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Legislation

Contents

I *Acts whose publication is obligatory*

- ★ Commission Regulation (EEC) No 1685/78 of 11 July 1978 laying down detailed rules for the implementation of the decision by the Guidance Section of the EAGGF to grant aid for projects designed to improve conditions under which agricultural products are processed and marketed 1
-

II *Acts whose publication is not obligatory*

Council

78/609/EEC:

- ★ Council Directive of 29 June 1978 amending for the fifth time Directive 73/241/EEC on the approximation of the laws of the Member States relating to cocoa and chocolate products intended for human consumption 10

78/610/EEC:

- ★ Council Directive of 29 June 1978 on the approximation of the laws, regulations and administrative provisions of the Member States on the protection of the health of workers exposed to vinyl chloride monomer 12

78/611/EEC:

- ★ Council Directive of 29 June 1978 on the approximation of the laws of the Member States concerning the lead content of petrol 19

78/612/EEC:

- ★ Council Directive of 29 June 1978 amending for the first time Directive 74/329/EEC on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs 22

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EEC) No 1685/78

of 11 July 1978

laying down detailed rules for the implementation of the decision by the Guidance Section of the EAGGF to grant aid for projects designed to improve the conditions under which agricultural products are processed and marketed

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 355/77 of 15 February 1977 on common measures to improve the conditions under which agricultural products are processed and marketed ⁽¹⁾, and in particular Article 19 (5) thereof,

Whereas supporting documents in respect of projects eligible for assistance from the EAGGF are forwarded, in some cases via the Member States concerned, by a department or agency designated by that Member State; whereas, with a view to ensuring an effective check on the execution of these projects, provision should be made to define the role of that department or agency and the nature of the supporting documents to be drawn up in compliance with the laws or regulations of the Member State concerned or with the measures laid down by the said department or agency, and also the checking arrangements to be made by each Member State; whereas the Commission needs to be informed that projects are being carried out under the conditions and within the time limits laid down;

Whereas the documentation to be forwarded by the intermediary authority so that the Commission may ascertain that all the conditions are fulfilled for payment of the aid, or a proportion thereof, should be specified; whereas that documentation must include full information, presented in a uniform manner, in order to facilitate examination and uniform treatment of payment applications;

Whereas, if the documents duly provided by the department or agency appear inadequate or incomplete

for the purpose of checking the financial or other conditions to which the projects are subject, the Commission should be able to request the intermediary authority to submit additional documents;

Whereas there should be provision, in connection with inspection visits, for cooperation between the Commission and the Member State concerned, so that the visit may achieve its intended purpose;

Whereas the procedure for suspending, reducing or terminating EAGGF aid should not be initiated without the Member State concerned first having been asked for its views and the beneficiaries having been given the opportunity to submit their comments;

Whereas, since EAGGF aid is paid to the beneficiary through an agency designated by the Member State, it is necessary to define the documents which that agency is to forward to the Commission;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the EAGGF Committee,

HAS ADOPTED THIS REGULATION:

I. Role of the department or agency responsible for forwarding supporting documents

Article 1

1. The department or agency responsible for forwarding supporting documents within the meaning of Article 19 (2) of Regulation (EEC) No 355/77 shall send to the

⁽¹⁾ OJ No L 51, 23. 2. 1977, p. 1.

Commission, either on a global basis within two months following the entry into force of this Regulation, or for each separate project within two months of notification of the relevant decision according an aid, a descriptive list of the supporting documents it intends to require. Any amendment to such list shall be communicated to the Commission within two months of its adoption.

'Supporting documents' means any document drawn up in accordance either with the laws or regulations of the Member State concerned or with the measures adopted by the abovementioned department or agency and establishing that the financial or other conditions imposed for the project in question have been fulfilled.

The descriptive list mentioned above shall contain:

- the name of each supporting document, together with a reference to the regulations or measures on the basis of which it is to be drawn up,
- a brief description of the contents of each document.

2. Within the time limit laid down in paragraph 1 the department or agency shall also send to the Commission a detailed description of the checking arrangements at its disposal on the basis of which it makes out the certificate referred to in Article 3.

3. The Commission may request Member States to add to the descriptive list other documents which it considers necessary for checking the eligibility for payment of the expenditure claimed in applications; it may to the same end request the Member States to strengthen their checking arrangements.

Article 2

On the expiry of two years from the date of notification of the decision granting aid, the department or agency shall forward to the Commission a document describing the progress made on uncompleted projects. Where, contrary to the information contained in the application for aid and the decision to grant it, the work has not begun at the end of this period of two years, the department or agency shall give reasons and, where necessary, shall submit to the Commission guarantees, provided by the beneficiaries, establishing that the project will be carried out in the near future.

Article 3

On completion of a project, or in the course of its implementation if the Commission decision makes provision for payment in instalments pursuant to Article 17 (1) of Regulation (EEC) No 355/77, the department or agency shall forward to the Commission a request for payment showing that the conditions for payment have been fulfilled.

