

COUNCIL DIRECTIVE 97/61/EC

of 20 October 1997

amending the Annex to Directive 91/492/EEC laying down the health conditions
for the production and placing on the market of live bivalve molluscs

THE COUNCIL OF THE EUROPEAN UNION,

HAS ADOPTED THIS DIRECTIVE:

Having regard to the Treaty establishing the European Community,

Article 1

Having regard to Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and placing on the market of live bivalve molluscs⁽¹⁾, and in particular Article 11 thereof,

The Annex to Directive 91/492/EEC is hereby amended as follows:

Having regard to the proposal from the Commission,

1. point 6 of Chapter II shall be replaced by the following:

Whereas Chapter V of the Annex to Directive 91/492/EEC sets the acceptable limit values for two types of marine toxin that constitute a danger to public health;

‘6. A registration document for the identification of batches of live bivalve molluscs during transport from the production area to a dispatch centre, purification centre, relaying area or processing plant must be issued by the competent authority upon request by the gatherer. For each batch, the gatherer must complete legibly and indelibly the relevant sections of the registration document which must contain the following information:

Whereas there is scientific evidence that a new marine toxin ‘Amnesic Shellfish Poisoning’ (ASP) that could endanger consumer health has appeared in the areas where bivalve molluscs are produced;

— the gatherer’s identity and address,

Whereas the public health requirements concerning live bivalve molluscs in Chapter V of the Annex to Directive 91/492/EEC must be adjusted to take account of this new marine toxin;

— the date of harvesting,

Whereas an acceptable limit value must be set for this new marine toxin, in order to protect public health;

— the location of the production area described in as precise detail as is practicable or by a code number,

Whereas experience has shown that the registration document for the identification of the batches of molluscs provided for in point 6 of Chapter II of the Annex to Directive 91/492/EEC should contain information concerning the health status of the area of origin and any purification or relaying operations that have been carried out on the molluscs;

— the health status of the production area as referred to in Chapter I,

Whereas it must be possible to trace the origin of bivalve molluscs placed on the market; whereas to do this it should be possible to link the information shown on the registration document with each batch placed on the market in a register kept by the dispatch centre;

— the shellfish species and quantity indicated in as precise detail as is practicable,

Whereas a standard registration document would be more easily understood by operators and inspection services regardless of the language in which it is drawn up; whereas such standard document should be introduced by the Commission,

— the approval number and place of destination for wrapping, relaying, purification or processing.

The registration document must be dated and signed by the gatherer.

The registration documents must be numbered regularly and in sequence. The competent authority must keep a register indicating numbers of registration documents together with the names of the persons collecting live bivalve molluscs to whom the documents were issued. The registration document for each batch of live bivalve molluscs must be date-stamped upon delivery of a batch to a dispatch centre, purification centre, relaying area or processing plant and must be kept by operators of such centres, areas or plants for at least twelve months. In addition, the gatherer is also obliged to keep it for the same period.

⁽¹⁾ OJ L 268, 24. 9. 1991, p. 1. Directive as amended by the 1994 Act of Accession.

However, if gathering is carried out by the same staff operating the dispatch centre, purification centre, relaying area or processing plant of destination, the registration document may be replaced by a permanent transport authorization granted by the competent authority. A standard registration document, containing a reference to the various requirements which are to be included in it and which are mentioned in Chapters II, III and IV of this Annex, will be introduced by the Commission in accordance with the procedure laid down in Article 12 of the Directive.;

2. point 9 of Chapter III shall be replaced by the following:

'9. after harvesting from the relaying area, batches must, during transport from the relaying area to the approved dispatch centre, purification centre or processing plant, be accompanied by a registration document, a specimen of which will be drawn up by the Commission in accordance with the procedure laid down in Article 12 of the Directive, setting out, in addition to the information specified in point 6 of Chapter II of this Annex, *inter alia* the location and approval number of the relaying area and the duration of relaying, together with any other information needed to identify and trace the product.

However, the above shall not be required where the same staff operate both in the relaying area and in the dispatch centre, purification centre or processing plant.;

3. the second subparagraph of point 13 of section III of Chapter IV shall be replaced by the following:

'Purification centres dispatching batches of live bivalve molluscs to dispatch centres must provide a registration document, a specimen of which will be drawn up by the Commission in accordance with the procedure laid down in Article 12 of the Directive, setting out, in addition to the information specified in point 6 of Chapter II of this Annex, *inter alia* the approval number and address of the purification plant and the duration of purification, the dates of entering and leaving the purification centre, together with any other information needed to identify and trace the product.;

4. point 4 of section IV of Chapter IV shall be replaced by the following:

'4. Dispatch centres must keep the following at the disposal of the competent authority:

- the results of microbiological tests on live bivalve molluscs from an approved production area or relaying area or from a purification plant,

- the dates and quantities of live bivalve molluscs delivered to the dispatch centre, together with the corresponding registration documents,
- dispatch details including the names and addresses of consignees, the dates and quantities of live bivalve molluscs dispatched, together with the corresponding entry registration document number(s).

These data must be classified chronologically and preserved for a period to be laid down by the competent authority, but not less than twelve months.;

5. The following point shall be inserted in Chapter V:

'7a. The total Amnesic Shellfish Poison (ASP) content in the edible parts of molluscs (the entire body or any part edible separately) must not exceed 20 micrograms of domoic acid per gramme using the HPLC method.'

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1998. 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 at the time of their official publication. The methods of making such a reference shall be laid down by the Member States.

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Luxembourg, 20 October 1997.

For the Council

The President

F. BODEN