Executive Order on organic aquaculture

Pursuant to section 2 subsections 2-5, sections 10-11 and section 12 subsection 2 of Act No. 118 of 3 March 1999, the Organic Act, and section 52 and section 78 subsection 3-4 of Act No. 471 of 1 July 1998 on food products, etc. (the Foodstuffs Act) the following must apply:

Chapter 1
Scope and definitions

Section 1. This Executive Order concerns:
1) The production of organic fish in aquaculture.
2) The production of breeding material for production in accordance with No. 1, including ova and semen.
3) Preparation of fish as mentioned in 1, i.e.:
   a) preservation and/or processing, including slaughtering and cutting up,
   b) packing and labelling at the aquaculture facilities, or
   c) packing and labelling at undertakings other than aquaculture facilities.
4) Marketing of fish mentioned in item 1, as well as breeding material with reference made to the organic production method.
5) Importing organic fish and products processed from these.
6) Wholesale storage of the fish mentioned in item 1, and
7) Storage of live organic fish at retail level.

Section 2. When used in the Executive Order, the following definitions must apply:
1) Organic aquaculture facility: a production unit that has received a final organic report for the production of organic fish.
2) Fish: salmonoid fish (Salmonidae) and European eels (Anguilla anguilla) and products derived from these species such as spawn. With imports from countries within the EU and EEA and from third countries, however, the term "fish" covers all species of fish and derived products.
3) Organic inspection: Inspection according to this Executive Order.
4) Organic report: A report specifying in detail the requirements the undertaking must fulfil in order to ensure compliance with the organic regulations.
5) Marketing: Storing or displaying with the intention of selling, offering for sale, selling, supplying, or any other way in which products are marketed.

Section 3. The requirements for production etc., cf. section 1, laid down pursuant to this Executive Order does not apply to organic fish or derived products which have been legally produced or marketed in the other EU Member States or in EEA countries.

Chapter 2
Conditions for aquaculture, including registration and inspection

Section 4. Organic fish and organic breeding material must be produced in an aquaculture facility that is subject to organic inspection by the Danish Veterinary and Food Administration.

Section 5. Operators must register with the Danish Veterinary and Food Administration before engaging in activities as described in section 1. Conversion to organic production can only commence once the operator has received a final organic report.

Section 6. On commencement of the organic production inspection, the Danish Veterinary and Food Administration must prepare an organic production report. The organic production report must specify the exact conditions for the inspected activities. The organic production report must include a plan for conversion to organic production and a description of activities and the facilities used for this purpose.

Subsection 2. The operator must prepare an auto-control programme to ensure compliance with the provisions of this Executive Order. Once the Danish Veterinary and Food Administration considers that the auto-control procedure is adequate, the procedure must be included in the organic production report and must constitute part of the terms specified in the organic production report. It is the duty of the operator to make notes for the purpose of documenting compliance with the terms. The documentation must at all times be available to the Danish Veterinary and Food Administration and must be kept for a minimum of five years.

Subsection 3. The owner or user must organise and carry out the production according to the provisions of this order from the time of commencement of the conversion to organic production, however special conditions may apply in respect of the conversion plan.
Subsection 4. The Danish Veterinary and Food Administration may make amendments to the organic production report in case of additional requirements for inspection.

Section 7. When performance organic inspection, including organic cross-checks, the Danish Veterinary and Food Administration must at all times, on due proof of identity and without a court order, be granted access to premises, financial statements, books of accounts, etc. including electronically stored materials, at undertakings that are subjected to organic production inspection. This may be with the assistance of the police if necessary.

Subsection 2. At the request of the Danish Veterinary and Food Administration, operators subjected to organic production inspection must submit all information, including financial and accounting information of importance to the performance of the organic production inspection, including organic cross-checks, and to provide free of charge the necessary assistance in connection with inspection, sampling, copying and provision of any written material and printing of electronic data.

Section 8. At the request of the Regional Veterinary and Food Control Centres or the Danish Veterinary and Food Administration, operators who are not registered and subjected to an organic production inspection must submit documentation on the purchase and sale of both conventional and organic products as described in this Executive Order to and from operators who are subjected to organic production inspection.

Chapter 3
Discontinuation

Section 9. The operator must immediately report any temporary or permanent discontinuation of the activities covered by the organic production report to the Danish Veterinary and Food Administration. With permanent discontinuation of the activities, the organic production report must no longer apply. If no activities have been carried out for one year, the Danish Veterinary and Food Administration may withdraw the organic production report.

