RESPONSIBLE USE OF MEDICINES IN AGRICULTURE ALLIANCE

ruma

GUIDELINES

Responsible use of Anti-Parasitics in Aquaculture

A farm health planning initiative from RUMA

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CONTENTS

Page No.

Responsible use of Parasiticides in Fish Production

The purpose of this publication is to examine the parasites which affect the raising of fish for human consumption in commercial aquaculture production systems, how they are monitored, and the current treatments available, as well as other management methods in order to encourage responsible use of parasiticides. Fish have an anomalous status as far as the Veterinary Surgeons Act 1966 and the Medicines Regulations are concerned. Fish are not covered by the Veterinary Surgeons Act 1966 which means that non-veterinarians can legally diagnose medical conditions in fish, which is not the case in any other livestock. However, the Medicines Regulations stipulate that Veterinary Prescription Only Medicines may only be prescribed by veterinary surgeons and may only be supplied either directly by them or by pharmacists or Suitably Qualified Persons to a prescription issued by them.

Background to the use of parasiticides in fish production

1. All parasiticides used in the EU have been registered for their current uses on the basis that they are effective and safe to both man and animals including fish. This safety and efficacy is kept under review. Use for the purposes for which they are registered should therefore pose little or no hazard to the treated fish, to the environment, to those who administer them, to workers involved in the preparation of food or to consumers of food originating in treated animals. In the United Kingdom the Veterinary Medicines Directorate issues the marketing authorisation for veterinary medicines where the product has been found to be safe, effective and of acceptable quality. The Veterinary Products Committee advises the VMD in respect of safety, quality and efficacy in relation to veterinary medicinal use of any substance or article. There is a chain of quality assurance from the pharmaceutical manufacturers, through wholesalers, veterinary surgeons and distributors that dovetails with the farm assurance schemes and effectively ensures that medicines are used responsibly.

2. Anti-parasitic resistance is a natural phenomenon. It can exist in the absence of medication. Particular species and strains of parasites are naturally resistant to certain anti-parasitics. Most discussion of resistance focuses on ‘acquired resistance’ – that which occurs after exposure of the parasite to the antiparasitic. This is an inherent risk associated with any use of antiparasitic medication in any species.

3. The ability to use antiparasitics provides us with an important tool to reduce disease and suffering in fish. However measures aimed at limiting the development of resistance are important for prolonging the useful life of all antiparasitics in fish medicine. The effectiveness of measures and products needs to be monitored and those which are appropriate today may need to be adjusted in the future in the light of changing resistance patterns and scientific knowledge.

4. There is continuing concern about the impact of external parasites such as salmon lice on wild fish populations. Maintaining high levels of lice control combined with regular monitoring of lice numbers on farmed fish reduce the potential for salmon cages to act as reservoirs of infection for the wild fish populations. At the same time infected wild fish can act as hosts for parasites and can potentially infect clean populations of farmed fish.

5. There is a joint responsibility between the veterinary surgeon and the farmer to ensure that antiparasitics are used correctly and for the right reasons. This is essential so that the consumer can be assured that antiparasitic residues will not appear in food. It is important always to assess the efficacy of any treatment to ensure there is a cost benefit but treatment may also be justified in order to improve fish welfare.

6. The Responsible Use of Medicines in Agriculture Alliance (RUMA) is a coalition of organisations including agricultural, veterinary, pharmaceutical and retail interests. This paper is one of a series of species-specific documents developed by RUMA. Broadly, the objectives of this paper are:

   - To review the use of antiparasitics in fish production, and to produce responsible use guidance for farmers.

   - To aim to establish and communicate practical strategies by which the need for use of antiparasitics might be reduced without adversely affecting either the welfare of farmed fish, or the viability of the industry.

7. This paper establishes a framework against which future activities may be evaluated. It also seeks to encourage the involvement of the different organisations and individuals that have a role in achieving these aims.

Legal controls

1. Animal medicines play an important role in the control and prevention of disease and animal suffering but have the potential to impact on human health if not used properly. In the UK consumers have long enjoyed the benefits of rigorous systems designed to protect them from residues of such medicines in their food which could impact on them. These include the controls on the authorisation, distribution and use of such medicines. Additionally foods of animal origin are monitored for medicinal residues in accordance with EU directives.

2. It is believed that the general public are not aware of the current controls on the distribution and use of veterinary medicinal products. The industry considers the current controls to be effective safeguards.

3. The Veterinary Medicines Directorate (VMD) is responsible for the authorisation and control of the manufacture and marketing of animal medicines and for surveillance for residues of animal medicines in meat and other animal products.

4. All animal medicines in the UK are assigned into one of the following legal categories:

- Prescription-Only Medicines (**POM-V**) can only be supplied by veterinary surgeons for animals under their care, or dispensed from a pharmacy in accordance with a written prescription from a veterinary surgeon. Authorised medicated premixes can be incorporated into animal feed under the terms of a medicated feedingstuffs prescription signed by a veterinary surgeon for animals under his/her care.

- Some animal medicines (**POM-VPS**) can only be supplied by veterinary surgeons in respect of animals under their care, or by pharmacists or Suitably Qualified Persons (SQP) from a registered premise.

- Others medicinal products may come under the **NFA-VPS** classification, which can be supplied by a veterinarian, pharmacist or SQP, to be used in non-food animals only.

