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Proposal for a

COUNCIL DIRECTIVE

on the approximation of Member States' laws, regulations and administrative provisions on the protection of the health of workers occupationally exposed to vinyl chloride monomer

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(submitted to the Council by the Commission)

M E M O R A N D U M

on the draft proposal for a Council Directive on the approximation of Member States' laws, regulations and administrative provisions on the protection of the health of workers occupationally exposed to vinyl chloride monomer.

Chloroethylene or vinyl chloride monomer (VCM) is a gaseous product and has been known for almost 150 years.

Its polymer (PVC), which has been manufactured on a commercial scale for over 40 years, forms together with polyethylene a major sector of the chemical industry.

In 1975 29 chemical companies in the countries of the European Community produced 5 million tonnes of vinyl chloride (VCM) in 26 different factories and 4.5 million tonnes of the polymer (PVC) in 35 factories. Of the persons employed in these chemical plants some 10 000 are exposed to vinyl chloride monomer.

Processing into semi-fabricated and finished products is done in some 5 700 plants by approximately 350 000 workers who in 1973 produced goods worth 4 520 million u.a.

Since the commercial production of vinyl chloride (VCM) commenced around 1930, we have known that gaseous vinyl chloride has a narcotic effect. However, only very few cases of acute intoxication have been recorded.

Up to 1966 its chronic toxicity was thought to be low, but since then an increasing number of publications have appeared with reports of health impairment caused by VCM exposure. The first reports were of a narcotic syndrome manifested by asthenic and neurotic symptoms. These were accompanied by digestive and liver troubles or neurovascular and skin diseases. In 1967 cases were reported of acro-osteolysis in connection with Raynaud's syndrome.

This was followed by a marked increase in animal experiments and industrial hygiene monitoring on an international scale. The malignant tumours found in both humans and animals, particularly liver tumours, brought worldwide reaction.

Both national parliaments and the European Parliament, as well as employer and worker organizations held discussions on the problems. The World Health Organizaion dealt with the risk of cancer presented by VCM at a meeting of the International Agency for Research of Cancer held in Lyon on 23-25 June 1974. The same problem was also debated by international experts at the conference on cancer held in Florence in October 1974. At the same time MEDICHEM added the carcinogenicity and genetic effects of this substance to the agenda of its seminar in Milan. Research contracts were awarded by the Ministries of Labour and Social Affairs in the countries concerned with the aim of defining the extent of the hazard and adopting more stringent safety measures.

Various meetings and one seminar were organized by the departments of the Commission during 1974 and 1975.

During this seminar at these meetings, the following areas were defined and correspond to the different health aspects:

A. Workplace
   1) Production of the base product: VCM
      Production of its polymer: PVC
   2) Transformation of the polymerisation products

B. Environmental protection

C. Consumer protection ‡

D. Waste disposal

The conclusions of these meetings and of other work carried out in parallel have led the Commission to propose a directive which the Council has adopted on the 27th July 1976 with regard to the harmonization of the legislation in Member States relative to the limitation of the marketing and use of certain dangerous substances and preprations. (+)

This directive represents the first Community measure aimed at the prohibition of the use of vinyl chloride monomer (VCM) as an aerosol propellent for any purpose.

This Directive also answers the requests made by the European Parliament in the form of two written questions++. It is the result of extensive discussions with independent experts and of two meetings with government experts (19 November 1975 and 8-8 December 1975). Its aim is to define preventive measures in terms of both technology and industrial hygiene which are geared to health protection at work.

