



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.06.1996
COM(96) 279 final

96/0157 (CNS)
96/0158 (CNS)

Proposal
for a
COUNCIL DIRECTIVE

amending, with regard to *Gyrodactylus salaris*, Directive
91/67/EEC concerning the animal health conditions governing
the placing on the market of aquaculture animals and products

Proposal
for a
COUNCIL DIRECTIVE
amending Directive 93/53/EEC introducing
minimum Community measures for the control of certain fish
diseases

(presented by the Commission)

EXPLANATORY MEMORANDUM

The creation of the internal market resulted in the establishment of Community rules concerning animal health questions governing the placing on the market of aquaculture animals and products¹, and minimum measures for the control of certain fish diseases². The aim of the present proposals is to amend the existing Community rules in order:

- to organise trade in salmonid fish in such a way as to prevent the introduction of the parasite *Gyrodactylus salaris* into regions declared officially free of that parasite;
- to introduce a certification requirement in order to prevent the spread of the diseases infectious haematopoietic necrosis (IHN) and viral haemorrhagic septicaemia (VHS);
- to bring EC rules more in line with the requirements established by the "Office International des Epizooties" (OIE-World Organisation for Animal Health)
- to limit the scope of Directive 93/53/EEC to viral fish diseases.

The first three objectives are achieved by amending Council Directive 91/67/EEC:

a) Gyrodactylosis

Directive 91/67/EEC contains the Community rules for organising the trade in aquatic animals in order to prevent the spread of serious diseases ("List II diseases"). The diseases currently covered by these rules are IHN and VHS which have a major economic impact on fish farming when introduced into a region previously free of these diseases. Movement of aquaculture animals is only possible from zones or certain farms with a high health status (free of IHN and VHS) towards zones or farms with a lower health status.

Recent reports have shown that gyrodactylosis, a disease of salmonids caused by the freshwater parasite *Gyrodactylus salaris*, occurs mainly in Scandinavia (Sweden, Finland, Norway). It has also been reported, but not officially confirmed, in certain other Member States. *Gyrodactylus salaris* causes widespread

¹Council Directive 91/67/EEC of 28 January 1991 (OJ N° L 46 of 19.02.1991, p. 1), as last amended by Directive 95/22/EEC (OJ N° L 243 of 11.10.1995, p. 1)

²Council Directive 93/53/EEC of 24 June 1993 (OJ N° L 175 of 17.9.1993, p. 23)

losses in riverine stocks of Atlantic salmon. Other salmonids, and in particular Baltic salmon (a strain of Atlantic salmon), brown trout and rainbow trout may act as non symptomatic carriers, and thus transfer the disease by commercial transfers or through migration within and possibly between rivers. Infection can be controlled in farmed stocks by chemotherapy, but it is virtually impossible to control it in the wild. It is therefore important to prevent the spread of the disease towards zones in the Community for which there is proof of absence of the disease.

Gyrodactylosis has thus all the characteristics for being considered as a list II disease for which Community measures should be applied in the same way as is the case for IHN and VHS. The proposed measure therefore aims to categorise gyrodactylosis as a list II disease and defines the rules under which a zone (water catchment area) or certain farms can be declared free of *Gyrodactylus salaris*, and for which the same movement patterns apply as for other list II diseases.

b) Certification for IHN and VHS

It appears necessary to introduce a certification requirement for fish, eggs and gametes placed on the market in a non approved zone (not officially declared free of IHN and VHS). Experience has shown that, in the absence of such requirement, fish from infected sites have been moved and contaminated non infected farms situated in these zones, which has led to severe financial losses. The amendment requires that in future consignments must be accompanied by a certificate issued by the competent authority, certifying that the fish, eggs or gametes originate in a farm not infected with either IHN or VHS.

c) Sampling requirements

In accordance with current EC legislation, a zone can obtain the approved status free of disease after a period of intensive sampling and testing of 4 years. The requirements adopted by OIE for obtaining approved status are that free status can be obtained after a two year period of sampling and testing. The present proposal aims to aline the EC requirements with the OIE requirements

The last objective is achieved by amending Directive 93/53/EEC and is a consequence of grading gyrodactylosis as a list II disease. This would render the requirements of Directive 93/53/EEC applicable to *Gyrodactylus salaris*. However, these measures are designed for the control of virus diseases, and should not therefore be applied as such to the parasite *Gyrodactylus salaris*. The scope of Directive 93/53/EEC must therefore be limited to viral diseases only.