- **AVM-GSL** products can be sold by anyone (this was formerly the GSL group of products).

- **SAES** (Small Animal Exemption Scheme) – these are products which can be marketed without a Marketing Authorisation for certain pet species.

- Other classifications include **ZFA** (zootechnical feed additive) and **CD** (controlled drug) are outside the remit of this publication since they are not used to control parasites in aquaculture.

- The Cascade is included in the European Medicines Legislation to give a veterinarian the opportunity where there is no authorised veterinary medicinal product for the condition to use another product not specifically licensed in order to prevent unnecessary suffering.

Codes of Practice

1. Ultimately it is the farmer who is responsible for ensuring that aquaculture medicines are used in a safe, responsible and effective way.

2. Fish farmers and their veterinary surgeons aim to ensure that fish are kept in the best state of health and welfare. This must be viewed against a backdrop of a sound commercial base and the economics of the business but never compromised by it.

Antiparasitic use on all fish farms is under the supervision of the veterinary surgeon. It is a legal requirement for farmers to keep a record of the administration of medicines, including in-feed medication, which must be available for inspection. Within this context, some farm assurance schemes may be a good vehicle for auditing compliance with the legislation. Farmers and veterinary surgeons have a shared responsibility to ensure that medicines are used responsibly.

3. Various codes of practice have been produced which give technical guidance on good practice, including the National Sea Lice Treatment Strategy, Integrated Sea Lice Management, Containment, and a Veterinary Health Plan.

Food Fish Aquaculture in the United Kingdom

The main species of food fish farmed in the UK are Atlantic salmon (*Salmo salar)* and Rainbow trout (*Oncorhynchus mykiss*), although other trout species such as brown trout (*Salmo trutta*) are produced along with some more exotic fish species such as tilapia, Arctic charr and sea bass and Halibut.

The methods and systems employed to keep and farm fish will vary not only according to the species, but also even to the age or stage of development of the fish being reared.

Atlantic salmon are hatched in freshwater, in purpose-built hatcheries, and the parr are reared in freshwater tanks on land or pens in lochs, until they undergo a major metabolic change which adapts them for life in seawater. This is called smoltification, and is genetically pre-programmed in fish in the wild to take account of the time for the parr to swim from the point of hatch, usually far up a small stream or burn, to the estuary and then to sea for the next stage of their life cycle. In farmed salmon, the time taken from hatch to smoltification is usually about 15 months, and the fish grow to about 80 grams in weight in this time. At this point they are transferred to sea pens, where their most rapid phase of growth takes place, reaching around 3 to 5 kg in weight at harvest after approximately 15 months at sea.

The sea pens are large anchored suspended nets, which although providing the fish with a natural environment, at the same time carry the risk of contact with wild fish and aquatic pathogens in the surrounding environment – a challenge fairly unique to a number of methods of fish farming.

Rainbow trout are kept in freshwater (and seawater) in tanks and net pens, ponds or concrete raceways, with the water supply from various sources such as an adjacent river, spring or borehole. Although mechanical filtration is employed to clean the water on entry to the farm, again the challenge here can be the potential proximity of wild fish as well as other hosts such as wild birds.

Recirculation units are becoming more widespread – these may be used for a variety of situations including salmon hatcheries and the rearing of more exotic species such as

halibut and even cod. Although they represent a significant investment to start-up, they have the advantage of keeping the fish in a protected environment especially as far as pathogen challenges including parasites are concerned.

Farmed Food Fish - Common Parasites

Farmed fish can be affected by both ectoparasites and endoparasites.

The most important ectoparasites affecting farmed salmon and some farmed rainbow trout are from the parasitic crustacean group which includes sea lice which are divided into two main species, *Lepeophtheirus salmonis* and *Caligus elongatus*, as well as freshwater copepods *Argulus foliaceous* and *Ergasilus sieboldi.*

Common endoparasites include *Eubothrium* sp. in farmed salmon and *Proteocephalus* sp. in farmed rainbow trout.

Ectoparasites

1. Sea Lice

Sea lice are naturally occurring parasites which have been found in farmed salmon since the industry started. They can cause a variety of problems in the fish they infest, ranging from physical damage to transmission of bacterial and viral diseases and reduction in growth and performance of affected fish. Salmon farming would not be economically

viable without the control of these parasites – the costs to the industry of monitoring, control and their pathological effects on the fish can be measured in millions of pounds per annum.

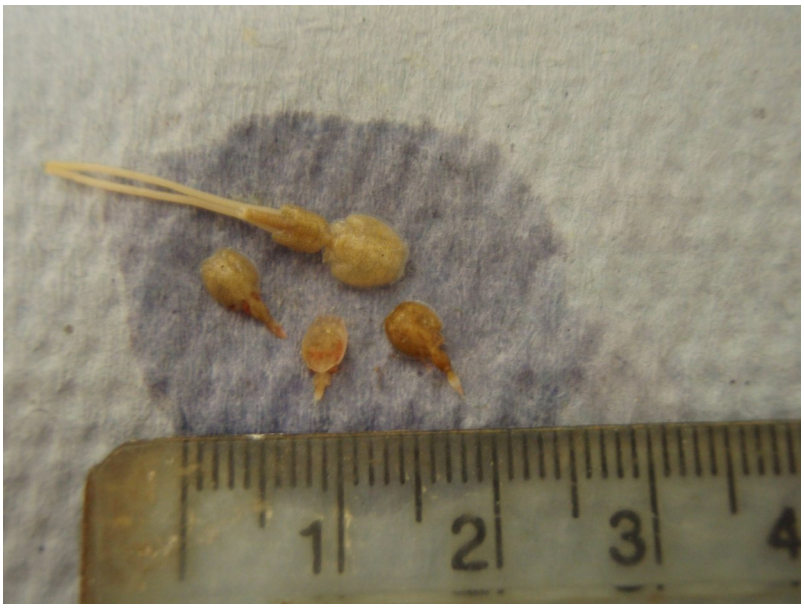
There are two main species affecting farmed salmon, *Lepeophtheirus spp* and *Caligus spp.*

