogenic action.

Special studies

A decision to utilise a process in which a carcinogen is employed or during which a carcinogen may occur, entails a "special study". Such special studies are aimed at minimising the duration of the dangerous operations and clearly identifying these operations for the information of those in charge of the plant. They also provide the necessary detail regarding the physical nature of the hazard, and a complete range of technical data for different stages: temperatures, pressures, etc.

Consideration should be given to research laboratories, pilot-operations and future full-scale production operations, and include:

- the study and recording of the operations of the process in which the carcinogen is present;

- carrying out process technology research in order to minimise the duration of these phases;

- consideration of waste products and any possible impurities;

- the forecast of any possible technical incidents or breakdowns;

- the development of analytical procedures for determining hazardous substances in the intermediate and final products, waste substances and environment.

Technological study

The installation is then designed on the basis of the specific data provided by the above special study in such a way that the equipment gives rise to no external contamination. The over-all and detailed phases of the technological study should deal in particular with:

- the plant location (premises with permanent ventilation equipment or open-air installations);

- the design of the plant itself, its equipment, the choice of materials, etc., making allowance for any subsequent maintenance or repair work which might entail a substantial hazard (for example, foresee the likelihood of the workers being involved in such operations having to wear complete airtight "divers" suits with maybe bulky, self-contained respirators), special gaseous, liquid or solid effluent circuits sealed off from the environment, and the special processing of effluents to ensure purification prior to waste disposal, and the development of decontamination procedures for spillage;

- safety and rescue procedures to minimise the risk of contamination and to deal with possible breakdowns or failures;

- suitable washing facilities (washbasins with a regular soap supply, disposable drying materials or hot-air dryers) and immediate decontamination facilities (emergency showers).

Operating instructions

Procedures should be established in relation to the potential hazards. They should be expressed clearly in language readily understandable so as to exclude all improvisation. They should be designed in such a way that, during potentially hazardous operational phases, the workers are not burdened by time limits. Possible incidents should be foreseen and simple precautionary measures indicated; if necessary, provision should be made for interruption of the process which can then be recommenced after a break.

Emergency exits and emergency protective equipment should be clearly marked and their location pointed out to each worker individually.

Foreseeable repair procedures should be drawn up, specifying the individual operations involved and the responsibility of each department in the total process.

These procedures should include the technical data and also specify personal protective measures such as special clothing, respiratory protection, and the rules for any possible personal decontamination that might prove necessary.

Depending on the severity of the potential hazard, maintenance and repairs should be carried out under the effective control of a supervisor or line manager with a special knowledge of the hazard and the necessary safety measures.

As far as possible, maintenance and repair work should always be entrusted to the same workers who will, consequently, acquire intimate knowledge of the plant and the work itself, become well aware of the hazards and the safety measures and, moreover, be subject to specific medical supervision.

3.3 Personal protective measures

Working clothes

Working clothes specially suited to the potential hazard should be given to workers engaged in operations involving potential exposure to carcinogenic substances. The type of clothing will depend on the nature of the product, its physical properties, its consistency, etc. Workers may receive complete sets of clothing including underclothes and footwear or may, for example, receive only overalls. The intervals at which this clothing is changed will depend on the foregoing properties.

An adequate stock of clean replacement clothing should be available to ensure correct laundering and immediate replacement in the event of soiling. The intervals at which this clothing is washed will depend on the severity of the potential hazard and the properties of the product. Special provision should be made for collecting and laundering contaminated clothing. If necessary the clothing may undergo special pre-treatment and then be washed separately from the rest of the working clothes in the plant. Before evacuation into the general sewage system, the effluents from this treatment may be required to undergo a purification process to remove the product in question.

Changing rooms

The changing rooms for these employees should be separate from the general changing rooms and their design related to the potential hazard. In general, they should be divided into three consecutive sections: town-clothing changing rooms, showers, work-clothing changing rooms, so that, at the end of the shift, there is no contact between the working clothes, which are all left in the work changing room in special containers where necessary, and the town-clothing; employees put on their town-clothes only after compulsory showers. Each employee should systematically be provided with suitable washing materials with clean towels daily.

