

Official Journal

of the European Communities

ISSN 0378 - 6978

L 297

Volume 35

13 October 1992

English edition

Legislation

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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 92/72/EEC

of 21 September 1992

on air pollution by ozone

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130s thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas the 1987 fourth Community action programme on the environment ⁽⁴⁾ provides for the possibility of action on photochemical pollution, and in particular pollution by ozone, in view of its harmful effects and the state of knowledge concerning its impact on human health and the environment;

Whereas, in order to protect human health, ozone concentrations in the air should be limited; whereas scientific and technical information needs to be utilized and promoted in order to obtain wider knowledge of this form of pollution and, in future, take effective and appropriate measures to reduce it;

Whereas as complete a knowledge as possible of ozone pollution levels is required in all Member States;

Whereas to obtain this knowledge it is necessary to set up measurement stations to provide data on ozone concentrations in the air;

Whereas in order to obtain results which are comparable in the context of this Directive, the methods used by Member States to determine concentrations need to be equivalent;

Whereas, in view of the special nature of photochemical pollution, the reciprocal exchange of information between Member States and the Commission including, once it is effectively set up, the European Environment Agency ⁽⁵⁾, is essential for a better understanding of the problem;

Whereas the setting of information or warning thresholds at which precautions should be taken by the public will make it possible to limit the impact of pollution episodes on health;

Whereas the numerical values of these levels should be based on the findings of work carried out in the framework of the World Health Organization (WHO), in particular as regards the dose-effect relationships established for the pollutant in question;

Whereas the information collected under this Directive should be regularly evaluated to make it possible to monitor the development of air pollution by ozone and the impact of national and Community provisions to reduce photochemical precursors and establish in the future new provisions concerning ozone and air quality; whereas such evaluation and information should be the subject of a report to be submitted by the Commission as soon as possible and by the end of a period of four years from the date of implementation of this Directive at the latest;

Whereas combating air pollution by ozone may also entail measures to reduce ozone precursors; whereas the Commission must therefore also submit, with the abovementioned report, proposals for controlling air

⁽¹⁾ OJ No C 192, 23. 7. 1991, p. 17.

⁽²⁾ OJ No C 150, 15. 6. 1992, p. 228.

⁽³⁾ OJ No C 49, 24. 12. 1992, p. 1.

⁽⁴⁾ OJ No C 328, 7. 12. 1987, p. 1.

⁽⁵⁾ OJ No L 120, 11. 5. 1990, p. 1.

pollution by ozone and, if necessary, reducing emissions of ozone precursors;

Whereas action by the Community and Member States against photochemical pollution should be coordinated in order for maximum effect to be achieved,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. The purpose of this Directive is to establish a harmonized procedure:

- for monitoring,
- for exchanging information,
- for informing and warning the population,

with regard to air pollution by ozone in order to enable the competent authorities of the Member States and the Commission to obtain wider knowledge of this form of air pollution in the Community, optimize the action needed to reduce ozone formation and guarantee a minimum amount of public information where concentration thresholds as referred to in points 3 and 4 of Annex I are exceeded.

2. For the purposes of this Directive:

- *health protection threshold* means the ozone concentration value given in Annex I, point 1, which should not be exceeded if human health is to be safeguarded in the event of prolonged pollution episodes,
- *vegetation protection thresholds* means the ozone concentration values given in Annex I, point 2, beyond which vegetation may be affected,
- *population information threshold* means the ozone concentration value given in Annex I, point 3, beyond which there are limited, temporary effects on human health in the event of short exposure of particularly sensitive sections of the population and at which steps must be taken by the Member States as laid down in this Directive,
- *population warning threshold* means the ozone concentration value given in Annex I, point 4, beyond which there is a risk to human health in the event of short exposure and at which steps must be taken by the Member States as laid down in this Directive.

Article 2

Each Member State shall designate a body to inform the Commission and to coordinate the implementation of the

harmonized procedure set out in Article 1 (1), and shall forthwith inform the Commission thereof.

Article 3

Member States shall where appropriate designate or establish measuring stations to supply the data necessary for the implementation of this Directive. The number and the location of these stations shall be determined by Member States in compliance with Annex II.

Article 4

1. For the measurement of ozone concentrations, Member States shall use:

- either the reference method specified in Annex V,
- or any other method of analysis shown to produce measurement results equivalent to those obtained using the reference method.

To this end, each Member State shall designate one or more laboratories responsible for evaluating the method used at national level in relation to the reference method in this Directive.

Furthermore, they shall organize at national level intercomparisons between laboratories taking part in the collection and analysis of the data.

2. Once the measuring stations have been established, Member States shall provide the Commission with the following information:

- the method used to determine ozone concentrations and, if it is different from the reference method in this Directive, proof of its equivalence with the latter,
- the geographical coordinates of the measuring stations, a description of the area covered by the stations, and the site-selection criteria,
- the results of any indicative measurement programmes carried out under the provisions of Annex II, point 2.

3. The Commission may organize, on a Community scale, intercomparison programmes between laboratories referred to in paragraph 1.