Subsection 2. If an aquaculture facility passes to a new owner, user or operator, the original owner, user or operator must notify the Danish Veterinary and Food Administration in writing immediately. If a new owner, user or operator wishes to continue the organic production, the Danish Veterinary and Food Administration must be notified, and a new organic production report be made available before the operations can be carried on.

Chapter 4
Operation

Section 10. Parallel operation of conventional and organic aquaculture is not permitted.

Subsection 2. Simultaneous operation of conventional and organic aquaculture may be permissible on application, cf. appendix 1, para. 2.

Section 11. Organic aquaculture facilities may only store ancillary substances, cf. appendix 6, drugs, cf. appendix 7, and feed, cf. the provisions in the Executive Order on feed for use in organic aquaculture facilities, the application of which is compatible with the provisions of this Executive Order.

Section 12. The existence of genetically modified, all female, cloned, zoo-technically and biotechnically treated fish, ova and semen, as well as triploid fish and ova are not be permitted in organic aquaculture facilities.

Section 13. Organic fish must be produced in compliance with the requirements for:
1) conversion and simultaneous operation of conventional and organic facilities, cf. appendix 1,
2) faunal passage, faunal disturbance and harmful game, cf. appendix 2,
3) production intensity and animal welfare, cf. appendix 3,
4) environmental conditions, cf. appendix 5,
5) ancillary substances, cf. appendix 6,
6) conditions applying to health inspection visits, vaccination and application of drugs, cf. appendix 7,
7) feed for use in organic aquaculture, cf. the provisions in the Executive Order on feed for use in organic aquaculture facilities, and
8) operations records, accounts, etc., cf. appendix 8.

Chapter 5
Preparation, Storage and Marketing

Section 14. Preparation of organic fish must take place pursuant to the provisions of Executive Order no. 761 of 14 August 2000 on organic foods etc. as subsequently amended, regarding requirements concerning composition and processing in Section 2, requirements concerning registration in sections 4-6 and requirements concerning inspection in sections 10-11 and
appendix 3 of this Executive Order, as well as article 5 and appendix III, the paragraph on general provisions and the paragraph on specific conditions, part B in Council Regulation No. 2092/91 of 24 June 1991 (EU Official Journal L 198, p. 1).

Section 2. Wholesale storage and wholesale marketing of organic fish must comply with the requirements of subsection 1.

Subsection 3. Transportation to a slaughter facility and slaughtering of organic fish, however, must take place according to the provisions of appendix 4 to this Executive Order.

Section 15. Storage of live fish at retail level must comply with the requirements concerning registration and control in Executive Order no. 761 of 14 August 2000 on organic foods etc., as subsequently amended, sections 4-6 and sections 10-11, as well as appendix 3 to this Executive Order.

Section 16. Fish that are organically labelled must be labelled with the code number of the Regional Veterinary and Food Control Centre in the region of the operator performing the last stage of the processing, cf. section 7 of the Executive Order no. 761 of 14 August 2000 on organic foods etc., as subsequently amended.

Section 17. If the conditions of parts II-IV of this Executive Order have been complied with, or if according to rules which the Danish authorities consider to be equivalent, organic fish produced as defined in section 2 subsection 2, item 1, which are prepared by operators subjected to organic production inspection by the Regional Veterinary and Food Control Centres pursuant to this Executive Order, may be labelled with the organic control logo (the Ø logo). This labelling must be in accordance with the regulation concerning this in section 5 of Executive Order no. 761 of 14 August 2000 on organic foods etc., as subsequently amended.

Chapter 6
Transport

Section 18. Transport of organic fish to other production and/or processing units or premises must be carried out according to the provisions of Council Regulation No. 2092/91 of 24 June 1991 (EU Official Journal L 198, p. 1), Appendix III, general provisions, item 7, and appendix 4 of this Executive Order.

Chapter 7
Import from Third Countries

Section 19. When importing organic fish from third countries, the operator must comply with the requirements concerning registration, control and import procedure according to sections 4-6 and sections 9a-11 of Executive Order no. 761 of 14 August 2000 on organic foods etc., as subsequently amended, and the provisions of Council Regulation No. 2092/91 of 24 June 1991 (EU Official Journal L 198, p. 1), Appendix III, general provisions and specific provisions, part C.

Section 20. Organic fish imported from a third country may only be marketed as organic, if the operator has obtained permission to do so from the Danish Veterinary and Food Administration prior to the import.