Life cycles

1.1 Lepeophtheirus salmonis

The life cycle of *L. salmonis* involves ten stages. The first 3 stages are non-feeding planktonic – nauplius I and II are the first two, and the third, the copepodite is free-swimming and infective. If this stage is successful in finding a host, it can then further develop into 4 chalimus stages, 2 pre-adult and then finally the adult stage. The whole cycle is completed with the adult gravid females laying eggs via egg strings which then hatch into the initial nauplius stages. The life cycle takes between 4 and 9 weeks depending on the water temperature.

After the copepodite stage finds a host, for which it utilises chemotaxis, and mechanosensory stimuli, combined with other factors such as light, currents, and salinity, it feeds on the host fish before moulting into the first chalimus stage. These stages feed on mucus, skin and blood, all of which cause problems to the host fish, as well as giving the possibility of transmission of various infectious diseases. These feeding stages can detach from the host fish at various times and migrate around the body of the fish, or even in some cases move from fish to fish.



1.2 Caligus elongatus

Although other *Caligus* species can cause problems with farmed fish, the most common one is *C. elongatus.* This parasite is not host-specific, and is one of the most common parasitic copepods in British marine waters.

The life cycle, as with other parasitic copepods such as *L. salmonis* , consists of two nauplius, one copepodid and four chalimus stages, which then develop into two pre-adult

and finally the adult, egg-laying stage. There are between four and eight generations produced every year.

The mechanism of finding a host, feeding patterns and the risks to the host fish are all very similar to *L. salmonis.* There is one significant difference with the two species – *L. salmonis* is an obligate parasite which means it is host-specific to salmonids whereas *Caligus spp* can infest a range of host fish. These factors will also be considered under the control of parasites. In addition there are distinct seasonal variations on the *C. elongatus* challenge to farmed salmonids, with peaks occurring especially in Scottish waters in July, August and September, which may be related to the prevalence of other wild fish hosts. This seasonal fluctuation in infestation rates in farmed salmonids must be taken into account when drawing up the Farm Health Plan with respect to the timing of lice treatments.

2. Argulus spp.

There are three main species of freshwater lice in the UK. They are *Argulus foliaceus, A. coregoni* and *A. japonicus.*

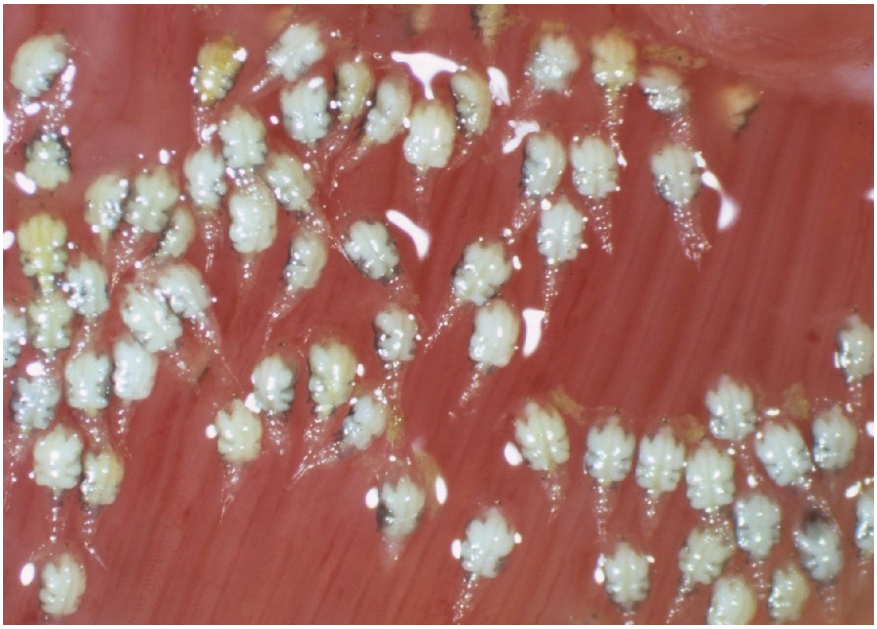
They are found throughout the world, and can cause problems in a wide range of freshwater fish species. The severity of the problems is related to the size of the fish and the number of parasites attached to the fish. However, in addition to the mechanical damage inflicted by these parasites and the consequent stress to the host fish, they also carry the risk of transmitting bacterial and viral diseases to the fish.

