## **COMMISSION OF THE EUROPEAN COMMUNITIES**

COM(94) 423 final Brussels, 14.10.1994 94/0235 (COD)

## Proposal for a EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

amending Council Directive 80/777/EEC on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters

(presented by the Commission)

### **EXPLANATORY MEMORANDUM**

## 1 MOTIVATION FOR THE PROPOSAL IN TERMS OF SUBSIDIARITY

# 1 What are the objectives of the action envisaged in relation to the obligations of the Community?

At the European Council held in Edinburgh on 11-12 December 1992, the Heads of State and Government took note of the intention of the Commission to rationalize certain Directives, the provisions of which may be unnecessarily detailed, and which, in accordance with the new approach, could be replaced by Directives limited to the essential requirements necessary to ensure the free movement of goods within the Community (Part A, Annex 2 point 2 of the Presidency conclusions). One of the Directives mentioned was Directive 80/777/EEC on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters<sup>(1)</sup>. The present proposal is intended to fulfil the undertakings given by the Commission in this respect.

2. Does the action envisaged result from an exclusive Community competence or a competence which is shared between the Community and the Member States?

The action envisaged results from an exclusive Community competence.

## 3. What is the Community dimension of the problem?

Adopted in 1980, Directive 80/777/EEC has harmonized the laws of the Member States relating to the exploitation and marketing of natural mineral waters. The adoption of the Directive represented a major step forward, taking into account the substantial differences in the provisions previously existing in the Member States. The Directive is based on the principle of mutual recognition. It ensures the free circulation of natural mineral waters, ensures a high level of protection of the consumer, and also provides the European consumer with the possibility of a wide choice of different natural mineral waters.

Since the adoption of the Directive, the annual consumption of natural mineral waters in the Community has expanded dramatically and steadily from 8 000 million litres in 1980 to approximately 22 000 million litres today. Information about the production of natural mineral waters is summarised in Annex I.

There are more than one thousand different natural mineral waters recognised in the Community. This recognition, which is carried out by the competent authorities of the Member States, is a prerequisite to their marketing. In order to ensure transparency, the Commission publishes in the Official Journal of the European Communities lists of the recognitions of natural mineral waters granted by Member States. The references to the relevant Official Journals are set out in Annex II.

<sup>(1)</sup> OJ No L 229, 30.8.1980, p. 1.

From the industrial point of view, the exploitation of natural mineral water is clearly in expansion, and there are also substantial exports of European natural mineral waters, notably to North America and the Middle East.

Directive 80/777/EEC relates to one food commodity, natural mineral waters, and in the conclusions of the Edinburgh Summit, this directive was grouped together with the so-called "vertical directives", establishing quality and compositional standards for fruit juices, marmalades, honey, coffee extracts, etc. However, Directive 80/777/EEC can be clearly distinguished from this group of directives because to a very large extent it is already limited to the "essential requirements" which should be the subject of Community legislation.

The Directive establishes a pre-marketing approval for these waters. Through the application of the concept of mutual recognition, the recognition of a natural mineral water by one Member State provides access to the entire Community market. The Directive defines the public health criteria for the granting of recognition, in particular in respect of the definition of the source and strict requirements for the absence of chemical or microbiological contamination. It also lays down certain specific provisions concerning labelling, notably in order to avoid misleading the consumer in respect of the therapeutic properties of these waters and to avoid confusion with other types of bottled waters.

The principles that inspired Directive 80/777/EEC during its preparation were later explicitly formulated in the communications from the Commission on the free movement of foodstuffs (Completion of the Internal Market: Community legislation on Foodstuffs, COM(85) 603 final, Communication on the free movement of foodstuffs within the Community (COM(89) 256 final)).

Following extensive consultations, it became apparent that producers of natural mineral waters were strongly against any fundamental changes in the basic principles underlying the Directive. Indeed, the Directive is perceived by industry as a valuable instrument in promoting the image of natural mineral waters, contributing to the rapid expansion in sales mentioned above. Consultation with the social partners, (industry, consumers, retailers, workers and farmers) produced similar results.

In addition, the Commission has undertaken extensive consultations with experts from the Member States, which have also shown that there is little support for fundamental changes to the Directive.

The Commission has therefore concluded that its proposal to rationalize Directive 80/777/EEC should be limited in scope, and should consist of:

- the updating of certain detailed provisions in the light of scientific and technical progress in the 14 years since the Directive was first adopted;
- bringing certain provisions of the Directive into line the general provisions of Community food law.