Subsection 2. The permit referred to in subsection 1 may only be granted if it can be sufficiently documented that the products have been manufactured and prepared according to regulations that are considered to be equivalent to the provisions laid down in Executive Order no. 761 of 14 August 2000 on organic foods etc. and the provisions of this Executive Order on organic production, and have been subject to an inspection which corresponds to the efficiency of the control procedures specified in articles 8 and 9 of Council Regulation No. 2092/91 of 24 June 1991 (EU Official Journal L 198, p. 1).

Subsection 3. At import, the products must be accompanied by a control certificate, cf. Appendix 3, certified by a controlling body as specified in the permit. The procedure laid down in Commission Regulation No. 1788/2001 (EU Official Journal 2001 L 243, p. 3) of 7 September 2001 must be complied with.

Chapter 8
Penalties and Entry into Force

Section 21. The following actions are punishable by fine:
1) violation of sections 4-5, 6 subsections 2 and 3, sections 9-20,
2) violation of a condition laid down in the organic report referred to in section 6, subsections 1 and 2, or
3) failure to provide assistance and information pursuant to sections 7 and 8.

Subsection 2. Undertakings etc. (legal persons) may incur liability according to the provisions of Part 5 of the Danish Penal Code.

Section 22. This order comes into force on 3 March 2004.
The Danish Veterinary and Food Administration, 23 February 2004
Per H. Kristiansen

/Thomas Ilum Damsgaard
Appendix 1,

1) Conversion and Simultaneous Operation of Conventional and Organic Aquaculture

1. Conversion

1.1. Fish or products made of fish can be described as organic if the fish have been kept under organic conditions from a weight of 25 g, or have been kept under organic conditions for a minimum of 12 months.

Ova and semen can be described as organic when produced by breeding fish that have been kept under organic conditions for a minimum of 6 months. It is permitted, however, to apply feed consisting of approved colouring agents for the breeding fish, cf. section 3 subsection 2 of the Executive Order on feed for application in organic aquaculture. In this case, the breeding fish may not be sold as organic.

1.2. Production facilities approved according to the “Eco-Healthy Eel Breeding” code of practice of 16 May 2000 can be considered to be converted immediately with regard to the fish that comply with the provisions of this code.

Elvers must only be caught in their natural environment where the national/regional/local competent authorities consider that the catch does not have a negative impact on the natural stock. The Danish Veterinary and Food Administration may grant permission for addition to the aquaculture facility when provided with documentation of sustainability from the appropriate authorities. This documentation must be obtained by the producers for each batch of elvers.

2. Simultaneous Operation of Conventional and Organic Aquaculture

An operator that operates several production units in the same area may apply for permission for simultaneous operation. The material submitted in each case must be evaluated and if necessary, the operations inspected before a decision is made as to whether permission can be granted. Permission will only be granted if conditions corresponding to those laid down in Appendix 3, specific conditions, Part A.1, item 3, 1st and 2nd paragraphs of Council Regulation No. 2092/91 (EU Official Journal L 198, p. 1) have been complied with.

Water that has been used by conventional fish farms may only be used in organic fish farms conditional on an upstream distance of at least 500 m. Net cages of organic sea farms must be placed at a minimum of 500 m from conventional sea farms.
Appendix 2

Faunal Passage, Faunal Disturbance and Harmful Game

1. Fauna and Faunal Passage
In order to secure unimpeded faunal passage all year round, organic fish farms must direct a minimum of 50% of the median minimum flow past the fish farm unused. This provision does not apply if the water supply comes from a borehole, a spring or from diffuse springs, or if otherwise prescribed by an environmental approval.

2. Leakage of Fish/Escape
In order to avoid faunal disturbance or genetic contamination from escaped fry or fish, organic aquaculture units must always be set up to prevent escape.

3. Harmful Game
As far as possible, harmful game must be prevented from causing damage to the stock of a fish farm. Unless otherwise provided for in writing by the Danish Veterinary and Food Administration in consultation with the wildlife management advisers of the National Forest and Nature Agency, harmful game can only be repelled by means of mechanical, acoustic or electric precautions. Rats, however, may be controlled according to applicable law.
Appendix 3

Production Intensity and Animal Welfare

Employees at organic aquaculture facilities must ensure that the fish are not subjected to unnecessary suffering resulting from stress, high stock density, feeding, internal environmental conditions, transport, handling or disease.

If work procedures require fish to be removed from the water, then the stay out of water must be made as short and as lenient as possible.