+ Directive 76/769/EEC, OJ L 262 of 27.9.1976.
++ European Parliament: written questions Nos 178/75 and 681/75

The Council of the European Communities,

- Having regard to the Treaty establishing the European Economic Community, and in particular Article 100,
- Having regard to the Proposal from the Commission,
- Having regard to the Opinion of the European Parliament,
- Having regard to the Opinion of the Economic and Social Committee,

Whereas in the past VCM has been recognized only as the cause of the generally reversible syndrome known as 'occupational acro-osteolysis';

whereas more recent evidence from epidemological studies and animal experimentation indicates that prolonged and/or repeated exposure to high concentrations of VCM in the atmosphere may cause a 'VCM' syndrome encompassing, in addition to occupational acro-osteolysis, skin diseases such as scleroderma, and liver disorders;

Whereas VCM should also be regarded as a carcinogen which may cause angiosarcoma, a rare malignant tumour which can also occur without any known cause;

Whereas although present-day working conditions are considerably better than those under which the above syndrome formerly occurred, a comparison of protective measures taken by each Member State reveals certain differences and therefore, in the interests of developing an economic and social balance, these national laws, which have a direct effect on the functioning of the common market, should be harmonized and improved;

Whereas the first action should be to take preventive and protective measures based on the latest scientific knowledge, so that the internal concentrations of VCM in the atmosphere in both existing and future factories can be reduced to minimal values;

Whereas medical surveillance of workers in the VCM/PVC industry should be carried out on the basis of the latest medical knowledge in order that the health of workers in this important economic sector of the chemical industry may be protected;

Whereas the urgency of the harmonization of laws in this field is recognized by both sides of industry, both of which took part in the discussion on this specific problem; whereas efforts must therefore be made towards the upward harmonization of laws, regulations and administrative provisions as envisaged in Article 117 of the Treaty;

Whereas it might prove necessary to revise the health protection standards contained in this Directive;

Whereas, to make it easier to adopt the necessary measures, there should be a procedure to ensure close cooperation between the Member States and the Commission within a Committee to amend this Directive in the light of technical progress,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1.1. The object of this Directive is the protection of workers employed in works in which
- vinyl chloride monomer, hereinafter referred to as VCM, is produced, reclaimed, stored, discharged into containers, transported or used in some other way,
- vinyl chloride monomer is converted into unformed vinyl chloride polymers, hereinafter referred to as PVC,

who are exposed to the effects of VCM in their working area.

1.2. This protection shall be ensured by the establishment of:
- limit values for the atmospheric concentration of VCM in the working area;
- measuring and monitoring techniques necessary for this purpose, as well as other preventive measures;
- guidelines for medical surveillance.

Article 2

For the purposes of this Directive:

2.1. The 'working area' means a section of a works with defined boundaries which may comprise one or more workplaces. It is characterized by the fact that the individual worker spends irregular periods of time within it at various workplaces in the course of his duty or duties, that the length of time spent at these individual workplaces cannot be more closely defined, and that further subdivision of the working area into smaller units cannot be made. It is assumed that the individual worker is normally employed in one working area only.

2.2. The 'technical long-term limit value' means the mean concentration of VCM, measured over 1 year, in the atmosphere of a working area which may not be exceeded during exposure to it for 8 hours a day or 40 hours a week.

For practical purposes, limit values for shorter reference periods (i.e. 1 month, week, shift or hour), corresponding to the technical long-term limit value, are given in Annex I.

Article 3

3.1. The fundamental aim of technical monitoring shall be to reduce to below measurable levels the atmospheric concentrations of VCM to which workers are exposed. All working areas in works referred to in Article 1.1. shall therefore be monitored for the presence of VCM.

3.2. For new VCM/PVC works, a maximum atmospheric concentration of 5 ppm, which may not be exceeded, shall be laid down as the technical long-term limit value for VCM.

3.3. For existing VCM/PVC works, a maximum atmospheric concentration of 10 ppm, which may not be exceeded, shall be laid down as the technical long-term limit value for VCM.

3.4. The necessary technical measures with respect to the limiting technical values given under 3.2. and 3.3. shall not in any case result in VCM pollution of the environment outside the works.

Article 4

The atmospheric concentration of VCM in the working area may be monitored by continuous and/or discontinuous methods.

4.1. The technical long-term limit values shall be considered to be complied with if the annual arithmetic mean concentration is found not to exceed this value, with a confidence coefficient of 95% (one-sided test).

4.2. Any measuring system giving a reliable analysis at one-third at least of the technical long-term limit value concentration shall be regarded as suitable.