# 4. What is the most efficacious solution in comparison with the means available to the Community and those of the Member States?

The Commission considers that the experience acquired since the adoption of Directive 80/777/EEC has shown that it is an efficacious means of ensuring the realisation of the internal market for natural mineral waters in a manner which has allowed production and sales to expand considerably. Radical changes to the existing Community provisions, or their abolition, would create uncertainty which would be harmful to the long-term interests of producers and consumers. On the other hand, the Commission recognises that there are limits to the extent of harmonization which is necessary to achieve the internal market.

During the process of the elaboration of the proposal, consideration was given to the further harmonization of the national rules concerning the types of therapeutic claims which may be made on the labelling of natural mineral waters in accordance with Article 9 of the Directive. However, in view of the limited practical importance of this question, and the very different approaches adopted by the Member States, the Commission has concluded that it would not be appropriate to bring forward further proposals on this point.

The Commission was also invited by certain Member States and other interested parties to consider extending the scope of the Directive to cover bottled waters other than natural mineral waters, in particular those products which are marketed under the names "eaux de source", "quellewasser", "agua de manantial", or "spring waters". So far as the composition and health characteristics of such waters are concerned, all bottled waters other than natural mineral waters are covered by Directive 80/778/EEC relating to the quality of water intended for human consumption<sup>(2)</sup>. Although some Member States have specific legislation on such waters, the rules differ somewhat from one Member State to another. The establishment of definitions at Community level could give rise to confusion and block further developments in this area. The Commission has therefore decided not to propose including such waters within the scope of Directive 80/777/EEC.

# 5. What is the concrete added value provided by the action envisaged by the Community and what would be the cost of inaction?

The Commission proposals will permit the up-dating of Community legislation in respect of natural mineral waters. The failure to update Community legislation in the light of scientific and technological developments would constitute a barrier to innovation.

## 6. What methods of action are available to the Community?

The amendment of Directive 80/777/EEC by a further Council directive is required.

<sup>(2)</sup> OJ No L 229, 30.8.1980, p. 11.

# 7. Are uniform rules necessary, or would a directive setting out general principles and leaving the implementation to Member States be sufficient?

As noted above, the Commission's proposal is based on the application of the "new-approach" through the establishment of essential requirements to ensure the safety of natural mineral waters. For other aspects, the Directive and the proposal for its amendment set out general principles, leaving the implementation to Member States.

## 2. SPECIFIC REMARKS

The Commission's proposals for detailed changes to the Directive are summarized below.

## The composition of natural mineral waters

Natural mineral waters are exempted from the provisions of Directive 80/778/EEC on drinking water for human consumption. Therefore, the limits for the presence of various parameters regarding the composition of drinking water established by Directive 80/778/EEC do not apply to natural mineral waters. In practice, only a limited number of mineral waters exceed the parameters laid down by Directive 80/778/EEC, but in these cases it is precisely the higher levels of certain chemicals which give the waters the properties which are sought after by consumers. In these circumstances, the Commission does not consider that it would be justified to prohibit the marketing of all natural mineral waters which exceed the parameters laid down by Directive 80/778/EEC.

On the other hand, it is necessary to ensure that the natural mineral waters concerned do not present a risk to public health. The Commission has requested the Scientific Committee for Food to study the question of the acceptability from the public health point of view of the presence of certain mineral constituents of national mineral waters, and the Committee is actively considering this question. In order to give effect to the recommendations of the Committee, the Commission is proposing that it should be possible to establish agreed Community-wide limits for the levels of certain constituents in natural mineral waters, using a Committee procedure. In addition, the Commission is proposing that, where necessary, analytical methods should be adopted by the same procedure to verify the absence of chemical or microbiological contamination of mineral waters.

## 2. Treatment of natural mineral waters with ozone

Article 4(1) of Directive 80/777/EEC currently permits the separation of certain unstable elements by filtration or decanting, possibly preceded by oxygenation. One Member State has interpreted this provision as also permitting the use of ozone enriched air treatments in order to separate certain elements from the water. The other Member States consider that the current text of the Directive does not permit such treatments, because they are not compatible with the natural status of the mineral water. The Commission is proposing that the Directive should be amended to indicate that ozone treatments are permitted, under strictly defined conditions as regards possible health effects to be laid down by a Committee procedure following consultation of the Scientific Committee for Food, provided that the treatment is specifically controlled by the competent authorities.