1. Sorting, Cleaning of Ponds, etc.
Before being subjected to handling, salmonoid fish weighing less than 25 g must be non-fed for a minimum of one and maximum of six days. Salmonoid fish weighing more than 25 g must be non-fed for a minimum of four and a maximum of ten days. Eels must be non-fed for a minimum of one and a maximum of ten days. The fish must be sprinkled with water at sorting.

2. Dead fish
In organic aquaculture facilities, dead and dying fish must be collected on a daily basis. In organic sea farms, dead and dying fish must be collected on a daily basis, weather permitting. The number of dead fish must be recorded in the operations log. In the event of unusually increasing mortality rates, a veterinary surgeon must be contacted for the purpose of establishing the reason for the increased rate of mortality. Corrective actions must be initiated and recorded in the operations log.

3. Feed and Feeding
Feed for application in organic aquaculture facilities must be of good quality and composed to meet the nutritional needs of the relevant fish species, cf. the Executive Order on feed for application in organic aquaculture facilities. Feeding must be organised in such a way as to ensure sufficient unimpaired access to the feedstuff for the entire stock of fish and to ensure the smallest possible waste to the surroundings.

4. Supply and Exchange of Water
In organic eel-producing aquaculture facilities, the water supplied must have the same quality as drinking water. Water exchange in breeding ponds must be a minimum of 5 l water per kilo of eels per hour. In organic salmonoid fish-producing aquaculture facilities, the exchange of water must take sufficient account of the physiological needs of the fish in terms of water flow and oxygen content. Furthermore, any negative impact from accumulated waste products and gasses must be prevented.

5. Oxygen and Nitrogen Saturation
Under normal operating conditions, the relative oxygen saturation rate of the water in which the fish are kept must range between 65 % and 100 %. Any deviation must be recorded in the operations log together with information on reason, period of time and any corrective action taken. In fish farms using sensors for automatic engagement of emergency oxygen supply, the oxygen content must be checked once a week as a minimum. The result of the check must be recorded in the operations log. In farms without automatic engagement of emergency oxygen supply, the oxygen content must be measured once a day as a minimum. The measurement results must be recorded in the operations log together with the time of the measurement.

Under normal operating conditions, the saturation of dissolved gasses must not be so high as to develop nitrogen narcosis in the fish. Any deviations must be recorded in the operations log together with information on duration, cause and any corrective actions taken. In the event of abnormal mortality rates or
abnormal behaviour in the stock of fish, the fish must be carefully examined to establish symptoms of nitrogen narcosis (appearance of bladders in eyes, gills or skin). If there are any signs of nitrogen narcosis, mechanical degassing of the water or other relief measures must be initiated without delay.

6. Storage Before End Use
Before end use in restaurants etc., organic fish must be stored live for a maximum of 21 days, provided that the requirements laid down in this appendix are complied with, with the exception of items 1 and 3.
Appendix 4

Requirements Concerning the Slaughtering of Fish Produced in Organic Aquaculture

1. Transport
Fish that are delivered for transportation must be clinically healthy. Fish from the same organic aquaculture facility must not be transported by the same lorry as fish from conventional aquaculture facilities. This applies to both vans and trailers.

1.1. Fasting
Before being subjected to transportation, salmonoid fish must be non-fed for a minimum of four and a maximum of ten days. Eels must be non-fed for a minimum of one and a maximum of ten days.

1.2. Transport Water and Exchange of Water
Fish must be transported in water only from the supplying facility or directly from a borehole or a well. Fish must be kept or transported in transport tanks for a maximum of six hours without the water being exchanged. Water must be exchanged only with water from a borehole or a well. Water must be exchanged at a place approved by the Danish Veterinary and Food Administration for exchanging water.

1.3. Transport Time and Storage in Transport Tanks in Denmark
The total length of storage in transport tanks and any storage in ponds at the undertaking performing the cutting up must not exceed 24 hours. However, storage in transport tanks must not exceed 12 hours. Time of loading and time of receipt must be recorded in the documents accompanying the consignment.

1.4. Oxygen Conditions
During transport, the fish must not be exposed to fluctuations in the oxygen content of the transport water. At all times during transport, the oxygen content must remain between 65% and 100% oxygen saturation.

2. Anaesthesia and Treatment at the Undertaking that Performs the Cutting Up

2.1. Segregation
Physically and in terms of water supply, storage tanks/ponds at the undertaking that performs the cutting up must be separated from any storage of conventionally produced fish.