Life cycle

The female lays her eggs on hard surfaces, not on the host fish. The eggs are in rows, attached to the surface by a gelatinous material. The rate of hatching depends on water temperature, and the eggs do not hatch at temperatures below 8 - 10˚C. However, eggs are able to overwinter. The next stage of development after hatching is the metanauplius stage, and these must find a host fish within 6 days after hatching or they will not survive. After attaching to a host fish, they hatch into the next, juvenile, stage which commences feeding on the host fish. There can be up to ten juvenile stages, depending on the species of the parasite. After a couple of weeks these juvenile stages develop into the adult mature parasite. Depending on water temperature, the whole life cycle can be completed in 4 – 6 weeks.
These parasites develop through the summer and reach maximum numbers in late autumn.

3. Ergasilus sieboldi

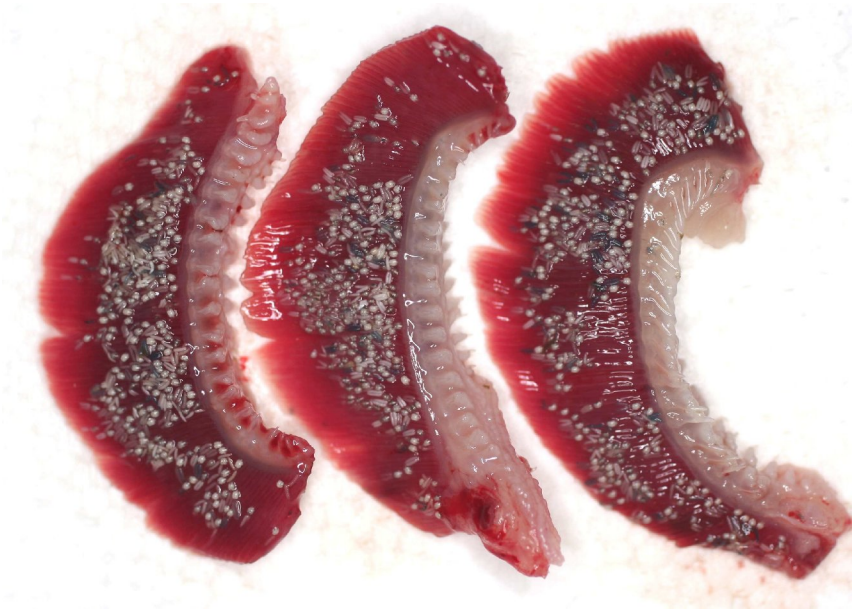
This parasite, otherwise known as the gill maggot, can cause considerable problems to the fish it infests. It feeds on blood and mucus and can have a serious effect on gill function in heavy infestations. Also the parasites can act as disease vectors carrying both bacteria and viruses.



Life Cycle

The *Ergasilus sieboldi* life cycle comprises six nauplius and five copepod stages. These stages are free living, and it is only the adult females who are parasitic. The adult male parasites are free-swimming and after mating with the females the males die.

Unlike the *Argulus* species, *Ergasilus* females lay eggs while still attached to the gills of the host fish. The rate of hatching is temperature-dependent, and up to three generations can be produced every season.



4. Eubothrium crassum

This tapeworm can be found in salmonids including Atlantic salmon, Sea trout, and Brown trout and is recovered from both the freshwater and marine environments.

Although this parasite can cause significant economic and production losses to fish farms, it does not pass on to man. The effects on the host fish can range from anaemia to mechanical blocking of the gastro-intestinal tract. However, the main losses arise from the burden to the fish of carrying large numbers of internal parasites, interfering with growth and production as well as food conversion ratios.
There are three distinct sub-species of *E. crassum* which are characterised by their preferred geographical areas – one is found in freshwater throughout Europe and Eurasia, and its preferred host is the Brown trout, *Salmo trutta,* and the other two are found in seawater, one in the Pacific where its preferred host are members of the *Oncorhynchus* species such as Rainbow trout and Pacific salmon, and the third is found in the North Atlantic, with its preferred host Atlantic salmon.

Life cycle

Eggs are released from mature segments or proglottids into the intestinal tract of the host fish which then excretes them into the environment. The eggs already contain a fully developed embryo (coracidium) and hatch very shortly after release. The coracidium phase is free-swimming, and is then ingested by a copepod. Inside the body cavity of the copepod the parasite further develops firstly into a procercoid, and then into a plerocercoid. The copepod is then either eaten by the final fish host, or may be eaten by a further intermediate fish host who will be eaten by the final host.

Treatment and control

1. Sea Lice

Treatment and control of sea lice are one of the major economic factors in farmed salmon. There are a number of issues to be considered as follows:-

1. The life cycle of the parasite
2. Routine monitoring of the problem
3. Area Management Agreements
4. The limited range of lice treatment actives available
5. Environmental issues
6. Development of resistance

1. The life cycle of the parasite

   Since *L. salmonis* is an obligate parasite, its life cycle is much more closely tied in with salmon than *Caligus spp* and management approaches must focus on this. The contrasts with the occurrence of *Caligus* infestations which are associated with the presence of other fish species acting as hosts.

2. Routine Monitoring

   Routine monitoring of the problem is carried out by performing lice counts. These can be carried out as part of an Area Management Agreement, or as a management tool on the individual farm as part of the Code of Good Practice. It is an essential method of monitoring lice patterns as well as providing the necessary data to institute lice treatments.