Proposal
for a
COUNCIL DIRECTIVE
of

96/0157 (CNS)

amending, with regard to *Gyrodactylus salaris*, Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,

Having regard to the proposal of the Commission¹,

Having regard to the opinion of the European Parliament²,

Having regard to the opinion of the Economic and Social Committee³,

Whereas *Gyrodactylus salaris* is a fresh water parasite of salmonids which is able of causing serious mortalities in *Salmo salar* (Atlantic salmon);

Whereas the disease has a serious economic impact would it occur in regions containing wild riverine stocks of *Salmo salar* previously free of the disease;

Whereas experience has shown that the disease can spread from infected regions through commercial transfers of salmon and other salmonids;

Whereas it is therefore necessary to prevent the spread of the disease from regions in the Community where the absence of the disease can not be certified, towards regions with a documented history of absence of the parasite;

Whereas prevention of spread of the disease can be achieved under the procedures applicable to diseases of list II of Annex A of Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products⁴, as last amended by Directive 95/22/EC⁵;

¹OJ N° C

²OJ N° C

³OJ N° C

⁴OJ N° L 46, 19.02.1991, p. 1

⁵OJ N° L 243, 11.10.1995, p.1.

Whereas *Salmo salar* being the species most susceptible to *Gyrodactylus salaris*, the measures must apply to that species;

Whereas however the parasite can be transferred by other salmonid species and measures must therefore be extended to such species;

Whereas the criteria to certify the absence of *Gyrodactylus salaris* must be established,

Whereas it is necessary to ensure that the placing on the market of fish from a non approved zone does not prejudice the health status of non infected farms situated in a non approved zone; whereas this can be achieved through certification of consignments,

Whereas it is necessary to adapt the sampling and testing requirements for fish diseases to international standards;

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/67/EEC is amended as follows:

1. In Article 7:

a) the introductory sentence of paragraph 1 is replaced by the following text:

"1. The placing on the market of live fish belonging to the species susceptible to IHN and VHS as listed in Annex A, column 2, list II, their eggs and gametes, shall be subject to the following additional guarantees:"

b) the following paragraph is added to paragraph 1:

"(c) where they are to be introduced into a non approved farm situated in a non approved zone, they must be accompanied, in accordance with article 11, by a movement document corresponding to a model to be drawn up in accordance with the procedure laid down in article 26, certifying that

- they comply with the requirements of article 3 and come from a farm which is not infected with IHN or VHS, or
- they come from an approved zone with regard to IHN and/or VHS, or
- they come from an approved farm situated in a non approved zone with regard to IHN and/or VHS."

c) paragraph 2 is replaced by the following paragraphs:

"2. The placing on the market of live fish belonging to the species susceptible to gyrodactylosis as listed in Annex A, column 2, list II shall be subject to the following additional guarantees:

- a) where they are to be introduced into an approved zone with regard to *Gyrodactylus salaris*, they must, in accordance with Article 11, be accompanied by a movement document corresponding to a model to be drawn up in accordance with the procedure laid down in article 26, certifying that they come from an approved zone with regard to *Gyrodactylus salaris*;
- b) where they are to be introduced into a farm which, although not situated in an approved zone, fulfils the conditions set out in Annex CI, they must in accordance with Article 11, be accompanied by a movement document corresponding to a model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from an approved zone or from an approved farm with regard to *Gyrodactylus salaris*.

3. The Commission may, in accordance with the procedure laid down in Article 26, adapt or delete the additional guarantees referred to in paragraphs 1 and 2, depending on the evolution of the animal health situation in the Community or in accordance with scientific evolution."