Applications for payment shall consist of a certificate and a list of the supporting documents; the latter shall be submitted in duplicate in the form shown in the Annexes (models 1 to 5) to this Regulation.

Article 4

To enable an effective check to be made on the execution of a project, the department or agency shall submit to the Commission, on request and within a time limit which the latter may fix, any supporting document within the meaning of Article 1 or a certified copy thereof, or any other document which shows that the financial or other conditions laid down for a project have been fulfilled.

Article 5

If the Commission considers it necessary to make an inspection visit, it shall give prior notice thereof to the Member State it intends to visit and shall invite that Member State to participate in the inspection; the Member States shall take all necessary steps to promote the efficacy of such inspection visits.

Article 6

Before initiating any procedure for suspending, reducing or terminating aid from the EAGGF in accordance with Articles 19 (2) and 20 (2) of Regulation (EEC) No 355/77, the Commission shall:

- invite the Member State on whose territory the project was to be carried out to express its views on the matter,
- consult the department or agency responsible for transmitting supporting documents,
- ask the beneficiary to provide, through the department or agency, an explanation for his non-compliance with the conditions laid down.

II. Role of the agency responsible for payment

Article 7

1. When the Commission is satisfied that the financial or other conditions laid down for the project have been fulfilled, it shall pay the aid from the EAGGF, or the appropriate portion thereof if payment is by instalments, in favour the beneficiary in accordance with Article 19 (1) of Council Regulation (EEC) No 355/77.

2. The agency shall immediately pay over the aid to the beneficiary and shall provide evidence to the Commission that this has been done within 15 days of payment.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 July 1978.

For the Commission

The President

Roy JENKINS

MODEL 1

CERTIFICATE FOR THE PAYMENT OF AN INSTALMENT OF AID

PROJECT No Title

BENEFICIARY: (Name and address)

The⁽¹⁾, being the department responsible for forwarding the supporting documents in accordance with the provisions of Article 19 (2) of Regulation (EEC) No 355/77 on common measures to improve the conditions under which agricultural products are processed and marketed,

HEREBY CERTIFIES THAT:

1. The supporting documents referred to in the descriptive list forwarded to the Commission pursuant to Article 1 of Regulation (EEC) No 1685/78 have been checked.
2. Work on the project was begun on on the site planned.
3. The work was in progress on; at that date the total cost was, of which had been actually disbursed by the beneficiary/beneficiaries.
4. The above expenditure was financed as shown in the Annex to this certificate.
5. The total cost stated above is allocated among the various items of work as shown in the list of supporting documents attached to this application for payment ⁽²⁾.
6. According to the declaration made by, the work done is in conformity with that described in the Commission decision to grant aid (with the exception of the item(s) concerning, as to which an explanation is given in the Annex to the list of supporting documents).
7. The amount of recoverable VAT included in the expenditure claimed is
8. The shares of the cost borne by the beneficiary and by the Member State are consistent with the provisions of Article 17 (2) of Regulation (EEC) No 355/77, or will be at the latest when work is completed.
9. The supporting documents are held by
10. By letter dated, the beneficiary has replied as regards the special conditions laid down in Article 1 (3) of the decision to grant aid.

Done at
.....*For the intermediary authority*.....
(signature)

.....
⁽¹⁾ Name of the intermediary authority.

⁽²⁾ Where the aid is allocated among several sub-projects, a separate list of supporting documents should be drawn up for each sub-project.

MODEL 2

CERTIFICATE FOR THE PAYMENT OF THE BALANCE OR THE WHOLE OF AN AID

PROJECT No Title

BENEFICIARY: (Name and address)

The ⁽¹⁾, being the department responsible for forwarding the supporting documents in accordance with the provisions of Article 19 (2) of Regulation (EEC) No 355/77 on common measures to improve the conditions under which agricultural products are processed and marketed,

HEREBY CERTIFIES THAT:

1. The supporting documents referred to in the descriptive list forwarded to the Commission pursuant to Article 1 of Regulation (EEC) No 1685/78 have been checked.
2. Work on the project was begun on on the site planned.
3. The work was completed on The actual cost amounts to, of which has been paid by the beneficiary/beneficiaries.
4. The above expenditure was financed as shown in the Annex to this certificate.
5. The total cost stated above is allocated among the various items of work as shown in the list of supporting documents attached to this application for payment; a table comparing the areas and capacities planned with those actually achieved is attached as Annex 2 to the list ⁽²⁾.
6. An inspection by showed that the work completed is in conformity with that described in the Commission decision to grant aid (with the exception of the items concerning, as to which an explanation is given in Annex 1 to the detailed list of documentary evidence).
7. The amount of recoverable VAT included in the expenditure claimed is
8. The shares of the cost borne by the beneficiary and by the Member State are consistent with the provisions of Article 17 (2) of Regulation (EEC) No 355/77.
9. The supporting documents are held by
10. In a letter dated, the beneficiary has replied as regards the special conditions laid down in Article 1 (3) of the decision to grant aid ⁽³⁾.

Done at

For the intermediary authority

.....
 (signature)

⁽¹⁾ Name of the intermediary authority.