2.2. Anaesthesia
The fish must be anaesthetised electrically or by the addition of carbon dioxide before being bled, cut up or cleaned. However, in case of sale from the aquaculture facility to end consumers, the fish may be rendered unconscious by a blow to the head immediately after being removed from the water.
Appendix 5

Environmental Conditions

1. Compliance with Objectives
Any organic aquaculture facility that is located on a stream must comply with the objectives laid down in the applicable regional plan for the stretch downstream from the installation.

2. Contamination from Outside
Where fish have been exposed to contamination, it is the duty of the operator to initiate the necessary examinations in order to make sure that the fish have not lost their organic status.

Where actual or potential contamination has come from outside an organically operated aquaculture facility, the operator must contact the Danish Veterinary and Food Administration immediately upon initiating the necessary measures for obtaining an assessment of the scope of the contamination and the impact on the continued organic status of the aquaculture. If, in the opinion of the Danish Veterinary and Food Administration, the contamination causes doubt as to the continued organic status of the aquaculture facility, the Danish Veterinary and Food Administration may deprive the aquaculture facility of its organic status, or suspend the permission until such time as the aquaculture facility complies with the rules and these have been incorporated in the organic production report.

3. Impact on the Aquatic Environment
An organic aquaculture facility must not cause contamination of a water course into which it discharges water, i.e. there must be no reduction of the fauna class, as specified according to the Danish Water Course Fauna Index. Measurements must be taken at measuring stations set up by the controlling authority upstream of the aquaculture facility. If the controlling authority can prove that a reduction of the Danish Water Course Fauna Index cannot be ascribed to the organic production, they may grant an exemption from the requirement. The inspection must be carried out in accordance with the national report on supervision of fish farming. The results of the counties’ examinations of the state of contamination must at all times be available for inspection by the Danish Veterinary and Food Administration.

An organic aquaculture facility must comply with the provisions of the Act on Environmental Protection, which includes having received an environmental approval, or having submitted a satisfactory application.

4. Internal Environmental Conditions

Summary of internal environmental parameters in organic aquaculture

<table>
<thead>
<tr>
<th>Measuring point</th>
<th>Requirement</th>
<th>Remarks</th>
<th>Control frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen content in breeding water</td>
<td>65-100%</td>
<td></td>
<td>Daily 1)</td>
</tr>
<tr>
<td>pH in breeding water</td>
<td>6-8</td>
<td>Eel breeding however: 5-7.5</td>
<td>Daily 2)</td>
</tr>
<tr>
<td>Nitrate in breeding water</td>
<td>Max. 300 mg/l, recirculation however, max. 500 mg/l</td>
<td>0.5 g salt/l is added if limits are exceeded</td>
<td>Weekly</td>
</tr>
<tr>
<td>Nitrite in breeding water</td>
<td>Max. 5 mg/l</td>
<td>0.5 g salt/l is added if limits are exceeded</td>
<td>Weekly</td>
</tr>
<tr>
<td>Ammonium in breeding water</td>
<td>Max. 5 mg/l</td>
<td></td>
<td>Weekly</td>
</tr>
<tr>
<td>Ammonia in breeding water</td>
<td>Max. 0.1 mg/l</td>
<td></td>
<td>Weekly</td>
</tr>
<tr>
<td>Temperature</td>
<td></td>
<td></td>
<td>Daily 2)</td>
</tr>
</tbody>
</table>
No chemical control of algae or plants, including application of anti-fouling agents in nets, must be permitted in organic aquaculture facilities.

Unless otherwise provided for in other legislation, only ancillary substances as provided for in Appendix 6 may be used.

In case of agricultural farming of the areas surrounding the ponds, only fertilisers or crop sprays as provided for in Council Regulation No. 2092/91 of 24 June 1991 (EU Official Journal L 198, p. 1), Appendix II, Parts A and B may be allowed.

21 Always provided that all breeding units are inspected at least once a week.
22 Always provided that all breeding units are inspected at least once a week.
23 Always provided that all breeding units are inspected at least once a week.
## Appendix 6