2. In Article 9, the first sentence of point 1 is replaced by the following text:

"Fish susceptible to IHN and VHS must be slaughtered and eviscerated prior to dispatch."

3. In Annex A:

- a) the following is added to columns 1 and 2 of list II under the heading "fish":

"Gyrodactylosis (<i>Gyrodactylus salaris</i>)"	" <i>Salmo salar</i> (Atlantic salmon) and other salmonid species"
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- b) in list III, under "Fish", the words "*Gyrodactylus salaris*" in column 1 are deleted.

4. In Annex B, point I,B is replaced by the following text:

"B. Grant of approval

1. In order to obtain approved status with regard to IHN and/or VHS, a continental zone must meet the following requirements:

- a) all fish are free for at least four years from any clinical or other sign of IHN and/or VHS.
- b) all farms in the continental zone are placed under the supervision of the official services. Two health inspections per year for two years must have been carried out.

The health inspections must have been carried out at the times of the year when the water temperature favours the development of these diseases. The health inspection must at least consist of:

- an inspection of fish showing abnormalities,
- the taking of samples in accordance with a programme established under the procedure provided for in Article 15, which are to be sent as quickly as possible to an approved laboratory to be tested for the pathogens in question.

However, zones having a historical record of absence of IHN and /or VHS, may obtain approved status if:

i) their geographical situation does not permit easy introduction of disease;

ii) an official disease control system has been in place for an extended period of time of at least ten years, during which:

- there has been regular monitoring of all farms,
- a disease notification system has been applied,
- no case of disease has been reported,
- under the rules in force, only fish, eggs or gametes from non-infected zones or farms subject to official checks and presenting equivalent health guarantees, were able to be introduced into the zone.

The period of 10 years referred to above may be reduced to five years as a result of the testing carried out by the official service of the requesting Member State, provided that, in addition to the requirements referred to in the first subparagraph, the regular monitoring of all farms referred to above

has included at least two health inspections per year involving at least:

- an inspection of fish showing abnormalities,
- a taking of samples of at least 30 fish at each visit.

Member States wishing to benefit from the provisions relating to historical records must submit their request no later than 31 December 1996.

- c) if there is no farm in a continental zone to be approved, the official services must have subjected fish from the lower part of the catchment area to a health inspection twice a year for four years, in accordance with paragraph b;
- d) the laboratory examinations of fish taken during health inspections have produced negative results as regards the pathogens in question.
- e) Where a Member State has requested approval for a water catchment area originating in a neighbouring Member State, or common to two Member States, the following provisions shall apply:
 - the two Member States concerned shall simultaneously submit a request for approval in accordance with the procedures laid down in Articles 5 or 10,
 - the Commission, in accordance with the procedure laid down in Article 26, after examining and checking the request and evaluating the health situation, shall, if need be, lay down any other provisions necessary for granting such approval.

The Member States, in accordance with Directive 89/608/EEC⁶ shall grant each other mutual assistance for the application of this Directive, and in particular of this paragraph;

2. In order to obtain approved status with regard to *Gyrodactylus salaris*, a continental zone must meet approval conditions established in accordance with the procedure provided for in Article 26.

However, where a Member State considers that its territory or part of its territory is free from *Gyrodactylus salaris*, it may submit to the Commission appropriate justifications,

⁶ OJ n° L 351, 2. 12 1989, p 34;

setting out in particular:

- i) the results of surveillance testing carried out over an extended period of time, and based on the identification of the parasite and the fact that the disease is compulsorily notifiable to the official service,
- ii) the period over which the surveillance was carried out,

Based on the above information, and in accordance with the procedure provided for in Article 26, it may be decided to grant the approved status to the territory or a part thereof of the applying Member State.

5. In Annex B,I,C point 2 is replaced by the following text:

- "2. a) each farm must undergo, with regard to IHN and/or VHS, two health inspections annually in accordance with point B,1(b); however, samples will be taken by rotation in 50% of the fish farms in the continental zone each year;
- b) the surveillance programme for maintenance of approved status with regard to gyrodactylosis is established in accordance with the procedure provided for in Article 26."