⁽²⁾ Where the aid is allocated among several sub-projects, a separate list of supporting documents and table of comparison should be drawn up for each sub-project.

⁽³⁾ This point concerns only requests for payment of the whole of the aid.

MODEL 3

ANNEX TO THE CERTIFICATE ON THE FINANCING OF EXPENDITURE INCURRED

FINANCING OF EXPENDITURE INCURRED UP TO

PROJECT No Title

1. Share of cost borne by the beneficiary

- own capital
- services in kind ⁽¹⁾
- loans ⁽²⁾

2. Share of cost borne by the Member State

- capital grant
- reduced interest loans ⁽³⁾ [.....]
(duration; rate)
- other aid

3. Other contributions

-
-

4. Total

.....

Date

.....
(signature)

⁽¹⁾ Indicate the method of calculation.

⁽²⁾ Indicate below the origin, amount, rate of interest, total term and conditions for repayment of each loan, giving details of the rate and duration of any interest rate subsidies.

⁽³⁾ Amount already included under 1.

MODEL 4

LIST OF SUPPORTING DOCUMENTS
(between and)

Work	Cost as per estimate	Supporting documents ⁽¹⁾					Payments made		
		No	Date ⁽²⁾	Issued by	Subject of expenditure	Amount	Method of payment	Date ⁽³⁾	Amount paid
I. Purchase of land									
									
									
		Total expenditure covered by this application of which VAT							
		Expenditure already declared of which VAT							
II. Roadworks and land clearance		Total expenditure on of which VAT							
									
									
									
III. Construction									
IV. Installations and equipment									
V. Other investments									
VI. Fees and overheads									
Total I to VI									

Date

.....
(signature)

Explanatory notes

⁽¹⁾ All documents relating to the project financed should be shown, including those referring to ineligible expenditure if it corresponds to an integral part of the project.

⁽²⁾ When expenditure has been entered in the accounts and/or paid *before* the application for aid is submitted to the Commission, a reason should be given. If payment was made in anticipation of the start of the works accounted for under headings II and III, the nature and amount of this work should be stated. If the payments relate to actions within headings IV and V the dates of ordering, delivery and installation should be submitted.

⁽³⁾ The date to be shown is that of the actual payment and not the date on which a debt falls due, for example in the case of payment by instalments.

ANNEX 1 TO THE LIST OF SUPPORTING DOCUMENTS

EXPLANATION OF DIFFERENCE BETWEEN WORK PLANNED AND WORK EXECUTED

Work planned		Work executed		Reason for changes
Brief description	Cost	Brief description	Cost	

MODEL 5

ANNEX 2 TO THE LIST OF SUPPORTING DOCUMENTS

COMPARAISON OF AREAS AND CAPACITIES PLANNED AND ACTUALLY ACHIEVED

(To be attached only for payment of the balance or the total amount of aid)

A. BUILDING WORKS	Area and/or capacity indicated in aid application	Area and/or capacity achieved ⁽¹⁾
1. Roadworks and land clearance		
2. Building		
- reception and dispatch		
- processing and packaging		
- refrigeration		
- storage		
- services		
- housing		
- other buildings		

B. INSTALLATIONS	Forecast as indicated in aid application			Actual		
	Capacity	Cost	Unit cost	Capacity	Cost	Unit cost
- processing						
- packaging						
- freezing/chilling						
- internal transport						
- external transport						
- services						
- protection of the environment						
- other installations						

⁽¹⁾ The units of measurement to be used must be the same as those employed in the estimate which accompanied the aid application.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 29 June 1978

amending for the fifth time Directive 73/241/EEC on the approximation of the laws of the Member States relating to cocoa and chocolate products intended for human consumption

(78/609/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Whereas item 1.19 of Annex I to Council Directive 73/241/EEC of 24 July 1973 on the approximation of the laws of the Member States relating to cocoa and chocolate products intended for human consumption ⁽³⁾, as last amended by Directive 76/628/EEC ⁽⁴⁾, defines gianduja nut chocolate;

Whereas the definition of this type of chocolate given in Annex I does not provide for the use of milk in various forms; whereas this could eventually prevent further manufacture of this type of chocolate, which is, moreover, a quality product;

Whereas the product may traditionally contain a certain quantity of milk; whereas therefore a better definition should be laid down and the addition of small quantities of milk in various forms authorized,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Item 1.19 of Annex I to Directive 73/241/EEC shall be replaced by the following:

‘1.19 *Gianduja (or one of the derivatives of the word “gianduja”) nut chocolate*

the product obtained firstly from chocolate having a minimum total dry cocoa solids content of 32 % including a minimum dry non-fat cocoa solids content of 8 %, and secondly from finely ground hazelnuts in such quantities that 100 g of the product contain not less than 20 g and not more than 40 g of nuts.

The following may also be added:

— milk or dry matter produced by the partial or complete dehydration of whole milk or partially or fully skimmed milk in a proportion such that the finished

⁽¹⁾ OJ No C 108, 8. 5. 1978, p. 16.

⁽²⁾ OJ No C 84, 8. 4. 1978, p. 7.