Article 5

In the event of the values given in Annex I, points 3 and 4, being exceeded, the Member States shall take the necessary steps for the public to be informed (e.g. by means of radio, television and the press), in accordance with Annex IV.

Article 6

1. As from 1 January 1995, Member States shall provide the Commission with the following information no later than six months following the annual reference period:

- the maximum, the median and the 98th percentile of the mean values over one hour and eight hours recorded during the year in each measuring station; the percentiles shall be calculated in accordance with the method given in Annex III,
- the number, date and duration of periods during which the thresholds laid down in Annex I, points 1 and 2, are exceeded.

A Member State may additionally submit information based on percentile 99,9.

2. Where the information threshold laid down in Annex I, point 3, is exceeded in the course of a calendar month, Member States shall inform the Commission by the end of the following month at the latest, of:

- the date(s) of occurrence(s),
- the duration thereof,
- the maximum hourly concentration recorded during each occurrence.

3. Where the warning threshold laid down in Annex I, point 4, is exceeded in the course of a week (from Monday to the following Sunday), Member States shall inform the Commission, by the end of the following month at the latest, of:

- the date(s) of the occurrence(s),
- the duration,
- the maximum hourly concentration during each occurrence.

This information shall be supplemented by relevant data which might explain the reasons for the occurrence.

4. Where the data referred to in paragraphs 1, 2 and 3 are available in the Member States for periods preceding the date referred to in Article 9, Member States shall send them to the Commission at the latest when they send the data relating to the first reference period. The duration of the reference period shall not exceed five years.

5. All the data referred to in paragraphs 1 to 4 shall be forwarded by the Commission to the European Environment Agency as soon as it is operational.

Article 7

The Commission shall regularly, and in any event at least once a year, evaluate the data collected under this Directive. The findings of that evaluation shall be forwarded to the Member States.

In order to coordinate actions by the Community and the Member States against photochemical pollution, the Commission shall organize, together with Member States, which shall involve the responsible body referred to in Article 2, consultations on the problem of photochemical air pollution, relating in particular to:

- the development of ozone concentrations throughout the Member States and whether any of the episodes recorded are of a transboundary nature,
- measures and programmes planned by the Member States to reduce air pollution by ozone,
- experience and knowledge concerning the problem of photochemical pollution.

Article 8

As soon as possible and no later than the end of a four-year period following the implementation of this Directive, the Commission shall submit to the Council a report on the information collected and on the evaluation of photochemical pollution in the Community. This report shall be accompanied by any proposals the Commission deems appropriate on the control of air pollution by ozone and, if necessary, for reducing emissions of ozone precursors.

Article 9

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 18 months after its adoption. They shall forthwith inform the Commission thereof.

When Member States adopt such provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedures for making such a reference shall be laid down by the Member States.

Article 10

This Directive is addressed to the Member States.

Done at Brussels, 21 September 1992.

For the Council

The President

J. GUMMER

ANNEX I

THRESHOLDS FOR OZONE CONCENTRATIONS IN THE AIR (*)

(The values are expressed in $\mu\text{g O}_3/\text{m}^3$. The volume must be standardized at the following conditions of temperature and pressure: 293 °K and 101,3 kPa)

1. **Health protection threshold**
110 $\mu\text{g}/\text{m}^3$ for the mean value over eight hours (**)
2. **Vegetation protection thresholds**
200 $\mu\text{g}/\text{m}^3$ for the mean value over one hour
65 $\mu\text{g}/\text{m}^3$ for the mean value over 24 hours
3. **Population information threshold**
180 $\mu\text{g}/\text{m}^3$ for the mean value over one hour
4. **Population warning threshold**
360 $\mu\text{g}/\text{m}^3$ for the mean value over one hour

(*) Concentrations must be measured continuously.

(**) The mean over eight hours is a non-overlapping moving average; it is calculated four times a day from the eight hourly values between 0 and 9.00, 8.00 and 17.00, 16.00 and 1.00, 12.00 and 21.00. For the information to be provided pursuant to Article 6 (1), first indent, the mean over eight hours is a simple moving average, calculated each hour h from the eight hourly values between h and h-9.

ANNEX II

MONITORING OF OZONE CONCENTRATIONS

1. The purpose of measuring ozone concentrations in ambient air is to assess:
 - (i) as closely as possible the individual risk of exposure of human beings to values in excess of the health protection thresholds;
 - (ii) the exposure of vegetation (e.g. forests, natural ecosystems, crops, horticulture) to the values given in Annex I.
2. The measurement points must be located at geographically and climatologically representative sites where:
 - (i) the risk of approaching or exceeding the thresholds laid down in Annex I is the highest;
 - (ii) it is likely that one of the targets referred to in paragraph 1 is exposed.

At places where the Member States do not have information concerning the sites referred to in (i) and (ii), they must carry out indicative measurement programmes in order to determine the siting of the measurement points to supply the data necessary for the implementation of this Directive.

3. Member States must establish or designate additional measurement points in order to:
 - (i) contribute towards the identification and description of the formation and transport of ozone and its precursors;
 - (ii) monitor changes in ozone concentrations in areas affected by background pollution.