These premises should be lined with materials which can be cleaned completely each day. The changing room cabinets should be designed so that nothing but clothes can be stored in them. Working clothes that have been worn should not be taken into the town-clothing changing room or into the showers. Only clean working clothes can be taken through the town-clothes changing rooms.

Workers should be informed of the best personal procedures for avoiding possible contamination, for example: precautions to be taken to avoid soiling the inside of gloves, contamination of tools, removal of clothing after any unusual contaminating operation, etc.

It should be forbidden to bring food and drink into the work area. Mess rooms for personnel working in the areas in question

should be located at a suitable distance from the workplace. Before entering these mess rooms, workers should be required to wash their hands carefully and to put on an overall to cover their working clothes. Should the nature of the carcinogen make it necessary, steps should be taken to prevent other possible causes of contamination (prohibition of smoking in the plant for example).

3.4 Emergencies

Detailed instructions should be laid down describing the action to be taken in the event of an incident such as a plant breakdown or other failure which may lead to contamination with potent carcinogens. These instructions should specify, in particular, the evacuation of all non-essential workers who might be subject to contamination.

Wherever possible, after arresting the escape of the contaminant, subsequent operations should be carried out under strict control, applying all the necessary safety measures. Such precautions should be of the highest order and may require the use of special equipment and clothing.

Following accidental contamination or work on an apparatus which may have caused contamination, systematic decontamination should be immediately carried out on:

- workers)
) where necessary even before clothing is removed
- clothes)
- equipment
- premises.

In such circumstances, special checks should also be carried out (see section 4).

Waste material, contaminated water and decontamination liquids resulting from such events should be held in special bunds or containers until they can be decontaminated.

4. EXPOSURE MONITORING

4.1 Workplace monitoring

Areas to be monitored

It is necessary to monitor all areas of potential exposure through

(a) fixed point monitoring (valves, gaskets, etc., where leaks may develop);

(b) spot sample monitoring;

(c) personal exposure monitoring.

Samples should be taken in sufficient number to ensure adequate characterisation of the work environment and individual exposures.

The samples should be taken in accordance with the most important mode of entry into the body for the carcinogen in question (for example, in the case of gaseous contaminants, samples are collected in the breathing zone of the worker).

In appropriate cases monitoring should be extended to: equipment surfaces, floors, etc. in the case of contaminants which, by their physical nature, would be readily deposited on them; solid, liquid or gaseous wastes; products of intermediate phases when they are isolated; unreacted residues in subsequent products; and working clothes (in the case of contaminants which do not vaporise rapidly).

Analytical techniques

The analytical measurement techniques should be developed or laid down by the competent laboratories using the most sensitive methods. The techniques should be suited to the areas in which monitoring is necessary.

Intervals between monitoring

The intervals at which each category of monitoring is systematically carried out should be presented. This shall include the number and type (fixed, spot or personal) of samples to be collected. Checks should be carried out at particularly short intervals when plant is started up and after incidents and repairs. Subsequently, repeated negative findings will make it possible to adopt longer intervals between sampling; nevertheless, on no account should these intervals exceed a specified maximum duration.

Special checks should be carried out immediately following a technical incident or work operation which may have led to contamination. If the findings should be above the prescribed level, checks should be repeated until negative findings are confirmed by repeated negative samples taken at significant intervals. Such checks should furthermore be carried out when processes are modified or new processes are introduced. Similarly, if during normal working conditions, any monitoring sample proves

positive, sampling should be regularly repeated in the manner specified in the preceding paragraph, whilst at the same time the cause of the contamination should be sought.

Responsibility for carrying out monitoring

The employer is directly responsible for ensuring that this monitoring is carried out in accordance with the procedures laid down (in particular concerning the technique, media, dates) as well as the special procedures.

Interpretation of results with regard to action

Within a minimum lapse of time as required for carrying out the analyses, the results of the workplace checks should be sent to those responsible for information and, as necessary, for implementation of corrective action.

Recording of monitoring results

These results should be kept in one or more registers or card indexes by both the head of service in question and by the works' medical officer. Extracts may be transferred to other special documents such as personal exposure records, work operations records or medical records. Should a department terminate its activities, these registers or monitoring records should be kept by the plant management. Should the plant terminate its activities, these registers or records should be kept by the corresponding management offices of the company. If the company should go out of business, the records should be transmitted to the appropriate agency of the competent government authority.