4.3. If non-selective systems are used for measuring VCM, the total measurement recorded shall be taken as the VCM concentration value.

4.4. Measuring instruments must be calibrated adequately at regular intervals.

4.5. Pending the approval at Community level of a standard method for checking VCM measuring techniques, suitable methods based on the latest state of the art shall be used for calibrating the measuring instruments.

Article 5

One or more measuring points may be set up in a working area, depending on its size.

5.1. Measuring points must be chosen in accordance with the particular characteristics of the works and so designed that the results indicate as accurately as possible the individual VCM level of exposed persons.
This does not necessarily mean that measurements must always be taken with devices worn by exposed persons. Fixed position instruments may also be used provided that the results obtained thereby are representative of the concentration throughout the working area.

5.2. If a number of fixed position measuring points are provided in one working area, the mean of the values from all the points may be regarded as the measurement for the whole working area.

5.3. In all cases of doubt as to whether the results obtained by fixed position measuring instruments are representative of the concentration in the working area, the measuring point for the technical long-term limit value in the working area shall be that point where the risk is greatest.

Personal dosimeters may be used for comparative measurements; where appropriate, the arrangement of the measuring points may be modified.

Article 6

A monitoring system which gives continuous mean values for at least one hour shall be provided to detect abnormal increases in concentration levels caused by technical failures in working areas in works producing VCM/PVC.

6.1. The threshold concentration at which the alarm is triggered shall depend on the measuring system and on operating conditions.

6.2. An increase in VCM concentration shall be regarded as abnormal when it exceeds approximately five times the mean weekly value. In such an event, technical measures to discover the causes shall be taken without delay.

6.3. The alarm threshold shall not, however, be greater than 40 ppm. If this value is exceeded, technical and personal protective measures shall be taken without delay.

Article 7

Appropriate personal protection shall be provided for certain operations (e.g. cleaning of autoclaves, servicing and repairs), during which it cannot be guaranteed that concentrations will be kept below the permitted limit values by means of operational or ventilation measures.

Article 8

Workers shall be informed at regular intervals of the health hazards involved and of the appropriate protective measures to be taken when handling VCM.

Article 9

A register shall be kept of workers employed on operations described in Article 1.1., with particulars of the type and duration of work, and the resulting exposure. A copy of this register shall be given to the industrial medical officer responsible for surveillance, unless the register is kept by the officer himself.

Article 10

Workers employed in working areas referred to in Article 1.1. shall undergo a medical examination by a qualified industrial medical officer on recruitment and also subsequently.

10.1. Without prejudice to national regulations, the industrial medical officer shall determine the frequency and the type of examination to be carried out in each individual case. The necessary guidelines are given in Annex II.

10.2. Medical records and the register provided for in Article 9 shall be kept until the possibility of occupational disease caused by VCM exposure can be excluded.
These records shall form the basis for further prognostic epidemiological surveys which prove necessary, the results of which shall be reported by the Member States to the Commission at three-yearly intervals.

Article 11

11.1. This Directive shall be reviewed at least every two years in the light of developments in technology and occupational medicine.

11.2. A Committee consisting of representatives of the Member States, with a representative of the Commission as Chairman, shall be set up for this purpose.

11.3. The Committee shall draw up its own Rules of Procedure.

Article 12

12.1. Where the procedure laid down in the preceding Article is to be followed, the Chairman shall refer the matter to the Committee, either on his own initiative or at the request of a representative of a Member State.

12.2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its Opinion on such measures within a time limit set by the Chairman according to the urgency of the matter. Forty-one votes shall be required to constitute a majority, the votes of the Member States being weighted in accordance with Article 148(2) of the Treaty. The Chairman shall not vote.

12.3. The Commission shall adopt the measures where they are in accordance with the Opinion of the Committee.

12.4. Where they are not in accordance with the Opinion of the Committee, or if no Opinion is delivered, the Commission shall forthwith propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

12.5. If the Council has not acted within three months of the date of the submission of the proposal, the Commission shall adopt the proposed measures.