Mandatory measurement of oxides of nitrogen and that recommended for volatile organic compounds be carried out in order to provide information on ozone formation, to monitor transboundary flows of volatile organic compounds and to make it possible to identify links between the different pollutants.

4. The final reading of the ozone measurement instruments must be carried out in such a way that the mean values over one hour and eight hours can be calculated, in accordance with Annexes I and III.

ANNEX III

CALCULATION OF THE MEASUREMENT RESULTS FOR THE ANNUAL REFERENCE PERIOD

1. Concentrations must be measured continuously.
2. The annual reference period will begin on 1 January and end on 31 December in any given calendar year.
3. For the validity of the calculation of the percentiles ⁽¹⁾ to be recognized, 75 % of the possible values must be available and, as far as possible, distributed uniformly throughout the period in question for the particular measurement site. If that is not the case, this fact must be mentioned when the results are communicated.

The calculation of the 50th (98th) percentile on the basis of the values recorded throughout the year must be carried out as follows: the 50th (98th) percentile must be calculated from the values actually measured. The measured values must be rounded off to the nearest $\mu\text{g}/\text{m}^3$. All the values are to be listed in increasing order for each site:

$$X_1 \leq X_2 \leq X_3 \leq \dots \leq X_k \leq \dots \leq X_{N-1} \leq X_N.$$

The 50th (98th) percentile is the value of k , to be calculated from the following formula:

$$k = 0,50(0,98) \cdot N$$

N being the number of values actually measured. The value of $0,50(0,98) \cdot N$ must be rounded off to the nearest whole number.

ANNEX IV

The following information must be circulated on a sufficiently large scale as soon as possible to enable the population concerned to take all appropriate preventive protective action. The information in question must be communicated to the media.

List of minimum details to be supplied to the public in the event of the occurrence of high ozone levels in the air

1. Date, hour and place of the occurrence of concentrations in excess of the thresholds defined in Annex I, points 3 and 4.
2. Reference to the type(s) of Community values exceeded (information or warning).
3. Forecasts: — change in concentrations (improvement, stabilization or deterioration),
— geographical area concerned,
— duration.
4. Population concerned.
5. Precautions to be taken by the population concerned.

⁽¹⁾ The median must be calculated as the 50th percentile.

ANNEX V

REFERENCE METHOD OF ANALYSIS TO BE USED FOR THE PURPOSES OF THIS DIRECTIVE

The reference method of analysis to be used in the context of this Directive to determine ozone is the UV absorption method. This method is being standardized by the ISO. Once the latter has published the standard in question, the method described therein will constitute the reference method in this Directive.

The following points must be taken into consideration when the measurement methods and instruments are used by the Member States in the field:

1. the conformity of the operating characteristics of the measurement instrument with those indicated by the manufacturer, in particular background noise, response time and linearity, must be verified initially in the laboratory and in the field;
2. the instrument must be totally calibrated regularly, using a reference UV photometer as recommended by the ISO;
3. in the field, the instruments must be calibrated regularly, e.g. every 23 or 25 hours. In addition, the validity of the calibration must be verified by regularly operating in parallel an instrument calibrated in accordance with paragraph 1.
If the instrument inlet filter is changed before calibration, calibration must be carried out after an appropriate period of exposure (from 30 minutes to several hours) of the filter to ambient ozone concentrations;
4. the sampling head must be placed at least 1 m away from vertical screens in order to avoid any screening effect;
5. the sampling head opening must be protected against rain and insects.
No prefilter is to be used;
6. sampling must not be influenced by adjoining installations (air-conditioning or data-transmission equipment);
7. the sampling line must be of inert material (e.g. glass, PTFE, stainless steel) which is not affected by the presence of ozone. It must be exposed beforehand to appropriate ozone concentrations;
8. the sampling line between the sampling head and the analysis instrument must be as short as possible. In particular, the time taken for the gas volume sample to pass through the sampling line must be as short as possible (e.g. of the order of a few seconds in the presence of other reagents such as NO);
9. condensation in the sampling line must be avoided;
10. the sampling line must be cleaned regularly, taking local conditions into account;
11. the sampling line must be tight and the flow rate must be inspected regularly;
12. sampling must not be influenced by gas discharges from the instrument or from the calibration system;
13. all necessary precautions must be taken to prevent temperature variations from producing measurement errors.

COUNCIL DIRECTIVE 92/73/EEC

of 22 September 1992

widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas differences currently existing between the provisions laid down by law, regulation or administrative action in the Member States may hinder trade in homeopathic medicinal products within the Community and lead to discrimination and distortion of competition between manufacturers of these products;

Whereas the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health;

Whereas, despite considerable differences in the status of alternative medicines in the Member States, patients should be allowed access to the medicinal products of their choice, provided all precautions are taken to ensure the quality and safety of the said products;

Whereas the anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated, as regards registration and marketing authorization, in the same way as homeopathic medicinal products;

Whereas the provisions of Directive 65/65/EEC ⁽⁴⁾ and the Second Directive 75/319/EEC ⁽⁵⁾, are not always appropriate for homeopathic medicinal products;

Whereas homeopathic medicine is officially recognized in certain Member States but is only tolerated in other Member States;