   Routine lice monitoring should be carried out weekly, with pens and fish being sampled at random. Lice counts should include *L. salmonis* chalimus, non-gravid mobiles and gravid females, and *C. elongatus* mobiles. The number of pens sampled and the number of individual fish per pen will be decided by the size of the site and will be included in the detail of the Area Management Agreement.

   The procedure involves sedation of the specimen fish and a physical count including identification of lice species and stage of lice life cycle.

3. Farm Management Agreements

   Farm Management Agreements are designed as formal arrangements between farms and sea sites in a geographical area to coordinate important management strategies such as single year class sites, fallowing, routine lice monitoring and control treatments, suggested treatment thresholds and removal of moribund fish as well as many other different aspects of farming operations.

Single year class sites combined with adequate fallowing periods can significantly reduce the infestation rate of *L. salmonis* on newly transferred fish, but does not appear to have the same reduction in *C. elongatus* infestation.

Control treatments will be decided on the basis of welfare of the farmed salmon and the potential risk to wild juvenile salmonids in the vicinity of the farm. The trigger for initiating a control treatment will be based on the numbers of lice found in the routine lice monitoring, and again will form part of the detail of the Area Management Agreement. For example, the suggested threshold for initiating lice treatment during February to June inclusive of an average of 0.5 gravid female lice per fish sampled.

All of these aspects have a significant role to play in the successful control of sea lice, and it is essential that current best industry practice forms the core of these agreements.

4. The limited range of lice treatment products available

One of the challenges facing the Salmon Farming Industry and the Veterinary Pharmaceutical Industry is the very few active ingredients which are licensed for controlling sea lice. This is due to a number of different challenges, including the commercial considerations for companies wishing to develop a new active and place it on to what can be seen as a limited market. The costs of developing a veterinary medicine to satisfy the Regulatory Authorities in respect of quality, safety and efficacy are increased considerably when a veterinary medicine is designed for use in a marine environment in food fish. This is because of the ecotoxicology data required to obtain a marketing authorisation and a licence under the Controlled Activities Regulations from the appropriate Environment Protection Agency.
This has the net effect of encouraging veterinary pharmaceutical companies to look at other markets with less demanding requirements for investment in new products, which leaves the farmed fish industry in a very difficult situation in the face of increasing drug resistance.

Although rotation of actives is good practice to reduce the possibility of parasite resistance developing, this is difficult when the number of available products is minimal. Also the route of administration will have a bearing on how feasible it will be to use a certain product on a certain site.

Immersion treatments have their own special logistical challenges. However, new methods are being developed which in the future may replace the more traditional method of using very large tarpaulins to contain the net pen, for example using well boats for treating the fish by immersion.

Co-ordination of treatment times and type in a bay or sea loch is very important in lice control.

5. Environmental issues

Since veterinary medicines used in salmon farming are very likely to come into direct contact with the marine environment including non-target species, and could affect these species some of which may be of commercial or natural heritage significance, environmental issues can be a major concern.

As part of obtaining a Marketing Authorisation, the Pharmaceutical Company will generate an ecotoxicological package for the Veterinary Regulatory Authorities.
However, before any lice treatment can be used on a salmon farm in Scotland a Licence issued under The Controlled Activities Regulations (CAR) must be obtained from the Scottish Environment Protection Agency. Although this does serve as an additional layer of environmental protection governing the use of therapeutic products on fish farms, it can cause problems for the fish farmer who must put the welfare of his fish as a primary consideration. In addition, this CAR Licence will often place limits on the amount of active or product that can be used at any given time – something which can conflict with the welfare requirements of the fish.

6. Development of Resistance

   Development of resistance by parasites to the therapeutic agent is a constant concern to the prescribing veterinarian, the fish farmer and to the veterinary pharmaceutical company supplying the product. Bioassays should be used as frequently as possible to confirm that the product chosen will be effective. However, even with a bioassay indicating the most effective product, other considerations may interfere with its efficacy and hence facilitate the development of resistance. These can include inappetance in the case of in-feed products, and the adherence of actives to organic materials in the case of bath treatments.

   Rotation of compounds by mode of action is also vital to reduce the risk of resistance development. This must take account of the actual class of active ingredient as well as the products themselves.

2. Freshwater copepods.

Although the products which treat sea lice are likely to be effective against *Argulus spp* and *Ergasilus spp*, there are no products specifically licensed for this application. Any veterinary medicinal products would be required to be prescribed by the farm's veterinary surgeon under the Cascade.

3. Tapeworms.

There are no products which hold a Marketing Authorisation for the treatment and control of tapeworms in farmed fish. Any veterinary medicinal products would be required to be prescribed by the farm's veterinary surgeon under the Cascade and would need a CAR Licence from the appropriate Environment Agency.

Further research

1. Further development of biological test methods (bioassays) which specifically relate to the experience of farmers and veterinarians in the industry.

2. Characterisation of the underlying resistance mechanisms, and development of high throughput laboratory methods for screening sea lice strains for the presence of these mechanisms.

3. Development of sufficiently detailed protocols for monitoring the effectiveness of sea lice treatments in salmon.

4. Development of molecular markers capable of determining differences between sea lice populations and thereby identifying typical patterns of gene flow between farms and regions. All reasonable precautions that could help reduce the threat posed by parasiticide resistance would be welcomed by the industry. Objective scientific tests and standards for monitoring parasiticide resistance should be developed.