### Ancillary Substances allowed in organic aquaculture

<table>
<thead>
<tr>
<th>Substance</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen</td>
<td>Oxygenation of inlet and outlet water and in transport tanks.</td>
</tr>
<tr>
<td>Rock salt, sea salt</td>
<td>Control of fungi and parasites. Bacterial gill infection. System stabilisation in facilities with re-circulating water.</td>
</tr>
<tr>
<td>Hydrated lime</td>
<td>Disinfection of ponds, canals and equipment. pH-regulation of inlet water in acid and ochre-polluted streams. pH-stabilisation in facilities with re-circulating water.</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>pH-regulation of inlet water and in facilities with re-circulating water.</td>
</tr>
<tr>
<td>Carbon dioxide</td>
<td>Anaesthetic used when handling and slaughtering.</td>
</tr>
<tr>
<td>Iodofor</td>
<td>Disinfection of ova and equipment. Iodofor residue may not be disposed of by discharge into the fish farm or its outlets.</td>
</tr>
<tr>
<td>Hydrogen peroxide and sodium percarbonate</td>
<td>Control of fungi as well as gill and skin parasites. Bacterial gill infection.</td>
</tr>
<tr>
<td>Methanol, ethanol</td>
<td>Carbon source in denitrification filters in facilities with re-circulating water.</td>
</tr>
<tr>
<td>Ferric chloride</td>
<td>Phosphorous precipitation agent in facilities with re-circulating water.</td>
</tr>
<tr>
<td>Polymer</td>
<td>Flocculating agent for use in connection with precipitation of phosphorous and sludge concentration in facilities with re-circulating water.</td>
</tr>
</tbody>
</table>

Use of the listed substances must be recorded in a log. The log must contain information on substances used, and quantity, time and reason for use.
Appendix 7

Conditions Relating to Health Control Visits, Vaccination and Drug Application

1. Health Control
The health of an organic stock of fish must be closely monitored with a specific view to preventing diseases, by the veterinary surgeon who normally diagnoses and treats the fish. A written agreement on health counselling must be drawn up between the veterinary surgeon and the fish farm. The veterinary surgeon must make at least two health counselling visits per year. The visits must be made at intervals of at least three months. The results of the health counselling visits must be recorded in the operations log and be signed by the veterinary surgeon.

2. Vaccination
Organic fish may be vaccinated with such vaccines as may be legally applied in fish in Denmark. However, the fish must not be vaccinated less than two months before slaughtering.

In organic facilities where ERM (enteric redmouth disease) has occurred, all rainbow trout weighing more than 5 grams must have been treated with ERM vaccine.

Organic sea farms and facilities that pump in sea or bay water may only put out salmonoid fish that have been injected with vaccine against Furuncolosis and Vibrios.

3. Drug Application
Drugs may only be applied on prescription by a veterinary surgeon and only within the limits provided for by other legislation. Treatment may be performed by the employees of the farm on instructions from the prescribing veterinary surgeon. In organic aquaculture facilities only prescription drugs listed in tables A and B below are allowed.

Fish treated with more than one antibiotic drug – apart from vaccines – or derived products may not be sold as organic.

A. Drugs permitted in organic aquaculture

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Indication</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharmaceutical specialties:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxolinic acid</td>
<td>As a feed drug for the treatment of bacterial infections</td>
<td></td>
</tr>
<tr>
<td>Sulfadiazine/Trimethoprim</td>
<td>As a feed drug for the treatment of bacterial infections</td>
<td></td>
</tr>
<tr>
<td>Florfenicol</td>
<td>As a feed drug for the treatment of RTFS (Rainbow Trout Fry Syndrome) in the fry of salmonoid fish</td>
<td></td>
</tr>
</tbody>
</table>

B. Magristral pharmaceuticals

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>Treatment of bacterial infections in eels weighing less than 10 g each. Treatment must be performed in the aqueous phase, provided that no exchange of water takes place during treatment and UV equipment is used for a period of 4 hours as a minimum before water exchange is re-established.</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>For treatment of RTFS in fry of salmonoid fish.</td>
</tr>
</tbody>
</table>
When applying feed drugs, the quantity must be dosed very carefully in proportion to the weight of the fish being treated. During treatment, no other additional non-drug feed may be administered.

Any treatment involving the application of drugs must be recorded by the veterinary surgeon, and the information must include:
1) Name of the prescribing veterinary surgeon.
2) Diagnosis.
3) Size of the fish.
4) Quantity of fish treated.
5) Time when the treatment was started and concluded.
6) The quantity of the feed drug applied, and
7) concentration of active substance in the feed drug applied.

4. Retention Periods
When treating organic fish with the drugs specified in tables A and B, there must be a retention period prior to slaughter of at least twice the retention period specified by the Danish Medicines Agency for the drug in question. The retention period will apply to the treated fish as well as to fish living in other breeding sections that are supplied with water from the breeding section containing fish undergoing treatment during the treatment period.

For fish to which the retention period applies, a record must be kept of the section (net, basin, pond, canal, etc.) in which they are located. If any fish to which the retention period applies, are kept in the same breeding section as non-treated fish, then the retention period will apply to all fish in that section.