⁽³⁾ OJ No L 228, 16. 8. 1973, p. 23.

⁽⁴⁾ OJ No L 223, 16. 8. 1976, p. 1.

- product contains no more than a total of 5 % by weight of dry milk solids including not more than 1.25 % of butterfat,
- almonds, hazelnuts and other nut varieties, either whole or broken, in such quantities that, together with the ground hazelnuts, they do not exceed 60 % of the total weight of the product;'
 - permit the marketing of products conforming to this Directive within two years of the date of notification;
 - ban the marketing of products not conforming with this Directive within three years of the date of notification.

Article 3

This Directive is addressed to the Member States.

Article 2

Within one year of the date of notification of this Directive, Member States shall amend their laws where necessary in order to comply with the provisions of this Directive and shall forthwith inform the Commission thereof.

Done at Luxembourg, 29 June 1978.

The laws thus amended shall be applied so as to:

For the Council

The President

S. AUKEN

COUNCIL DIRECTIVE

of 29 June 1978

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

(78/610/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Whereas, in the past it was recognized that vinyl chloride monomer was capable of giving rise only to the generally reversible disease known as 'occupational acro-osteolysis'; whereas more recent evidence from epidemiological studies and animal experimentation indicates that prolonged and/or repeated exposure to high concentrations of vinyl chloride monomer in the atmosphere may give rise to a 'vinyl chloride monomer' syndrome encompassing, in addition to occupational acro-osteolysis, the skin disease scleroderma and liver disorders;

Whereas vinyl chloride monomer 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 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; whereas, therefore, in the interests of balanced economic and social development, these national laws, which directly affect the functioning of the common market, should be harmonized and improved;

Whereas the first step should be to take technical preventive and protective measures based on the latest scientific knowledge so that the values of concentrations

of vinyl chloride monomer in the atmosphere in the works can be reduced to an extremely low figure;

Whereas medical surveillance of workers in the vinyl chloride monomer and vinyl chloride polymer industry should take account of the latest medical knowledge, in order that the health of workers in this important sector of the chemical industry may be protected;

Whereas the urgent need to harmonize laws in this field is recognized by both sides of industry which took part in the discussion on this specific problem; whereas efforts must therefore be made towards the approximation, while the improvement is being maintained, of the laws, regulations and administrative provisions of the Member States as envisaged in Article 117 of the Treaty;

Whereas the provisions of this Directive constitute minimal requirements which may be re-examined in the light of the experience gained and of progress in medical techniques and knowledge in this field, the final objective being to achieve optimum protection of workers,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. The object of this Directive is the protection of workers:

- employed in works in which vinyl chloride monomer is produced, reclaimed, stored, discharged into containers, transported or used in any way whatsoever, or in which vinyl chloride monomer is converted into vinyl chloride polymers, and
- exposed to the effects of vinyl chloride monomer in a working area.

2. This protection shall comprise:

- technical preventive measures,
- the establishment of limit values for the atmospheric concentration of vinyl chloride monomer in the working area,

⁽¹⁾ OJ No C 163, 11. 7. 1977, p. 11.

⁽²⁾ OJ No C 287, 30. 11. 1977, p. 11.

- the definition of measuring methods and the fixing of provisions for monitoring the atmospheric concentration of vinyl chloride monomer in the working area,
- if necessary, personal protection measures,
- adequate information for workers on the risks to which they are exposed and the precautions to be taken,
- the keeping of a register of workers with particulars of the type and duration of their work and the exposure to which they have been subjected,
- medical surveillance provisions.

Article 2

For the purpose of this Directive:

- (a) '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 there 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 is not possible;
- (b) 'technical long-term limit value' means the value which shall not be exceeded by the mean concentration, integrated with respect to time, of vinyl chloride monomer in the atmosphere of a working area, the reference period being the year, with account being taken only of the concentrations measured during the periods in which the plant is in operation and of the duration of such periods.

For guidance and for practical reasons, Annex I contains a table of the corresponding limit values obtained from statistics with a view to being able to detect, over shorter periods, the risk of the technical long-term limit value's being exceeded.

The concentration values recorded during the alarm periods referred to in Article 6 shall not be taken into account in the calculation of the mean concentration.

- (c) 'competent doctor' means the doctor responsible for the medical surveillance of the workers referred to in Article 1 (1).

Article 3

1. The fundamental aim of the technical measures adopted to meet the requirements of this Directive shall be to reduce to the lowest possible levels the concentrations of vinyl chloride monomer to which workers are exposed. All working areas in works referred to in

Article 1 (1) shall therefore be monitored for the atmospheric concentration of vinyl chloride monomer.

2. For the works referred to in Article 1 (1), the technical long-term limit value shall be three parts per million.

An adjustment period not exceeding one year in which to comply with the technical long-term limit value of three parts per million shall be provided for in the case of existing plant at such works.

Article 4

1. The concentration of vinyl chloride monomer in the working area may be monitored by continuous or discontinuous methods. The permanent sequential method shall be regarded as being a continuous method.