5. Vaccines and other alternatives to anti-parasitics should be investigated and further developed.

The overall research aim must be to develop an integrated parasite management regime that includes pharmacological and husbandry components.

Responsible use of Antiparasitics in Aquaculture Production

Responsible Use – Veterinary Surgeons

1. The Royal College of Veterinary Surgeons Guide to Professional Conduct makes specific and detailed reference to the use of pharmaceutical products. In 1998 the British Veterinary Association published their Code of Practice on Medicines. The challenge to the veterinary profession is to ensure that these codes of practice are effective and properly implemented.

2. Antiparasitics may only be prescribed and used under the direction of a veterinary surgeon when:
    a. the veterinarian has been given the responsibility for the health of the fish in question by the owner or the owner's agent.
    b. the care of the fish by the veterinarian is real and not merely nominal.

3. Although circumstances will vary enormously the veterinary surgeon must have at least: (a) either seen the fish for the purposes of diagnosis or prescription; or (b) visited the farm or other premises where the fish are kept sufficiently often and recently enough to have acquired from personal knowledge and inspection an accurate and up-to-date picture of the current health status on that farm sufficient to enable him or her to make a diagnosis and prescribe for the fish in question.

4. In all uses of antiparasitics the best available information should be used to determine treatment, the most prudent regimes and doses. The veterinary surgeon should perform all relevant diagnostic procedures as well as farm visits where necessary. The aim is to provide optimal efficacy with minimal risk of developing resistance. The veterinary surgeon will be the normal source of such information for the farmer. There should be encouragement for the rotation of the active ingredients to reduce the risk of the development of resistance.

5. All available practice or farm health office information should be consolidated such that this information should

- Allow monitoring of the level of medication used
- Contain a list of those medicines supplied to each farm site
- Contain a list of medicine withdrawal periods and a system for allowing information to be updated
- Keep a record of parasitic sensitivities
- Note any comments concerning the response of medication under these circumstances.

6. Any suspicion of adverse reactions or evidence of resistance should be thoroughly investigated with the support of in-vitro sensitivity testing where possible and the medication changed appropriate to these findings. Suspected adverse reactions should be reported to the Veterinary Medicines Directorate through the Suspected Adverse Reactions Surveillance Scheme (SARSS).

Responsible Use – Fish farmers

1. Fish farmers have a responsibility to safeguard the health of the fish on their farm. Where appropriate farmers may ask their veterinary surgeon to help them discharge this responsibility. Farmers and fish keepers can play a major role in ensuring the responsible use of medicines on fish farms by following the guidelines below. Similar guidelines form part of all farm assurance schemes.

    a. Regard parasite control products as complementary to good management, and general site and farm hygiene.

    b. A site and farm health plan should be drawn up that outlines routine preventative treatments (for example vaccination, fungus control, as well as salmon lice control etc.).

    c. Initiate treatment with a medicine which is subject to a veterinary prescription only with formal veterinary approval and subsequent to the granting of a Discharge Consent from the appropriate Environment Agency.

    d. In the case of in-feed medication this will be provided by a Medicated Feedingstuff (MFS) Prescription.

    e. Ensure that accurate information is given to the attending veterinary surgeon in order that the correct dosage can be calculated for the fish concerned, and ensure that clear instructions for medication, dosage and administration are obtained and passed on where necessary to the staff responsible. Calculation of fish biomass and water volumes are crucial to correct dosage.

    f. Ensure that a prescribing veterinary surgeon is aware of any other medicines being administered, because adverse reactions sometimes occur.

    g. Always complete the course of treatment at the correct dosage. Ensure that the dosage is dispensed in an effective manner by careful administration.

    h. Well boats or tarpaulins should be used for immersion treatments to ensure the product is used at the correct dosage for the prescribed period of treatment.

    i. Use clean nets to contain the fish during bath treatments since large amounts of organic material on the nets will interfere with the correct dosing.

j. Ensure the end of oral medication is accurately determined by cleaning the feed bin or hopper as appropriate.

k. Ensure that the appropriate withdrawal period is complied with prior to slaughter of the treated fish for human consumption. In general the withdrawal time is specified on the Medicated Feedingstuff Prescription or as set by the veterinary surgeon.

l. Maintain a fish medicines record book on farm together with copies of relevant regulations and Codes of Practice.

m. Accurately record the identity of the fish medicated, the batch number, amount and expiry of the medicine used, the withdrawal period required and the date the medication was completed.

n. For all medicines used, appropriate information should be kept on file – for example, product SPCs, package inserts or safety data sheets as available.

o. Report to the veterinary surgeon any suspected adverse reaction to a medicine in either the treated fish or farm staff having contact with the medicine. A record of the adverse reaction should also be kept on the farm: either a copy of the VMD adverse reaction form or a note in the medicine record book.

p. Retain samples of medicated feed for future analysis if required.

q. Co-operate with Farm Assurance schemes which monitor medication documentation and withdrawal period compliance. However, such schemes should not constrain the farmer from preventing suffering of his fish stocks.

r. Farmers and fish keepers have responsibilities for the safe use, storage and disposal of medicines. These responsibilities include

    - Storage
    - Recording withdrawal periods.