Results shall be made available to the competent authority as required.

Information of workers

The results of monitoring checks should be made available to the workers directly concerned; they should also be informed directly of any results indicating abnormal contamination and of measures taken or to be taken to prevent recurrences. Such information should also be made available to members of the safety and health committee of the enterprise.

4.2 Biological monitoring

Where carcinogenic agents are used, working conditions should be evaluated in regard to hazards and decisions made as to the best techniques available for evaluating personal contamination. This may be done through the determination of the carcinogenic substances in question or their metabolites, as the case may be, in samples of urine, blood, stools and expired air.

Biological procedures

It should be ascertained whether suitable procedures have been published in the literature. If not, information should be sought from the laboratories mentioned above that carry out the workplace monitoring, or from appropriate authorities, international organisations or universities in order to find out if techniques are available.

Examinations should be carried out by a qualified laboratory to be designated with the agreement of the industrial medical officer, and which may or may not form part of the plant or the company.

Monitoring periodicity

Based on the nature of the work done by each person in question, a decision should be taken by, or in consultation with, the industrial medical officer as to frequency of testing. This should be reconsidered in case of any modification of processes or introduction of new processes. In the event of abnormal contamination revealed by environmental samples or in the event of a technical accident or incident, special personal measurements should be carried out systematically. In addition, the medical officer should decide on any personal checks he deems useful.

Interpretation of results with regard to action

The data concerning the results of the medical examinations and the biological tests should be normally covered by medical secrecy. However, the detection of abnormal exposure or contamination should lead to a prompt search for the causative factors, and to the implementation of technical modifications or other measures, such as improved personal hygiene, needed to rectify the situation.

Recording the results of personal monitoring checks

Monitoring results should be maintained in two forms:

- collectively; since the results when grouped together make it possible to study environmental or workplace contamination and the trend in this contamination; and,

- individually; together with all the other personal records resulting from the medical supervision of the workers,

These documents should be kept in the same manner as all other personal medical supervision records (see section 5).

Information of workers

The medical officer should personally inform the individual worker of the results of these examinations and environmental monitoring. When the results are not satisfactory, he should enter into any appropriate discussions with the person concerned.

5. PERSONNEL ADMINISTRATION

5.1 Choice of personnel

In order to organise effectively, the appropriate preventive measures a list of workplaces covered by the measures laid down in this guide should be established. A special selection procedure should be applied for all categories of workers to be assigned to these places, including heads of service, engineers and line management, supervisors and workers. Whenever possible workers employed by external contractors should not be assigned at these workplaces. Also, work of this type should not be allocated to a worker as his first job in the plant.

Depending on the severity of the hazards involved, workers allocated to these workplaces should be selected for their personal qualities, which should include technical competence, conscientiousness, well-balanced personality, team spirit, good personal hygiene and a perfect command of the language.

5.2 Informing workers

Personnel assigned directly or occasionally to this kind of work should be adequately informed as to the nature of specific hazard, the reasons for the safety measures applied, the effects of work procedures and the form of medical supervision. This information shall include, but not be limited to, the carcinogenic risk. Other hazardous properties such as explosiveness, flammability, acute, chronic and other toxic effects should also be adequately identified.

A briefing should take place before assignment and regularly thereafter. It should include essential basic data on signing-on; a regular repetition of the initial brief and presentation of any newly available information; the results of measurements of group contamination and, individually, the results of measurements of personal exposure (where these measurements are possible), together with any comments necessary to draw relevant conclusions; and details of any incidents that may have occurred.

5.3 Labour turnover

The competence needed for normal operations and for handling incidents can be best achieved if the workforce is stable; this is also a prerequisite of adequate medical supervision. To comply with the provisions of the ILO Recommendation concerning prevention and control of occupational hazards caused by carcinogenic substances and agents regarding the reduction of a number of workers exposed to carcinogens, it is desirable to have as low a labour turnover as possible. These considerations refer equally to intermittent workers such as maintenance personnel, as well as to workers employed by external contractors where these are necessary. It is to be noted that the availability of a sufficient number of competent and well-trained workers has a bearing on the safe operation of an installation. The same considerations apply to workers employed by external contractors.

5.4 Lists of workers

Lists of workers directly assigned to this type of work or employed occasionally on such jobs should be drawn up and kept as indicated under section 7.1.