Whereas, even if homeopathic medicinal products are not always officially recognized, they are nevertheless prescribed and used in all Member States;

Whereas it is desirable in the first instance to provide users of these medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety;

Whereas the rules relating to the manufacture, control and inspection of homeopathic medicinal products must be harmonized to permit the circulation throughout the Community of medicinal products which are safe and of good quality;

Whereas, having regard to the particular characteristics of these medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those traditional homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient;

Whereas, however, the usual rules governing the authorization to market medicinal products should be applied to homeopathic medicinal products placed on the market with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect; whereas, in particular, those Member States which have a homeopathic tradition should be able to apply particular rules for the evaluation of the results of tests and trials intended to establish the safety and efficacy of these medicinal products provided that they notify them to the Commission,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope

Article 1

1. For the purposes of this Directive, 'homeopathic medicinal product' shall mean any medicinal product

⁽¹⁾ OJ No C 108, 1. 5. 1990, p. 10 and OJ No C 244, 19. 9. 1991, p. 8.

⁽²⁾ OJ No C 183, 15. 7. 1991, p. 322 and OJ No C 241, 21. 9. 1992.

⁽³⁾ OJ No C 332, 31. 12. 1990, p. 29.

⁽⁴⁾ OJ No 22, 9. 2. 1965, p. 369/65. Directive as last amended by Directive 89/341/EEC (OJ No L 142, 25. 5. 1989, p. 11).

⁽⁵⁾ OJ No L 147, 9. 6. 1975, p. 13. Directive as last amended by Directive 89/341/EEC (OJ No L 142, 25. 5. 1989, p. 11).

prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the *European Pharmacopoeia* or, in absence thereof, by the pharmacopoeias currently used officially in the Member States.

2. A homeopathic medicinal product may also contain a number of principles.

Article 2

1. The provisions of this Directive shall apply to homeopathic medicinal products for human use, to the exclusion of homeopathic medicinal products prepared in accordance with a magistral or an officinal formula as defined in Article 1 (4) and (5) of Directive 65/65/EEC and of homeopathic medicinal products which satisfy the criteria laid down in Article 2 (4) of the said Directive.

2. The medicinal products referred to in paragraph 1 shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.

CHAPTER II

Manufacture, control and inspection

Article 3

The provisions of Chapter IV of Directive 75/319/EEC shall apply to the manufacture, control, import and export of homeopathic medicinal products.

Article 4

The supervision measures and the sanctions provided for in Chapter V of Directive 75/319/EEC shall apply to homeopathic medicinal products, together with Articles 31 and 32 of the same Directive.

However, the proof of therapeutic efficacy referred to in Article 28 (1) (b) of the same Directive shall not be required for homeopathic medicinal products registered in accordance with Article 7 of this Directive or, where appropriate, admitted in accordance with Article 6 (2).

Article 5

Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic medicinal products manufactured and marketed within the Community, and in particular the information referred to in Articles 30 and 33 of Directive 75/319/EEC.

CHAPTER III

Placing on the market

Article 6

1. Member States shall ensure that homeopathic medicinal products manufactured and placed on the market within the Community are registered or authorized in accordance with Articles 7, 8 and 9. Each Member State shall take due account of registrations and authorizations previously granted by another Member State.

2. A Member State may refrain from establishing a special, simplified registration procedure for the homeopathic medicinal products referred to in Article 7. A Member State applying this provision shall inform the Commission accordingly. The Member State concerned shall, by 31 December 1995 at the latest, allow the use in its territory of homeopathic medicinal products registered by other Member States in accordance with Articles 7 and 8.

3. Advertising of the homeopathic medicinal products referred to in paragraph 2 of this Article and in Article 7 (1) shall be subject to the provisions of Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use ⁽¹⁾, with the exception of Article 2 (1) of that Directive.

However, only the information specified in Article 7 (2) may be used in the advertising of such medicinal products.

Moreover, each Member State may prohibit in its territory any advertising of the homeopathic medicinal products referred to in paragraph 2 and in Article 7 (1).

Article 7

1. Only homeopathic medicinal products which satisfy all of the following conditions may be subject to a special, simplified registration procedure:

- they are administered orally or externally,
- no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto,
- there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

At the time of registration, Member States shall determine the classification for the dispensing of the medicinal product.

⁽¹⁾ OJ No L 113, 30. 4. 1992, p. 13.

2. In addition to the clear mention of the words 'homeopathic medicinal product', the labelling and, where appropriate, package insert for the medicinal products referred to in paragraph 1 shall bear the following, and no other, information:

- the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 1 (1),
- name and address of the person responsible for placing the product on the market and, where appropriate, of the manufacturer,
- method of administration and, if necessary, route,
- expiry date, in clear terms (month, year),
- pharmaceutical form,
- contents of the sales presentation,
- special storage precautions, if any,
- a special warning if necessary for the medicinal product,
- manufacturer's batch number,
- registration number,
- 'homeopathic medicinal product without approved therapeutic indications',
- a warning advising the user to consult a doctor if the symptoms persist during the use of the medicinal product.