Article 13

13.1. Member States shall bring into force the laws, regulations and administrative provisions needed in order to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.

13.2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

Article 14

This Directive is addressed to the Member States.

Statistical basis for the technical long-term limit value

1. Owing to differences in definition the recommended values for the permissible concentration of hazardous substances in the air at the workplace currently vary from country to country.

   This Directive is therefore concerned with a new, statistically defined reference value - the technical long-term limit value, which should be regarded as a mean annual value (Article 2.2.).

2. The limit values for shorter reference periods are based on data obtained by extensive measurement of VCM concentrations in the PVC industry. These results coincide with data for other harmful substances and for other sectors of industry.

   This information can be summarized as follows:

   a) the concentrations distribution of harmful substances can be represented log normally.

   b) the logarithmic variance $\sigma^2(\tau, T)$ is dependent on the mean time for the individual values τ and the assessment period T during which the individual values are obtained.

3. This relationship can be expressed by the following equation:

$$\sigma^2(\tau, T) = \lambda \log (T/\tau).$$

   Given these conditions, a mean ratio of the limit values for shorter reference periods to the long-term limit value can be established:

Table 1

Reference period	Existing plant Limit value in ppm (rounded off)	New plant Limit value in ppm (rounded off)	Short-term value Technical long-term limit value - coefficient -
1 year	10	5	1
1 month	17	8	1.7
1 week	20	10	1.95
8 hours	23	11	2.3
1 hour	26	13	2.55

4. Limit values for shorter reference periods shall be regarded as being within the permitted limits if at least 95 % of the measurement values established over a total period of one year are below the limit values given in Table 1.

Guidelines for medical surveillance

1. Current knowledge indicates that over-exposure to VCM can give rise to the following disorders and diseases:

   - sclerodermatous skin disorders
   - circulatory disorders in the hands and feet (similar to Raynaud's syndrome)
   - acro-osteolysis (in the region of various bone structures and affecting particularly the hand phalanges)
   - liver and spleen fibroses (similar to perilobular fibrosis, known as Banti's syndrome)
   - lung function disorders
   - thrombocytopenia and
   - hepatic angiosarcoma.

2. Medical surveillance should take account of all symptoms and syndromes, with particular emphasis on the area of greatest risk. As far as is known, no symptoms, occurring separately or in combination have been identified as precursors or transitional stages of hepatic sarcoma. As no specific methods of preventive analysis are known for this disease, medical action must include at least the following measures as minimum requirements:

   1) records of the worker's medical and occupational history
   2) clinical examination of the extremities, the skin and the abdomen
   3) X-ray of the hand bones (every two years).

   Further tests, particularly laboratory tests, are desirable. These should be decided by the medical officer in the light of the most recent developments in industrial medicine.

   The following laboratory tests are suggested at present for prognostic epidemiological surveys:

   - urinalysis (glucose, proteins, salts, bile pigments, urobilinogen);
   - erythrocyte sedimentation rate;
   - blood platelet count

- determination of total bilirubin level
- determination of transaminase levels (SGOT, SGPT)
- thymol turbidity test
- alkaline phosphatase level
- determination of cryoglobulin.

3. As in the case of all biological examinations, the results of the tests must be interpreted in the light of the laboratory techniques used and their normal results. Generally speaking, the significance of a functional disorder is revealed by joint consideration of the results obtained with the various methods and by developments in the anomalies observed. As a general rule, abnormal results must be further investigated and, if necessary, additional specialist examinations carried out.

4. The industrial medical officer shall decide in each case whether a worker is suitable for a particular working area.

The industrial medical officer shall also be competent to decide what contra-indications apply.
The most important of these are:

- typical vascular and neurovascular lesions,
- lung function disorders,
- clinical or biological hepatic insufficiency,
- diabetes,
- chronic renal insufficiency,
- thrombocytopenia and hemorrhagic disorders,
- certain chronic skin diseases such as scleroderma,
- abuse of alcohol and/or addiction to drugs.

This list, which is intended merely for guidance, has been drawn up using pathological data obtained from previous retrospective studies.