## 3. Labelling of natural mineral waters

Currently, there is no obligation to include a statement of the analytical composition of natural mineral waters on the labelling, although most producers do in fact provide this information. In the interests of consumer information, the Commission is proposing to make the inclusion of such a statement obligatory. In addition, the proposal envisages that specific provisions may be laid down, using a Committee procedure, to ensure that the consumer is informed of the presence of unusually high levels of certain constituents in natural mineral waters.

## 4. Natural mineral waters imported from third countries

Natural mineral waters extracted in third countries may be imported into the Community provided that they have been recognised by the competent authority of one of the Member States. In accordance with the current provisions of the Directive, this recognition must be renewed every two years. Experience suggests that this requirement is unnecessarily bureaucratic, and the Commission is therefore proposing that renewal should be required only once every ten years.

## 5. General provisions

In order to align the Directive with other Community food legislation, the Commission is proposing to include in the Directive a specific obligation to consult the Scientific Committee for Food before the adoption of measures which may have an effect on public health. A further amendment would introduce a safeguard clause procedure into the Directive in order to provide a basis for rapid decisions at Community level should serious problems of the contamination of natural mineral waters arise.

Finally, in the light of the developments in the case law of the Court of Justice, it now appears that the provisions of the Directive constitute a sufficient basis for the free movement of natural mineral waters within the Community. The Commission is therefore proposing that the free circulation clause contained in Article 10(1) of the Directive should be made of general application. Therefore the possibility allowed Member States to block imports of natural mineral waters from other Member States in application of non-harmonized provisions should be repealed.

## Annex I

#### NATURAL MINERAL WATERS IN THE EUROPEAN UNION

## Production and consumption in 1980 and 1992 \*

| Country        | Production Mio. I. |       | Consumption, l.per capita |      |  |
|----------------|--------------------|-------|---------------------------|------|--|
|                | 1980               | 1992  | 1980                      | 1992 |  |
| Belgium        | 427                | 700   | 53                        | 105  |  |
| Denmark        | n.a.               | n.a.  | n.a.                      | n.a. |  |
| Greece         | n.a.               | n.a.  | n.a                       | n.a. |  |
| Spain          | 785                | 1825  | 21.3                      | 44   |  |
| France         | 2980               | 5300  | 49.5                      | 80   |  |
| Germany        | 2355               | 6315  | 39.2                      | 932  |  |
| Ireland        | n.a.               | 20    | n.a                       | 6    |  |
| Italy          | 1510               | 6500  | 26                        | 116  |  |
| Luxembourg     | n.a.               | n.a.  | n.a                       | n.a  |  |
| Netherlands    | n.a.               | 66    | n.a.                      | . 15 |  |
| Portugal       | 153                | 286   | . 15.3                    | 29   |  |
| United Kingdom | n.a.               | 370   | n.a.                      | 10   |  |
| E. U.          | 8210               | 21382 | 36                        | 53   |  |

<sup>(\*)</sup> Source: Annual Reports of GISEM-UNESEM, for 1982 and 1993.

for 1981.

<sup>2.</sup> not including the new Länder

n.a not available.

Annex II

# References to the publication in the Official Journal of the European Communities of the lists of natural mineral waters recognized by the Member States (29.6.1994)

| Member State   | Refer  | Reference in the Official Journal |             |   |
|----------------|--------|-----------------------------------|-------------|---|
| Belgium        | 1993   | C224                              | 19.08.1993  |   |
| Denmark        | 1993   | C224                              | 19.08.1993  |   |
| Germany        | 1994   | C64                               | 02:03.1994  |   |
|                | 1993   | C224                              | 19.08.1993  |   |
| Cássas         | 1994   | C64                               | 02.03.1994  |   |
| Greece         |        |                                   | ,           |   |
|                | 1993ء  | C224                              | 19.08.1993  |   |
| Spain          | 1994   | C176                              | 29.06.1994  |   |
| France         | 1994   | C176                              | 29.06.1994  |   |
|                | 1994 . | C64                               | 02.03.1994. |   |
|                | 1993 1 | C224                              | 19.08.1993  |   |
| Ireland        | 1993   | C224                              | 19.08.1993  | 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - |
| Italy          | 1992   | C018                              | 24.01.1992  |   |
|                | 1990   | C307                              | 07.12.1990  |   |
|                | 1990   | C186                              | 27.07.1990  |   |
|                |        | <u> </u>                          |             |   |
| Luxembourg     | 1993   | C224                              | 19.08.1993  |   |
| Netherlands    | 1994   | C64                               | 02.03.1994  |   |
|                | 1993   | C224                              | 19.08.1993  |   |
| Portugal       | 1993   | C261                              | 25.09.1993  |   |
| United Kingdom | 1994   | C176                              | 29.06.1994  | .,                                      |
|                | 1994   | C64                               | 02.03.1994  |   |
|                | 1993   | C224                              | 19.08.1993  | · .                                     |