3. Notwithstanding paragraph 2, Member States may require the use of certain types of labelling in order to show:

- the price of the medicinal product,
- the conditions for refunds by social security bodies.

4. The criteria and rules of procedure provided for in Articles 5 to 12 of Directive 65/65/EEC shall apply by analogy to the special, simplified registration procedure for homeopathic medicinal products, with the exception of the proof of therapeutic efficacy.

Article 8

An application for special, simplified registration submitted by the person responsible for placing the product on the market may cover a series of medicinal products derived from the same homeopathic stock or stocks. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned:

- scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered,
- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography,
- manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentization,
- manufacturing authorization for the medicinal product concerned,
- copies of any registrations or authorizations obtained for the same medicinal product in other Member States;
- one or more specimens or mock-ups of the sales presentation of the medicinal products to be registered,
- data concerning the stability of the medicinal product.

Article 9

1. Homeopathic medicinal products other than those referred to in Article 7 of this Directive shall be authorized and labelled in accordance with Articles 4 to 21 of Directive 65/65/EEC including the provisions concerning proof of therapeutic effect and Articles 1 to 7 of Directive 75/319/EEC.

2. A Member State may introduce or retain in its territory specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic medicinal products other than those referred to in Article 7 (1) in accordance with the principles and characteristics of homeopathy as practised in that Member State.

In this case, the Member State concerned shall notify the Commission of the specific rules in force.

CHAPTER IV

Final provisions

Article 10

1. Member States shall take the measures necessary to comply with this Directive by 31 December 1993. They shall forthwith inform the Commission thereof.

When Member States adopt the said measures, they shall contain a reference to this Directive or be accompanied by such reference when they are officially published. The

procedure for making such reference shall be adopted by the Member States.

Article 11

This Directive is addressed to the Member States.

2. Applications for registration or for marketing authorization for medicinal products covered by this Directive lodged after the date set in paragraph 1 shall comply with the provisions of this Directive.

Done at Brussels, 22 September 1992.

3. Not later than 31 December 1995, the Commission shall present a report to the European Parliament and the Council concerning the application of this Directive.

For the Council
The President
R. NEEDHAM

COUNCIL DIRECTIVE 92/74/EEC

of 22 September 1992

widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas differences currently existing between the provisions laid down by law, regulation or administrative action in the Member States may hinder trade in homeopathic veterinary medicinal products within the Community and lead to discrimination and distortion of competition between manufacturers of these products;

Whereas the essential aim of any rules governing the production, distribution and use of veterinary medicinal products must be to safeguard human and animal health;

Whereas, despite considerable differences in the status of alternative medicines in the Member States, free choice of treatment should be guaranteed, provided all precautions are taken to ensure the quality of products;

Whereas the provisions of Directive 81/851/EEC ⁽⁴⁾ are not always appropriate for homeopathic veterinary medicinal products;

Whereas homeopathic medicine is officially recognized in certain Member States but is only tolerated in other Member States;

Whereas, even if homeopathic medicinal products are not always officially recognized, they are nevertheless prescribed and used in most Member States;

Whereas it is desirable in the first instance to provide users of these medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety;

Whereas the rules relating to the manufacture, control and inspection of homeopathic veterinary medicinal products must be harmonized to permit the circulation throughout the Community of medicinal products which are safe and of good quality;

Whereas, having regard to the particular characteristics of these medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those traditional homeopathic medicinal products which are placed on the market without specific therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the animal;

Whereas in the light of current knowledge it appears difficult to allow according to a special, simplified registration procedure the marketing of medicinal products intended to be administered to animals whose flesh or products are intended for human consumption; whereas, however, this question should be re-examined during the preparation of the overall report on the application of this Directive which has to be submitted by the Commission not later than 31 December 1995;

Whereas, however, the usual rules governing the authorization to market veterinary medicinal products must be applied to homeopathic veterinary medicinal products marketed with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect; whereas Member States should be able to apply particular rules for the evaluation of the results of tests and trials intended to establish the safety and efficacy of these medicinal products for pet animals and exotic species, provided that they notify them to the Commission,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope

Article 1

1. For the purposes of this Directive, 'homeopathic veterinary medicinal product' shall mean any veterinary

⁽¹⁾ OJ No C 108, 1. 5. 1990, p. 13.

⁽²⁾ OJ No C 183, 15. 7. 1991, p. 323 and OJ No C 241, 21. 9. 1992.

⁽³⁾ OJ No C 332, 31. 12. 1990, p. 32.

⁽⁴⁾ OJ No L 317, 6. 11. 1981, p. 1. Directive as amended by Directive 90/676/EEC (OJ No L 373, 31. 12. 1990, p. 15).

medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the *European Pharmacopoeia* or, in absence thereof, by the pharmacopoeias currently used officially in the Member States.

2. A homeopathic veterinary medicinal product may also contain a number of principles.

Article 2

1. The provisions of this Directive shall apply to homeopathic medicinal products for veterinary use.

This Directive shall not apply to homeopathic veterinary medicinal products which meet the conditions of Article 4 (4) of Directive 81/851/EEC; however, the withdrawal period referred to in the second subparagraph of that Article 4 (4) shall not apply with regard to homeopathic veterinary medicinal products in which the level of active principles is equal to or less than one part per million.