6. MEDICAL SUPERVISION

6.1 Special medical examinations

Special medical supervision comprises a number of individual examinations intended to:

- determine suitability for the work;
- monitor, individually, the level of exposure (see section 4.2); and
- provide detection of any early deviation from normal health or biological changes.

It covers workers employed on or assigned to a specific workplace and it is an essential factor in helping the medical officer to decide on a worker's suitability for a specified job prior to assignment and regularly thereafter.

The nature of the examinations required for each of the objectives indicated above and the intervals between them should be decided upon by a physician. The examination procedure will depend on the product in question and, if necessary, on the type of work involved. Moreover, examinations may be modified to suit the worker's individual characteristics. The physician should also determine such examinations as may be desirable after a worker has left one of these assignments, and all possible measures should be taken to facilitate the implementation of these examinations.

In deciding the examinations to be carried out, consideration should be given to the latest trends and available knowledge concerning this type of medical supervision.

Considerations of medical secrecy should be taken into account.

Interpretation of these results is the responsibility of the medical officer, checks being made where necessary.

Decisions concerning fitness for work resulting from the interpretation of these results should also be a medical responsibility. Any technical defects that may be highlighted following these medical examinations (for example, individual overexposure) should be immediately brought to the attention of those having technical responsibility for the plant. Correction of defects is the responsibility of the technical personnel.

6.2 Information to be supplied to the responsible physician

Basic technical information

The medical officer should be kept informed systematically of any plans for start-up or modification of a process or the introduction of new chemicals into the workplace.

Operational information

The medical officer should be immediately informed of any incident, breakdown or failure or any unusual operation that might result in abnormal exposure in order that such information may be recorded for the individual worker.

Information on monitoring results

The results of monitoring of the environment, of waste and of products, etc., should be sent in writing to the medical officer.

Information concerning the workers

The medical officer should receive routine information on absences from work due to illness amongst workers in these workplaces. Workers should also have access to the medical officer to report symptoms or signs of ill-health. The medical officer should also attempt to record information as to employee's use of tobacco, alcohol and prolonged medication. Workers should not return to these posts after illness until they have undergone a medical examination and the approval of the medical officer has been obtained.

6.3 Assignment to specified workplaces

No worker should be assigned to a new post nor continue to work in a specified workplace, nor resume his work in such places after an absence due to illness, unless he produces a fitness certificate delivered by the industrial medical officer.

6.4 Personal work logbook

Any person having worked in one of the specified workplaces should receive, when he finishes work at the plant, a document which contains:

- the dates on which he started work and left the plant;
- the dates on which he was assigned to and finished work at the workplaces under consideration, together with a definition of the work involved and a statement as to the carcinogenic agent involved (chemical as well as trade name);
- recommendations as to future medical surveillance including special bioassay measurements where appropriate.

7. REGISTERS AND RECORDING

The registers and documents referred to below are intended to provide information on the magnitude of the exposed industrial population and on the technological process involving a risk of occupational cancer; to keep under surveillance the various aspects of preventive and protective action taken in this connection; and to improve knowledge on occupational cancer.

These registers and documents should be kept up to date in a special file in the personnel department of the enterprise. A copy should be made available to the medical service in order to permit the degree of biological protection provided by the preventive measures to be assessed and to discover any untoward health effect in the exposed workers.

Additionally, it would be useful for national authorities to have some system of national register with the object of recording the name of exposed persons, the results of technical monitoring, medical examinations and laboratory tests performed on these workers. This would allow for both the competent authority and selected scientific workers to keep a close watch on the magnitude of the problem of occupational cancer in the country, on the level of risk involved in the various types of exposure, the dose-response relationship and the effectiveness of preventive action. In this way, increased knowledge of the various aspects of occupational cancer epidemiology can be gained.

7.1 Technical files

A list of all workers employed on processes using carcinogenic agents should be drawn up, kept up to date and held indefinitely. This list should cover workers of all categories; if appropriate, it may also cover persons working regularly in the immediate neighbourhood who might be subject to contamination due to atmospheric pollution.

The list should at least indicate:

- the identity of each worker;
- the dates of the beginning and end of his assignment;
- the workplace(s) held and the nature of his job;
- specific substances used or formed in the process.