However, the use of a continuous or permanent sequential method shall be obligatory in enclosed vinyl chloride monomer polymerization plant.

2. In the case of continuous or permanent sequential measurements over a period of one year, the technical long-term limit value shall be considered as having been complied with if the arithmetic mean concentration is found not to exceed this value.

In the case of discontinuous measurements, the number of values measured shall be such that it is possible to predict with a confidence coefficient of at least 95 % — accepting the relevant assumptions made in Annex I — that the actual mean annual concentration will not exceed the technical long-term limit value.

3. Any measurement system which records accurately for the purposes of analysis at least one third of the technical long-term limit value concentration shall be regarded as suitable.

4. If non-selective systems of measurement are used for measuring vinyl chloride monomer, the measurement recorded shall be taken as the total vinyl chloride monomer concentration value.

5. Measuring instruments shall be calibrated at regular intervals. Calibration shall be carried out by suitable methods based on the latest state of the art.

Article 5

1. Measurements of the atmospheric concentration of vinyl chloride monomer in a working area for the purpose of verifying compliance with the technical long-term limit value shall be carried out using measuring points chosen so that the results obtained are as representative as possible of the individual vinyl chloride monomer exposure level of workers in that area.

2. Depending on the size of the working area, there may be one or more measuring points. If there is more than one measuring point, the mean value for the various measuring points shall be considered in principle as the representative value for the whole working area.

If the results obtained are not representative of the vinyl chloride monomer concentration in the working area, the measuring point for checking compliance with the technical long-term limit value shall be that point in the working area where the worker is exposed to the highest mean concentration.

3. Measurements carried out as described in this Article may be combined with measurements based on individual sampling, i.e. using devices worn by exposed persons for the purpose of verifying the suitability of the measuring points chosen and of obtaining any other information relevant to technical prevention and medical surveillance.

Article 6

1. In order that abnormal increases in vinyl chloride monomer concentration levels may be detected, a monitoring system capable of detecting such increases shall be provided in places where they may occur.

In cases involving such an increase in the concentration level, technical measures shall be taken without delay to determine and to remedy the causes thereof.

2. The value corresponding to the alarm threshold shall not exceed, at a measuring point, 15 parts per million for mean values measured over a period of one hour, 20 parts per million for mean values measured over 20 minutes or 30 parts per million for mean values measured over two minutes. If the alarm threshold is exceeded, personal protection measures shall be taken without delay.

Article 7

Appropriate personal protection measures 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 limit values through operational or ventilation measures.

Article 8

Employers shall inform the workers referred to in Article 1 (1), both upon recruitment or prior to their

taking up their activities and at regular intervals thereafter, of the health hazards associated with vinyl chloride monomer and of the precautions to be taken when this substance is being handled.

Article 9

1. Employers shall keep a register of the workers referred to in Article 1 (1), with particulars of the type and duration of work and the exposure to which they have been subjected. This register shall be given to the competent doctor.

2. A worker shall, at his request, be given the opportunity to note the particulars in the register concerning him.

3. Employers shall make available to workers' representatives at the undertaking, at their request, the results of the measurements taken at the places of work.

Article 10

1. Employers shall be required to ensure that the workers referred to in Article 1 (1) are examined by the competent doctor, both upon recruitment or prior to their taking up their activities and subsequently.

2. Without prejudice to national provisions, the competent doctor shall determine in each individual case the frequency and type of the examination provided for in paragraph 1. The necessary guidelines are given in Annex II.

3. Member States shall take the necessary steps to ensure that the registers referred to in Article 9 and the medical records are kept for at least 30 years from the date on which the activity of the workers referred to in Article 1 (1) was taken up.

For workers already engaged in such activity on the date of entry into force of the provisions adopted pursuant to this Directive, the 30-year period shall commence on that date.

Member States shall determine how the registers and the medical records are to be used for study and research purposes.

Article 11

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

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

Done at Luxembourg, 29 June 1978.

Article 12

This Directive is addressed to the Member States.

For the Council

The President

S. AUKEN

ANNEX I

STATISTICAL BASIS FOR THE TECHNICAL LONG-TERM LIMIT VALUE

(Article 2 (b))

1. Owing to differences in definition, the recommended values for the permissible atmospheric concentration substances injurious to health at the workplace currently vary from country to country.

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

2. The limit values for shorter reference periods are based on data obtained by extensive measurement of vinyl chloride monomer concentrations in the vinyl chloride polymer industry. These measurements accord with the data resulting from observations both on other substances injurious to health and for other sectors of industry.

The data can be summarized as follows:

- (a) the distributions of concentrations of substances injurious to health can be represented log normally;
- (b) the logarithmic variance $\sigma^2(\tau, T)$ is a function of the reference period τ from which the mean of the individual values is calculated and of the assessment period T over which all individual values extend.