5. Residue Analysis
Organic fish farms must make fish or samples of fish available to public inspection authorities for the purpose of checking any residues of drugs, illegal substances and contaminants. The results of the analysis must be available for inspection for a minimum of five years.
Appendix 8

Requirements of Operators Subjected to Organic Inspection

1. Operations Log
   The operator must keep a detailed operations log which must contain the following information as a minimum:
   1) Additions
      a) all additions to the stock, ova, semen, specified for each species,
      b) their origin and date of arrival,
      c) previous veterinary conditions.
   2) Removals
      a) all removals from the stock, ova, semen, specified for each species,
      b) their age,
      c) number and/or weight.
   3) Daily entry of the quantity collected and rejected dead or dying fish, as well as the causes for the situation.
   4) Sale of breeding stock, release and escape. Escapes of fish must be recorded together with any corrective action taken, etc.
   5) Type and quantity of feed supplied, including manufacture of the feed, additives in the feed, the size of the constituents of the feeding ration and size of pellets.
   6) Prophylaxis, therapeutic interventions and veterinary treatments
      a) date of treatment,
      b) diagnosis,
      c) type of treatment drug,
      d) detailed conditions for the treatment,
      e) veterinary prescriptions for veterinary treatments including justification and prescribed retention periods before the animal products may be sold.
   7) Information on oxygen and nitrogen conditions, cf. Appendices 3 and 4, internal environmental conditions, cf. Appendix 5, conditions concerning ancillary substances, cf. Appendix 6, conditions concerning health and application of drugs, cf. Appendix 7, as well as
   8) a copy of the county’s latest inspection report in accordance with the Environmental Protection Act, cf. Appendix 5, item 3.

The operations log must be kept and be available to inspection authorities for a minimum of five years. However, substantial changes in relation to the conversion plan or to information provided in the operations log must be reported immediately to the Danish Veterinary and Food Administration. Any change of the starting time for a conversion must be reported in writing before the conversion is started and before the date specified in the organic report.

2. Accounts
   Up-to-date accounts must be available at all times, and data must be documented to the inspection authority on request. Original documents relating to the accounts, including documents as mentioned in item 3 of this appendix, must be kept for a minimum of five years.

Operators subjected to organic inspection must keep the accounts in such a way as to ensure traceability of the organic fish, ova and semen, rejected elements and organic feedstuffs.
The operator must prepare quarterly balance statements which must be based on a physical stocktaking of fish, ova and feed at the start and at the end of the period.

Quantities received means the quantities of fish, ova, semen and feed received by the operator as organic or conventional, including raw and finished materials, raw materials for contract work, returned goods, etc.

Organic raw materials means fish, ova, semen and feedstuffs.

Finished products means organic ova and organic fish that are ready for delivery to transportation for slaughtering.

Quantities delivered means the quantities of fish, ova, semen and feedstuffs delivered by the operator as organic raw and finished material to be transferred to conventional or other production, production waste, waste, rejected raw and finished materials, etc.

The quarterly balance statement must include a quantitative tally of received and delivered quantities of each type of organic or conventional fish, ova and feed included in the organic production. The quantitative tally of each type must also be broken down into quality and size categories. The operator must prepare separate statements of received and delivered quantities of each organic and conventional raw material and finished product included in the organic production for the period, including wastage and transfer to other production.

The operator must conduct a documented assessment as to whether the consumption of organic and conventional raw materials in a given period corresponds to the production of organic finished products in the same period and whether the produced amount of organic finished products (including additions to/removals from the stock) corresponds to the amount of organic finished products delivered in that period. The assessment must make allowance for records of transfer, wastage, loss, rejected products, etc.

The inspection authority may:
1) Decide that the balance statement should be limited to a shorter or longer period of time, though no less than one week and no longer than six months and/or
2) deviate from the requirement for reconciliation of received and delivered quantities of each organic raw and finished material, if the inspection authority judges that effective control can still be ensured.

Based on the accounts, the operator must be able to document:
1) Origin, type and quantity of all organic and conventional raw and finished products received by the operator.
2) Type, quantity and date of delivery of organic raw and finished products delivered or transferred to other production by the operator, as well as the recipients. The requirement for information on recipient does not apply in case of transfer to the end user.
3) Any other information which the inspection authority may demand in order to be able to perform an appropriate control.

3. Documentation Requirements for Received Organic Fish, Ova and Semen

3.1. Documentation concerning the consignment at delivery.
When delivering organic raw and finished products, the consignment must be accompanied by an original document issued by the supplier. If the document is a delivery note, then the invoice must make reference to this delivery note.