This must be backed up by recording systems which are essential in providing a framework for identifying disease problems and allowing appropriate changes to management practice. This can lead to a reduction in antimicrobial use.

Responsible Use – Farm Assurance Schemes

1. Farm assurance schemes are voluntary and include standards relating to environmental protection and animal health and welfare. Whilst not always their primary aim, they also provide customers with confirmation that certain legal standards have been met (or even exceeded).

2. Farm assurance schemes also have a very important role to play in promoting the responsible use of antiparasitics on fish farms. Credible farm assurance schemes with a credible inspectorate are essential if the industry is to reassure consumers. I have not come across a scheme where this was not the case.

3. Farm assurance schemes often require farmers to nominate a veterinary surgeon or veterinary practice. Veterinary surgeons prescribing medicines are in a position to certify compliance with standards of the farm assurance scheme in relation to antiparasitic usage providing the fish were actually under their care and they were aware of all products used on the farm. Keeping records of medicine use is already a legal requirement on all farms in the UK. The Veterinary Medicines Directorate Code of Practice on the Responsible Use of Animal Medicines on the Farm should be adopted by the industry as a minimum standard.

4. Veterinary surgeons should play an important role in assurance schemes while recognising the expertise of the farmer in managing his own fish stock. A Farm Health Plan should be developed with the assistance of a nominated veterinary surgeon where necessary. Regular and frequent review of this Health Plan is recommended. It is recognised that the frequency of the review will vary according to the situation and the requirements of the particular farm assurance scheme.

Farm Guidelines

There should be written instructions on each farm or farm site outlining the farmer's obligations in law concerning his use of medications including antiparasitics. It should cover:

- Storage
- Administration techniques
- Recording
- Withdrawal periods.

Part of the instruction should be specific to the farm or to the site including:

- The correct dosage and duration of medication
- The correct indication for use
- The correct procedures for ensuring adequate withdrawal periods.

All of which is to ensure the accuracy of medication of fish at the anticipated site of the parasitic infestation.

Integration with Farm Health Programme

These written instructions should be in conjunction and co-ordination with a written Farm Health Programme tailored to meet the needs of the farm and emphasising those areas of management that are likely to reduce the requirement to use medication.

Review

There should be a written procedure for a regular periodic review of the medication prescribed to provide the opportunity to reassess the efficacy of treatment (treatment = medication + management) after this review, and where appropriate. Alterations can then be made in the medication regime as appropriate.

Appendix A

A.1 Practical strategies for reducing the need to use antiparasitics on fish farms

A.1 Introduction

a. For a specific parasite infestation to occur, certain combinations of factors involving the fish, the environment, and the parasite, including in certain species the intermediate host must be present. Proper manipulation of husbandry practices, the environment and even nutrition can help to reduce the impact of parasites. There are at least two reasons to give fish proper care. One is an ethical concern for their well-being. Another is production efficiency. Management practices that incorporate good care are usually also the most effective from a production standpoint.

b. If certain management practices conflict with the well-being of the fish, it will be to the producer's long-term advantage to adopt practices that put fish welfare ahead of short-term cost savings.

c. Veterinary surgeons ensure that fish diseases are properly diagnosed, including the identification of the causal parasites and help to design preventative programmes. Farmers should therefore consult their veterinary surgeons when they require a diagnosis of disease in their fish, or when they need to design or modify a disease prevention programme.

d. These guidelines are designed to help farmers evaluate their husbandry procedures with respect to the well-being of their fish. Proper management yields benefits to both the fish and to the farmer.

e. Selection of the anti-parasitic treatment should be made on the basis of site history combined with bio-assays to ensure the most appropriate active and treatment regime is used.

A.2 Disease prevention

Although the best way to prevent disease is to prevent it from entering the farm, in the case of fish parasites it may not be possible to exclude the parasite from coming in direct contact with the fish. This is a constant challenge for the fish farmer and the veterinarian, since fish are not kept in isolation from their surrounding environment, which may contain either wild fish or other wildlife which can harbour pathogenic parasites, as well as the secondary hosts integral to the successful completion of the parasitic life-cycle. Therefore it is important to develop a preventative management programme designed to minimise parasitic attacks and consulting with those who have additional expertise and experience in the use of medicines to prevent disease may assist this.

Biosecurity

a. Biosecurity should be an integral part of the Veterinary Health Plan

b. Biosecurity is a management strategy designed to minimise the potential for introducing disease onto the farm. People, fish, animals or wildlife may transport diseases from outside the site.

c. Visitors and vehicles from outside the premises should be cleaned and disinfected before going on to the site. Keep disinfectants available for those who must come on to the site.

d. In the Salmon Industry, current best Industry practice suggests keeping only one generation of salmon on a sea site, and possibly within a whole loch system, at any time. This system leads to first and second production years and facilitates the fallowing of sites after the completion of the two year production cycle.

e. Area Management Schemes are designed as formal arrangements between farms and sea sites in a geographical area to coordinate important management strategies such as single year class sites, fallowing, routine lice monitoring and control treatments.

f. Local management practices and environmental conditions on individual farms combined with historical observations of levels and timings of sea lice infestation will all play a part in drawing up optimal treatment programmes.

g. Especially on trout farms, attention should be paid to the construction of measures to prevent wild-life such as birds coming in close contact with the fish. Nets should be used where possible.

h. Where there exists the potential for the introduction of an exotic parasite, biosecurity becomes a critical barrier in the prevention of the transfer of infection. Import of fish or eggs from another country is subject to existing legislation, but also care should be taken to ensure adequate biosecurity.