This relationship can, with a degree of approximation, be expressed by the following equation:

$$\sigma^2(\tau, T) = 2.5 \cdot 10^{-2} \log(T/\tau).$$

3. Assuming these data, a mean ratio of the limit values for shorter reference periods to the technical long-term limit value can be established:

Reference period	Limit value in parts per million (rounded off)	Ratio of short-term value to technical long-term limit value
One year	3	1
One month	5	1.7
One week	6	1.95
Eight hours	7	2.3
One hour	8	2.55

4. The above limit values for reference periods shorter than one year must have a maximum 5 % probability of being exceeded when the annual arithmetic mean of atmospheric vinyl chloride monomer concentrations is three parts per million.

ANNEX II

GUIDELINES FOR THE MEDICAL SURVEILLANCE OF WORKERS

(Article 10 (2))

1. Current knowledge indicates that over-exposure to vinyl chloride monomer 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 (affecting certain bone structures, particularly the phalanges in the hand),
- liver and spleen fibroses (similar to perilobular fibrosis, known as Banti's syndrome),
- lung function disorders,
- thrombocytopenia,
- hepatic angiosarcoma.

2. Medical surveillance of the workers should take account of all symptoms and syndromes, with particular emphasis on the area of greatest risk. As far as is known at present, 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 shall include at least the following measures as minimum requirements:

- (a) records of the workers's medical and occupational history,
- (b) clinical examination of the extremities, the skin and the abdomen,
- (c) X-ray of the hand bones (every two years).

Further tests, particularly laboratory tests, are desirable. These should be decided by the competent doctor 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),
- determination of gamma glutamyl transferase (GT) level,
- thymol turbidity test,
- alkaline phosphatase level,
- determination of cryoglobulin.

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

4. The competent doctor shall decide in each case whether a worker is suitable for a working area.

The competent doctor shall also 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.

COUNCIL DIRECTIVE

of 29 June 1978

on the approximation of the laws of the Member States concerning the lead content of petrol

(78/611/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Whereas the protection and improvement of public health and of the environment currently constitutes a major preoccupation common to all industrialized countries and pollution caused by products emitted in the exhaust gas of vehicles has reached a disquieting level owing to the continuous increase in the density of motor traffic; whereas, following the introduction of measures in Directive 70/220/EEC ⁽³⁾, as last amended by Directive 77/102/EEC ⁽⁴⁾, designed to curb air pollution caused by the emission of carbon monoxide, unburned hydrocarbons and nitrogen oxide from motor vehicles, action should be taken at this stage with a view to limiting lead particle emissions by such vehicles, the lead in question deriving from plumbiferous petrol additives acting as an anti-knock agent;

Whereas the national laws concerning the composition of petrol, and in particular the rules governing the limitations of the lead content in motor vehicle petrol, vary from one Member State to another; whereas such differences directly affect the proper functioning of the common market;

Whereas, owing to the important effect of lead upon public health and the environment, it is necessary to reduce the lead content of petrol at Community level;

Whereas the financial, economic, industrial and qualitative consequences of a reduction of the level of lead in

petrol to a maximum value of between 0.40 g/l and a value of 0.15 g/l have demonstrated that such a reduction is feasible within a relatively short period;

Whereas lead is only one of the constituent elements in the composition of petrol; whereas the reduction of this element must not have the effect of aggravating the air pollution by other pollutants which would be one of the main consequences of any modification in this composition;

Whereas detailed studies of the various aspects of the measures which might serve to reduce atmospheric lead should be continued at Community level; whereas Member States should for this purpose provide the Commission with relevant information;

Whereas the reduction of the lead content of petrol raises specific technical and economic problems in Ireland; whereas a temporary derogation for that country should not have severe repercussions on trade in petrol given that Irish refining installations at present only partially cover domestic requirements and that all petrol exported by that country to another Member State will have to comply with the provisions of the Directive which apply in that State; whereas there should therefore be a derogation from the provisions concerning the reduction of the lead content of petrol in Ireland;

Whereas a sudden change in the supply of crude oil or petroleum products in clearly defined circumstances could lead a Member State to authorize an increase in the lead content of petrol; whereas an appropriate procedure should therefore be laid down for such a situation,

HAS ADOPTED THIS DIRECTIVE:

Article 1

For the purpose of this Directive, 'petrol' means any fuel intended for the operation of internal combustion spark-ignited engines used for the propulsion of vehicles.

⁽¹⁾ OJ No C 280, 8. 12. 1975, p. 9.

⁽²⁾ OJ No C 116, 30. 9. 1974, p. 18.

⁽³⁾ OJ No L 76, 6. 4. 1970, p. 1.

⁽⁴⁾ OJ No L 32, 3. 2. 1977, p. 32.

Article 2

1. From 1 January 1981, the maximum permitted lead compound content, calculated in terms of lead, of petrol placed upon the Community internal market shall be 0.40 g/l.

2. Without prejudice to paragraph 1, a Member State may require, in respect of petrol placed upon its market, that the maximum permitted lead content be less than 0.40 g/l. However, it shall not establish limits lower than 0.15 g/l.

Article 3

Member States shall take all appropriate steps to ensure that the reduction of the lead content does not cause a significant increase in the quantities of other pollutants or to a deterioration in the quality of petrol.

Article 4

The lead content of petrol shall be established in accordance with the procedures set out in the Annex.