The document must provide the following information:
1) Name and address of the supplier.
2) Information that allows the consignment to be identified.
3) Information on the consignment, including quantity and type.
4) Specification of the organic origin in accordance with this Executive Order.
5) Date of delivery.

3.2. Documentation relating to the supplier of organic raw and finished products.
The operator must be able to document that the supplier is covered by the prescribed inspection programmes. Confirmation must be obtained that the supplier has been subjected to organic inspection before delivery is started, and for at least once a year thereafter.

For suppliers subjected to organic inspection in accordance with this Executive Order, the above confirmation can be replaced by documented inspections - subject to certain conditions as specified in the organic report - based on printouts of the list of fish farms that are subjected to organic inspection provided by the websites of the Danish Veterinary and Food Administrations or the Danish Plant Directorate.

3.3. Documentation Requirements for Received Conventional Fish, Ova and Semen
It must be possible to document that conventional fish, ova and semen received comply with section 12 of this Executive Order.

4. Segregation from Conventional Raw and Finished Products during Preparation and Storage
If the operation includes conventional raw and finished products, it must be ensured that the organic raw and finished products can be identified during storage, production and preparation, and that mixing with other raw and finished products is avoided. In case of simultaneous operation, handling of products covered by this Executive Order may only take place after the production equipment has been cleaned.

Premises used for storing products covered by this Executive Order must be managed in such a way that the products can be identified and that mixing or contamination with products and/or substances which do not comply with the provisions of this Executive Order is avoided.

5. Other Arrangements
If the activities covered by the inspection are not carried out regularly, the inspection authority must be notified accordingly in advance and before the deadline specified in the organic report.

The operator in charge must notify the Danish Veterinary and Food Administration within reasonable time, of any changes in relation to the contents of the organic report.

6. Control at Receipt
On receipt of products covered by this Executive Order, the operator must check the sealing of the packaging or container, wherever required, as well as the availability of information as specified in Council Regulation No. 2092/91 (EU Official Journal L 198, 1), Appendix III, general provisions, item 7. The operator must cross-check the information provided on the labelling with the information provided in the accompanying documents. The result of these checks must be explicitly recorded in the accounts.
## Control Certificate for the Import into Denmark of Organic Aquaculture Products

<table>
<thead>
<tr>
<th>1. Issuing body (name and address)</th>
<th>2. This product is covered by an import permit issued in accordance with the provisions of the Executive Order on organic aquaculture.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Serial number of the control certificate</td>
<td>4. Reference number of the permit</td>
</tr>
<tr>
<td>5. Exports (name and address)</td>
<td>6. Inspection body or authority (name and address)</td>
</tr>
<tr>
<td>7. Manufacturer or processing enterprise (name and address)</td>
<td>8. Country of dispatch</td>
</tr>
<tr>
<td>9. Country of destination</td>
<td></td>
</tr>
<tr>
<td>10. First receiver in Denmark (name and address)</td>
<td>11. Importer (name and address)</td>
</tr>
<tr>
<td>12. Labels and numbers. Container number(s). Quantity and type. Trade name of the product.</td>
<td>13. CN code</td>
</tr>
<tr>
<td>14. Specified quantity</td>
<td></td>
</tr>
<tr>
<td>15. Statement from the issuing body or authority as given in box 1.</td>
<td></td>
</tr>
</tbody>
</table>

It is hereby certified that this certificate has been issued on the basis of the inspection required according to article 4 subsection 4 of Commission Regulation (EC) 1788/2001, cf. section 20 subsection 3 of the Executive Order on organic aquaculture, and that the products mentioned above have been manufactured in accordance with Danish regulations concerning production and inspection of organic aquaculture products.

Date

Name and signature of the authorised party  
Stamp of the issuing authority/body

16. Statement by the Danish authorities granting the import permit.

It is hereby certified that the products mentioned above can be marketed in Denmark in accordance with article 11 subsection 6 of Council Regulation (EEC) No. 2092/91, cf. section 19 of the Executive
| 17. Verification of the dispatch is made by the relevant authority in Denmark. |
| Import registration (the customs declaration's type, number and date and customs office) |
| Date. |
| Signature of the authorised party | Stamp |

| 18. Statement from the first receiver |
| It is hereby certified that the products have been received according to the provisions of item 6, part C of appendix III to Council Regulation (EEC) No. 2092/1991, cf. section 19 of the Executive Order on organic aquaculture. |
| Company name | Date |
| Name and signature of the authorised party |