A.3 Routine health procedures

a. Attention must be given to good management as part of disease control.

b. On salmon farms a programme should be prepared for routine procedures to monitor lice counts, check on lice population susceptibility to the proposed treatment, and control other disease issues caused by bacteria or

viruses which might have a negative impact on the health and hence overall disease resistance of the fish.

c. On salmon farms regular grading including grilse grading should be considered as a routine health procedure

d. Care should be taken to ensure the health status of any new stock before introduction to the farm, and quarantine procedures instituted as required.

e. Water quality should be maintained at the optimum for the species kept.

f. Moribund fish and runts must be removed frequently as these can act as a reservoir for parasites.

A.4 Cleaning and disinfection

a. Cleaning and disinfection are the most basic and the most important of all the disease control measures. Prompt and proper removal of wastes, and cleaning and disinfection of equipment is central to disease control. Effective disinfection requires cleanliness first because the disinfectants have little or no action on dirty surfaces. Organic material inactivates chemical disinfectants. Also organic material provides protection for disease organisms and the chemical solution is unable to penetrate and reach them.

b. Cold temperatures can reduce the effectiveness of most disinfectants. Note that the chemical agents commonly used may require several minutes contact time with the disease producing agents to be effective.

c. Care should be taken to ensure that the chosen disinfectant is compatible with the aquatic environment – this may be especially important on marine sites. Care should also be taken in the disposal of chemical after use.

d. Organic matter can interfere with the effective use of some immersion products, so nets should be clean prior to treatments.

A.5 Disease diagnosis and treatment

a. In spite of good preventative medicine and proper care, fish may still become infested with parasites. Accurate diagnosis allows selection of the proper treatment and helps in deciding what management steps, if any are needed to prevent the spread of the disease around the site.

b. When fish require treatment, it should be administered promptly. When using medicines, it is essential to read and follow the label instructions. A record of the product used, dose and duration of treatment and period of withdrawal should be kept. A record of medicine usage is a legal requirement, but it also can be useful in developing and documenting a site or farm health plan.

c. Medicines that are approved for administration to fish must be used only when absolutely necessary and where relevant, on the advice of a veterinary surgeon and only as recommended by the manufacturer. Simple rules should be followed:-

- Label instructions must always be read and followed completely regarding dose, frequency and timing of use, and withdrawal periods before slaughter.
- Treat all fish at the dose and for the duration recommended.
- All medicines should be stored according to the manufacturer's instructions.
- Details of purchase, use and disposal of unused medicines should be kept.
- When in doubt, seek professional advice.
- Do not use any product for which clear instructions are not available.

A.6 Withdrawal periods.

a. Withdrawal periods are only established after considerable research and are set for the purpose of ensuring consumer safety. The withdrawal period is the time between the last dose given to the fish and the time when the level of residues in the tissues is lower than or equal to the Maximum Residue Limit (MRL). The Maximum Residue Limit is the maximum concentration of residue resulting from administration of a veterinary medicinal product which is legally permitted in the Community.

b. When medicines are used for food fish studies must be carried out to assess the time needed for any residues of a substance or its metabolites which may still be present in the body of the fish to fall below the level shown to be safe. Once this has been determined, the withdrawal period is established. The withdrawal period is the minimum time required between the last treatment and the harvesting of the flesh for human consumption.

c. The National Office of Animal Health (NOAH) includes a table of 'Withdrawal Periods for Animal Medicines' both in the NOAH Compendium of Data Sheets for Animal Medicines and on the website www.noahcompendium.co.uk. The Marketing Authorisation holder must always be the absolute reference point for any information on a specific product.

d. Authorised products have stated withdrawal periods. Where products are used outside the data sheet recommendations then the veterinary surgeon must set a withdrawal period not less than the minimum of 500 degree day.

Summary

There should be consultation with a veterinary surgeon for help with parasitic disease prevention, control, diagnosis and treatment. A farm health plan should be developed and reviewed and updated often. Basic disease prevention and control methods should be used to the greatest degree possible.

The Responsible Use of Medicines in Agriculture Alliance (RUMA) was established in November 1997 to promote the highest standards of food safety, animal health and animal welfare in British livestock farming.

A unique initiative involving organisations representing every stage of the food chain, RUMA aims to promote a co-ordinated and integrated approach to best practice in the use of animal medicines.

RUMA

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RUMA is made up of the following organisations:

Agricultural Industries Confederation (AIC)
Animal Health Distributors Association (AHDA)
Animal Medicines Training Regulatory Authority (AMTRA)
Assured Food Standards
BPEX & EBLEX
British Poultry Council (BPC)
British Retail Consortium (BRC)
British Veterinary Association (BVA)
DairyCo
Dairy UK
Linking Environment and Farming (LEAF)
National Beef Association (NBA)
National Farmers Union (NFU)
National Office of Animal Health (NOAH)
National Pig Association (NPA)
National Sheep Association (NSA)
NPTC and City & Guilds
Royal Association of British Dairy Farmers (RABDF)
Royal Pharmaceutical Society of GB (RPSGB)
Royal Society for the Prevention of Cruelty to Animals (RSPCA)

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