An appended document should contain:

- the results of group exposure measurements;
- technical incidents; and
- technical modifications that may have a relationship with the level of exposure.

7.2 Medical files

The following personal data should be systematically attached to the normal medical records of each person on the lists drawn up in accordance with the previous paragraph; they may either be added to the normal medical record or be contained in a special medical record appended to the normal file:

- data about assignment, and workplace;
- dates, duration and causes of absences;
- dates and results of personal exposure measurements;
- dates and results of specific medical supervision and detection examinations.

A document should collate the results of the specific individual examinations to provide material for an over-all study.

The results of various group measurements should be filed by the medical officer and kept in a form in which they can be used for each individual case or for an over-all study.

These documents should be drawn up under the responsibility of the medical officer and kept for at least 30 years. Should the plant close down, they should be sent to the company's central medical service, due consideration being paid to normal medical secrecy. In the event of the company ceasing to trade, the records should be sent to the appropriate agency of the competent authority. A copy of these various personal medical documents should be given to the workers in question on request.

APPENDIX 1[1]

Carcinogenic substances* and agents

GROUP 1 - Contact should be avoided

2-naphthylamine
nitrosamines (dialkyl)
benzidine
4-aminodiphenyl
2-acetylaminofluorene
2-nitronaphthylamine
4-dimethylaminoazobenzene
4-nitrodiphenyl
methylnitrosourea (MNU)
bis(chloromethyl) ether

*Use caution concerning any derivatives of substances possessing a carcinogenic risk. Although some are considered to be non-carcinogenic, such as the sulfonated derivatives of aromatic amines, extreme care should be exercised until results are demonstrated.

GROUP 2 - Exposures should be limited through the application of stringent protective measures

1-naphthylamine**
propane sultone
asbestos
vinyl chloride
ionising radition and radioactive substances
methylchloromethyl ether**
diazomethane
1,1-dimethylhydrazine
benzene
β-propiolactone

**With these compounds, as with many others, there is difficulty in determining whether the basic chemical or its impurities (or both) is the active agent(s). Until such information is available, both the chemical and its contaminant(s), i.e., the mixture, must be considered to possess carcinogenic risk.

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[1] The indicative lists given above have been drawn up by the ILO Panel of Consultants as a guide to implementation of the preventive measures referred to in the present document. A number of national lists of toxic substances for which exposure limits are prescribed make reference to carcinogenic substances. The lists will be found together with complementary information in "Occupational exposure limits for airborne toxic substances" (ILO, Occupational Safety and Health Series No. 37).

GROUP 3 - Exposure should be kept to a minimum through the use of the most feasible and applicable controls

inorganic arsenic
nickel carbonyl
4,4'-methylene-bis-o-chloraniline (MOCA)
dimethyl sulfate
3,3'-dichlorobenzidine
o-tolidine
dianisidine
ethylenimine
ethylene thiourea

Materials of complex composition* whose use represents a significant carcinogenic risk

Exposure to be kept at a minimum through the use of technical and personal protective measures.

coal tar
high boiling petroleum residues
cutting mineral oils
shale oil
creosote oil
coal pitch
soot

*Using common terminology. All of these materials are known to have caused cancer in man.

Industrial processes involving significant carcinogenic risk

Exposure should be kept to a minimum through the use of the most feasible and applicable controls.

treatment of chromium ores
treatment of nickel ores
auramine manufacture
magenta manufacture
hematite mining
coke-oven operations
manufacture of isopropyl alcohol
pressing of paraffin wax from petroleum
use of antioxidants and accelerators in the rubber and cablemaking industry

ILO international instruments

Convention 139

CONVENTION CONCERNING PREVENTION AND CONTROL OF OCCUPATIONAL HAZARDS CAUSED BY CARCINOGENIC SUBSTANCES AND AGENTS

The General Conference of the International Labour Organisation,

Having been convened at Geneva by the Governing Body of the International Labour Office, and having met in its Fifty-ninth Session on 5 June 1974, and

Noting the terms of the Radiation Protection Convention and Recommendation, 1960, and of the Benzene Convention and Recommendation, 1971, and

Considering that it is desirable to establish international standards concerning protection against carcinogenic substances or agents, and