Article 5

Where a Member State establishes, on the basis of a test performed in accordance with the procedures described in Article 4, that any petrol fails to comply with the requirements of Articles 2 and 3, it shall take the necessary measures to ensure that these requirements are fulfilled.

Article 6

Member States shall, at the Commission's request, supply it with information on:

- (a) the effects of the implementation of this Directive, and in particular Article 3 thereof;
- (b) developments as regards systems to reduce the emission of lead and of any polluting substitutes in exhaust gases;
- (c) development of the concentrations of lead and polluting substitutes in the urban atmosphere and their effect on public health;
- (d) the effects on energy policy of the various possible ways and means of reducing pollution caused by lead emission in exhaust gases.

The Commission shall report to the Council and the European Parliament on the information thus obtained and, in the light of the data compiled, shall make any

suitable proposals for such data to be taken into account in order to develop further Community policy on the lead content of petrol.

Article 7

1. Notwithstanding Article 2 (1), the Government of Ireland may provide that for a period of five years commencing on 1 January 1981 petrol may be placed on the market in Ireland even though its lead content is greater than 0.40 g/l, without, however, exceeding the current content of 0.64 g/l.

2. Before the end of the period referred to in paragraph 1 the Council shall, acting by a qualified majority on a proposal from the Commission, decide on the duration of a second derogation period of not more than five years.

Article 8

If, as the result of a sudden change in the supply of crude oil or petroleum products, it becomes difficult for a Member State to apply the limit to the concentration of lead in petrol referred to in Article 2 (1), that Member State may, after having informed the Commission, authorize a higher limit within its territory for a period of four months. The Council, acting by a qualified majority on a proposal from the Commission, may extend this period.

Article 9

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

2. The Member States shall ensure that they communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

Article 10

This Directive is addressed to the Member States.

Done at Luxembourg, 29 June 1978.

For the Council

The President

S. AUKEN

*ANNEX***Reference methods**

For the measurement of the lead content of petrol the reference method shall be that laid down in the international standard ISO 3830 (First edition of 15 February 1977) 'Petroleum products — petrol — measurement of the lead content — iodine monochloride method'.

The results of individual measurements shall be interpreted on the basis of the method described in BS 4306: 1968, published by the British Standards Institution.

For the methods indicated, the versions in the various languages published by the ISO and the BSI respectively shall be authentic, as shall other versions which the Commission certifies as conforming to them.

COUNCIL DIRECTIVE

of 29 June 1978

amending for the first time Directive 74/329/EEC on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs

(78/612/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Whereas Annex I to Directive 74/329/EEC ⁽³⁾ lays down a single list of emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs which may be authorized in the Member States;

Whereas it appears that the presentation of certain provisions of Annex I to Directive 74/329/EEC may give rise to conflicting interpretations and that these provisions should therefore be worded more clearly;

Whereas having regard to the most recent scientific information on the safety of the mixed acetic and tartaric esters of mono- and diglycerides of fatty acids, their use may be authorized by including them under E 472 (f);

Whereas the reference to polyphosphates (E 450) in the aforementioned Annex I must be worded more precisely to take account of commercial practice;

Whereas the criteria of purity for carrageenan (E 407) are also applicable to furcelleran (E 408); whereas therefore E 408 is not now necessary;

Whereas tamarind seed flour (E 411) and stearyl-2-lactylic acid (E 480) are no longer commercially available for use in foodstuffs;

Whereas ethylcellulose (E 462) has no technical function as an emulsifier, stabilizer, thickener or gelling agent;

Whereas the addition of sugars as defined in Directive 73/437/EEC ⁽⁴⁾ is necessary, especially in the case of carrageenan (E 407), pectin (E 440 (a)) and amidated pectin (E 440 (b)), in order to ensure that users are supplied with a product having a constant gelling power;

Whereas it is appropriate to use for these products, as the case may be, the designations 'carrageenan', 'pectin' or 'amidated pectin'; whereas, however, the user of these products should be informed of the presence of the added sugars, though it is impractical to require a statement of the quantity of sugar utilized, which may vary according to the natural gelling properties of the substances concerned,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The following shall be added to Article 2 of Directive 74/329/EEC:

'3. However, as regards the substance referred to in Annex I under E 440 (b), the Council, acting in accordance with the procedure provided for in Article 100 of the Treaty, may decide, before 31 December 1982 and after an enquiry by the Commission, to delete it from that Annex or otherwise to change its status.'

Article 2

Article 6 of Directive 74/329/EEC shall be amended as follows:

1. The third indent of paragraph 1 (a) shall be replaced by the following:

'— they shall not contain more than 50 mg/kg of copper and zinc taken together of which the

⁽¹⁾ OJ No C 266, 7. 11. 1977, p. 45.

⁽²⁾ OJ No C 59, 8. 3. 1978, p. 41.

⁽³⁾ OJ No L 189, 12. 7. 1974, p. 1.

⁽⁴⁾ OJ No L 356, 27. 12. 1973, p. 71.

zinc content must in no case exceed 25 mg/kg, subject to any exception deriving from the specific criteria of purity referred to in (b);'.