## Proposal for a EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

amending Council Directive 80/777/EEC on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters

## THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Whereas Council Directive 80/777/EEC<sup>(3)</sup> has harmonized the laws of the Member States relating to the exploitation and marketing of natural mineral waters;

Whereas the primary purposes of any rules on natural mineral waters should be to protect the health of consumers, to prevent consumers from being misled and to ensure fair trading,

Whereas it is desirable to amend Directive 80/777/EEC to take account of technical and scientific progress since 1980; whereas it is also desirable to rationalise the provisions of that directive with other provisions of Community food law;

Whereas it is necessary to extend the period of recognition for natural mineral waters originating from non-member countries in order to simplify the administrative procedures;

Whereas it is necessary to clarify the circumstances under which the use of air enriched in ozone may be permitted in order to separate unstable elements from natural mineral waters under conditions which will ensure that the composition of the water as regards its essential constituents is not affected:

Whereas the inclusion of the statement of the analytical composition of a natural mineral water should be made compulsory in order to ensure that consumers are informed;

Whereas it is advisable in order to ensure a smooth running of the internal market for natural mineral waters to introduce a procedure to allow for coordinated action between the Member States in cases of urgent situations which may present a risk to public health,

(2)

<sup>(1)</sup> 

OJ No L 229, 30.8.1980, p. 1; as last amended by the EEA Agreement.

Whereas a procedure to lay down certain provisions of a detailed nature concerning natural mineral waters, notably in respect of the limits for the levels of certain constituents of natural mineral waters should be established, whereas provisions for the indication, on labelling, of high levels of certain constituents should also be adopted and methods of analysis, including limits of detection, to check the absence of pollution of natural mineral waters and sampling procedures and methods of analysis for checking the microbiological characteristics of natural mineral waters should be determined;

Whereas any decision on natural mineral waters likely to have an effect on public health should be adopted following consultation of the Scientific Committee for Food,

### HAVE ADOPTED THIS DIRECTIVE:

## Article 1

Directive 80/777/EEC is hereby amended as follows:

- 1. In Article 1(2), the third sub-paragraph is replaced by the following:
  - "The validity of the certification referred to in the second subparagraph may not exceed a period of 10 years. It shall not be necessary to repeat the recognition procedure referred to in the first subparagraph if the certification is renewed before the end of the said period."
- 2. In Article 4, the following paragraph 1a is inserted:
  - "la. In addition, the separation of iron, manganese and sulphur compounds and arsenic by treatment with ozone enriched air shall be permitted, in so far as such treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that:
    - the treatment complies with the conditions for use to be laid down in accordance with the procedure laid down in Article 12;
    - the treatment is specifically controlled by the competent authorities."
- In Article 7, paragraphs 2 and 3 are replaced by the following:
  - "2. Labels on natural mineral waters shall also give the following mandatory information:
    - (a) a statement of the analytical composition, giving its characteristic constituents;
    - (b) the place where the spring is exploited and the name of the spring

- In the absence of Community provisions, Member States may also introduce provisions which require information on any treatments referred to in point (a) of Article 4(1)."
- 4. Paragraph 4 of Article 9 is deleted.
- 5. Paragraph 2 of Article 10 is deleted.
- 6. The following Article 10a is inserted:

## "Article 10a

- 1. Where a Member State has detailed grounds for considering that a natural mineral water does not comply with the provisions laid down in this Directive, or endangers public health, albeit freely circulating in one or more Member States, that Member State may temporarily restrict or suspend trade in that product within its territory. It shall immediately inform the Commission and the other Member States thereof and give reasons for its decision.
- 2. At the request of any Member State or the Commission, the Member State which has recognized the water shall provide all relevant information concerning the recognition of the water, together with the results of the regular checks.
- 3. The Commission shall examine as soon as possible the grounds adduced by the Member State referred to in paragraph 1 within the Standing Committee for Foodstuffs, and then shall deliver its opinion forthwith and take appropriate measures.
- 4. If the Commission considers that amendments to this Directive are necessary in order to ensure the protection of public health, it shall initiate the procedure laid down in Article 12, with a view to adopting those amendments. The Member State which has adopted safeguard measures may, in that event, retain them until the amendments have been adopted."
- 7. Article 11 is replaced by the following:

## "Article 11

The following may be adopted in accordance with the procedure laid down in Article 12:

- limits for the levels of constituents of natural mineral waters.
- any necessary provisions for the indication on the labelling of high levels of certain constituents;
- methods of analysis, including limits of detection, to determine the absence of pollution of natural mineral waters;

- the sampling procedures and the methods of analysis necessary for checking the microbiological characteristics of natural mineral waters;
- the conditions of use of ozone enriched air referred to in Article 4(1a)."
- 8. The following Article 11a is inserted:

## "Article 11a

Any decision likely to have an effect on public health shall be adopted by the Commission following consultation of the Scientific Committee for Food."

## Article 2

Member States shall, where necessary, amend their laws, regulations or administrative provisions so as to:

- permit trade in products complying with this Directive by not later than ... (4);
- prohibit trade in products not complying with this Directive with effect from... (5). However, trade in products placed on the market or labelled before that date and not conforming with this Directive may continue until stocks run out...

They shall immediately inform the Commission thereof.

## Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

## Article 4

This Directive is addressed to the Member States.

Done at Brussels.

For the European Parliament The President

For the Council The President

Date 12 months after the date of adoption.

Date 24 months after the date of adoption.

# IMPACT ASSESSMENT FORM THE IMPACT OF THE PROPOSAL ON BUSINESS.

with special reference to small and medium sized enterprises

Title of proposal: Proposal for a Directive of the European Parliament and the Council amending Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters.

Document Reference number: 111/5502/93

## The proposal

1. Taking account of the principle of subsidiarity, why is community legislation necessary in this area and what are its main aims?.

See Explanatory Memorandum.

## The impact on business

- 2. Who will be affected by the proposal?
  - which sectors of business

Those responsible for the placing on the market of natural mineral waters.

which sizes of business (what is the concentration of small and medium sized firms)

Although there are a limited number of larger businesses, the sector is primarily made up of small and medium sized companies, exploiting a single source of natural mineral waters.

- are there particular geographical areas of the Community where these businesses are found

No.

3. What will business have to do to comply with the proposal?

Many of the changes proposed are designed to clarify, up-date, simplify and bring the provisions of the Directive into line with the general provisions of Community food law. As such they do not impose specific obligations on business.

The new requirement to indicate the composition of the water on the labelling reflects the current practice of most producers, will not require any additional analyses, and in view of the lengthy implementation periods proposed, will not result in significant changeover costs. This is also the view of industry

- 4. What economic effects is the proposal is likely to have?
  - on employment
  - on investment and the creation of new businesses
  - on the competitive position of businesses

The natural mineral waters sector has expanded considerably since the adoption of Directive 80/777/EEC, from a total annual production of 8 000 million litres in 1980 to 21 000 million in 1992. The producers attribute this expansion in part to the existence of harmonized rules guaranteeing the quality of these products.

It is unlikely that the relatively minor changes proposed by the Commission will have any significant direct impact on the employment, on investment or on the competitive position of businesses in this sector.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

No. All companies are treated equally, independent of their size.

## **Consultation**

6. List the organisations which have been consulted about the proposal and outline their main views.

The Advisory Committee for Food, established by the Commission Decision 80/1073/EEC of 24 October 1980, was consulted on 20 January 1994. The Committee consists of representatives of industry, consumers, commerce, workers and agriculture. All the groups expressed general support for the changes proposed by the Commission, while not supporting the extension of the directive at this time to cover spring waters. Following these and other representations, the Commission has decided to follow this advice, and has not included spring waters within the scope of Directive 80/777/EEC.

Additional technical consultations were held with GESEM/UNESEM, which represents the interests of the mineral water producers at Community level GESEM/UNESEM has favoured the update of the directive in the sense proposed by the Commission to preserve its main characteristics and to align it with the "new approach" limiting itself to the essential requirements, and therefore leaving flexibility for the Member States and the operators.

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# **DOCUMENTS**

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