Taking account of the relevant work of other international organisations, and in particular of the World Health Organisation and the International Agency for Research on Cancer, with which the International Labour Organisation collaborates, and

Having decided upon the adoption of certain proposals regarding control and prevention of occupational hazards caused by carcinogenic substances and agents, which is the fifth item on the agenda of the session, and

Having determined that these proposals shall take the form of an international Convention,

adopts this twenty-fourth day of June of the year one thousand nine hundred and seventy-four the following Convention, which may be cited as the Occupational Cancer Convention, 1974:

Article 1

1. Each Member which ratifies this Convention shall periodically determine the carcinogenic substances and agents to which occupational exposure shall be prohibited or made subject to authorisation or control, and those to which other provisions of this Convention shall apply.

2. Exemptions from prohibition may only be granted by issue of a certificate specifying in each case the conditions to be met.

3. In making the determinations required by paragraph 1 of this Article, consideration shall be given to the latest information contained in the codes of practice or guides which may be established by the International Labour Office, as well as to information from other competent bodies.

Article 2

1. Each Member which ratifies this Convention shall make every effort to have carcinogenic substances and agents to which workers may be exposed in the course of their work replaced by non-carcinogenic substances or agents or by less harmful

substances or agents; in the choice of substitute substances or agents account shall be taken of their carcinogenic, toxic and other properties.

2. The number of workers exposed to carcinogenic substances or agents and the duration and degree of such exposure shall be reduced to the minimum compatible with safety.

Article 3

Each Member which ratifies this Convention shall prescribe the measures to be taken to protect workers against the risks of exposure to carcinogenic substances or agents and shall ensure the establishment of an appropriate system of records.

Article 4

Each Member which ratifies this Convention shall take steps so that workers who have been, are, or are likely to be exposed to carcinogenic substances or agents are provided with all the available information on the dangers involved and on the measures to be taken.

Article 5

Each Member which ratifies this Convention shall take measures to ensure that workers are provided with such medical examinations or biological or other tests or investigations during the period of employment and thereafter as are necessary to evaluate their exposure and supervise their state of health in relation to the occupational hazards.

Article 6

Each Member which ratifies this Convention—

(a) shall, by laws or regulations or any other method consistent with national practice and conditions and in consultation with the most representative organisations of employers and workers concerned, take such steps as may be necessary to give effect to the provisions of this Convention;

(b) shall, in accordance with national practice, specify the persons or bodies on whom the obligation of compliance with the provisions of this Convention rests;

(c) undertakes to provide appropriate inspection services for the purpose of supervising the application of this Convention, or to satisfy itself that appropriate inspection is carried out.

Article 7

The formal ratifications of this Convention shall be communicated to the Director-General of the International Labour Office for registration.

Article 8

1. This Convention shall be binding only upon those Members of the International Labour Organisation whose ratifications have been registered with the Director-General.

2. It shall come into force twelve months after the date on which the ratifications of two Members have been registered with the Director-General.

3. Thereafter, this Convention shall come into force for any Member twelve months after the date on which its ratification has been registered.

Article 9

1. A Member which has ratified this Convention may denounce it after the expiration of ten years from the date on which the Convention first comes into force, by an act communicated to the Director-General of the International Labour Office for registration. Such denunciation shall not take effect until one year after the date on which it is registered.

2. Each Member which has ratified this Convention and which does not, within the year following the expiration of the period of ten years mentioned in the preceding paragraph, exercise the right of denunciation provided for in this Article, will be bound for another period of ten years and, thereafter, may denounce this Convention at the expiration of each period of ten years under the terms provided for in this Article.

Article 10

1. The Director-General of the International Labour Office shall notify all Members of the International Labour Organisation of the registration of all ratifications and denunciations communicated to him by the Members of the Organisation.

2. When notifying the Members of the Organisation of the registration of the second ratification communicated to him, the Director-General shall draw the attention of the Members of the Organisation to the date upon which the Convention will come into force.

Article 11

The Director-General of the International Labour Office shall communicate to the Secretary-General of the United Nations for registration in accordance with Article 102 of the Charter of the United Nations full particulars of all ratifications and acts of denunciation registered by him in accordance with the provisions of the preceding Articles.

Article 12

At such times as it may consider necessary the Governing Body of the International Labour Office shall present to the General Conference a report on the working of this Convention and shall examine the desirability of placing on the agenda of the Conference the question of its revision in whole or in part.