2. Paragraph 1 (b) shall be replaced by the following:

'(b) the specific criteria of purity determined in accordance with Article 7 (1).'

3. The following paragraph shall be added:

'3. Member States shall also provide that the substances listed in Annex I under E 407 and E 440 may, for the purposes of standardization, contain one or more sugars as defined in Directive 73/437/EEC.'

Article 3

Article 8 of Directive 74/329/EEC shall be amended as follows:

1. Paragraph 1 (b) shall be replaced by the following:

'(b) the number and designation of the substance as given in Annex I, qualified in the case of substances to which sugars have been added for standardization in accordance with Article 6 (3) by adding to the designation the statement "standardized with sugar(s)";'.

2. In paragraph 1, the following subparagraph shall be inserted:

'(d) appropriate words for the substance referred to in Annex I under E 420 (ii), where it contains after hydrosysis a level of total sugars of more than 1 %;'

3. In paragraph 1, subparagraph (d) shall be replaced by the following:

'(e) in the case of substances listed in Annex I, whether or not standardized with sugars in accordance with Article 6 (3), when mixed with each other, with other additives and where relevant with substances in which such other additives can be dissolved or diluted:

- the number or the designation of the substance as given in Annex I, qualified as necessary in accordance with paragraph 1 (b);
- the designation of each other additive and where relevant the substances in which such additives can be dissolved or diluted;

— the percentage of each component where this requirement is laid down in provisions relating to other categories of additives.'

4. The following sentence shall be added to the first subparagraph of paragraph 2:

'In the case of substances to which sugars have been added in accordance with Article 6 (3), this percentage incorporates the sugar used for standardization.'

Article 4

The following shall be added to Article 9:

'(e) products containing pectin and derived from dried apple pomace or dried peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralization with sodium or potassium salts.'

Article 5

Annex I to Directive 74/329/EEC shall be replaced by the Annex to this Directive.

Article 6

Member States shall, within one year of the notification of this Directive, amend their laws in accordance with the preceding provisions and shall forthwith inform the Commission thereof. The laws thus amended shall be implemented two years after notification of this Directive.

Article 7

This Directive is addressed to the Member States.

Done at Luxembourg, 29 June 1978.

For the Council

The President

S. AUKEN

ANNEX

'ANNEX I

Emulsifiers, stabilizers, thickeners and gelling agents which may be used in foodstuffs

EEC No	Designation	Conditions of use
E 322	Lecithins	
E 339	Sodium orthophosphates	
E 340	Potassium orthophosphates	
E 341	Calcium orthophosphates	
E 400	Alginic acid	
E 401	Sodium alginate	
E 402	Potassium alginate	
E 403	Ammonium alginate	
E 404	Calcium alginate	
E 405	Propane-1,2-diol alginate	
E 406	Agar	
E 407	Carrageenan	
E 410	Locust bean gum	
E 412	Guar gum	
E 413	Tragacanth	
E 414	Acacia or gum arabic	
E 420	(i) sorbitol (ii) sorbitol syrup	
E 421	Mannitol	
E 422	Glycerol	
E 440 (a)	Pectin	
E 440 (b)	Amidated pectin	
E 450 (a)	(i) diSodium dihydrogen diphosphate (ii) triSodium diphosphate (iii) tetraSodium diphosphate (iv) tetraPotassium diphosphate	
E 450 (b)	(i) pentaSodium triphosphate (ii) pentaPotassium triphosphate	
E 450 (c)	(i) sodium polyphosphates (ii) potassium polyphosphates	
E 460	Microcrystalline cellulose	
E 461	Methylcellulose	
E 463	Hydroxypropylcellulose	
E 464	Hydroxypropylmethylcellulose	
E 465	Ethylmethylcellulose	
E 466	Carboxymethylcellulose	

EEC No	Designation	Conditions of use
E 470	Sodium, potassium and calcium salts of fatty acids	Exclusively in the manufacture of 'Dutch' type rusks up to a level singly or in combination of not more than 1.5 % of flour used
E 471	Mono- and diglycerides of fatty acids	
E 472 (a)	Acetic acid esters of mono- and diglycerides of fatty acids	
E 472 (b)	Lactic acid esters of mono- and diglycerides of fatty acids	
E 472 (c)	Citric acid esters of mono- and diglycerides of fatty acids	
E 472 (d)	Tartaric acid esters of mono- and diglycerides of fatty acids	
E 472 (e)	Mono- and diacetylartaric acid esters of mono- and diglycerides of fatty acids	
E 472 (f)	Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids	These substances may not be used in bread unless permitted under national law
E 473	Sucrose esters of fatty acids	
E 474	Sucroglycerides	
E 475	Polyglycerol esters of fatty acids	These substances may not be used in bread unless permitted under national law
E 477	Propane-1,2-diol esters of fatty acids	
E 481	Sodium stearyl-2-lactylate	
E 482	Calcium stearyl-2-lactylate	
E 483	Stearyl tartrate	