2. Without prejudice to Article 7 (2), the medicinal products referred to in paragraph 1 shall be identified by the inclusion on their labels, in clearly legible form, of the words 'homeopathic medicinal product for veterinary use'.

3. This Directive shall not apply to immunological homeopathic veterinary medicinal products, which shall be authorized by Member States in accordance with the provisions of Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products⁽¹⁾.

CHAPTER II

Manufacture, control and inspection

Article 3

The provisions of Chapter V of Directive 81/851/EEC shall apply to the manufacture, control, import and export of homeopathic veterinary medicinal products.

Article 4

The supervision measures and the sanctions provided for in Chapter VI of Directive 81/851/EEC shall apply to homeopathic veterinary medicinal products.

However, the proof of therapeutic effect referred to in Article 37 (1) (b) of the same Directive shall not be required

for homeopathic veterinary medicinal products registered in accordance with Article 7 of this Directive or, where appropriate, admitted in accordance with Article 6 (2).

Article 5

Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic veterinary medicinal products manufactured and marketed within the Community, and in particular the information referred to in Articles 39 and 42 of Directive 81/851/EEC.

CHAPTER III

Placing on the market

Article 6

1. Member States shall ensure that homeopathic veterinary medicinal products manufactured and marketed within the Community are registered or authorized in accordance with the provisions of Articles 7, 8 and 9. Each Member State shall take due account of registrations and authorizations previously granted by another Member State.

2. A Member State may refrain from establishing a special, simplified registration procedure for the homeopathic veterinary medicinal products referred to in Article 7. A Member State applying this provision shall inform the Commission accordingly. The Member State concerned shall, by 31 December 1995 at the latest, allow the use in its territory of homeopathic veterinary medicinal products registered by other Member States in accordance with Articles 7 and 8.

Article 7

1. Only homeopathic veterinary medicinal products which satisfy all of the following conditions may be subject to a special, simplified registration procedure:

- they are intended for administration to pet animals or exotic species whose flesh or products are not intended for human consumption,
- they are administered by a route described in the *European Pharmacopoeia* or, in absence thereof, by the pharmacopoeias currently used officially in the Member States,
- no specific therapeutic indication appears on the labelling of the veterinary medicinal product or in any information relating thereto,
- there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a veterinary prescription.

⁽¹⁾ OJ No L 373, 31. 12. 1990, p. 26.

At the time of registration, Member States shall determine the classification for the dispensing of the medicinal product.

2. In addition to the clear mention of the words 'homeopathic veterinary medicinal product without approved therapeutic indications', the labelling and, where appropriate, package insert for the medicinal products referred to in paragraph 1 shall bear the following information and no other information:

- the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used in accordance with Article 1 (1),
- name and address of the person responsible for marketing and, where appropriate, of the manufacturer,
- method of administration and, if necessary, route,
- expiry date, in clear terms (month, year),
- pharmaceutical form,
- contents of the sales presentation,
- special storage precautions, if any,
- target species,
- a special warning if necessary for the medicinal product,
- manufacturer's batch number,
- registration number.

3. The criteria and rules of procedure provided for in Articles 8 to 15 of Directive 81/851/EEC shall apply by analogy to the special, simplified registration procedure for homeopathic veterinary medicinal products, with the exception of the proof of therapeutic effect.

Article 8

A special, simplified application for registration submitted by the person responsible for marketing may cover a series of medicinal products derived from the same homeopathic stock or stocks. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned:

- scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered,
- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate

homeopathic bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence of pathogens,

- manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation,
- manufacturing authorization for the medicinal products concerned,
- copies of any registrations or authorizations obtained for the same medicinal products in other Member States,
- one or more specimens or mock-ups of the sales presentation of the medicinal products to be registered,
- data concerning the stability of the medicinal product.

Article 9

1. Homeopathic veterinary medicinal products other than those referred to in Article 7 shall be authorized in accordance with the provisions of Articles 5 to 15 of Directive 81/851/EEC, including the provisions concerning proof of therapeutic effect, and labelled in accordance with Articles 43 to 50 of the same Directive.

2. A Member State may introduce or retain in its territory specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic veterinary medicinal products intended for pet animals and exotic species whose flesh or products are not intended for human consumption, other than those referred to in Article 7 (1), in accordance with the principles and characteristics of homeopathy as practised in that Member State.

In this case, the Member State concerned shall notify the Commission of the specific rules in force.

CHAPTER IV

Final provisions

Article 10

1. Member States shall take the measures necessary to comply with this Directive by 31 December 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Applications for registration or for marketing authorization for products covered by this Directive lodged after the date set in paragraph 1 shall comply with the provisions of this Directive.

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 22 September 1992.

3. Not later than 31 December 1995, the Commission shall present a report to the Council and to the European Parliament concerning the implementation of this Directive.