Article 13

1. Should the Conference adopt a new Convention revising this Convention in whole or in part, then, unless the new Convention otherwise provides—

(a) the ratification by a Member of the new revising Convention shall *ipso jure* involve the immediate denunciation of this Convention, notwithstanding the provisions of Article 9 above, if and when the new revising Convention shall have come into force;

(b) as from the date when the new revising Convention comes into force this Convention shall cease to be open to ratification by the Members.

2. This Convention shall in any case remain in force in its actual form and content for those Members which have ratified it but have not ratified the revising Convention.

Article 14

The English and French versions of the text of this Convention are equally authoritative.

Recommendation 147

RECOMMENDATION CONCERNING PREVENTION AND CONTROL OF OCCUPATIONAL HAZARDS CAUSED BY CARCINOGENIC SUBSTANCES AND AGENTS

The General Conference of the International Labour Organisation,

Having been convened at Geneva by the Governing Body of the International Labour Office, and having met in its Fifty-ninth Session on 5 June 1974, and

Noting the terms of the Radiation Protection Convention and Recommendation, 1960, and of the Benzene Convention and Recommendation, 1971, and

Considering that it is desirable to establish international standards concerning protection against carcinogenic substances or agents, and

Taking account of the relevant work of other international organisations, and in particular of the World Health Organisation and the International Agency for Research on Cancer, with which the International Labour Organisation collaborates, and

Having decided upon the adoption of certain proposals regarding control and prevention of occupational hazards caused by carcinogenic substances and agents, which is the fifth item on the agenda of the session, and

Having determined that these proposals shall take the form of a Recommendation,

adopts this twenty-fourth day of June of the year one thousand nine hundred and seventy-four the following Recommendation, which may be cited as the Occupational Cancer Recommendation, 1974:

I. General Provisions

1. Every effort should be made to replace carcinogenic substances and agents to which workers may be exposed in the course of their work by non-carcinogenic substances or agents or by less harmful substances or agents; in the choice of substitute substances or agents account should be taken of their carcinogenic, toxic and other properties.

2. The number of workers exposed to carcinogenic substances or agents and the duration and degree of such exposure should be reduced to the minimum compatible with safety.

3. (1) The competent authority should prescribe the measures to be taken to protect workers against the risks of exposure to carcinogenic substances or agents.

(2) The competent authority should keep the measures prescribed up to date, taking into account the codes of practices or guides which may be established by the International Labour Office and the conclusions of meetings of experts which may be convened by the International Labour Office, as well as information from other competent bodies.

4. (1) Employers should make every effort to use work processes which do not cause the formation, and particularly the emission in the working environment, of carcinogenic substances or agents, as main products, intermediates, by-products, waste products or otherwise.

(2) Where complete elimination of a carcinogenic substance or agent is not possible, employers should use all appropriate measures, in consultation with the workers and their organisations and in the light of advice from competent sources, including occupational health services, to eliminate exposure or reduce it to a minimum in terms of numbers exposed, duration of exposure and degree of exposure.

(3) In cases to be determined by the competent authority, the employer should make arrangements for the systematic surveillance of the duration and degree of exposure to carcinogenic substances or agents in the working environment.

(4) Where carcinogenic substances or agents are transported or stored, all appropriate measures should be taken to prevent leakage or contamination.

5. Workers and others involved in occupational situations in which the risk of exposure to carcinogenic substances or agents may occur should conform to the safety procedures laid down and make proper use of all equipment furnished for their protection or the protection of others.

II. Preventive Measures

6. The competent authority should periodically determine the carcinogenic substances and agents to which occupational exposure should be prohibited or made subject to authorisation or control, and those to which other provisions of this Recommendation apply.

7. In making such determinations the competent authority should give consideration to the latest information contained in the codes of practice or guides which may be established by the International Labour Office, and in the conclusions of meetings of experts which may be convened by the International Labour Office, as well as to information from other competent bodies.

8. The competent authority may permit exemptions from prohibition by issue of a certificate specifying in each case—

(a) the technical, hygiene and personal protection measures to be applied;

(b) the medical supervision or other tests or investigations to be carried out;

(c) the records to be maintained; and

(d) the professional qualifications required of those dealing with the supervision of exposure to the substance or agent in question.