6. In Annex B,II, paragraph B is replaced by the following text:

"B. *Grant of approval.*

In order to obtain approved status with regard to IHN and/or VHS, a coastal zone for fish must meet the requirements laid down for continental zones referred to in point IB, first paragraph.

Where necessary, the requirements for obtaining the approved status with regard to gyrodactylosis for coastal zones are laid down in accordance with the procedure provided for in Article 26."

7. In Annex C,I,A point 4 is replaced by the following text:

- "4. it must comply, *mutatis mutandis*, with the requirements set out in Annex B,I,B. Furthermore, where approval with regard to IHN and/or VHS is requested on the basis of a historical record with an official control system for a 10-year period, it must have been submitted, at least once a year, to a clinical inspection and the taking of samples to be tested for the pathogens in question in an approved laboratory;"

8. In Annex C, I point B is replaced by the following text:

"B. Maintenance of approval

Maintenance of approval shall be subject to the requirements set out in Annex B I C. However, sampling with regard to IHN and/or VHS must be carried out once a year

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1997. They shall forthwith notify 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 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 governed by this Directive.

Article 3

This Directive shall enter into force 20 days after 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 Council

Proposal
for a
COUNCIL DIRECTIVE
amending Directive 93/53/EEC introducing minimum Community
measures for the control of certain fish diseases

96 | 0158 (CNS)

THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty establishing the European Community,
and in particular Article 43 thereof,

Having regard to the proposal of the Commission¹,

Having regard to the opinion of the European Parliament²,

Having regard to the opinion of the Economic and Social
Committee³

Whereas Council Directive 91/67/EEC OF 28 January 1991 concerning
animal health conditions governing the placing on the market of
aquaculture animals and products⁴ as last amended by Directive
95/22/EC⁵ lays down the animal health conditions for the placing
on the market of aquaculture fish susceptible to the diseases
listed in its Annex A; whereas this list includes viral diseases
such as IHN and VHS, as well as gyrodactylosis caused by the
parasite *Gyrodactylus salaris*;

Whereas Council Directive 93/53/EEC of 24 June 1993 introducing
minimum Community measures for the control of certain fish
diseases⁶, as amended by the Treaty of accession of Austria,
Finland and Sweden, lays down control measures for infectious
salmon anemia (ISA), infectious haematopoietic necrosis (IHN), and
viral haemorrhagic septecemia (VHS);

Whereas the measures provided for in Directive 93/53/EEC are
designed for the control of viral diseases; whereas those
measures are not appropriate for gyrodactylosis;

¹OJ N°

²OJ N°

³OJ N°

⁴OJ N° L 46 of 19.2.1991, p 1

⁵OJ N° L 234 of 11.10.1995, p.1

⁶OJ N° L 175 of 19.7.1993, p 23

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 93/53/EEC is amended as follows:

1. Article 1 is replaced by the following text:

" Article 1

This Directive defines the minimum Community measures for the control of the fish diseases referred to in Article 2, points 1 and 2."

2. In Article 2, point 1 is replaced by the following text:

"1 List I diseases: infectious salmon anaemia as referred to in Annex A, list I to Council Directive 91/67/EEC;"

3. In Article 2, point 2 is replaced by the following text:

"2. List II diseases: infectious haematopoietic necrosis and viral haemorrhagic septicaemia, as referred to in Annex A, list II to Directive 91/67/EEC;"

Article 2

1. Member States shall bring into force laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1997. They shall forthwith notify 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 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 governed by this Directive.

Article 3

This Directive shall enter into force 20 days after 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 Council

ISSN 0254-1475

COM(96) 279 final

DOCUMENTS

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Catalogue number : CB-CO-96-286-EN-C

ISBN 92-78-05523-9

Office for Official Publications of the European Communities
L-2985 Luxembourg