For the Council

The President

R. NEEDHAM

COUNCIL DIRECTIVE 92/75/EEC

of 22 September 1992

on the indication by labelling and standard product information of the consumption of energy
and other resources by household appliances

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas measures should be taken progressively to achieve the internal market by 31 December 1992;

Whereas certain Member States already have their own voluntary schemes for energy labelling and the provision of other energy consumption information for household appliances; whereas one Member State has formally proposed introducing its own compulsory labelling scheme, and other Member States are considering such introduction; whereas the existence of a number of compulsory national schemes would create barriers to intra-Community trade;

Whereas Article 130r of the Treaty requires prudent and rational utilization of natural resources; whereas the rational use of energy is one of the principal means by which this objective can be achieved and environmental pollution reduced;

Whereas the provision of accurate, relevant and comparable information on the specific energy consumption of household appliances may influence the public's choice in favour of those appliances which consume less energy, thus prompting manufacturers to take steps to reduce the consumption of the appliances which they manufacture; whereas it will also, indirectly, encourage the efficient use of these appliances; whereas, in the absence of this information, the operation of market forces alone will fail to promote the rational use of energy for these appliances;

Whereas information plays a key role in the operation of market forces and it is therefore necessary to introduce a uniform label for all appliances of the same type, to provide potential purchasers with supplementary standardized

information on those appliances' costs in terms of energy and the consumption of other resources and to take measures to ensure that potential purchasers who do not see the appliance displayed, and thus have no opportunity to see the label, are also supplied with this information;

Whereas to this end the energy consumption of and other information concerning each type of appliance must be measured in accordance with harmonized standards and methods and the application of these standards and methods must be monitored at the marketing stage;

Whereas Directive 79/530/EEC ⁽⁴⁾ sought to promote these aims in the case of household appliances; whereas, however, only one implementing Directive for electric ovens has been adopted and few Member States have introduced this label; whereas it is therefore now necessary to learn from the experience acquired and to strengthen the provisions of that Directive; whereas Directive 79/530/EEC must therefore be replaced and Directive 79/531/EEC ⁽⁵⁾ applying to those electric ovens should be revised and subsequently integrated into the present scheme;

Whereas a completely voluntary scheme would lead to only some appliances being labelled, or supplied with standard product information, with the risk that this might result in confusion for some consumers; whereas the present scheme must therefore ensure that for all the appliances concerned, the energy consumption is indicated by labelling and standard product fiches are provided;

Whereas household appliances use a wide variety of forms of energy, with electricity and gas being the most important; whereas this Directive must therefore in principle cover appliances using any form of energy;

Whereas Council Directive 86/594/EEC of 1 December 1986 on airborne noise emitted by household appliances ⁽⁶⁾ provides for an indication of noise emission to be included on energy labels, where appropriate; whereas provision must therefore be made for the incorporation of any other information and labelling covered by Community schemes;

Whereas only those types of appliances whose aggregate energy use is significant and which afford adequate scope for increased efficiency need be included,

⁽¹⁾ OJ No C 235, 10. 9. 1991, p. 5.

⁽²⁾ OJ No C 125, 18. 5. 1992, p. 172 and
OJ No C 241, 21. 9. 1992.

⁽³⁾ OJ No C 49, 24. 2. 1992, p. 32.

⁽⁴⁾ OJ No L 145, 13. 6. 1979, p. 1.

⁽⁵⁾ OJ No L 145, 13. 6. 1979, p. 7.

⁽⁶⁾ OJ No L 344, 6. 12. 1986, p. 24.

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. The purpose of this Directive is to enable the harmonization of national measures on the publication, particularly by means of labelling and of product information, of information on the consumption of energy and of other essential resources, and additional information concerning certain types of household appliances, thereby allowing consumers to choose more energy-efficient appliances. This Directive shall apply to the following types of household appliances, even where these are sold for non-household uses:

- refrigerators, freezers and their combinations,
- washing machines, driers and their combinations,
- dishwashers,
- ovens,
- water heaters and hot-water storage appliances,
- lighting sources,
- air-conditioning appliances.

2. Further types of household appliances may be added to the list in this Article in accordance with Article 9 (b).

3. This Directive shall not apply to the rating plate or its equivalent affixed for safety purposes to such appliances.

4. For the purpose of this Directive:

- *dealer* means a retailer or other person who sells, hires, offers for hire-purchase or displays household appliances to end-users,
- *supplier* means the manufacturer or his authorized representative in the Community or the person who places the product on the Community market,
- *information sheet* means a standard table of information relating to the appliance in question,
- *other essential resources* means water, chemicals or any other substance consumed by an appliance in normal use,
- *supplementary information* means other information concerning the performance of an appliance, which relates to, or is helpful in evaluating, its use of energy or other essential resources.

5. There shall be no obligation to label or to provide fiches in respect of models of appliances of which production has ceased before the relevant implementing directive comes into effect, or second-hand appliances.

Article 2

1. Information relating to the consumption of electric energy, other forms of energy and other essential resources and supplementary information shall be brought to consumers' attention by means of a fiche and a label related to household appliances offered for sale, hire, hire-purchase or displayed to end-users.

2. Details relating to the label and the fiche shall be defined by directives relating to each type of appliance adopted pursuant to this Directive in accordance with Article 9.