9. (1) For substances and agents subject to authorisation or control, the competent authority should—

(a) secure the necessary advice, particularly as regards the existence of substitute products or methods and the technical, hygiene and personal protection measures to be applied, as well as the medical supervision or other tests or investigations to be carried out before, during and after assignment to work involving exposure to the substances or agents in question;

(b) require the institution of such measures as are appropriate.

(2) The competent authority should further establish the criteria for determining the degree of exposure to the substances or agents in question, and where appropriate should specify levels as indicators for surveillance of the working environment in connection with the technical preventive measures required.

10. The competent authority should keep the determination of carcinogenic substances and agents made in pursuance of this Part of this Recommendation up to date.

III. Supervision of Health of Workers

11. Provision should be made, by laws or regulations or any other method consistent with national practice and conditions, for all workers assigned to work involving exposure to specified carcinogenic substances or agents to undergo as appropriate—

(a) a pre-assignment medical examination;

(b) periodic medical examinations at suitable intervals;

(c) biological or other tests and investigations which may be necessary to evaluate their exposure and supervise their state of health in relation to the occupational hazards.

12. The competent authority should ensure that provision is made for appropriate medical examinations or biological or other tests or investigations to continue to be available to the worker after cessation of the assignment referred to in Paragraph 11 of this Recommendation.

13. The examinations, tests and investigations provided for in Paragraphs 11 and 12 of this Recommendation should be carried out as far as possible in working hours and should be free of cost to the workers.

14. If as the result of any action taken in pursuance of this Recommendation it is inadvisable to subject a worker to further exposure to carcinogenic substances or agents in that worker's normal employment, every reasonable effort should be made to provide such a worker with suitable alternative employment.

15. (1) The competent authority should establish and maintain, where practicable and as soon as possible, in association with individual employers and representatives of workers, a system for the prevention and control of occupational cancer including—

(a) the institution, maintenance, preservation and transfer of records; and

(b) exchange of information.

(2) In establishing such a system of records and exchange of information, account should be taken of the assistance which may be provided by international and national organisations, including organisations of employers and workers, and by individual employers.

(3) In the case of closure of an undertaking, records and information held in compliance with this Paragraph should be dealt with in accordance with the directions of the competent authority.

(4) In any country in which the competent authority does not establish such a system of records and information, the employer, in consultation with representatives of workers, should make every effort to attain the objectives of this Paragraph.

IV. Information and Education

16. (1) The competent authority should promote epidemiological and other studies and collect and disseminate information relevant to occupational cancer risks, with the assistance as appropriate of international and national organisations, including organisations of employers and workers.

(2) It should endeavour to establish the criteria for determining the carcinogenicity of substances and agents.

17. The competent authority should draw up suitable educational guides for both employers and workers on substances and agents liable to give rise to occupational cancer.

18. Employers should seek information, especially from the competent authority, on carcinogenic hazards which may arise with regard to any substance or agent introduced or to be introduced into the undertaking; when a carcinogenic potential is suspected, they should decide in consultation with the competent authority on the additional studies to be carried out.

19. Employers should ensure that in the case of any substance or agent which is carcinogenic there is at the workplace an appropriate indication to any worker who may be liable to exposure of the danger which may arise.

20. Employers should instruct their workers before assignment and regularly thereafter, as well as on introduction of a new carcinogenic substance or agent, on the dangers of exposure to carcinogenic substances and agents and on the measures to be taken.

21. Employers' and workers' organisations should take positive action to carry out programmes of information and education with regard to the hazards of occupational cancer, and should encourage their members to participate fully in programmes of prevention and control.

V. Measures of Application

22. Each Member should—

(a) by laws or regulations or any other method consistent with national practice and conditions, take such steps, including the provision of appropriate penalties, as may be necessary to give effect to the provisions of this Recommendation;

(b) in accordance with national practice, specify the bodies or persons on whom the obligation of compliance with the provisions of this Recommendation rests;

(c) provide appropriate inspection services for the purpose of supervising the application of the provisions of this Recommendation, or satisfy itself that appropriate inspection is carried out.

23. In applying the provisions of this Recommendation, the competent authority should consult with the most representative organisations of employers and workers concerned.