3. Technical documentation shall be established which shall be sufficient to enable the accuracy of the information contained in the label and the fiche to be assessed. It shall include:

- a general description of the product,
- the results of design calculations carried out, where these are relevant,
- test reports, where available, including those carried out by relevant notified organizations as defined under other Community legislation,
- where values are derived from those obtained for similar models, the same information for these models.

4. The supplier shall establish the technical documentation described in paragraph 3. To this end it may use documentation already required on the basis of relevant Community legislation. The supplier shall make this documentation available for inspection purposes for a period ending five years after the last product has been manufactured.

Article 3

1. All suppliers placing on the market the household appliances specified in the implementing directives shall supply a label in accordance with this Directive. The labels used shall in all respects comply with this Directive and with the implementing directives.

2. In addition to the labels, suppliers shall provide a product fiche. This fiche shall be contained in all product brochures. Where these are not provided by the supplier, he shall supply fiches with other literature provided with the appliance. The fiches used shall in all respects comply with this Directive and with the implementing Directives.

3. Suppliers shall be responsible for the accuracy of the labels and fiches that they supply.

4. The supplier shall be deemed to have given his consent to the publication of the information given on the label or the fiche.

Article 4

In respect of labelling and product information, the following provisions shall apply:

- (a) whenever an appliance specified in an implementing directive is displayed, dealers shall attach an appropriate label, in the clearly visible position specified in the relevant implementing directive, and in the relevant language version;
- (b) the supplier shall supply the necessary labels free of charge, to dealers referred to in paragraph (a). Suppliers are free to choose their own system for delivery of labels. However, where a dealer sends a request for labels, the supplier must ensure that the requested labels are delivered promptly.

Article 5

Where the relevant appliances are offered for sale, hire or hire-purchase by mail order, by catalogue, or by other means which imply that the potential customer cannot be expected to see the appliance displayed, the implementing directives shall make provision to ensure that potential customers are provided with the essential information specified in the label or the fiche before buying an appliance.

Article 6

The implementing Directives shall make provision for the inclusion on the label or on the fiche of information on airborne noise, where such information is provided pursuant to Directive 86/594/EEC and of other public information relating to the relevant appliance, which is provided pursuant to other Community legislation.

Article 7

Member States shall take all necessary measures to ensure that:

- (a) all suppliers and dealers established in their territory fulfil their obligations under this Directive;
- (b) if this is likely to mislead or confuse, the display of other labels, marks, symbols or inscriptions relating to energy consumption which do not comply with the requirements of this Directive and of the relevant implementing directives is prohibited. This prohibition shall not apply to Community or national environmental labelling schemes;
- (c) the introduction of the system of labels and fiches concerning energy consumption is accompanied by

educational and promotional information campaigns aimed at encouraging more responsible use of energy by private consumers.

Article 8

1. Where the provisions of this Directive and of the implementing directives are satisfied, Member States shall neither prohibit nor restrict the placing on the market of the household appliances covered by an implementing directive.

2. Unless they have evidence to the contrary, Member States shall deem labels and fiches to comply with the provisions of this Directive and the implementing directives. They may require suppliers to furnish evidence within the meaning of Article 2 (3) concerning the accuracy of the information supplied on their labels or fiches when they have reason to suspect it is incorrect.

Article 9

The measures relating to the establishment and operation of the scheme shall be adopted and adapted to technical progress in accordance with the procedure set out in Article 10. These measures are:

- (a) the implementing directives;
- (b) the addition of further household appliances to the list in Article 1 (1) where significant energy savings are likely to be achieved.

Article 10

The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the EEC Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the

Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures, by a simple majority.

Article 11

After the expiry of a period of three years from the application of this Directive, the Commission shall make an assessment of the implementation thereof and the results obtained. The assessment shall be the subject of a report to be submitted to the European Parliament and the Council.

Article 12

The implementing directives shall specify:

- (a) the exact definition of the type of appliances to be included;
- (b) the measurement standards and methods to be used in obtaining the information referred to in Article 1 (1);
- (c) details of the technical documentation required under Article 2 (3);
- (d) the design and content of the label referred to in Article 2, which as far as possible shall have uniform design characteristics;
- (e) the location where the label shall be fixed to the appliance. Where appropriate they may provide for the label to be attached to or printed on the packaging;
- (f) the content and where appropriate the format and other details concerning the fiche or further information specified in Article 3 (2). The information on the label shall also be included on the fiche;
- (g) the information to be provided in the case of offers for sale covered by Article 5, and the manner in which it is to be provided.

Article 13

Directive 79/530/EEC is hereby repealed, with effect from 1 January 1994.

Directive 79/531/EEC shall be considered as implementing this Directive for electric ovens; however Member States may refrain from its compulsory introduction, until a date set in a revised implementing directive concerning ovens passed in accordance with the procedure laid down in Article 10.

Article 14

1. Member States shall adopt the provisions necessary to comply with this Directive by 1 July 1993. They shall immediately notify the Commission of these measures.

They shall bring these provisions into force by not later than 1 January 1994.

2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

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

Article 15

This Directive is addressed to the Member States.

Done at Brussels, 22 September 1992.

For the Council
The President
R. NEEDHAM